



Document: ISO/TC 176/SC 2/N **1254**

Secretariat of ISO/TC 176/SC 2

Date: 17 June 2015

To the Members of
ISO/TC 176/SC 2 -
Quality Management and
Quality Assurance/
Quality Systems

Collation of comments received on ISO/DIS 9001 and prEN ISO 9001, including "Observations of the Secretariat"

Please find attached a copy of the above collation of comments.

Please note that we have been advised that the comments against the French and (EN) German versions of the DIS have been processed separately by the member bodies responsible for those translations.

The comments have been reviewed in the preparation of ISO/FDIS 9001.

The "Observations of the Secretariat" have been provided using the following legend:

EAF	Editorial comment, accepted fully	TAF	Technical comment, accepted fully	C	Comment, noted
EAP	Editorial comment, accepted in part	TAP	Technical comment, accepted in part		
EN	Editorial comment, not accepted	TN	Technical comment, not accepted		

Yours sincerely

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ISO/TC 176/SC2/N1254

Template for comments and secretariat observations

Date: 2015-06-17	Document: ISO/TC 176/SC2/ N1254	Project: ISO 9001
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No.	MB/ NC ¹	Line number	Clause/ Subclause	Paragraph/ Figure/ Table/	Type of comment ²	Comments	Proposed change	Observations of the secretariat
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1. General comments

1.1 General comments - General

No.	MB/ C ¹	Comments	Proposed change	Observations of the secretariat
1	IT	Please see our accompanying document to the Italian comments Secretariat comment: The text of the document is now given here, in the right hand column	Italy deems that the current DIS is a significant improvement over the previous CD, so that our position is positive. Nevertheless, some issues are still to be improved and this could affect our position concerning the following FDIS stage. These issues are referred to as "CRITICAL COMMENT" in our commenting template (see "Comments" column) and the main reasons behind them can be summarized as follows: Applicability of the standard (clauses 1, 4.2 and A.3): the new approach regarding the applicability of the standard may lead to a wide range of interpretations, so that even core elements of the QMS itself could be considered as "not applicable"; Clause 2: it is unacceptable to have no reference to ISO 9000, which is and shall be still the reference document for a comprehensive understanding of the fundamentals of quality management; Clause 3: the presence of 69 terms (from both HLS and ISO/DIS 9000) represents a discontinuity with the past and will negatively affect the perceived value and use of future ISO 9000. Moreover, some terms are different from the corresponding ones of ISO/DIS 9000; Clause 3: the new definitions provided for "output", "product" and "service" generate an unacceptable circularity between the definitions themselves. In addition to this, we deem that is essential to provide clear and consistent definitions, easy to understand by the users of the standard; Documented information: we feel the need for some clarifications regarding how documented information is to be managed and especially maintained (for instance, according to the current draft, the scope seems to be the only documented information which is required to be maintained); Risk-based approach: we deem that the HLS-requirements specified in clause 6.1 (i.e. risks and opportunities and related actions) are still almost disjointed from the other clauses of the document, namely clauses 8 and 10; Implementation of QMP 3 - Engagement of people: clause 7.1.2 is	C

			definitely insufficient to fulfill this principle.	
2	JP1	Japan appreciates the efforts of WG24 members and the other related people who are working hard toward the publication of DIS 9001 in 2015. However, there are some technical issues remaining to be resolved to proceed to the FDIS stage. Overall, Japan thinks that the following six issues have to be discussed. Please refer to individual comments for details. • Knowledge (See comments JP110 and JP187) • Human error prevention (See comment JP137) • Outsource (See comment JP133 etc) • Terminology (See comment JP16) • Deviation from Annex SL (See comment JP87) • Relationship among the requirements (See comments JP114 and JP157)		C
3	LC	The format and approach of this revision is excellent, as it reduces the heavy technical language of 2008, and simplifies the language for the average user. Additionally, the approach to engage the Top Management and have top management take greater responsibility for the QMS as opposed to having “a Management Representative” assigned is most refreshing, consequently gives a more balanced approach to how management demonstrates commitment. Additionally, the Risk-Management Approach that has been neatly written into the document under 6.1 and the restructuring of the Performance Evaluation through to Improvement Clauses, and recognized as positive changes.		C
4	GR	Our voting is positive recognizing that ISO/DIS 9001 moves, generally, in the right updating path.		C
5	MY	There are many requirements in this standard that are ambiguous	ISO TS 9002 should address the expectations of those requirements	C
6	LU	The terms used are often too conceptual. Thus, the understanding of the standard by SME's could be very low. By ex. Some definitions are confusing : Product, Information, Documented information, knowledge, information, characteristic		C
7	LU	Some requirements are so wide, the audit of its will be very difficult and the audit findings will be totally linked to the understanding and meaning of the auditor, by ex. 7.4 Communication.		C
8	PT	Justification of vote: the Portuguese mirror committee recognizes significant progress was achieved at DIS Stage of ISO 9001:2015 and that the standard is, in general, progressing to the next level according to the strategic intent and purpose of the revision. Nevertheless, the Portuguese Committee identified that several requirements need to be further improved and provides the following comments.		C
9	IS	Abstention - Lack of expertise.		C
10	HR	Lack of experts		C
11	PH/B PS	Draft captures the essence of the QMS' role as a business management system.		C
12	DE	Only three processes are specifically addressed: 8.2.1 processes for communicating with customers 8.2.2 process to determine the requirements for the products and services to be offered to potential customers 8.3.1 development process	Review the whole document especially Clause 8 and add mandatory processes	TN
13	DE	process approach	Review the whole document, because the requirements of 4.4 are not fully	TN

		4.4 lists certain requirements that apply to all processes. However, the following clauses identify specific requirements for specific processes, but never the full spectrum (see matrix in annex 2 to the German comments) Secretariat comment: The annex 2 matrix is given at the end of this collation	addressed by clause 8 and either a) mention process requirements only in 4.4 and refer to these later on b) or explain why for some processes only specific requirements apply	
14	FI	The text as a whole is fragmented and includes lot of confusing repetitions	The text finalization is needed	C
15	FI	Product requirements management process is fragmented in separate clauses. 5.1.2, 8.2.2, 8.2.3, 8.3.3 However, ISO 9001 still has a customer focus		C

1.2 General comments - Validation

No.	MB/ NC1	Comments	Proposed change	Observations of the secretariat
16	ANSI	Comment related to negative vote by ANSI. Validation not completed as indicated in the project plan for ISO 9001:2015. ISO/TC176/SC2/WG24/N8 indicated that validation would be conducted. The validation would be initiated in June 2014 and analyzed in August 2014. While the United States has undertaken a process to complete validation in the United States, the fact that the international validation has not been initiated to date provides a strong indication that it will not be completed. The results from the validation are critical to the experts drafting the standard in confirming the level of understanding of users or potential users of the standard. Both comments from the United States Technical Advisory Group (TAG) to ISO TC 176 as well as public comments have indicated some level of concern with certain aspects of the standard. Furthermore, validation is a critical aspect of ISO 9001:2015 as well as following design specifications. Not completing this activity is in direct conflict with the process that ISO TC 176/SC2 has long prided itself on. While a validation initiative has begun after this comment was developed, the timing of it will make incorporating these results very difficult.		C
17	ID	In accordance with ISO/IEC Directives, validation of DIS advances to be FDISstage should be processed with external validation	External validation from DIS to be FDIS stage should be processed properly to this standard in accordance to ISO/IEC Directives	C
18	IE	The validation study information will not be available before the ISO DIS ballot closes. This is a concern. While the DIS ballot can be viewed as feedback from users it does not negate the commitment to complete a validation study.	Validation data needs to be reviewed before moving to the FDIS stage.	C
19	AU	In the Project Plan for ISO 9001 (Doc SC 2 N1089) it states that validation was going to be carried out during the DIS Ballot. There is no evidence that this validation has been carried out. Could you please advise when the validation will be carried out or provide the "documented information" showing the results of the validation? If validation has not been completed then the draft should be delayed until validation has been completed.		C
20	CA-01	The DIS has not been subject to a Validation process, as per the Project Plan. The validation activity is likely to identify technical and editorial changes to the	We must follow our own Design Specification and Project Plan, and can NOT accept proceeding to FDIS until the Validation process is completed,	C

		document. ISO/IEC Directives do not permit editorial or technical changes at the FDIS stage, only corrections of errors that occurred in creating the FDIS. Therefore, the DIS MUST NOT proceed to FDIS until the Validation process is completed, and the Validation Report recommendations resolved.	including resolution of identified issues.	
21	SII	Validation process which is needed before going to FDIS was not performed		C
22	FI	Finland votes "Disapproval with Comments" Design Specification verification is still needed: A confusion: A validation program is very late! when, very likely, essential changes are needed to ISO/DIS 9001, it is very challenging to implement big changes in DIS/FDIS stage. *** We are still waiting for a review between Design Specification (SC2/N1088) and ISO/DIS 9001 (especially results and an analysis of the verification) After this review and its results a real succeed of the (main target) revision (renewing ISO 9001) will be hopefully clear. Are the goals yet fulfilled? Design Specification (ISO/TC 176/SC 2/N 1088) for the revision of this standard calls for significant requirement for the standard for its future relevance. Is this happened? The standard should • Take into account changes in quality systems practices and management technology and to provide a stable core set of requirements for the next 10 years or more. The last major revision to ISO 9001 was published in 2000 and factually based on the situation of the last years of the 1990's. Since that big changes have taken place organizational arrangements, business management practices, working situations and technologies. That development will continue in the next 10 years. • Ensure that requirements in this standard reflect the changes in the increasingly complex, demanding, and dynamic environments in which organizations operate. • Needs to be capable of being applied by the widest possible range of organizations with varying degrees of maturity of their quality systems. Some ideas were collated during the work on developing "Future Concepts for use in the work of ISO/TC 176/SC2" (SC2/N1013). Taking into account these requirements may be carried out only through quite radical changes in many clauses of the standard and contributions from the experts of member organizations. Now the existing draft is no satisfactory in this sense. Here some related information: It is today very typical that products (and in particular services) are not produced only by one supplier organization but a network of many organizations or an ecosystem. An example is global growdsourcing. Network services are strongly based on information and ICT, like radio frequency identification (RFID), internet and in particular internet of things (IoT), mobile payment technology, ubiquitous IT, etc. Modern examples include cloud services and mashup products. IoT is also known as machine-to-machine (M2M), which means that not only a service provider is represented by an automatic means but also the recipient may be a machine. The IoT emphasize sensors that can	Before DIS 9001 will be ready, a careful verification - Design Specification vs. ISO/DIS 9001 - shall be implemented, its results shall be analysed, and ISO/DIS 9001 shall be updated if (and when) needed).	C

		connect objects to the internet and automatically send their data to IT systems. The objects can be everything from health care monitors to traffic lights, thermostats, or trains. Information security characteristics have an important role in this kind of strongly information based products. New technologies also provide more possibilities to services that may disturb customers or even generate frauds. In addition to the development and achievements in information technology, wide collaboration activities have provided new challenges in many areas of technology for the inclusive growth in product development. These include biotechnology, nanotechnology, energy technology, social technology, etc. Complexity is a very relevant issue in today's business operations. According to Ralph Stacey, business processes are "complex responsive processes of relating". Managing complexity is a requirement of every process, and it goes beyond simplistic management tools. Management of processes cannot be carried out only by rational means and total certainty or agreements based on explicit information, but also non-rational (emotional) and even irrational (spiritual) viewpoints must be taken into account. Also: ISO/DIS 9000 should be first corrected and modified and these renewed terms and definitions should be then taken account in ISO/DIS 9001(as a normative reference).		
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1.3 General comments – Alignment of ISO 9001, ISO 14001 and other ISO MSS

No.	MB/ NC1	Comments	Proposed change	Observations of the secretariat
23	CQI1	This is a golden opportunity to enhance the compatibility of the two most important ISO management system standards – ISO 9001 and ISO 14001. The adoption of Annex SL by both standards is an excellent beginning; but every effort should be made to minimise difference in requirements.	Make every effort to minimise the differences in requirements between ISO 9001 and ISO 14001.	C
24	ANSI	The US TAGs to 176 and 207 Liaison Group conducted parallel reviews of their DIS documents. This review resulted in some areas where it is believed alignment is not necessary and cannot be achieved based on the differences between the scopes of the two standards. However, there are many instances where the use of different terminology poses a great threat to lack of understanding or confusion of users because slightly different terminology is being used. Specific comments are being submitted for both standards. Alignment areas are listed under proposed change.	5.1.1 b) 5.1.1 d) 5.1.1 Note 5.2.1.1 6.2.1 9.2.2 d) 9.3.1 e) 10.1 10.2.1	C
25	MY	Some parts of this standard are inconsistent with the Annex SL directive on common text, hence the alignment of this standard with other MSSs is not facilitated. Examples of these are the application of the 'risk and opportunity' approach throughout the standard, definition of 'risk', the use of the term 'intended results' instead of 'intended outcome', the changed positioning of clause on monitoring and measuring resources from Clause 9 to Clause 7. One of the intentions of adopting the Annex SL is to assist organisations in developing multiple disciplined	To relook at these and attempt to reduce deviations in order to facilitate organisations in developing multi-disciplined management systems.	C

		management systems and by making many deviations will not be very helpful.		
26	SE	The transition phase for new ISO 9001 should be matched with new ISO 14001/ISO TC 207.		C
27	UY	In order to align this standard with the future standards ISO 14001 and ISO 45001, we suggest include a section that proposes "Evaluation of compliance". We think that it's important for organization implement a systematic evaluation of compliance instance of legal and regulatory requirements (as well as it is important in environmental management systems and occupational health and safety management).	Include a clause of "Evaluation of compliance" in 8.2 clause.	TN
28	TH	Terms and definitions should comply with those in the environmental management standards and Annex SL. They should also include intended result, opportunities, process outputs, and skills.		TN
29	SG	AS 9100 and TS 16949 should be aligned with ISO 9001: 2015.		C

1.4 General comments - Risk

No.	MB/NC ¹	Line number	Clause/Subclause	Paragraph/Figure/Table/	Type of comment ²	Comments	Proposed change	Observations of the secretariat
30	IT	329 981 1018 1047 1049 1055 1059 1061 1514 1632 1642 1651 1680	0.6 4.4 5.1.2 6.1 6.1.1 6.1.2 6.1.2 6.1.2 9.3.1 A.4 A.4 A.5 A.7	2 nd par 3 rd bullet 2 nd par Bullet f) 1 st par Bullet b) Title 1 st par Bullet a) 2 nd par Note 2 nd par Bullet d) 1 st par 4 th par 1 st par 2 nd par	te/ge	The wording " <i>risks and opportunities</i> " can be misleading and it is not in accordance with ISO 31000 and ISO/Guide 73. The wording used by ISO/DIS 14001:2014 is more clear and it is also in accordance with HLS.	Adopt ISO/DIS 14001 wording replacing " <i>risks and opportunities</i> " with " <i>risks associated with threats and opportunities</i> ". Anyway, ensure consistency between the future editions of ISO 9001 and ISO 14001 on this matter.	TN
31	NL					The Netherlands is voting positive on the DIS 9001 although the degree of application of the concept of risk management in its complete cycle is still unsatisfactory for us. We have chosen however to support the DIS and at the same time to add some small changes in the text to make the risk management concept at a more satisfactory level. (see 6.1.1, 6.1.2 and 6.3). Overall we support the DIS and find it a mature		C

						standard after all the efforts made of the teams within SC 2, especially WG 24.		
32	CQI 2					Change all instances of 'risks and opportunities' to 'opportunities and risks' to emphasize the positive nature of a Quality Management System. Of all the ISO Management System Standards, only ISO 9001 focuses on the creation of products and services through opportunities (whether driven by customer requirements, innovation, new technologies, new marketplaces etc) in contrast with all other ISO MSSs which focus on risk (accidents, pollution, security breaches etc). The proposed change does not materially alter the nature of any requirement in the standard, but will differentiate quality.	Change all instances of 'risks and opportunities' to 'opportunities and risks'. See individual comments of each instance.	TN
33	ANS I					Information related to negative vote by ANSI. Consideration of the word risk. The US TAG to ISO TC176 supports the use of the word risk and risk-based thinking in ISO 9001. With that said, we are greatly concerned regarding the ongoing debate about the definition of the term, concerns raised by ISO TC 262, and different approaches being undertaken in ISO TC 176 and ISO TC 207. (This includes discussion between the United States mirror committees (US TAGs) for ISO 9001 and ISO 14001). The purpose of Annex SL is to bring commonality for users of more than one management system standard. The different approaches being discussed by ISO TC 176 and ISO TC 207 for ISO 9001 and ISO 14001 has the potential to cause more confusion in the marketplace than to improve understanding. In addition, the definition of risk includes opportunities which seems to be driving much of the discussion related to the term risk. The US TAGs to 176 and 207 Liaison Group agree with the rational of this comment	Eliminate the word opportunities and use risks and its effects. This solution is the consensus position of the US TAG to TC176. The US TAG 207 does not specifically agree with this proposed change, but do agree that a change is needed. It is crucial that risk be as consistent as possible between the two working groups. Therefore, liaison between 176 and 207 is necessary.	TN
34	IN					The ISO 9001 Standard shall be incorporating a risk based approach to quality for the first time. Unlike other risk based standards (ISO 14001, 27001) which are contextual and where related risks can be easily identified, ISO 9001 is generic and cuts across business sectors. It may be difficult for implementers of the revised ISO 9001 to understand and readily identify the risks to	A document for the proposed informative annex is being submitted as a part of this comment (attached at the end of the document). The document uses the approach of risk identification that appears as a requirement in Clause 5.1.2 – '(Top management shall ensure) the risks and opportunities that can affect conformity of products and services and the ability to	TN

						quality. It is therefore proposed that an Informative Annex may be provided in ISO 9001 for the guidance on identification of risks during various stages of the product / service lifecycle.	enhance customer satisfaction are determined and addressed' ; and clause 6.1.1 'determine the risks and opportunities that need to be addressed to: prevent, or reduce, undesired effects'. The paper identifies the typical and generic risks that may appear at six stages of the product / service lifecycle and the undesired effects it may have on the organization, customers and other interested parties.	
35	NL					Using the term risks and opportunities is confusing: The definition in DIS 9001: 3.09 risk "effect of uncertainty on an expected result" Note 1 to entry: An effect is a deviation from the expected — positive or negative. Explanation in SC 2/N1222: Risk is commonly understood to be negative. In risk-based thinking opportunity can also be found – this is sometimes seen as the positive side of risk. The explanation in document N1222 is not helping to understand the difference between positive risk and opportunity.	Only use the term risk in ISO 9001. Delete the term opportunity/opportunities when used in combination with risk.	TN
36	FI					In text the term Risk is not logical with the definition according to ISO 9000. The Risk -definition already includes a positive effect. In ISO/DIS 9001 the wording "Risk and opportunities" is used. It is not logical, but confusing.	check the Risk definition	C
37	SII					Risk management is handled by existing documents. It is not clear why this overlapping is necessary. Have the existing documents been found to be ineffective?		C
38	ANS I					Comment related to negative vote by ANSI. There has been reluctance to change Annex SL text in certain areas. Confusion related to documented information and changes to "records". The members have agreed that transition to documented information can be achieved. However, there is one technical issue with the requirement related to changes and documented information. Because there is no distinction made between documents and records, the requirements in clause 7.5 apply to both legacy terms. Clause 7.5.3.2 c) implies that one can "change" documented information of any type so long as version control is maintained.	Each of the outlined issues in Annex SL need to be resolved and incorporated into ISO 9001:2015 based upon offered solutions in the relevant sections.	C

						What we used to call records (i.e. attestations of fact) can be 'corrected' but not "changed." This is an important legal issue, because no court of law would support records being changed. Because many of the issues seem to come from the definition of risk that is being used along with the term opportunities which is included in the definition will continue to cause issue until resolved.. Additionally, compromise on the Working Group level for ISO 9001 and ISO 14001 is needed to ensure that the approaches are not conflicting and will not cause confusion. A cross functional team should be established to discuss this matter prior to any advancement of the DIS to FDIS since technical changes cannot be made at the FDIS stage.		
39	IT	986 - 988 1172-1204 1660-1672	4.4 7.5 A.6		ge/ge	We deem that some clarification on the management documented information is needed. Despite of what is stated in clauses 4.4, 7.5 and A.6, the scope is the only documented information that is required to be maintained. This would imply the risk of having no written procedures and no explicit rules "to support the operation of processes" with consequent difficulties in carrying out auditing of different nature. Moreover, in some clauses, the rationale behind the documented information requirement seems not clear. For instance, in clause 8.3, retaining documented information is required in sub-clauses 8.3.5 and 8.3.6 but not for the other ones. [CRITICAL COMMENT]	Explain how documented information is to be managed and, especially maintained, in a more clear and consistent way. Modify relevant clauses accordingly. According to another above IT comment, replace "risks and opportunities" with "risks associated with threats and opportunities".	TAP C TN

1.5 General comments - Technical

No.	MB/NC ¹	Line number	Clause/ Subclause	Paragraph/ Figure/ Table/	Type of comment ²	Comments	Proposed change	Observations of the secretariat
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40	IT	392 - 393 959-963 1647- 1658	1 4.3 A-5		te/ge	The new approach related to the applicability of the standard is shareable in principle but, in the light of the current generic wording, can lead to a wide range of (even extreme) interpretations. This will also significantly affect the auditing of the future standard. [CRITICAL COMMENT]	Identify a core of essential clauses which are indispensable for the implementation of an ISO 9001-compliant QMS and which cannot be consequently excluded.	TN
41	ES					We have identified 4 cases where the references to "interested parties" create significant conflicts: • 4.2. b) • 4.3 b) • 9.3.c) 5 • A.3	Consider Spanish comments on 4.2. b) 4.3 b) 9.3.c) 5 A.3	C
42	ANS I					Information related to negative vote by ANSI. Use of interested parties. Clarity has been added to the clause 4.2 Understanding the needs and expectations of interested parties, that the interested parties for the quality management system are only those that have an impact or potential impact on meeting statutory or regulatory requirements. However, the definition where an interested party is one that perceives themselves to be affected by a decision or activity is causing confusion. It is also not clear that customers are relevant interested parties since the clarification that has been provided indicates "those that have an impact or potential impact on meeting statutory or regulatory requirements." In the case of customers, the goal is to meet their statutory and regulatory requirements. Improved clarity is needed to avoid misinterpretation of this requirement.	Definitions and use of interested parties must be clarified to eliminate the "perceived."	TN
43	SE					The application of requirements and expectations of "interested parties" is confusing. According to the scope of the standard (Clause 1) the organization shall "provide product or service that meets customer and applicable statutory and regulatory requirements". However, Note 4 to the definition of "requirement" (3.03) indicates that "requirements can be generated by different interested parties". According to the list of examples provided together with the definition of "interested parties" (3.02) such may include "competitors or opposing pressure groups" which looks like a potential source of problems both for the organization and for its customers. It is stated	The different requirements stated in the draft in respect of requirements and expectations of "interested parties" should be reviewed. The result of this review should be that changes are made that make the resulting requirements consistent and clear. Change requirements of interested parties to "needs and expectations". See also comment to row 415.	TN

						in 4.2 that it is up to the organization to determine which interested parties are relevant. In the sub-subsequent requirement text reference to "interested parties" is made in a few places: 7.1.5 includes a requirement on "interested party expectation" on measurement traceability. Unexpected requirement in the actual context. 8.2.3 NOTE addresses requirements of "interested parties" in conjunction with review of requirements. Unexpected requirement in the actual context. 8.3.1 states that the existence of requirements of "interested parties" may initiate a design and development process. Unexpected requirement in the actual context. Taken together, the different statements in respect of requirements and expectations of "interested parties" give a confusing impression which makes it difficult for the organization to understand how to deal with such requirements and expectations.		
44	ANS I					Information related to negative vote by ANSI. Use of Performance, quality performance, performance indicators, underperformance. The inconsistent and incorrect uses of these terms have great potential for misinterpretation by users. The US TAG to ISO TC176 supports an organization driving results for the quality management system, but recommends a different approach. Using the phrase "achieve intended results" versus using terms such as "quality performance, performance indicators, or underperformance" provides the same result with less potential for misinterpretation. Specific examples include: • Annex SL requires that the word quality be used in front of the word performance in some cases. In particular, the use of the phrase quality performance as it relates to competence in clause 7.2 does not clarify to whom competence applies. Without this boundary, some users feel that the word competent needs to be added to specific roles, in particular quality auditors. • There appears to be confusion between the terms "quality performance" and "performance of the quality management system." Both phrases are used which	Eliminate the "fill-in-the blank" process when discussing quality performance and address each requirement specifically to ensure correct usage. Specific proposed changes have been provided on the requirements affected by this language.	TAP

						implies that these are two distinct concepts. In fact, 9.1.1 states "The organization shall evaluate the quality performance and the effectiveness of the quality management system" while 5.3 states "reporting on the performance of the quality management system." The requirement to use the fill-in-the blank approach by using quality in front of performance as required by Annex SL is driving the confusion. In fact, the experts revising ISO 14001 have developed a definition for environmental performance for that reason. Finally, using performance indicators in 4.4 for the processes will drive performance metrics for processes. The relationship of this activity to quality objectives is not clear. In addition, this requirement is more prescriptive which is contrary to the overall philosophy of the standard which is to make ISO 9001 more generic and less prescriptive.		
45	ANS I					Comment related to negative vote by ANSI. Organizational Knowledge. There has been ongoing debate related to this topic, but it remains unclear. Specifically, the difference between competence and knowledge is not clear. The current language in the DIS is somewhat improved, but the note provides examples of attending seminars, which would be the same activities used to achieve competence. This confusion is further compounded by providing information related to competent people in the annex. The annex states "The balance between knowledge held by competent people and knowledge made available by other means is at the discretion of the organization, provided that conformity of products and services can be achieved.	The clause must be structured better or deleted. See proposed change in 7.1.6	C
46	ANS I					Comment related to negative vote by ANSI. Use of the word innovation. It has been agreed multiple times by the working group experts that the word innovation would not be used in the standard. There has been ongoing discussion of this issue by the working group experts since the initial working draft was developed in St. Petersburg, Russia. Agreements made in Belo Horizonte, Brazil, indicated the following: That decision stated "The standard shall accommodate	It should be determined prior to the meeting in Galway based on prior discussions to eliminate innovate or innovation. Any further discussion on this matter is non-value added and reversing already agreed upon consensus.	TAP

						innovation. It may even mention innovation. It will not require accidentally or otherwise the organization to innovate or be seen to be innovative. Neither will it imply the above." The use of innovation does not meet this criteria since the standard currently indicates that top management will report on the performance of the quality management system and the need for change or innovation. One of the final conversations of the WG24 experts in Versailles, France, included a conclusion on innovation that this term would not be used.		
47	SII					See lines 708-712 and 1040-1043 The views in Israel are divided regarding innovation in this Standard. Some feel it is important and of significant added value Those opposed are express their objection as follows: The scope of ISO 9001 as stated in this DIS has nothing to do with a specific requirement for innovation. It is all about meeting customers requirements and to enhance customer satisfaction. Innovation is indeed an important factor in a company's success but it definitely can't be a requirement for certifying a company QMS and more than that there are no objective ways to audit existence of innovation in a company. It is also stated that all requirements in this standard are generic and applicable for all types of organizations many of which may have a very traditional product which if changed by innovation may lose its whole customer base.		C
48	NL					What is the intended result of ISO 9001: • Provide products and services that meet customer and applicable statutory and regulatory requirements (4.2, 5.1.2, 7.1.2, 8.2.3, 8.4.2); • Ensure conformity of products and services (4.3, 6.1.2, 7.1.3, 7.1.4, 7.1.5, 7.1.6, 8.5.2, 9.1.3, 9.3) • Achieve conformity to products and service requirements (8.1) • Conformity of products and services and the ability to enhance customer satisfaction (5.1.2, 6.2.1) • Conformity to requirements (8.5.2, 8.5.4, 8.7)	In clauses where only part of the scope is being referred to, repair this by explicitly referring to the elements of the scope: <i>meet applicable statutory and regulatory requirements and aims to enhance customer satisfaction.'</i> <i>products and services that meet customer requirements</i> NB For this element of the scope we know that a list has been agreed in WG 24 about which clauses should state this explicitly.	TN

						Enhance customer satisfaction (9.1.3, 10.1) In annex A3 is stated: <i>'The Scope states, in part, that this International Standard is applicable where an organization needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements and aims to enhance customer satisfaction.'</i> Regarding the scope and specific clauses it is clear that in clauses only part of the scope is being referred to. This gives misinterpretation regarding the intended result of ISO 9001.		
49	GR					There is a need to stress the relation between Management principles and Std's requirements and between the organization's strategy and its QMS.	Consider the inclusion of management principles as a new Clause, after Clause 3 and before requirement's Clauses	TN
50	IE					It is a pity that some key elements of a good QMS are not been emphasised here. For companies starting out on the quality maturity journey they need some milestones. Examples here are: A Quality Manual. Clear guidance on the need to have documented procedures for the core functions associated with the control of any system or process: Document and record control, control of non-conforming product, Corrective and preventive action, Auditing, Clear demonstration of how processes interact.	Make these MANDATORY.	TN
51	NL					The abundant use of the word requirements in different setting (25 times), with different adjectives makes it difficult to interpret what the essence of 'requirements' actually is. Especially 'applicable, specified, detailed requirements' have an unclear distinct usage.	Restrain in usage of the word requirements and/or cut back on the adjectives. The Dutch experts will have available a proposal at the Galway meeting.	C
52	CA-03					Looks like we are re-producing part of ISO 9000 here. With definitions and associated notes, the standard becomes too long to read	Many times notes are repetitions of the notes from ISO 9000 – should try to minimize the number of notes and/or just refer to ISO 9000 or consider for inclusion in ISO/TS 9002 See comment CA-21	TAP
53	ZA					Correlation matrix not as accurate and helpful as	Add the following sub-headings to the document	TN

						it could be. Generally speaking, the greater the number of headings there are, the greater will be the precision of the resulting mapping.	to aid precision in the creation of an accurate correlation matrix. 5.2.1 Establish quality policy 5.2.2 Publish quality policy 6.1.1 Issues to be considered when addressing risks and opportunities 6.1.2 Risks and opportunities planning 6.2.1 Establish quality objectives 6.2.2 Planning how to achieve quality objectives 7.5.3.1 Required documented information 7.5.3.2 Documented information controls 9.2.1 Purpose of internal audits 9.2.2 Establish internal audits 9.3.1 Purpose of management review 9.3.2 Management review outputs 10.2.1 Purpose of nonconformity and corrective action 10.2.2 Nonconformity and corrective action documented information	
54	GOS T R/R U					DIS 9001 text contains in different clauses phrases "retain documented information" or "maintain documented information". The difference is not clear. This leads to confusion and to problems for translation to other languages.	Leave one single term whether «retain» or «maintain» concerning «documented information» within all DIS 9001 text to avoid confusion	TN
55	MY					The requirement "to retain documented information" is explicitly specified in many areas of the standard. However, there is inconsistency in that this is not specified in relation to some requirements where the need to retain documented information is clearly applicable.	To review the document and include this requirement in all areas where the need to retain documented information is clearly applicable. To relook at these and attempt to reduce deviations in order to facilitate organisations in developing multi-disciplined management systems.	C
56	NZ					The terms 'maintain' and 'retain' have very similar meanings in English and might be translated by the same word in some other languages. Using 'retain' could be interpreted as 'code' for records, rather than simply being used to make grammatical sense. This differentiation might be undesirable since it could undermine the use of 'documented information'. ISO 9001:2008 used 'maintain records'. However there is a risk that using 'maintain documented information' throughout could imply additional process documentation. Each requirement therefore needs to be clear in context, whether 'retain' or 'maintain' is used.	The WG needs to discuss translation of 'retain' but in any case, the difference between 'maintain' and 'retain' is small and could be confusing for those reading in English as a second language. The most straightforward option is to use 'maintain' throughout (including where 'keep' or 'retain' is used in Annex SL text), but ensure that the intent of each requirement is clear from the context. If 'retain' is used, the requirements should still be qualified (as already occurs in most cases) to show the intent, eg 'as evidence of ...'. This would allow translation of 'maintain' and 'retain' by the same word but maintain (or retain!) the differentiation in English.	C
57	AU	987 , 1074,				For consistency & translatability replace 'retain' with 'maintain' throughout the DIS		TN

		1128, 1155, 1214, 1252, 1307, 1313, 1383, 1414, 1442, 1455, 1496, 1519, 1548, 1672						
58	SG					What happened to original clause 6.4 on Work Environment in ISO 9001: 2008? The ISO9001:2008 Clause 6.4 should be expanded rather than diminished.		C
59	SG					What happened to original clause 7.4 on Purchasing in ISO 9001: 2008?		C
60	IT					We deem that in ISO/CD 9000 there were some significant references to methods and techniques which can be seen as complementary to the QMS (e.g. Six sigma, lean, market research and competitive analysis, business continuity management, etc.).	Consider to reintroduce those references adding specific notes in relevant clauses.	C
61	SE					There are several sub-clauses that contain lists that state general requirements on issues for which detail requirements are stated in other places in the draft. This means that requirements are duplicated and that a complex structure is created which makes both understanding and auditing more difficult. Such lists of general requirements are included in: 4.4 Quality management system and its processes 5.1.1 Leadership and commitment for the quality management system 5.1.2 Customer focus 7.4 Communication 8.1 Operational planning and control 9.1.1 Monitoring, measurement, analysis and evaluation, General	It should be considered whether such lists contain redundant information and should be deleted.	C
62	SE					General comments on the phrasing and the intent of the changes in this standard. I question a lot of parts of it due to as I see an incorrect focal point. I think it is important to understand the role of a QMS in an organization.	Review the complete mass of text according to the perspective of a QMS as a supporting system and not a process of its own!	C

						According to my experience a good QMS supports the existing business processes in the organization in a good way. Using this focus when reviewing the text gives a very clear indication that partly the text has the opposite focal point.		
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1.6 General comments - Editorial

No.	MB/NC ¹	Comments	Proposed change	Observations of the secretariat
63	ANSI	There is inconsistent use of "persons" and "people" throughout the document. It appears that "persons" is the preferred term and it should be used for improved consistency.	Change every occurrence of "people" to "persons" throughout the document, including the annexes.	EAP
64	BW	7.1.2 onwards Use a word consistently throughout the standard, e.g. "people" should be used throughout instead of using it interchangeably with person(s)		EAP
65	AR	"persons" is used in numerous places even in the paragraph titled 7.1.2 People on 1097 – while this may be correct it seems awkward and could be improved for consistency to people – persons is used in lines: 201, 548, 1005, 1099, 1151, 1157, 1159, 1182, 1372, People is used in lines: 87, 245, 330, 404, 414, 444, 628, 633, 1097, and appendix	Macro change to "people" all locations	EAP
66	SE	The word "people" is used in several places in this standard. In the text the wording "persons", "personell" are also used.	Align the wording "people" and "persons" so the title and text is harmonized	EAP
67	AR	ISO 9000 and ISO 9001 refer to "assess" and "evaluate" separately throughout the documents. evaluate (9001) 238 / 1058 / 1080 / 1153 / 1453 / 1457 / 1469 / 1537 assess (9001) 213 / 238 / 1473 / 1476 / 1477 These two terms in English are virtually synonymous and in French and maybe other languages have only one term that applies to these concepts. Short dictionary definitions: evaluate to think carefully about something before making a judgment about its value, importance, or quality assess to carefully consider a situation, person, or problem in order to make a judgment	Use "evaluate" throughout the ISO 9000 series of standards, unless it is thought that there is a genuine difference in concept within the field of quality management. In which case the different characteristics of each concept should be clearly stated in the definitions.	TAP

		ISO 17000 conformity assessment vocabulary standard recommends adopting the word "assess" for all such references. Some years ago it was agreed as follows: ISO 17000 series (Conformity assessment) use "assess". Other ISO deliverables use "evaluate".		
68	GR	"Goods" and "products" are synonyms. Use "products" as preferred term	Use "products" instead of "goods"	TAF
69	CA-04	What is the difference between "fulfil", "satisfy", "meet", "conform", in relation to requirements? Some of the phrases used are: - requirements have been fulfilled - requirements have been met - fulfilment of a requirement - conform to specified requirements - satisfy applicable requirements - conformity to requirements - meets customer requirements If "fulfil", "meet", etc. were used because they had different meanings, then the terms must be defined, so as to avoid confusion for the user.	Choose one term, and use it consistently. It appears that "conform" and derivatives is used most frequently, so perhaps that is the best choice 9.1.2 Customer satisfaction The organization shall monitor customer perceptions of the degree to which customer's expectations have been fulfilled. 5.3.1 Developing the Quality Policy Top management shall establish, implement and maintain a quality policy that: c) includes a commitment to satisfy applicable requirements;	TAP
70	CA-05	The document frequently uses the term "conformity of products and services" without mentioning to what criteria, In 3 instances (clauses 7.1.5, 8.1 and 9.1.3) it does indicate the criteria: "conformity of products and services <u>to requirements</u> ". The Standard should be specific and consistent, as to the criteria.	Use: "conformity of products and services to requirements" consistently, throughout the document	C
71	CA-07	The terms "consider" and "take into account" are not explained/defined, and as a result, there may be a potential for confusion with the application of these terms in ISO/DIS 14001, which states, In it's Annex A.3: "The word ' <i>consider</i> ' means it is necessary to think about but can be rejected; and ' <i>take into account</i> ' means it is necessary to think about but cannot be rejected." The objective of Annex SL is to create some level of alignment between various MSSs, but if generic terms, such as these, are defined and applied inconsistently, it will subvert that objective.	Must liaise with TC 207, to ensure a consistent application of these terms, in both ISO 9001 and ISO 14001	C
72	FI	The verb address is used frequently in requirements. The verb is too ambiguous and difficult to translate	The whole text should be checked and changed	C TN
73	SE	The wording "relevant" is used in many places and is often superfluous. It is already covered by "as appropriate".	Delete: "relevant" when superfluous. See also comment on 5.2.2 c) below.	TN
74	SE	Use of terms "outcome", "output" and "result" For translational purposes it would be advantageous if English synonyms without direct counterparts in other languages like Swedish could be kept to a minimum. One example is the use of the term "outcome". A simple analysis of the use of the terms "outcome", "output" and "result" (noun) is shown below.	See comments below.	C
75	CZ	All referenced terms throughout the text should be in italics and provided with reference numbers.	To be corrected.	C
76	CZ	organisational vs. organizational organisation vs. organization	Use the same spelling.	EAF
77	TC210	The spelling of 'organization' varies with 'organisation' throughout the document	Use 'organization' consistently	EAF
78	AR	Inconsistent spelling of organization vs. organisation such as organisation used in	Macro change "organisation" to "organization"	EAF

		lines 194, 943, 1233, 1333, 1339, 1404, 1462, 1491, 1530, and appendix vs. Organization used in lines 71, 72, 79, 91, and numerous other locations.		
79	CA-06	The document continues to flip-flop between "organisation" and "organization", The ISO 9000 family of standards has, since 1987, used "organization", and the current ISO 9000 DIS maintains that spelling.	Use "organization", throughout the document.	EAF
80	UY	We suggest clarify the difference between "note to entry" and "note to definition" because it is a kind of note used more in assessment conformity standard than quality management system standards.	Clarify the difference between "note to entry" and "note to definition".	C
81	FR	Reviewing the size and harmonize police characters. Some paragraphs are written with different sizes.	Reviewing the size and harmonize police characters. Some paragraphs are written with different sizes.	EAF
82	MX	unify page numbers: Arabic numerals vs Roman		EN
83	DE	The verbal forms in ISO/IEC-Directives - Part 2:2011, Annex H, shall be used to indicate requirements strictly to be followed in order to conform to the document and from which no deviation is permitted. [see ISO/IEC Directives - Part 2:2011, Annex H]	The verbal form „can" shall be used for statements of possibility and capability, whether material, physical or causal. If you want to express a permission, please use „may" or „need not". [see ISO/IEC Directives - Part 2:2011, Annex H]	C

1.7 General comments – Cross reference matrix

No.	MB/NC ¹	Comments	Proposed change	Observations of the secretariat
84	PH/B PS		A need to include a Cross Reference between ISO 9001:2008 and 2015	TN
85	MY	Since this is a major restructure of the standard, correspondence between the old standard and revised standard should be included as an annex	To consider incorporating an annex on "Correspondence between ISO 9001:2008 and ISO 9001:2015."	TN
86	CA-02	Include the Correlation Matrices as an Annex, as they will be very helpful for users, when migrating from ISO 9001:2008 to ISO 9001:2015	Include in an Annex, the matrix mapping 2008 -> 2015 and the matrix mapping 2015 -> 2008	TN
			Secretariat Note: A cross-reference matrix is available to download (for free) from www.iso.org/ct176/sc02/public	

1.8 General (and some Specific) comments on the relationship to ISO 9000, including:

- the inclusion of Terms and Definitions,
- Normatively Referencing ISO 9000,
- cross-references within the terms
- alphabetically listing terms
- the need for an alphabetical index of terms

- the inclusion of the Quality Management Principles

Please note that other comments relating to these issues are given within the main collation of Specific comments below

No.	MB/NC ¹	Line number	Clause/ Subclause	Paragraph/ Figure/ Table/	Type of comment ²	Comments	Proposed change	Observations of the secretariat
87	IE					ISO9001 should not duplicate anything that is in ISO9000. This includes the process model, process approach and definitions		C
88	UY					We suggest include all definitions only in ISO 9000 std to centralize all definitions in one only document and avoid confusion.	Delete all definitions of ISO 9001 and centralize them in the ISO 9000 standard. Include in the chapter 3 the same text of the ISO 27001 standard: "For the purpose of this document, apply the terms and definitions given in ISO 9000 Standard"	TAF
89	DE				GE	Germany highly appreciates the general content of ISO/DIS 9001 and the improvements made since the CD, but disapproves ISO/DIS 9001 for the following main reason: the draft currently duplicates both the quality management principles and many terms and definitions included in ISO 9000. This duplication shall be avoided, as it raises the risk of deviations in both standards, but even more important, diminishes the value of ISO 9000 as THE standard on fundamentals and vocabulary of quality management.		TAF
90	ANS I				GE	Comment related to negative vote by ANSI. ISO 9000 should be listed as a normative reference and the definitions removed from ISO 9001:2015. There were a substantial number of comments related to the ISO 9000 definitions being included in the DIS for ISO 9001:2015. While the text indicated that the definitions were being provided for commenting purposes, this has brought with it much confusion since WG24 only passes the comments on the definitions onto SC1.	List ISO 9000 as a normative reference.	TAF
91	ANS I				GE	There are several issues related to terminology. While it is agreed, that the specific language in most terms can be transferred to SC1 for their review, it is critical that some of these terms and concepts are considered as part of the WG24 activities. These specific terms are highlighted in	Review issues with terminology that could impact the development of ISO 9001.	TAF

						the definitions.		
92	CN	400 - 930	3		T	There are too much terms and definitions in ISO 9001:2015.	Delete the terms and definitions in ISO 9000:2015.	TAF
93	JP 16	400 - 930	3		ge	Many of the cross-references are incorrect. In addition, terms that are not used in the requirements but are used only to define other terms are included. It is proposed to include the list of terms from ISO 9000 without their definitions.	List only the terms that are used in the requirements without their definitions. Delete the terms that are used in the requirement with dictionary meanings. Delete the terms that are used only to define other terms. (If the definitions are included, these terms should not be deleted.)	EN EAF EAF
94	CQI 14	400 - 929	3	Entire clause	Te	The terms and definitions in clause 3 are very useful included in ISO 9001. However, it would be very useful if there was a list similar to Annex C (informative) Alphabetical index of terms in Clause 3 in ISO DIS 14001.	Create a new annex (attached) with an Alphabetical index of terms in Clause 3.	EN
95	INLA C	400 - 929	3.0		Te	There is no need to include 13 pages of definitions (69 in total) in the standard. As current ISO 9001, reference to ISO 9000 is just enough. For current and future users, section 2.0 and Annex A in ISO 9000 are key elements in understanding the intent of ISO 9001. Section 3.0 should encourage users to study ISO 9000.	Change paragraph in line 400: For the purposes of this document, the terms and definitions given in ISO 9000 apply. Remove all definitions in the standards (3.01 - 3.69).	EAF
96	NL	401 - 930	3		Ge	Number of terms and definitions (14 pages) too high and creates barrier at the beginning of the standard already	Reduce number of terms and definitions to the elementary ones and refer to ISO 9000.	EAP
97	CH	400 - 929	3	All	Ge	It is welcomed that all relevant terms used in ISO 9001 are now contained in ISO 9001 itself. In this way they will be read and better understood. <u>However</u> there appear to be some terms in clause 3 which are not being used in ISO/(DIS) 9001 and are therefore redundant.	<u>Remove</u> from clause 3 all terms which are not used in ISO 9001.	EAF
98	IT	400 - 929	3	Whole clause	te/ge	69 terms are reported in clause 3 and some of them are different from the corresponding ones specified in ISO 9000. This is unacceptable: it can create confusion and decrease the value and actual use of future ISO 9000. Terms and definitions should be also ordered in a more useful way too (e.g. in alphabetical order). [CRITICAL COMMENT]	Limit terms and definitions to a very small number of indispensable ones for the comprehension of ISO 9001. Consider a different and more useful ordering of terms.	EAP C
99	SE	400 - 929	3	All	te	The clause takes 13½ pages and is copied from ISO 9000. This is an unnecessarily heavy burden to the document, leading to high purchase cost. Moreover, if all terms and definitions in ISO/DIS 9001 should remain in the final standard is seems questionable whether there is a real need for ISO 9000, when also Annex B "quality management	Replace the text by a statement "For the purpose of this International Standard the terms and definitions given in ISO 9000 and those mentioned below apply." Delete at least all which refer to ISO 9000 and not mentioned in "Annex SL". i.e. 3.22-3.69.	EAP EAP

						principles" are taken into consideration.		
100	SE	400 - 929	3	All	te	ISO Directives Part 2 states: "D.1.4 Choice of concepts to be defined" Any term, symbol or appellation (for brevity, "terms, symbols and appellations" are hereinafter referred to collectively as "terms") which is not self-explanatory or commonly used and which can be differently interpreted in different contexts shall be clarified by defining the relevant concept. General language expressions and commonly used terms shall be included only if they are used with a specific meaning in the relevant context (and thus the usage of the expression or term may cause misunderstanding if not defined). Trade names, trademarks, obsolete, archaic and colloquial terms shall not be included."	Some terms defined in ISO/DIS 9001 and ISO/DIS 9000 do not seem to have any specific meaning and it is unfortunate that they have been included. Terms of this kind are indicated below. All terms necessary to define, common to a majority of management system standards, and their definitions should be developed and added into an extended Annex SL.	C C
101	CZ	402 - 929	3.01 – 3.69		ge	Clause 3 includes too many terms and definitions that are in fact the purpose of ISO DIS 9000:2014 standard. This situation is not transparent enough for use. Use only the terms that are crucial for this document, others should be referenced to ISO DIS 9000 or other standards. If this comment could not be accepted it is necessary to align numbering with ISO DIS 9001 as well as with that of EMS.	Fundamental and new terms should be kept, e.g. 3.02 interested party, 3.08 objective, 3.09 risk, 3.11 documented information, 3.13 performance, 3.14 outsource, 3.24 context of the organization, 3.25 function, 3.26. customer, 3.27 supplier; provider.	EN
102	TBS	402 - 925	3	all	te	All definitions in the field of quality management should be included in ISO 9000 Quality Management systems- Fundamental and Vocabulary	Shift the definitions in ISO 9001 to ISO 9000 and clause 3 should read " The definition in ISO 9000 applies"	EAF
103	AR	402 / 929	3		te	Simplicity should be taken into consideration for this revision, quoting too much (69, 14pages) ISO 9000 terms and definitions into ISO 9001 standard is not very friendly and may bring negative impact to users. ISO 9000 is drafted to harmonize the terminology used in all the documents developed by ISO/TC176. By this way, users' misunderstandings are avoided increasing prestige and confidence to ISO documents. 69 terms and definitions are arranged in an inconsistent way, following neither ISO/IEC Directives, Part 2, D.1.2, Arrangement, nor terminological requirements stated in standards developed by ISO/TC37 (ISO 704:2009, ISO 10241-1:2011).	We propose deleting the vocabulary and adding a reference to ISO 9000 in Clause 2.	EAF
104	ZA	402 / 929	Clause 3		te	ISO 9000 is drafted to harmonize the terminology used in all the documents developed by	Take out the vocabulary and add a reference to ISO 9000 in Clause 3 or alternatively rearrange	EAF

						ISO/TC176. This way, misunderstandings are avoided.	alphabetically	
105	ZA	402 / 929	Clause 3		te	Terms and definitions are arranged in an inconsistent way, following neither ISO/IEC Directives, Part 2, D.1.2, nor terminological requirements stated in standards developed by ISO/TC37 (ISO 704:2009, ISO 10241-1:2011).	Take out the vocabulary and add a reference to ISO 9000 in Clause 3, or alternatively rearrange alphabetically	EAF
106	DK					In general the references between ISO 9001 and ISO 9000 are incorrectly given.	Change references to be correct. DK will on demand deliver a list of needed changes.	C
107	DK					Move the Quality Management Principles to ISO 9000 as they should be read by easily accessible for the user of this standard.	Move the Quality Management Principles to ISO 9000 from DIS 9000.	EAF
108	BR	1694	Annex B			The QMPs presented in Annex B are already presented in a more detailed form in ISO /DIS 9000. The present ISO 90001 doesn't present the QMPs, because they are already presented in ISO 9000.	Delete Annex B.	EAF
109	DE	1694	Annex B		ge	Please do not "duplicate" the content of ISO 9000 in this annex. The content of Annex B is completely given in ISO 9000. That will hold a highly risk and high maintenance effort.	Please delete Annex B and add clause "Normative references" and refer to ISO 9000. By that way the "problem" with doubled terms and definitions and the doubled content of Annex B will be terminated. That will improve usability and "customer focus".	EAF
110	ANS I	400	3	ALL	Ge	Several references within terminology section taken from DIS 9000 are inaccurate and need to be corrected	Correct references in terminology within 9000:2015	EAF
111	DE	400	3		ge	A large number of concepts from ISO 9000:2014 have been adopted into the clause "Terms and definitions" of this document. It is not clear to see, why. ISO/IEC-Directives – Part 2:2011, Annex D.1.5 read: "If the concept is used in several documents, it should be defined in the most general of those documents, or in an independent terminology standard. The other documents should then refer to this document or terminology standard, without repeating the definition of the concept." According to ISO/IEC-Directives – Part 2:2011, 6.3.1 it would have been an obvious solution to prefix the clause "Terms and definitions" with the text "For the purposes of this document, the terms and definitions given in ISO 9000:2014 and the following apply." and then to list only those concepts not comprised in ISO 9000. Some of the adoptions show discrepancies within a number of concepts which lead to deviations	Please delete all terms and definitions from ISO 9001 in order to improve usability of ISO 9001 and decrease future maintenance work. Please refer to the terms in ISO 9000 by adding a normative reference to ISO 9000 in clause 2	EAF

						between ISO 9000 und ISO 9001. This does not adhere to the rules. <u>All German comments relating to the content of terms and definitions have therefore only been submitted to ISO/DIS 9000.</u>		
112	AU	400	Clause 3			The definitions should be the same as those in DIS 9000. Therefore the following comments MUST be read in conjunction with the definitions in DIS 9000 to ensure that the two sets of definitions are the same		C
113	GOS T R/R U	400	3		ge	Reasons to include in DIS 9001 text terms and definitions from DIS 9000 are not clear.	Exclude DIS 9000 terms and definitions .	EAF
114	ES	400	3		te	Excessive definitions in Clause 3. Clause 3 should not be included in ISO 9001 if already included in ISO 9000. Terms and definitions should not be duplicated.	Delete clause 3 or select only the relevant terms from ISO 9000	EAP
115	AT	400	3		ge	We appreciate the inclusion of the terms and definitions used in the body of this document in Clause 3 instead of referencing to ISO 9000. The terms shall be in alphabetic order and only those terms used in this document shall be listed in Clause 3.	The terms shall be in alphabetic order and only those terms used in this document shall be listed in Clause 3.	EN EN
116	PH/ BPS	400	3		te	Section 3- Terms and definitions made reference to ISO DIS 9000:2014. Would the Terms and Definitions be part of the standard (ISO 9001:2015)? If this is so, this would result to increase in the number of pages of the standard and when that happens, it will add impact on the cost of the standard especially to MSMEs. Some countries sell the standard on a per page basis.	Consolidate all terms and definitions in the ISO DIS 9000:2014. Instead, just indicate the statement : Terms and definitions specified in ISO DIS 9000:2014 shall apply.	EAF
117	BG	400	3.		ed	The number of terms and definitions included duplicate the definitions given in ISO 9000.	Under cl.3 of ISO 9001:2015 to include only the definitions connected to the new and revised requirements of the standard.	EN
118	CL	400	3	--	te	3 Terms and definitions The National Committee believes that it is better to keep the reference to the definitions contained in ISO 9000, as was in ISO 9001: 2008.	We suggest to change to: "3 Terms and definitions For the purposes of this document, the terms and definitions given in ISO 9000 apply"	EAF
119	TN	400		3	ge	<u>Chapter made large due to the reversal of terms defined in ISO 9000 (cited as reference to this standard).</u>	Eliminate this redundancy	EAF
120	IQN ET	400	Section 3		Te/GE	Inclusion of terminology in the standard is a great enhancement as it will allow for people to read all terms (and not only HLS ones) in the same document and makes it easier to interpret. However, many terms defined here are not	Critically revise all terms and eliminate from 9001, those that are the same or better in a common dictionary, that add no value to comprehension of document and make it too lengthy Examples: supplier, system, management, top	EN

						necessary as they are equal to what is said in the dictionary and putting them here adds no value and makes document longer. Others contradict somehow what is said in the standard , are very confusing or deviate from the usual meaning in the dictionary which may cause confusion in the reader, and thus be contrary to design spec	management, effectiveness, competence, monitoring, customer, improvement, object, feedback, measurement. These can be put in a glossary with the exact meaning with which they are used put taken from the dictionary. Critically revise all other terms to make sure they provide clarity to the reader.	
121	IQN ET	400 GE	Section 3		GE/ ed	All section in the beginning of the document (13 pages) makes the document hard to read and disrupts the introduction and scope from the requirements that are core. Terminology is useful but is not core, as it is used for consultation purposes On the other hand we must recognize standard are now frequently sold as pdf and read in computer and these 13 pages make consultation harder	Keep section 3 to keep consistency of structure, but remove terms to the end of the document as an appendix (normative). In section 3 say something like: For the purpose of this document, the definitions and terms defined in Annex D apply. In the standard section 4 to 10, provide a linkage in the pdf to enable people that are reading it in the pc to click in the term and go to the definition.	EN
122	TC4 6/SC 11 Liaison (AU)	400	3		Te	There is no apparent order to the terms and definitions and there is no alphabetical index to aid users in locating the terms.	Explain the order of terms and definitions and include an alphabetical index.	EN
123	TC4 6/SC 11 Liaison (AU)	400	3		Ed	Incorrect entry numbers are referenced in parentheses throughout this section	Check entry numbers for accuracy and amend where necessary	EAF
124	ISS/ RS	400	3		te	Numbers in definitions for referencing with ISO DIS 9000 are mostly wrong	Correct mistakes	EAF
125	ISS/ RS	400	3.01-3.69		ed	There is no need for all stated terms and definitions because standard ISO 9000 contains almost all of them	Move definitions that have already been mentioned in ISO 9000	EAF
126	IE	400	3 terms and definitions		ge	Why repeat what is already in ISO9000. It is NEVER good practice to repeat core information in two separate locations	Write introduction here that states ' Unless stated otherwise the definitions given in ISO9000:???? apply. ' If it is felt necessary list these terms but do not define them.	EAF
127	IE	400	3		ed	This section should include only those terms and definitions that are not included in ISO 9000.	(a) Include only those terms and definitions that are not included in ISO 9000. (b) Consider including the relevant ISO 9000 terms and definitions as an Annex.	EN
128	CA-	400	3		te	Do NOT change definitions radically in ISO 9000,	Restrict the extent of changes in ISO 9000/9001	EAF

	20					and therefore 9001 - too confusing with all the other 9001 changes in structure and content, and not necessary - it will create problems during auditing. (change in definition of "auditor" is a good example)	definitions.	
129	CA-22	400	3		te	It is not clear why we have a Clause for Terms and Definitions within ISO 9001 standard, while ISO 9000 already covers it in plenty of detail. There are 69 terms defined, and they are in random alphabetic sequence, which makes it VERY difficult to find if (a) a term is defined, and (b) where it is located. It would be far better to leave all definitions for ISO 9000, as was the case in the past. If we insist in retaining these definitions in ISO 9001, then either provide an index at the start of section 3, OR as an Index at the back of the document. Otherwise, people will waste hours searching for a definition.	Options, in order of preference: 1) remove all terms & definitions from ISO 9001 2) provide an Index at the back of the document 3) provide an index at the start of section 3	EAP
130	FI	400	3		ge	Our (FI) comments regarding terms and definitions have been presented in the context of ISO/DIS 9000		C
131	FI	400	3		ge	Do not include ISO 9000 definitions in this standard	ISO 9000 should be as a normative reference	EAF
132	NZ	400	3		te	There are important changes to definitions. We assume that ISO 9000 is likely to be published in parallel with ISO 9001. However not all users of ISO 9001 have ready access to ISO 9000. The number of pages of terms and definitions in ISO/DIS 9001 is unacceptable. Referencing the ISO Online Browsing Platform for online access to terms and definitions would be preferable to including terms and definitions in ISO 9001. (Note: NZ has submitted comments on definitions to the revision of ISO/DIS 9000 since this is a later draft with some errors corrected.)	Whether or not ISO 9000 is published in parallel with ISO 9001, add a Note on the ISO OBP and request the SC1 Secretary to ensure that the definitions are published promptly on the OBP. Note: The ISO Online Browsing Platform (iso.org/obp) provides a searchable database including terms and definitions used in ISO International Standards. The search can be refined for terms and definitions specific to ISO 9001 by selecting the Committee ISO/TC 176/SC 1 or ISO/TC 176/SC 2.	C
133	TH	400	3		ge	Terms and definitions should comply with those in the environmental management standards and Annex SL. They should also include intended result, opportunities, process outputs, and skills.		TN
134	GB	400	3	General	Listing	The current listing of the vocabulary section is random.	Leave the terms and definitions to ISO 9000 Rearrange the terms and definitions in clause three to mirror the thematic listing of ISO 9000 renumbering where appropriate. Add an alphabetical listing of the terms and definitions in clause 3 at the end of the clause unless ISO objects in which case add to the back of the standard.	TAF C EN

135	TC2 10	398 - 399 and 401	2 and 3	Paragraph 1 of each clause	te	ISO 9000 is not normative reference and all definitions are not contained in ISO 9001. It is confusing for the user that there are different definitions in the two standards. Since the revision of this family of standards are synchronized, they should have the same definitions or difficulty will result.	Change 2 as follows and revise 3 according to this.. (to define ISO 9000 as normative reference) 2. Normative references The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies. ISO 9000:201X, <i>Quality management systems — Fundamentals and vocabulary</i> <i>3. For the purposes of this document, the terms and definitions given in ISO 9000 together with the following apply. The following definitions should be regarded as generic, as definitions provided in appropriate national regulatory requirements can differ slightly and take precedence.</i>	EAF EAP
136	FR	400	3	General	te	The introduction represents nearly 10% of the total number of pages of the standard. The terms and definitions represent almost 25% of the text.	Remove chapter 0.2 from the introduction and add it to the annexes. Remove section 3 "Terms and definitions" from ISO 9001 and re-introduce the normative reference to ISO 9000.	EAP EAF
137	FR	400	3	Terms and definitions	ed	Regroup terms and definitions by family as in ISO 9000	If the terms and definitions are to be maintained in ISO 9001, they should be regrouped in families of terms as in ISO 9000.	C
138	ES	401	3		ge	Terms should follow alphabetic order or be grouped by concepts like in ISO 9000	Put terms following an order	C
139	IN	401	3.0	-	ed	For ease of reference all terms and definitions should appear in alphabetical order	All terms and definitions to appear in alphabetical order	EN
140	PL	401	Whole clause 3		ge	Not all terms and definitions are needed in this standard. To repeat a lot of terms from ISO 9000 is redundant effort. We suggest to remain only terms from SL level, potentially also from standards other than ISO 9000. We suggest to include the statement that terms and definitions from ISO 9000- are applied with the following terms.	"For the purposes of this document, the terms and definitions given in ISO 9000 and the following apply."	EAF
141	CZ	401			ge	In compliance with the below mentioned comments to clause 3, the introductory sentence should be amended.	"For the purposes of this document, the terms and definitions given in ISO DIS 9000 and the following terms and definitions apply."	EAF
142	BR	402	Clause 3		te	ISO 9000 is drafted to harmonize the terminology used in all the documents developed by ISO/TC176. By this way, users'	We propose deleting the vocabulary and adding a reference to ISO 9000 in Clause 3.	EAF

						misunderstandings are avoided when just a reference to ISO 9000 is done in what the definitions are concerned.		
143	BR	402	Clause 3		te	69 terms and definitions are arranged in an inconsistent way, following neither ISO/IEC Directives, Part 2, D.1.2, Arrangement, nor terminological requirements stated in standards developed by ISO/TC37 (ISO 704:2009, ISO 10241-1:2011).	We propose deleting the vocabulary and adding a reference to ISO 9000 in Clause 3.	EAF

2. Specific comments

No.	MB/NC ¹	Line number	Clause/Subclause	Comments	Proposed change	Observations of the secretariat
144	L	60	Contents	The depth of clause indexing is not the same for all clauses and also some sub-clauses are not indexed.	Please re-index the contents to include all the clauses to the same depth.	EAF
145	NZ	60	Contents	0.3 and 7.5.3 not picked up in ISO template	Check FDIS contents list	EAF
146	ANS I	64 -65	Contents	Contents Missing 0.3 Process Approach	Add 0.3 Process Approach to Contents section	EAF
147	IT	64 -65	Contents	Missing clause.	Add clause "0.3 Process Approach"	EAF
148	JP2	64 -65	Contents	"0.3 Process Approach" is missing.	Add "0.3 Process Approach."	EAF
149	IR	64 and 65	Contents	The clause number and title of the sub-clause 0.3 Process approach is missing.	Add The clause number and title of the sub-clause 0.3 Process approach between lines 64 and 65.	EAF
150	ES	65	0.3	Typo – "0.3 Process approach" is missing		EAF
151	ANS I	65	Contents	Contents has left off 0.3 Process approach	Add "0.3 Process approach" on page "7"	EAF
152	ID	65	Contents	0.3 Process approach not included in the contents	insert point 0.3 Proses approach	EAF
153	AR	65	Contents	Contents has left off 0.3 Process approach	Add "0.3 Process approach" on page "7"	EAF
154	IT	77 -78	Contents	Missing sub-clauses.	Add the following sub-clauses: 5.1.1 Leadership and commitment for the quality management system – 26 5.1.2 Customer Focus - 27	EAF
155	BR	77	Contents	Missing sub-clause "5.1.1 Leadership and commitment for the quality management system" related to page 26. To maintain uniformity with other clauses.	Add item "5.1.1 Leadership and commitment for the quality management system" to the Contents in page 3	EAF
156	BR	77	Contents	Missing sub-clause "5.1.2 Customer focus" related to page 27. To maintain uniformity with other clauses.	Add item "5.1.2 Customer focus" to the Contents in page 3	EAF
157	IR	77 to 79	Contents	Commitment with respect to the quality management system and with respect to the needs and expectations of customers along with other commitments to establish Quality Policy and assignment of the responsibilities and authorities for relevant roles within organization are requirements of this standard to be met by top management to demonstrate its leadership of organization. Commitment is a result of adhering to the Quality Management Principle "Leadership". Hence, as commitment is an aspect of leadership	Delete the title and number of the sub-clause 5.1 and re-number the current sub-clauses 5.1.1 as 5.1, 5.1.2 as 5.2, 5.2 as 5.3 and 5.3 as 5.4 and list the Clause 5 and its sub-clauses in the contents page as follows: 5. Leadership 5.1 Commitment for the quality management system 5.2 Customer focus 5.3 Quality policy 5.4 Organizational roles, responsibilities and authorities	EN

				the two words "Leadership" and "Commitment" are not to be used at the same level and therefore the word commitment should not appear together with the term leadership on the same sub-clause title. There is a proposal to modify the titles and numbers of sub-clauses 5.1, 5.1.1 and 5.1.2 for sake of clarity. Besides that, the sub-clauses 5.2 and 5.3 are also to be re-numbered and relevant titles are to be stated in the contents page as proposed in the next column.		
158	IT	97-98	Contents	Missing sub-clause.	Add the following sub-clauses: 7.5.3 Control of documented information - 32	EAF
159	JP3	97-98	Contents	"7.5.3 Control of documented information" is missing.	Add "7.5.3 Control of documented information."	EAF
160	BR	97	Contents	Missing sub-clause "7.5.3 Control of documented Information" related to page 32. To maintain uniformity with other clauses.	Add item "7.5.3 Control of documented Information" to the Contents in page 3	EAF
161	CA-08	97	Table of contents	7.5.3 Control of documented Information not shown in English version; is correct in French version	Add 7.5.3 to Table of Contents	EAF
162	ANS I	98	Contents	Reference to 7.5.3 Control of documented information is missing even though 7.5.1 and 7.5.2	Add 7.5.3 Control of documented information	EAF
163	AR	98	Contents	Reference to 7.5.3 Control of documented information is missing even though 7.5.1 and 7.5.2	Add 7.5.3 Control of documented information	EAF
164	CA-09	147	Foreword	The last sentence" ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization." is duplicated in clause 0.6, lines 354 and 355.	Delete this sentence	EAF
165	IQN ET	152 161 346	Foreword Introduction 0.6	It would be useful to apply unified notation for references to web sites. In these cases it is written: " www.iso.org/directives , URL, web site at:" It makes translation more difficult.	uniform notation.	Referred to ISO C/S EN
166	ANS I	160	Foreword	"adherence to the WTO" does not define WTO as it does for technical Barriers to Trade (TBT	Revise to "adherence to the World Trade Organization (WTO)" to be consistent	Referred to ISO C/S EN
167	AR	160	Foreword	"adherence to the WTO" does not define WTO as it does for technical Barriers to Trade (TBT	Revise to "adherence to the World Trade Organization (WTO)" to be consistent	Referred to ISO C/S EN
168	FR	160	Foreword	Add extended meaning of WTO.	Add extended name of WTO.	Referred to ISO C/S EN

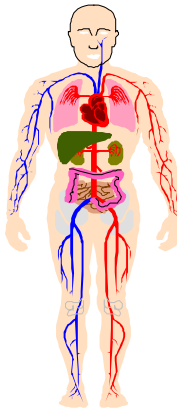
169	ANS I	161	Foreword	Line 161 references a website via hyperlink without providing the actual URL. A reader of the print edition would have impeded access to the website.	Change "Foreword – Supplementary Information" to the actual URL. Add a period at sentence end as grammar correction.	Referred to ISO C/S EN
170	IE	166	Forward	Phrasing "and of new concepts" is poor.	Replace "and of new concepts" With: "and the incorporation of new concepts"	EN
171	ANS I	170 -178	Foreword	The inclusion of this text in the DIS is very helpful to the understanding of this standard. It is no less useful to users of the final IS and should be retained in the Foreword in order to indicate how Annex SL impacts this standard.	Consider retaining this text to assist with transition or consider including it in Annex A.1	EN
172	JP4	177 -78	Foreword	For users of this standard, it will be better to distinguish the Annex SL text from the discipline-specific text by using different colour fonts at least for the electric version.	Change to: This will not be incorporated in the final version of ISO 9001 <i>in the hardcopy, but be incorporated in the softcopy.</i>	EN (However, ISO C/S is considering producing an annex SL version)
173	GB	189	Introduction	The Introduction includes separate sections on "0.3 the process approach", "0.4 PDCA" and "0.5 risk-based thinking", which is extremely confusing. No adequate explanation is given as to how an organization is supposed to apply these three approaches to its QMS. While partial statements giving explanations are included in 0.3, para 5, and 0.6 para 4, a clearer rationale for these 3 approaches first needs to be given in 0.1 .	Suggest adding text to 0.1 such as: ISO 9001 employs a number of different approaches that an organization can consider when establishing and maintaining its quality management system: - the process approach - the "Plan-Do-Check-Act", PDCA, (or Deming) approach - a risk based approach The process approach allows an organization to plan its processes and (critically) their interactions. The PDCA approach allows an organization to ensure that its processes are adequately resourced and managed, and that opportunities for improvement are identified. The risk based approach enables an organization to determine the factors that could cause its processes and its quality management system to become ineffective, and to put in place preventive controls to ensure that this does not happen. As such, all three approaches can be used to complement each other. Further details of these separate approaches are given in clauses 0.3, 0.4 and 0.5.	TAP
174	FR	189	Introduction	The introduction represents nearly 10% of the total number of pages of the standard. The terms and definitions represent almost 25% of the text.	Remove chapter 0.2 from the introduction and add it to the annexes. Remove section 3 "Terms and definitions" from ISO 9001 and re-introduce the normative reference to ISO 9000.	TAF
175	FI	190	0.1-0.6	This kind of anecdotal text is not suitable for the requirement standards	The text should be moved to some presentation material or into ISO 9000	TN

176	FR	190	Introduction	The use of the word « Robust » is not appropriate. Very subjective and hard to evaluate.	Remove the word « Robust »	TAF
177	FR	190	Introduction	During the Porto meeting, a paragraph concerning the applicability of the standard for SME's was added to the introduction. This paragraph is missing in the DIS version.	Add the following texte at the end of section 0.1 General : "Where any requirement(s) cannot be applied due to the small size of an organization, the application of the requirement(s) could be adapted regarding to the management model, the type of the organizations activities, and the adaptation of the risks. (See the future Guidelines on the application of ISO 9001 - ISO/TS 9002).	TN
178	ANS I	191-202	0.1	This information appears to be requirements. It provides a strong possibility for confusion as it relates to clause 4.1	Delete a) through g) and include in 4.1 or annex.	TAP
179	CQI 3	191	0.1	State clearly that managing quality requires the identification and management of those aspects of the (existing) management system which impact on the quality of what is produced. It is not a separate add-on.	The adoption of a quality management system ought to be a strategic decision for an organization. All elements of the quality management system should be integrated into the organization's business processes. A robust quality management system can help an organization to improve its...	TN
180	ANS I	191	0.1	It would seem the word "ought" has been used to avoid using should. There is no real difference in meaning. The adoption is a strategic matter whether or not the organization realizes it as such.	Change "ought to be" to "is"	EAF
		191	01	The expression "ought to be " we suggest to change for " it is necessary ... ", or "it is expected to be ..." because of better translation and simpler expression; also in formal standardization language it is somewhere between <u>shall</u> and <u>should</u> what cause additional difficulties to show clearly difference in the meaning	The adoption of a quality management system <u>ought is expected</u> to be a strategic decision for an organization.	EAP
182	AU	191	0.1	"ought to be" is too passive	Replace "ought to be" with "is".	EAF
183	ZA	191	0.1	Use of the word "ought" is old colloquial English and is out of place. It is also the only place that this word is used. I have never seen it used in any other ISO MS Standard.	Replace "ought" with "should" as per annex H of the ISO directives	EAP
184	CA-10	191	0.1	"The adoption of a quality management system ought to be....." The term "ought" Seems strange, why not "should"	"The adoption of a quality management system should be..."	EAP
185	GB	191	0.1	This implies a quality management system is a system of rules. One adopts rules whereas processes are developed. Also whether formalised or not a system exists once an organizations is formed to fulfil a specific	Change to: The development of a formal quality management system in compliance with ISO 9001:2015 ought to be a strategic decision for an organization.	TN

				purpose, therefore it's a decision to formalise that system that is strategic.		
186	SE	191	0.1	"A robust QMS can help an organization to improve its overall performance and forms an integral component of sustainable development initiatives."	Change to: "The purpose of the QMS is to improve the performance of the organization and forms an integral component of sustainable development initiatives."	TN
187	RO	192	0.1	The term robust is not defined.	To delete "robust".	TAF
188	BR	193	0.1	The expression "sustainable development" shows up for the first time in this standard. It needs a definition	Craft a definition to the expression "sustainable development" or delete it.	TN
189	MX	193		Forms an integral component of sustainable development initiatives	Forms an integral component of ORGANIZATIONAL sustainable development initiatives RATIONALE: There may be different development initiatives in an organization, hence it is important to state in this paragraph the standard refers to organizational ones	TN
190	IE	193	0.1	There are statements here about how a QMS can help improve overall performance and is a component of sustainable development. But there is no statement on how it does this – what are the benefits. This is an opportunity to spell out to potential users the reasons/benefits in implementing a QMS	Add potential benefits on implementing a QMS in line with the requirements of this standard e.g. • Focusing on defining customer requirements • Designing products to meet these requirements • Setting quality objectives • Carrying out self checks/audits • Eliminating and reducing non-confirming products • External recognition of a QMS that meets international standards	TAP
191	ANS I	194 /195	0.1	Simplifies. The context is always 'the context' regardless of changes.	"and the changes in the context" to "" (i.e., delete the phrase)	TAP
192	BR	194		To be consistent throughout the standard, spell organization with "z".		EAF
193	AU	194		Although organisation with an "s" is the more correct spelling, the standard uses the American spelling with a "z" is used for this draft.	Replace "organisation" with "organization" throughout the draft.	EAF
194	SE	194	0.1	Recognized practice in ISO standards.	Spell "organization" with "z".	EAF
195	NL	196 -202	0.1	Sequence of sentences is not in line with the level of importance	Change sequence to: a, d, c, b, e, f and g	TAP
196	TT	196	0.1	The term 'specific' objectives - should be used in reference to the operational or tactical levels. When looking at the context of an organization, a strategic approach is generally applied as with the strategic intent of this Clause.	Change 'specific' to 'strategic objectives.	TAP
197	NL	198	0.1	Missing: statutory and regulatory requirements	The needs and expectations of its customers, other relevant interested parties, statutory and	TAF

					regulatory requirements.	
198	CH	198	0.1	Present wording does not correspond with Annex A.3, because the concept of 'relevant' needs and expectations is missing.	Add the word 'relevant' to read: "c) the RELEVANT needs and expectations of its customers and other relevant interested parties;"	TAP
199	FR	198	Introduction	Quality is primarily focused on customers. It would be convenient to place bullet c) first so it becomes bullet a).	Switch bullets c) and a) to read : a) the needs and expectations of its customers and other relevant interested parties b) c) its specific objectives	EAP
200	BR	201	0.1	To be consistent with the new QMP, add engagement	f) the competence and engagement of persons within...	TN
201	CQI 4	202	0.1	Risk is addressed in bullet a) but there is no mention of opportunity in the context of the organization. Surely the QMS is primarily focused on the opportunity to provide products and services to customers. Add a new bullet h) to address opportunity.	h) potential opportunities for improvement	TAP
202	GOS TR	202	01 General	To move up as more logical	e) its size and organizational structure.	EN
203	CQI 5	203 - 204	0.1	The context of an organization can include internal <u>factors</u> such as organizational culture, and external <u>factors</u> such as the socio-economic conditions under which it operates; consequently... For consistency (e.g. 4.1), factors should be replaced with issues.	The context of an organization can include internal factors issues such as organizational culture, and external factors issues such as the socio-economic conditions under which it operates; consequently...	EN
204	GOS TR	203	01 General	To exclude word "can",	The context of an organization includes internal factors such as organizational culture, and external factors such as the socio-economic conditions under which it operates	EN
205	ZA	203	0.1	Only keep "Organizational culture" if adequately defined in ISO 9001.	Request SC 1 to provide a definition for "organizational culture	TN
206	ANS I	205	0.1	Corrects grammar. Comma before conjunction.	"Standard are generic but" to "Standard are generic, but"	EN
207	ANS I	206	Introduction, 0.1 General	The word "Accordingly" is not needed.	Start the paragraph with "It is not the intent...."	EN
208	CQI 6	209	0.1	The only place where 'opportunity' (instead of as one of the pair 'risk and opportunity') is addressed in the standard is when used with improvement i.e. 'opportunity for improvement'. This could leave users with the impression that a quality management system does not address opportunities in their own right. An organization comes into being via an opportunity and thereafter opportunities are either seized or created; this is not improvement, it is the essence of any organizations success	The quality management system (in contrast to other management systems) is focussed on seeking, selecting and addressing opportunities relating to products and services. Typical opportunities are inventing, adapting or adopting new technologies, inventing new products and services, seeking new markets.	TAP

209	ANS I	210 -211	Introduction, 0.1 General	The sentence in this paragraph makes no sense. There is no link established to products and services. The sentence adds no value to the discussion.	Delete this paragraph in its entirety.	TN
210	GOS T R	210 -211	01 General	To exclude. Requirements to QMS can not be identify with the requirements to product and service		TN
211	ANS I	212	0.1 Intro	While NOTES are clarified, the use of the annex has not been included. It was agreed that the Annex would be normative and this clarification is needed since it provides much needed for clarification for some topics that are not well understood.	Add The Annex is considered normative and provided to provide additional understanding of specific requirements.	TN
212	NL	212	0.1	Improve understanding of comment about the purpose of notes, to avoid unnecessary interpretation problems.	Information marked "NOTE" is for guidance in understanding or clarifying the associated requirement, however "NOTE" is not a requirement.	TN
213	GB	213 -216	0.1	The current text is unclear as the three uses described do not all flow from the introductory descriptor	<i>Amend to:</i> This International Standard can be used by internal and external parties to assess the organization's ability to consistently meet a) customer, statutory and regulatory requirements applicable to the products and services it provides, b) its own requirements and c) its aim to enhance customer satisfaction.	EN
214	TC2 10	213 -216	0.1	The current text is unclear as the three uses described do not all flow from the introductory descriptor	Amend to This International Standard can be used by internal and external parties to assess the organization's ability to consistently meet a) customer, statutory and regulatory requirements applicable to the products and services it provides, b) its own requirements and c) its aim to enhance customer satisfaction.	EN
215	ANS I	213	0.1	Corrects grammar. Comma not needed.	"external parties, to assess" to "external parties to assess"	EN
216	GB	214	0.1	Customer, statutory and regulatory requirements are all elements of 'Compliance Obligation'. 14K DIS uses this terms and is much more concise and all embracing.	Replace all references to 'customer, statutory, regulatory requirements' in the standard to its 'compliance obligations' to align with 14k DIS.	TN
217	FI	215	0.2	The organizations own requirements are not relevant in the scope of this standard.	the organizations own requirements should be deleted	EN
218	NL	216	0.1	Some users consider the requirements of the standard as the maximum they ought to do. This view results in systems which do not contribute to the success of the organization. Clarification is	Add The requirements in this standard should be regarded as the minimum arrangements that an organization must implement in order to have an	TN

				needed, since .	effective QMS. Using this system, including the introduction of supplementary arrangements, will support the organization in improving its quality performance.	
219	AU	216	0.1	There needs to be a statement to ensure ISO 9001 is not invested with more significance than is intended. The Standard addresses the management of processes leading to the traded product or service.	Insert, "It is not, however intended to replace product conformity mechanisms relating to specific customer, market or regulatory requirements"	TN
220	CQI 7	217	0.2	There needs to be a greater link to the ISO 9000 management system concepts. Add a new clause.	0.2 Management System Concepts A management system is a living entity comprising a number of sub-systems that are organised in such a way as to deliver outcomes and business results. Although all organisations are different, their Management Systems always need to recognise this. Organizations, like humans, are organic adapting and changing based upon the external environment in which they sit. The Human system has a set of organs that work together to deliver their outcomes. The organisational system has a set of key business process that do the same thing.  Figure 1 – The human being as a s The key concepts, the way to think about such a management system, are: A. 'Systems, sub-systems and business processes can be organic or mechanistic or more	TN

					usually a combination of the two based upon its objectives and purpose. Fully Mechanistic approaches define processes which have linear characteristics: A always leads to B, They are robotic, where people have no choice in what they do, They can be defined precisely often designed to meet a contract or specification Risks are managed by QC and statistical techniques to drive out variability. Fully Organic processes and systems are the opposite, They are Messy and non-linear Risks emerge as the system or process takes place People have choice in what they do They can never be fully defined or documented. Managing any system or process effectively is a combination of the two, based upon its purpose, desired outcomes, business objectives and results. No one size fits all situations and Quality Management needs to recognise this. B. A Quality Management System is comprised of people collaborating and working together with the appropriate resources to deliver desired results. Documents such as procedures, process maps, system diagrams and records are not "the real world" - they are at best a model or an interpretation of the real world and therefore need to be treated as such. C. A management system is bounded by its external environment and must adapt to that environment for it to survive and achieve its aims. Each cross-functional process or sub-system that makes up that management system is also bounded and recognising these boundaries ensures they can be managed effectively and are aligned with each other. D. System and process effectiveness, capability of and risk within the management system should be determined by i) measuring the results of past activities and ii) analysing indicators that help to predict future performance E. Effective audits collect both tangible (reports, KPIs, documents etc) and intangible evidence including the impact or outcome of people's	
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					behaviour. This evidence needs to be consistently analysed in terms of its impact in order to to identify levels of emerging risk to conformance, capability and sustainability in meeting business objectives/ results, stakeholder requirements and outcomes. By the time poor performance appears on a graph or KPI it is too late, so lead indicators of risk are needed. F. Closed systems can be generally measured to drive out variability using statistical techniques, as the inputs and other variables can be controlled from within the system. Where these cannot be controlled from within the system they are open systems and must therefore have the capability to manage variety and measure performance using non-traditional statistical techniques. Many processes are partly closed and partly open. Successful implementation and audit of ISO9001:2015 depends upon an understanding of these concepts and how they work together. More detail of these concepts can be found in ISO9000:2015.	
221	BY	217	0.2	Should be added the name of the standard.	We offer changed to: «- ISO 9001 Quality management systems – Requirements (this International Standard) specifies requirements aimed ...»	EN
222	IE	217	0.2	As clause 4.3 states that where a requirement can be applied it shall be applied. It would be useful to provide some guidance to users on when design and development should be considered as applicable to an organization	Need to provide some guidance to users on when to consider design and development	TN
223	IE	217	0.2	ISO TR 9002 should be added as a reference	Add ISO TR 9002	TN
224	FI	218	0.2	the word portfolio should be replaced by a word series	replace the word portfolio with the word series	TN
225	SE	218	0,2	Given that there will be a ISO/TS 9002, there will be four core standards, not three	Add information on ISO/TS 9002.	TN
226	CQI 8	221 - 227	0.2	ISO 9000 <i>Quality management systems — Fundamentals and vocabulary</i> provides an essential background for the proper understanding and implementation of this International Standard. The quality management principles described in detail in ISO 9000 were developed by ISO/TC 176, and have been taken into consideration during the development of this International Standard. These principles are not requirements in themselves, but they form the foundation of the requirements specified by this International Standard. An outline of the quality	ISO 9000 <i>Quality management systems - concepts and fundamentals</i> provides a way of thinking about an organisation in order to develop a management system that meets the needs of ISO9001:2015. This way of thinking is profoundly different to the more traditional quality approach; one better suited to the needs of the 21st century. The real-world organisation is the quality management system, a living entity adapting as required to minimise emergent risk to the delivery of	TN

				management principles is included in an Annex B to this International Standard. There needs to be a stronger link between ISO9001:2015 and ISO9000:2015 from a technical and conceptual perspective to set the application of ISO9001:2015 in better perspective.	customer, stakeholder and Society's requirements. These key concepts of need to be applied in the way the quality management is designed and applied: a) comprise human beings collectively behaving in such a way to maximise the sustainability and capability of the organisation. b) are a mix of organic and mechanistic quality thinking based on the purpose of the system or sub-system being managed	
227	CA-11	221	0.2	"ISO 9000 <i>Quality management systems — Fundamentals and vocabulary</i> " This clause gives some explanation of the QM principles but does not even mention the main purpose of the standard which is to provide the definitions of the vocabulary.	Add the following sentence. This standard includes definitions for key items of the vocabulary, however it should be noted that many of the definitions are repeated in clause 3 of 9001.	TN
228	CA-12	221	0.2	The above also raises the age old question as to why the 9000 and 9001 are not combined into a compendium. Between clause 3 (13 ½ pages) and annex A(3 pages). Over 16 pages total of the 52 pages are really 9000.	Delete clause 3 and annex A and combine the 2 standards as a package. Alternately, see comment CA-21	TN
229	CH	221	0.2	ISO 9000 also provides essential background to ISO 9004.	Add to read: "ISO 9000 ... provides an essential background for the proper understanding and implementation of this International Standard AND OF ISO 9004."	TN
230	AU	226-227		Needs to be more prescriptive	Change to 'the quality management principles are included in Annex B'	TN
231	PT	226/227	0.2	Instead of An outline of the quality management principles is included in an Annex B to this International Standard.	Read Annex B to this International Standard includes the transcription of the statement and rationale of the quality management principles	TN
232	2.	227	0.2	A Syntactical correction is required	Please replace: " ... principles is included in an Annex B to ...", with: " ... principles is included in Annex B to"	EN
233	GB	227	0.2	Delete 'an' before Annex B	An outline of the quality management principles is included in an Annex B to this International Standard.	EN
234	RO	228	0.2	To be correct, the type of requirements shall be defined.	After "requirements" bee insert "for organisation's QMS".	TN
235	IN	228	0.2	... requirements aimed primarily at giving confidence in the products and services provided by an organization ... ISO 9001 requirements are not appropriate to	... requirements aimed primarily at giving confidence in an organization's ability to provide consistently conforming products and services ...	TN

				provide confidence in products and services. Reword in alignment with the Scope.		
236	DE	228	0.2	... requirements aimed primarily at giving confidence in the products and services provided by an organization ... ISO 9001 requirements are not appropriate to provide confidence in products and services. This is a widely spread misperception. Reword in alignment with the Scope.	... requirements aimed primarily at giving confidence in an organization's ability to provide consistently conforming products and services ...	TN
237	GOS T R	231 -232	0.2 The ISO standards for quality management	.. better understanding ... of the organization's processes is not a goal of Standard implementation. To exclude or change on "better determining"	Its proper implementation can also be expected to bring other organizational benefits such as improved internal communication, better determining and control of the organization's processes, and reduction in defects and waste.	TN
238	IE	231 -232	0.2	The current sequence emphasises "internal communication and better understanding and control of the organization's processes" at the expense of the more significant "reduction in defects and waste"	Rephrase as follows: such as reduction in defects and waste , improved internal communication and better understanding and control of the organization's processes.	TN
239	SE	232	0.2	"...and reduction in defects and waste." Also other nonconformities should be mentioned.	Change to: "...and reduction of nonconformities, and waste."	TN
240	IT	234 -239	0.2	This synthetic description should be more consistent with introduction clause in ISO 9004:2009.	Modify as follows: [...] (This International standard) provides guidance for organizations that choose to progress beyond the requirements of this International Standard of ISO 9001 to address a broader range of topics that can lead to continual improvement of the organization's overall performance meet the needs and expectations of their customers and other interested parties, over the long term and in a balanced way. ISO 9004 includes [...]	TN
241	SII	235		See lines 235-239 in the DIS introduction. What is stated about ISO 9004 is totally wrong when reading the following text in the Introduction part of ISO 9004- 2009 : This International Standard provides a wider focus on quality management than ISO 9001; it addresses the needs and expectations of all relevant interested parties and provides guidance for the systematic and continual improvement of the organization's overall performance. An extended model of a		TN

				process-based quality management system incorporating the elements of ISO 9001 and ISO 9004 is given in Figure 1		
242	IT	241-247	0.2	The list of guidelines should be fully consistent consistency with the Annex C. On the other hand, there is no need to list in the paragraph the guidelines included in annex C.	Complete the list or simply make reference to Annex C, for instance modifying clause as follows: <i>Other standards that have been developed to support the implementation of a quality management system include those in the ISO 10000 number range. These include guidelines on customer satisfaction, quality plans, quality management in projects, configuration management, measurement processes and measuring equipment, documentation, financial and economic benefits of quality management, training, statistical techniques, the involvement and competence of people, selection of quality management system consultants and auditing of management systems various topics relevant to the quality management system (e.g. handling of complaints, statistical techniques, etc.). These standards are described further in Annex C of this International Standard.</i>	TN
243	ANS I	242		Iso 10000 range	Iso 10000 series	TN
244	CH	242	0.2	The sentence on 'other standards' should also mention ISO 19011.	<u>Add</u> to first sentence to read: "... include those in the ISO 10000 number range AND ISO 19011."	TN
245	AT	246-247	0.2	Delete "These standards are described further in Annex C of this International Standard." There is no need for such a description. Annex C shall be deleted.	Delete "These standards are described further in Annex C of this International Standard."	TAF
246	MX	248	0.3	Clause 0.3 does not explain what a process is. Neither explains what their elements are. We need clarification of process' objectives, outputs, inputs, resources and activities, especially to differentiate objectives from outputs and resources from inputs.	It is suggested to include a note that references ISO 9000: (See ISO 9000)	TN
247	CO	248	0.3	Include information to improve the understanding of the concept	Include conventions. Value adding activities Information flow	TN
248	IE	248	0.3	To emphasise the legitimate requirements of interested parties. clarify value of process model/approach	Line 268 delete work 'can' line 269 delete the two entries of 'customer' Lines 271 - 274 Rewrite:	EAF EAF TN

					'The schematic model shown in Figure 1 covers all the requirements of this International Standard as well as the individual processes at a detailed level. Each process and the system as a whole can be	
249	CO	248 & 280	0.3 - 0.4	Improve the flow and the understanding of concepts.	Change the order of the clauses. Plan-Do-Check-Act cycle 0.4 Process approach	TN
250	CQI 9	249 -250	0.3	'Consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes that <u>function</u> as a coherent system.' The use of the word function here may cause confusion with its definition in 3.25. Operate is a better term.	'Consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes that function operate as a coherent system.'	EN
251	CQI 10	249 -250	0.3	<Process approach.> This is not the fundamental concept of (managing by) process – it mixes the concepts of a “process” and “a management system”.	'Consistent and predictable results are achieved more effectively and efficiently when the activities and resources required to meet an objective are understood and managed as a coherent system.'	TN
252	ANS I	249	0.3	The text states “...to enhance customer satisfaction by meeting customer requirements...”. Meeting customer satisfaction does not necessarily enhance customer satisfaction	Delete the words “to enhance customer satisfaction by meeting customer requirements.”	TN
253	RO	249	0.3	In this standard do not use “efficiently”	To delete “and efficiently”	TN
254	IAQ G	250 -254	0.3	Regarding the process approach, DIS states “This International Standard promotes the adoption of a process approach when...” as recommendation. On the other hand, regarding “Clause 4.4 of this International Standard includes specific requirements considered essential to the adoption of a process approach”, so it states that process approach includes essential requirements. Those may mislead user with wrong interpretation and should be clarified.	Reword - clarify Proposal: Merge two sentences together and change as follows. “This International Standard includes specific requirements considered essential to the adoption of a process approach in clause 4.4 when ...”	TN
255	ANS I	250	0.3	'Coherence' often refers to mental faculties. 'Cohesive' gets more to the intended meaning.	“as a coherent system” to “as a cohesive system”	EN
256	GB	250	0.3	This International Standard promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements...GAWD..I can see a vast shaking of heads at this.	Replace with: This International Standard promotes a process approach to develop, implement and improve the effectiveness of a quality management system in order to enhance customer satisfaction by meeting customer requirements.	TAP
257	SE	251	0.3	“...when developing, implementing and improving	Add “maintaining” as follow:	TN

		-252		the effectiveness..." The maintenance should not be forgotten.	...when developing, implementing, maintaining and improving the effectiveness..."	
258	AU	251	03	This International Standard promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements.	Change to - meet customer requirements and enhance customer satisfaction. This International Standard promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system to meet customer requirements and enhance customer satisfaction	EN
259	ANS I	252	0.3	Remove the comma after "system"	"...system to enhance..."	EN
260	DE	252	0.3	Sentence not clear The effectiveness is not developed or implemented	Please reword: ...the adoption of a process approach when developing and implementing a quality management system and improving its effectiveness...	EN
261	CA-13	252 0269	0.3	"Consistent and predictable results to enhance customer satisfaction by meeting customer requirements" : : : "Figure 1 illustrates the process linkages In addition, the needs and expectations of other relevant interested parties can also play a role in defining those requirements. Monitoring of customer satisfaction requires the evaluation of information relating to customer perceptions as to whether the organization has met these requirements" These statements are now inconsistent with the new definition of "customer satisfaction" (§3.57) which replaced the word "requirements" (in ISO 9000:2005) with "expectations", as follows: "customer's (3.26) perception of the degree to which the customer's expectations have been fulfilled" Further, why do the "customer perceptions as to whether the organization has met these requirements" come to bear when "these requirements" were defined by "the needs and expectations of other relevant parties"?	Change in paragraph 1 to: ".... to enhance customer satisfaction by fulfilling customer requirements and expectations" Change paragraph 4 to: "Monitoring of customer satisfaction requires the evaluation of information relating to customer perceptions as to whether the organization has met: - the customer's requirements; - the customer's expectations, and; - the needs and expectations of other relevant interested parties" The last bullet point should only be included, if the 4th paragraph retains the statement: "In addition, the needs and expectations of other relevant interested parties can also play a role in defining those requirements."	EN TN TN
262	IE	252 ,253	clause 0.3	Scope of parties to be satisfied is not broad enough	Change enhance customer satisfaction to ENHANCE THE SATISFACTION OF CUSTOMERS AND INTERESTED PARTIES DELETE CUSTOMER FROM LINE 253	TN
263	DE	254	0.3	The link between 0.3 an the requirements in 4.4	add the following text and the figure in Annex 1 in	TAP

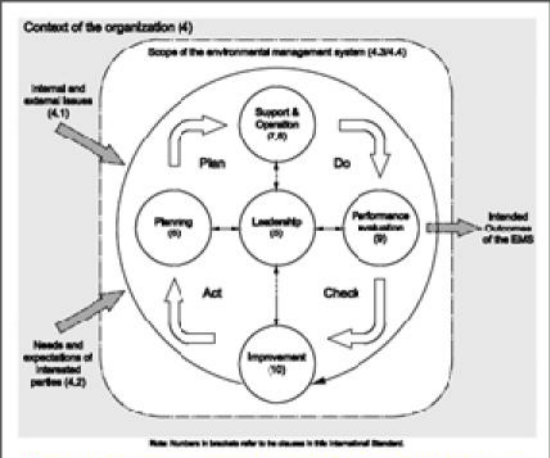
				is missing in the text - additional guidance on the process approach is necessary	0.3 after 1st paragraph (line 254): Based on the definition of a process, first all activities required for the fulfillment of the intended output for each process must be defined. Normally activities handle with transforming, transportation and storing in all cases. It is essential that both the starting point and the end point for each process are defined. Only in this case the interrelation between the different processes could be managed. Every process needs different inputs coming from other processes and diverse sources like customers, suppliers or other processes. The output of a process could be a product or service in different degree of completion or a decision. These outputs are addressed to several receivers like customers, suppliers or other processes.	
264	FI	255-259	0.3, 0.4, 0.6	Has it been decided that PDCA is not used in MSSs'?	If so, PDCA methodology should be deleted from this standard. This means that figures 1 and 2 should be also deleted.	TAP
265	AU	257	0.3	Grammar	Insert, 'of', between, 'and' and, 'the system'.	EN
266	IT	258-259	0.3	"Risk based thinking" is not only aimed at preventing undesirable outcomes, but also at achieving objectives and seizing opportunities.	Modify as follows: [...] "Risk based thinking" aimed at realizing potential opportunities whilst preventing undesirable outcomes	TAP
267	AU	258		As the ISO 9001:2014 DIS is about the "Context of the organization" – it should not just specify PDCA as the only improvement methodology (See also 1557)	Change it to "achieved using a problem solving and improvement methodology such as PDCA"	TN
268	SE	259, 465, 1829	0.3 3.08 ISO 10017	These are the only three places where the term "outcome" appears. There is no counterpart to this term in e.g. Swedish, and it is suggested to replace it with a directly translatable term.	Replace "outcome" with "result" in lines 259, 465 and 1829.	EAP
269	CQI	260	0.3	'....., the process approach ensures: ...' Of itself	'....., the process approach ensures enables ...'	EAF

	11			the process approach does not ensure anything, it is simply one possible approach of many.		
270	ANS I	260	Introduction, 03 Process approach	This sentence needs some clarification since there is no guarantee that the process approach will ensure anything.	Replace “ensures” with “helps to ensure:”	EAP
271	ANS I	260	0.3	The list of what the process approach does not include any mention of Customers either satisfaction, requirements or other attribute. With a reference to Figure 1, one would expect that there would be mention of Customer.	Add Understanding and consistently meeting customer requirements	TN
272	AU	260	0.3	Perhaps ‘enable’ rather than ‘ensure’ is a more accurate outcome of applying the process approach?	When used within a quality management system, the process approach ensures enables:	EAP
273	FI	260	0.3	a word ensures	Ensures => may promote	EAP
274	SE	260	0.3	0.3 3rd Paragraph: To say that the process approach ensures a, b, c and d is a pretty strong claim.	change ensures to promotes or supports	EAP
275	ANS I	262	0.3	When used within a quality management system, the process approach ensures: ... b) “...consideration of processes in terms of added value...”. This statement is not necessarily true.	Delete line 262	TN
276	AU	262		Value is okay but not well defined	...added value as perceived by customers	TN
277	ANS I	264	0.3	“data and information” – the definition for information is meaningful data. Seems redundant to have both and data does not seem to be as meaningful. The use of information in multiple ways will also confuse users	d) improvement of processes based on evaluation of data and information	TN
278	IE	264	0.3	To emphasize risk based thinking	add to item d) ... evaluation of data, information and risk based thinking	TN
279	ANS I	265	Introduction, 03 Process approach	The term “among” is the proper preposition when more than two items are compared.	Change “between” to “among” for proper grammar.	EAP
280	IE	271-272	0.3	The phrase “does not show the individual processes at a detailed level” is unclear, confusing and unnecessary.	Rephrase as follows: “ . . . of Figure 1 illustrates the high-level processes of this International Standard. Each of these processes”	EAP
281	SE	272-274	0.3	“Each of these processes, and the system as a whole, can be managed using the PDCA methodology described in clause 0.4 of this International Standard.” The sentence repeats what is already stated in paragraph 2, lines 257-259.	Delete.	TAP

282	IE	272	0.3	This figure is a retrograde step from previous revisions. It is amateurish and confusing. Ideally it would like to see it restored to previous form. Taking support processes away from planning seems silly as this was implied in resources in the previous model. THIS IS A TERRIBLE MODEL	Restore simplicity of previous model. Interested parties should be included in output satisfaction. Support processes should be included in Planning The current figure is not value adding and should be deleted. Do we need a figure at all? Also line 272 implies that processes are needed for each clause – this is misleading.	TAP
283	AU	273		PDCA again -	Should say a problem solving methodology such as PDCA consistent with or within context of the organisation	TAP
284	IAQ G	275 -278	0.3	The new process model is not easy to understand or explain	Revise diagram - improve Proposal: Suggest simplifying the new process model and making it more professional looking. This may require showing more than one diagram to accomplish.	TAP
285	ANS I	275 - 277		It is not clear what the meaning behind the asterisks is.	The asterisks that are included in the figure should have further clarification or meaning associated with them.	TAP
286	JP5	275 -276	0.3	The meaning of the circle is not clear. The difference between black arrows and white arrows is not clear either.	Please clarify the meanings of the circle and the difference between black arrows and white arrows.	TAP
287	DE	275 /276	0.3	Please improve quality and readability of figure 1.	Please act as noted beside.	TAP
288	NG	275 /276	0.3	The arrow inside the core processes is one way directional	It should be two-way directional	TAP
289	CQI 12	275	0.3	Customer satisfaction is stated on the right hand side of the model. I have an issue because the quality management system model considers other interested parties as well as customers as an input.	Customer satisfaction -> Customer satisfaction (and impact on <i>relevant interested parties</i>)	TAP
290	MUR	275	0.3 Figure 1	Delete "Continual" from the model of process based approach as Clause 10 refers to Improvement and to be consistent with the others	10 Continual improvement	TAF
291	IIOC	275		Figure 1 in line 275 shows 10 Continual Improvement this should read 10 Improvement	Remove the word Continual from Continual Improvement in section 10 of model	TAF
292	ES	275	0.3	Clause titles in figure 1 not consistent with those in the draft. E.g. Clause 10 "Continual improvement", should be "Improvement"	Update clause titles in figure	TAF
293	ES	275	0.3	Left column may be misinterpreted as giving to the requirements from relevant interested parties the same obligatory status as an input to the system than the requirements from customers.	Modify to separate clearly the different exigency level	TN
294	BW	275	0.3	The quality of the Figure needs to be improved		C

295	DE	275	0.3	Meaning of asterisk is not clear If the circle indicates the organization, several boxes would have to be placed partly inside the circle Boundaries are not clear Box titles do not reflect the clause title	Please improve figure with the aim to avoid the asterisk connectors Please consider placing box 7, box 10 and context box partly into the circle Clearly indicate the boundary of the QM system Align box titles with clause titles	TAP
296	IQNet	275	FIGURE 1	Subtitles should be harmonized with the title of the clauses.	e.g. 10. Improvement, 8 Operation	TAF
297	IQNET	275	Figure 1	Reference to 7. Support Processes indicates a type of process approach that is not required in the standard section 4.4 and may create confusion	In the figure change 7. Support processes to 7. Support	TAF
298	QS	275	0.3	The quality of Figure-1 to be improved as some words are not clear	Improve the sharpness/clarity of Figure-1	C
299	AU	275	0.3	The meaning of the two asterisks may be unclear to readers	Insert legend, * : defines the point of entry into the PDCA cycle"	TN
300	AU	275		Suggest 2 separate diagrams. One with 4.1, 4.2, 4.3 going into 4.4 & one with the remainder of the current diagram with the changes suggested. Remove the asterisks and the top LHS box.	Operations should include the ISO 9001:2008 flowchart Chevrons; "leadership arrow to Requirements – should be to the outer rim of the circle not just to Leadership and same as right arrow next to Performance evaluation	TN
301	CA-14	275	0.3	George Box famously said that 'all models are wrong but some are useful'. We have repeatedly failed to provide 'useful' models in our standards. At present this model represents the 'downloading of a tortured mind'. We still not convinced that have we addressed the nagging criticism of our standard that it dwells more on the QMS itself and not enough on the real goal, which is what the MSS is all about and that is quality of the product and/or service supplied. We therefore need some action in Figure 1 that deals specifically with the product/ service.	This model must be simplified to meet the needs of the reader and not the needs of the writer. TC207 have done a far better job with far less 'clutter', identifies the PDCA wheel, and provides a useful benchmark. One useful addition to the DIS 14001 figure, would be a box on the right, for "customer satisfaction", as we have in DIS 9001, with an arrow back to "performance evaluation" that reads " trends in product/service quality" This would create an incentive for organizations to track trends in the quality of their product/ service supplied by tracking product nonconformances, premature product failures, warranty claims, production delays due to component defects, etc., so that early corrective action can be taken. Let's not be convinced that the customer satisfaction surveys are going to reveal that information anyway as it may be realized too late to be of any value in the survival of the organization.	TAP
302	CH	275	0.3	The modified Fig. 1 showing links is generally OK, but in the left hand box with 'Customers & other relevant interested parties', the sub-box should refer to 'relevant requirements'.	Add to the sub-box to read: "RELEVANT requirements"	TAP
303	CH	275	0.3	The 2 horizontal double-ended arrows (from box 5 and from box 9) contain no text. Equivalent	Add text "Information flow" inside the empty arrows.	TN

				arrows in the 2008 issue are identified as 'information flow'.		
304	NZ	275	0.3	The intent of the asterisk symbol (an * in a circle) is not clear. Presume it is meant to show a link from clauses 4.1, 4.2 & 4.3 to 4.4 in the centre. Following the logic of the diagram is difficult for a reader. It is not self-explanatory. As with many diagrams the asterisk linkage might be useful in a presentation where explanations can be given but it does not work in this context.	Figure 1 needs to be improved or replaced. Suggest delete asterisks and both 4.x boxes. Put a box level with double-headed arrow to '5 Leadership' <i>inside</i> the left hand vertical box (like 'Requirements' box) labelled '4 Context of the organisation'. Make 'relevant' in this box standard text, not bold italic. There is no need to be defensive about including relevant interested parties in planning inputs.	TAP
305	TH	275		Details of process in the figure should be in line with the requirements. The difference between black and white arrows should be clarified.		TAP
306	IT	275	0.3	Not all the titles of the clauses shown in figure 1 are consistent with the title of the same clauses in the text, namely clauses 4.4 and 7.	Verify consistency between the titles of clauses in figure 1 and the text.	TAP
307	GB	275	0.3	Figure 1 makes reference to 10 Continual improvement but, the title of section 10 refers to "Improvement" not "Continual Improvement".	Encourage consistency by renaming 'box' in figure 1 - "10 Improvement"	TAF
308	FR	275	Introduction	The figure is not very explicit	Add a legend to precise what the « * » are aimed for and harmonize the use of « arrows ».	TAP
309	FR	275	Introduction	This figure is very useful. However, it would be convenient to place the PDCA cycle on it as well.	Add the « PDCA » cycle on figure 1. P : for chapters 4, 5 & 6 D : for chapters 7 and 8 C : for chapter 9 A : for chapter 10	TAP
310	FR	275	Introduction	Add a legend for the arrows	Add a legend for the arrows précisant that white arrows concerns activities with Added Value (chapter 8 Operations)	TAP
311	MY	275, 276	0.3	Figure 1 in this standard is different from Figure 1 in ISO 14001; to facilitate alignment in MSS as required by HLS, the figure should be consistent with other MSSs	To indicate P-D-C-A in Figure 1 and remove the clause titles	TAP
312	HU	276-277	0.3	The titles of some boxes in the Figure 1 are not harmonized with the title of relevant Clauses: 10 Continual improvement; 7 Support processes	The suggested titles in boxes: 10 Improvement; 7 Support	TAF
313	MX	276	Figure 1	The competence and awareness of staff, infrastructure operation, measurements, directions on how to do the work and other elements contained in Chapter 7 are essential to provide the satisfaction of customers and other stakeholders; and keep them out of the wheel gives the impression that it is not very important	Include The 7 Support Processes in the box	TAP

				to control them. That box is within 7 Support Processes wheel before 8		
314	AU	276	0.3	The Quality System diagram shouldn't contain asterix, especially at the start of the PDCA cycle.	Insert the expression in full	TAP
315	AU	276	0.3	Text not clear, hard to read. Use original diagram or redraw.		C
316	CH	276	0.3	The diagram presented is not consistent with that which appears in other MSS.	Together with the technical for other MMS, develop a common figure.	TAF
317	SE	276	0.3	What do you want to show in the Figure? Difficult to interpret.	Please try to simplify the Figure 1 and harmonize to ISO/DIS 14001, see below. 	TAF
318	JP6	276	0.3	The descriptions in Figure 1 are not consistent with the clause titles.	Replace: - "Establish context" by "Understanding the organization and its context" - "Define relevant interested parties & scope of QMS" by "Understanding the needs and expectations of interested parties and determining the scope of the QMS" - "4.4 QMS – General & Process Approach" by "QMS and its processes" - "6 Planning" by "6 Planning for the QMS" - "7 Support processes" by "7 Support" - "8 Operations" by "8 Operation" - "10 Continual improvement" by "10 Improvement"	TAP
319	ES	277	0.4	The title of the figure does not describe accurately the figure as explained in lines 292-	Change to: Figure 2 – Schematic representation of a single	TN

				293	process within the QMS using the PDCA cycle	
320	MX	277	0.3	Figure 1 is also blurred.		C
321	IR	277	Introduction 0.3	Taking into account the PDCA methodology described in the sub-clause 0.4 the QMS model given in the Figure 1 needs correction in terms of arrangement and place of the main clauses in the figure. As Leadership deals with leading all the activities of the organization towards achieving its objectives, the clause 5 "Leadership" is to be placed on the top of the figure and the clause 10 "Continual Improvement" that relates to the "Act" phase of the PDCA cycle needs to be placed inside the circle in place of current clause 5 "Leadership". Meanwhile, the reference to the sub-clause 4.4 is to be moved to the top of the figure.	Place the clause 5 "Leadership" on the top of the figure in place of the clause 10 "Continual Improvement" and place the clause 10 "Continual Improvement" inside the circle in place of current clause 5 "Leadership". Meanwhile, move the reference to the sub-clause to the top of the figure.	TAP
322	ZA	277		The model in figure 1 refers to clause 10 with the heading of Continual Improvement. The actual heading depicted by clause 10 only refers to Improvement.	Change the heading in Clause 10 to improvement.	TAF
323	CN	277	General	Some tiles do not be completed in this figure.	4.1,4.2,4.3 should be understand context..... 4.4 should be QMS and its process 6 should be planning for QMS 7 should be support 10 should be improvement	TAP
324	LC	277	0.3	Schematic is not clear, makes 'support processes' appear to be and external process of QMS	Include '7 Support processes' within circle	TAP
325	LC	277	0.3	In Figure 1 4.4, what is meant by the "General Approach"? Is it something outside the Process Approach?	Clarification on 'general approach' required	C
326	GB	280 -293	0.4	The focus of the revision is on the risk based approach. This needs to be enhanced in the explanation to enable a better comprehension by the reader.	0.4 Plan-Do-Check-Act cycle The methodology known as "Plan-Do-Check-Act" (PDCA) can be applied to all processes and to the quality management system as a whole. The clauses of this International Standard broadly follow the PDCA cycle which can be briefly described as follows: — Plan: establish the objectives of the system and its component processes, the risks in achieving the objectives and the resources needed to deliver results in accordance with customers' requirements, statutory and regulatory requirements and the organization's policies. — Do: implement what was planned. — Check: monitor and (where applicable)	TN

					measure processes and the resulting products and services against policies, objectives and requirements, and report the results. Compare the impact of risks identified against the risk mitigation actions implemented and evaluate new risks that emerge in the practice — Act: take actions to improve process performance, as necessary including updating the risk assessment and mitigation strategies identified. Figure 2 shows schematically how a single process within the quality management system can be managed using the PDCA cycle.	
327	IE	280	0.4	As silly 'quality 101' figure	Delete figure 2 – no value add	TAF
328	JP7	282	0.4	For clarification and consistency with A.1.	Change to: The <u>clause structure</u> of this International Standard broadly follow the PDCA cycle which can be briefly described as follows:	TAP
329	IN	285	0.4	... the system and its component processes ... The qualifier "component" leads to confusion as the reader may believe that "component processes" are a specific type of processes. In addition, it is difficult to translate "component" in this context. Suggestion: As "component" appears to be superfluous, leave it out.	... the system and its component processes ...	TAF
330	DE	285	0.4	... the system and its component processes ... The qualifier "component" leads to confusion as the reader may believe that "component processes" are a specific type of processes. In addition, it is difficult to translate "component" in this context. Suggestion: As "component" appears to be superfluous, leave it out.	... the system and its component processes ...	TAF
331	CH	285	0.4	... the system and its component processes ... The qualifier "component" leads to confusion as the reader may believe that "component processes" are a specific type of processes. In addition, it is difficult to translate "component" in this context. Suggestion: As "component" appears to be superfluous, leave it out.	... the system and its component processes ...	TAF

332	JP8	285	0.4	Planning of objectives and planning of the system to achieve them should be clearly distinguished from each other. In addition, policy and objectives should be written as a set.	Change L285 to: Plan: establish the organization policy and objectives in accordance with customer requirements and determine the system and its component processes to achieve them with considering the resources to deliver results.	TN
333	INLA C	286	0.4	In the QMS the requirements are not only of the customers, but of the ones of the organization and legal and regulatory, and still having a common structure for management systems should be included conceptually	Change: Plan: establish the objectives of the system and its component processes, and the resources needed to deliver results in accordance with customer's requirements and legal and statutory requirements and the organization's policies.	TN
334	BR	286	0.4 Plan-Do-Check-Act cycle	Include the interested parties in the planning (Plan phase), considering its needs to plan the management system	Plan: establish the objectives of the system and its component processes, and the resources needed to deliver results in accordance with customers' requirements, interested parties needs and the organization's policies.	TN
335	GOS T R	286	0.4 Plan-Do-Check-Act cycle	Add phrase "statutory and regulatory requirements applicable to the products and services"	... needed to deliver results in accordance with customers' and statutory and regulatory requirements applicable to the products and services and the organization's ...	TN
336	IAQ G	289 -982	0.4 & 4.4g)	0.4 Measure where applicable 4.4 g) measuring as appropriate	Add text - improve Proposal: To be consistent, put 'measure where applicable' in the text.	C
337	RO	289 -290	0.4	Consistency of approach	Check: monitor and (where applicable) measure processes and the resulting intended products and services against policies, objectives and requirements, and report the results.	EN
338	CH	289	0.4	How to monitor and measure processes and products / services? Isn't it the performance of processes and the quality of products and services which could be monitored / measured?	Monitor and (where applicable) <u>measure the performance of</u> processes and the quality of the resulting products and services ...	TN
339	INLA C	291	0.4	The improvement and sustained success, are a whole concept to lead throughout the standard, so the term "as necessary" is left over	Change: Act - take actions to improve process performance	TN
340	IN	292	0.4	Figure 2 shows schematically.... Consistency with previous statements	shows to be replaced by 'illustrates'	EAF
341	SE	296 -297	0.4	"Risk" is indicated only regarding "Plan" in Figure 2. "Risk" should be considered for any of the phases Plan, Do, Check, Act.	If Figure 2 is retained: Delete "(Extent of planning depends on RISK)" Add after " Figure 2 - Schematic representation of a single process within the system ": "Extent of Plan-, Do-, Check and Act- activities depend on RISK."	TN
342	DE	296	0.4	The figure is not clear and does not adequately reflect the intended content	Please delete figure	TAF

343	DE	296	0.4	In case proposal to delete Figure 2 is not supported, please improve quality and readability of figure 2.	Please act as noted beside.	C
344	GOS T R	296	0.4	PLAN shall be placed after INPUT		TN
345	QS	296	0.4	Product performance, is an important indicator for measuring process performance.	Change the check block as follows Check-monitor / measure process/product performance	TN
346	AU	296	Fig. 2	Change 'extent' to 'nature' as don't want to create impression that high risk requires more extensive planning as this doesn't necessarily follow.		TN
347	JP9	296	0.4	To be consistent with the explanation of L281 and after. Clause 0.4 does not address risk. Description of "Plan" does not include planning of objectives. The meaning of "process performance" is not clear.	Change to: Plan - objectives for the outputs and the processes to achieve them with considering relationships between the objectives and the processes Check – check whether the outputs conform to the objectives	TN
348	FR	296	Introduction	Harmonize the use of arrows with those of figure 1	Use black arrows to show the PDCA cycle and white arrows to show added value by the transformation of Inputs to outputs.	TN
349	BR	297	0.4	The figure is technically incorrect, it shows more than a single process. Plan, do, check and act phases do not necessarily belong to the same process. Furthermore, the PDCA cycle is well known and the figure does not add value.	Delete figure 2.	TAF
350	AT	297	0.4	This figure is confusing and misleading as well as inconsistent and against conventional wisdom. Either this figure shall be redrafted or preferably deleted.	Delete Figure 2.	TAF
351	AR	297	0.4	Fig 2 title does not accurately describe the figure.	Change title to: "Schematic representation of the PCDA cycle within a single process"	TN
352	GB	297	0.4	According to preceding text the diagram shows how a single process can be managed using the PDCA cycle therefore the title needs to be changed accordingly.	Change to: Figure 2 Schematic representation of how a single process within the system is managed.	TN
353	SE	297	0.4 Plan-Do-Check-Act cycle	The figure is messy and hard to understand.	Delete the Figure 2.	TAF
354	MU R	299	0.5	Further guidance on the application of the "risk-based thinking" to development of the QMS and how it integrates the identification and implementation of "preventive actions", is important to ensure effective understanding and use of this approach by organizations.	Development and communication of ISO support documents on the application of the risk-based approach to QMS.	C
355	AT	299	0.5	Replace "risk-based thinking" by "risk-oriented thinking" in the whole document.	Replace "risk-based thinking" by "risk-oriented thinking"	TN

356	RO	299	0.5	Consistency of formulation (see process approach)	Replace "Risk-based thinking" with "Risk-based approach".	TN
357	PH/ BPS	299	5	In section 0.5, what is Risk based thinking?	A need to elaborate on this thru a note.	TAP
358	SG	299	Introduction 0.5	To elaborate more on the risk based thinking approach to be more explicit and clearer.	Risk based thinking should emphasize on the following factors: - Products and services (already addressed) - People - Processes - Infrastructure - Environmental - Legal requirements - Other interested parties - Financial	TN
359	FR	299	Introduction	Add a reference to the definition of risk	Add a reference to the definition of risk	TN
360	GB	300 -315	0.5	The focus on risk aspects needs to be elaborated so as to provide clarity on the context. 1) For consistency with the definitions of risk in ISO Guide 73, expected results should be replaced by objectives. Any activity is towards targeted results or desired results - which are the objectives of the activity. 2) Considering that many small organisations are adopting the standard, is it correct to introduce the concept of risk based thinking at this level. I think it is time to introduce the concept of maturity levels incorporated in the design of QMS of organisations. 3) This is being proposed, since medium and large scale organisations need to adopt risk based thinking. In order to ensure this - the adoption of risk based thinking should be linked to the size of the organisation and the number of processes that an organisation uses in its QMS. 4) The use of outsourced processes should form the number of processes an organisation uses. 5) The processes that should be counted for the implementation of the risk based QMS should be those used in the product realisation process including delivery and sophistication of the product realisation process, e.g. automation. Manual operations may be exempt from the risk aspects of the QMS.	0.5 "Risk-based thinking" Risk is the effect of uncertainty on an expected result objective and the concept of risk-based thinking has always been implicit in ISO 9001. This International Standard makes risk-based thinking more explicit and incorporates it in requirements for the establishment, implementation, maintenance and continual improvement of the quality management system. Organizations can choose to develop a more extensive risk-based approach than is required by this International Standard, and ISO 31000 provides guidelines on formal risk management which can be appropriate in certain organizational contexts. Not all the processes of the quality management system represent the same level of risk in terms of the organization's ability to meet its objectives, and the consequences of process, product, service or system nonconformities are not the same for all organizations. For some organizations, the consequences of delivering nonconforming products and services can result in minor inconvenience to the customer; for others, the consequences can be far-reaching and fatal. "Risk-based thinking" therefore means considering risk qualitatively (and, depending on the organization's context, quantitatively) when defining the rigour and degree of formality needed to plan and control the quality management system, as well as its component processes and activities.	TAP Moved to Annex
361	GB	300	0.5	(NB continued comment from above)	(Continued suggested text)	TN

		-315			NOTE 1 to entry Product realisation processes shall be the focus of the risk based QMS requirements of this International Standard. NOTE 2 to entry Product realisation processes that are essentially manual shall be exempt from the requirement of adopting a risk based approach of this Standard. NOTE 3 to entry Product based risk aspects are generally the aspects related to statutory and regulatory requirements. These would be captured as part of the customer and regulatory requirements. Organisations may voluntarily adopt product based risk aspects related to safety, environmental impact and occupational health and safety.	
362	ANS I	300-306	0.5	Clause 0.5 introduces the concept of risk based thinking. The first sentence tries to define risk but will be very confusing to users of the standard. Further there is no explanation of "what is risk based thinking"	Risk is the effect of uncertainty on an expected result whether this effect results in positive or negative consequence(s) to the organization. This International Standard incorporates risk-based thinking as a concept in requirements for the establishment, implementation, maintenance and continual improvement of the quality management system. Organizations can choose to develop a more extensive risk-based approach than is required by this International Standard, and ISO 31000 provides guidelines on formal risk management which may be appropriate.	TAP
363	SE	300-301	0.5	It is debatable if "The concept of risk-based thinking has always been implicit in ISO 9001." Anyway, the statement is irrelevant. What matters is if it is to be considered in ISO 9001:2015 or not.	Delete the following text: on line 300-301: "...and the concept of risk-based thinking has always been implicit in ISO 9001."	TAP Moved to Annex
364	FI	300	0.5	The word result should be replaced with the word objectives (ISO 31000). Ref. to line 309	instead of the word <i>result</i> the word <i>objectives</i> should be used	TN
365	IT	300	0.5	Since "objective" is, by definition (3.0.8), a "result to be achieved", there seems to be no reason nor added value in modifying ISO Guide 73 definition. An objectives can imply the achievement of more than one result. The term "objective(s)" is therefore broader than "an expected result". Moreover, the use of term "objective(s)" highlights that uncertainty can affect the whole process of planning and achieving relevant expected result, including the following: establish objective(s) and its targets;	Modify as follows: <i>Risk is the effect of uncertainty on an expected result objective [...]</i>	TN

				determine all activities and actions necessary to achieve established objective(s); carry out determined activities and actions in order to achieve expected results.		
366	GB	300	0.5	Risk is the effect of uncertainty on an expected result...Strange claim since how can you have an "expected result" if it is subject to uncertainty? I know that few authoritative definitions of risk exist, but the one above sounds extremely clumsy.	Change to: Risk is the variation in an expected result due to unforeseen circumstances	TN
367	GB	300	0.5	The first line states "...concept of risk-based thinking has always been implicit in ISO 9001" However, it is difficult to see which portion of the 2008 version implies that. We are leaving the field wide open for the auditors to interpret the requirement as per their own perceptions. It will be more appropriate to limit the field covered. For example, it might be better to reword as suggested in proposed change:	Change to: "The organisation shall identify the risks that may adversely impact meeting the product and delivery requirements committed to customer. Depending upon the seriousness and probability of occurrence of such risks, the organisation shall have a plan to mitigate, or accept the risks fully/partially as appropriate to the prevailing circumstances"	TN
368	FR	300	Introduction	Add ISO 31000 to the bibliography	Add ISO 31000 to the bibliography	TAF
369	JP 11	303	0.5	The verb "develop" does not fit to the object "approach."	Change "develop" to "take", for example.	TAP
370	TC4 6/SC 11 Liaison (AU)	304	0.5	ISO 31000 is referenced in the text but is not included in the Bibliography	Add ISO 31000 to the Bibliography	TAF
371	CA- 15	304	0.5	The sentence reads".....and ISO 31000 provides guidelines..."	This standard should be referenced in the bibliography	TAF
372	GB	304	0.5	I don't have a problem with Risk Based Thinking being included in the Introduction as this is what ISO 9001 has always been about. The problem I have is where you have included on line 304 reference to ISO 31000. ISO 31000 is one of many guidance standards and including this in ISO9001 demonstrates a failure to understand the structure of ISO standards (see www.pdqm.co.uk) and the restrictive role of ISO 9001 as defined in its scope.	Change line 304 to following text : "Organizations choosing to go beyond the requirements of this standard and develop a risk management system may wish to consider using the requirements of ISO 31000 as a basis for such a management system."	TAP
373	TC2 10	304	0.5	The reference to ISO 31000 is too specific and could cause misunderstanding due to the definition of risk and other concepts that should not be part of a quality management system.	Delete the "ISO 31000 provides" and replace with "other ISO standard which provide guidelines..."	TN

374	DK	305	0.5	ISO 31000 can be appropriate in any organizational context and not only in “certain” organizational context.	Change “formal risk management which can be appropriate in certain organizational contexts” into “formal risk management which can be appropriate in certain organizational contexts .”	TAP
375	FR	305	Introduction	Remove the word « formal » from line 305	Remove the word « formal » from line 305	TAP
376	JP 10	306	0.5	Need to clarify that there is no requirement to adopt a formal risk management specified by ISO 31000.	Add the following sentence at the end of the paragraph. “However, this International Standard does not require organizations to adopt a formal risk management specified by ISO 31000.”	TN
377	ANS I	308 -315	0.5	The word fatal can cause potential liability issues. Other changes are needed to clarify the word risk and use it correctly.	Not all processes of the quality management system represent the same level of risk in terms of the organization's ability to meet its objectives, and the consequences of process, product, service or system nonconformities are not the same for all organizations. For some organizations, the consequences of delivering nonconforming products and services can result in minor inconvenience to the customer; for others, the consequences can be far-reaching. “Risk-based thinking” therefore means considering the effects(s) of uncertainty qualitatively (and, depending on the organization's context, quantitatively) when defining the rigor and degree of formality needed to plan and control the quality management system, as well as its component processes and activities.	TAP used in annex
378	ANS I	308	0.5	Unnecessary word.	“Not all the processes” to “Not all processes”	EAP
379	BY	311	0.5	Suggest adding the phrase.	«For some organizations, the consequences of delivering nonconforming products, services and performance systems can result in minor inconvenience to the customer; for others, the consequences can be far-reaching and fatal.»	TN
380	CA- 16	311	0.5	The sentence reads “For some organizations, the consequences of delivering nonconforming products and services can result in minor inconvenience to the customer; for others, the consequences can be far-reaching and fatal” This would indicate that all customers receive only minor inconvenience	Revise to read “..... For some organizations..... may result in minor inconvenience to some customers: for others.....”	TAP
381	ANS I	315	0.5	To make consistent with the language in the other clauses of the Introduction.	Add “Clause 6.1 specifies Actions to address risks and opportunities.”	TN
382	ANS I	316	0.6	Risk-based thinking should address the issue of preventive action here as well as the annex.	A risk-based thinking process, planned actions to address uncertainties and reviewing the	TAP Moved to Annex

					effectiveness of the actions implemented, is intended to address what was previously described as preventive action.	
383	AU	316	0.4	The Standard should not be construed as a replacement for product/service conformity assessment schemes.	Insert, 'Where conformity to specified product/service requirements must be independently verified, this International Standard should be seen as complementary to not as a replacement for product/service conformity assessment regimes'.	TN
384	SII	316	0.5	We propose to promote proactive approaches	The risk based thinking can be used also at the working level by applying proactive thinking while planning and doing the work	TN
385	IT	317	0.6	Editorial suggestion.	Change title to: " Compatibility and relationship with other management system standards ".	TAP
386	SE	318-320	0.6	It is not clear what high-level structure implies.	Amend line 318-320 to: This International Standard applies the high-level structure, identical sub-clause titles, identical text, common terms, and core definitions defined in Annex SL, Appendix 2 of the ISO/IEC Directives, Part 1, Consolidated ISO Supplement, and therefore maintains compatibility with other management system standards that have adopted the Annex SL. This common approach defined in the Annex SL will be useful for those organizations that choose to operate a single management system that meets the requirements of two or more management system standards.	TN
387	JP 12	318	0.6	The "high-level structure" is only a part of Annex SL. Better to use the full title of Annex SL to prevent misunderstanding as in ISO/IEC 27001.	Change "high-level structure" to "Annex SL of ISO/IEC Directives, Part1 Consolidated ISO Supplement developed by ISO to improve alignment among ISO management systems standards."	TN
388	IR	318 to 337 and lines 345 to 348	Introduction 0.6	It seems the information given in the text of the lines 318 to 337 and lines 345 to 348 is of a general nature and hence does not relate to the sub-clause 0.6 and needs to be moved from the current place to the sub-clause 0.1 General.	Move the text of the lines 318 to 337 and lines 345 to 348 from the current place to the sub-clause 0.1 General!	TN
389	JP 13	320	0.6	The "high-level structure" is only a part of Annex SL.	Change "high-level structure" to "the Annex SL."	TN
390	ANS I	322, 334-337	Introduction, 0.6 Compatibility	The statement that organizations are not required to follow the "high-level structure" sequence identically with Annex SL is extremely important and should be highlighted better.	Move the text in paragraph 3 in its entirety to line 322 for added emphasis and a more logical flow.	TN
391	IT	326	0.6	Editorial suggestion.	Add ";" at the end of each bullet.	EAF

		-333				
392	CQI 13	329	0.6	Processes for planning and consideration of <u>risks and opportunities</u> (Clause 6) Change 'risks and opportunities' to 'opportunities and risks'. This does not in a material way change the requirement, but it emphasize the positive nature of ISO 9001 (i.e. the creation of products and services through opportunities) in contrast with all other ISO MSSs which focus on risk.	Processes for planning and consideration of risks and opportunities <u>opportunities and risks</u> (Clause 6)	TN
393	ANS I	329	0.6	The use of the word risk has caused a large amount of comment from those who are experienced with the application of risk as well as those who are involved in ISO 31000. The term "opportunities" is not defined. Since the definition of "risk" is included, and contradicts those of other ISO standards which treat risk and opportunity as identical ("positive risk"), this must be corrected. Using this terminology as it is written in Annex SL is technically incorrect and has resulted in much feedback has the potential for lack of understanding and misinterpretation in the marketplace. Risks and its opportunities should be replaced by risks and its effects with some clarification added in the requirements related to terminology.	Processes for planning and consideration of risks and its effects opportunities (Clause 6)	TN
394	DE	329	0.6	This text is ambiguous.	- Processes for planning which include the consideration of risks and opportunities	TN
395	AU	329	0.6	"risks and opportunities" is a false dichotomy. An opportunity when its consequence and likelihood have been identified is a "risk". An opportunity might be characterised as a potential positive consequence. According to the definition in ISO Guide 73 and to line 951 of this DIS, a risk includes positive consequences.	Separate into two sentences: 'Processes for planning and consideration of risks (Clause 6) Processes for planning and consideration of opportunities (Clause 6)'	TN
396	CH	329	0.6	This text is ambiguous.	Processes for planning <u>which include the</u> consideration of risks and opportunities	TN
397	GB	329	0.6	Change "risks and opportunities" to "opportunities and risks", to emphasize the positive nature of ISO 9001		TN
398	RO	330	0.6	Resources include people and information and not only.	- Processes for support, including resources, such as people and information	TN
399	ANS	333	0.5	While this section discusses compatibility with	Add Statement	TN

	I			other management systems, the fact that there is some text differences between the different MSS's is not clear.	It is important to note that while common text is used between the management system standards for specific clauses, in some cases the requirements may slightly differ due to unique situations with a MSS that need to emphasize.	
400	3.	336	0.6	A Syntactical correction is required	Please replace: "... in clauses 0.3 to 0.5 of this International Standard.", with: "... in clauses 0.3 to 0.5 of the introduction of this International Standard."	TN
401	IAQ G	336	0.6	Process approach is presented in 0.3-0.4 and risk-based thinking is presented in 0.5	Reword - improve Proposal: Change to 'described in clauses 0.3 and 0.4'	TN
402	LU	336	0.6	Include the term improvement and risk in the sentence	to use the Process, <i>Improvement and risks based</i> Approach, as described in clauses 0.3 to 0.5 of this International Standard	TN
403	ANS I	338 thru 344	0.6	This paragraph presents an unsubstantiated opinion and will be of little or no use to many readers.	Delete lines 338 thru 344	TAF
404	MX	340	0.6	However, this International Standard enables an organization to use the	However, this International Standard provides a framework for an organization to use the Rationale: The word "enables" is too weak, the phrase "provides a framework" is more strong	TN
405	GOS T R	343 -344	0.6	Compatibility with other management system standards "It is possible for an organization to adapt its existing management system in order to address the requirements of this International Standard". Shall be excluded as no substantial significance and obvious requirement.		TAF
406	SII	344	0.6	We propose to support an integrated management system	It is possible for an organization to integrate some or all management systems standards into one integrated management system	TN
407	SE	345 -347	0.6	How secure is it to have a reference to a website? Can ISO ensure that the link does not change during the lifetime of the standard?	Add a correlation table as an Annex into the standard.	TN
408	GB	345	0.6 Introduction	Replace "A matrix" by "Correlation matrices" to be consistent with document SC2/N1224	Replace "A matrix" by "Correlation matrices"	TN
409	DK	349 -383	0.6	Should be part of the "foreword"	SC2 Secretariat comment: Text incorrectly included and will be deleted	EAF
410	ANS I	349 -367	Introduction, 0.6 Compati- bility	This entire text is redundant as it duplicates the text already contained in the Foreword. This text should be deleted for consistency.	Delete text in lines 349-367 as it duplicates text in the Foreword.	EAF
411	CZ	349 -361	0.6	These three paragraphs are identical with that in Foreword.	We recommend to delete this text in 0.6.	EAF

412	ZA	349 - 355	0.2	Repeat of lines 142-148	Remove – copied and pasted from foreword	EAF
413	PT	349		The text from this line to line 367 is out of context. There should be a title or other way of putting into context!		EAF
414	CA-17	349		349 to 357--Are repetitions of lines 142 to 150	Remove	EAF
415	4.	349 to 382	0.6	These lines should be erased as they should be part of the Forward. Also need to start the Scope on a new page.	Please erase lines 349 to 382 and move necessary parts to the Forward.	EAF
416	IR	349 to 382	Introduction 0.6	It seems the text of the lines 349 to 382 relates to the Foreword and hence needs to be moved from the current place to the Foreword.	Move the text of the lines 349 to 382 from the current place to the Foreword!	EAF
417	ZA	356 -357	0.2	Repeat of lines 151-152	Remove – copied and pasted from foreword	EAF
418	ZA	358 -361	0.2	Repeat of lines 162-163	Remove – copied and pasted from foreword	EAF
419	ZA	362 -363	0.2	Repeat of lines 153-154	Remove – copied and pasted from foreword	EAF
420	PT	575 375 /376	3.21		Add: [SOURCE: ISO DIS 9000:2014, 3.3.2]	EAP
421	MX	382 and line 383		Page jump inserted between the lines to better understanding		EAF
422	NL	387 -388	1	Text is not identical with text in Introduction, line 198	Make both parts of text the same.	TN
423	BR	387	1	To be consistent to other usage of the expression "products and services" within the standard.	To change "provide product or service that meets..." for "provide <u>products</u> and <u>services</u> that meet..."	EAF
424	ANS I	387	1(a)	Line appears to be missing a word. Insert "a" prior to "product or service" as correction.	Change to "...provide a product or service..."	EAP
425	AU	387	1a)	Most organisations supply more than 1 product or service	Change to: 'products or services that meet'	EAF
426	CH	387	1	An organization generally provides more than just one product or service. Elsewhere in the DIS, the term 'products and services' is used	<u>Change</u> to read: "... <u>PRODUCTS</u> and <u>SERVICES</u> which meet ..."	EAF
427	RO	388 391	1	The legal requirements are for intended product and service.	Add after "requirements", " related to intended product and service ".	TN
428	IIOC	389 -391		Lines 389 to 391 item b) in this item a reference is made to processes for continual improvement, however in the continual improvement clause (10.3) there is no requirement for a process for continual improvement	determine if a process is required for continual improvement or otherwise and ensure consistency throughout the standard	C
429	BR	389	1	"by means of" to refer to a series of actions fits better than "through".	To change "through" for "by means of".	EN
430	ZA	389	1	Failure of the previous standards is based on the omission of organizational growth.	Reword to include... "aims to enhance customer satisfaction, sustainability and organizational	TN

					growth "...	
431	CA-18	389	1	"aims to enhance customer satisfaction assurance of conformity to customer and applicable statutory and regulatory requirements". Because of the proposed change to the definition of "customer satisfaction" (3.57), which now deals with "customer expectations" instead of "customer requirements", this statement in the Scope is not aligned with the definition. Perhaps there is a need to determine what is the primary focus of the Standard – to conform/-satisfy/fulfil customer requirements OR, to enhance customer satisfaction?	REGARDLESS whether the primary focus is on "requirements" or "customer satisfaction", it is necessary to change item b) to: "aims to enhance customer satisfaction and the assurance of meeting customer expectations and complying with customer and applicable statutory and regulatory requirements." in order to align with the new definition of "customer satisfaction" AND If the primary focus is on "requirements", change all instances of conformity to/satisfy/fulfil "customer and applicable statutory and regulatory requirements" to: "...enhance customer satisfaction and conform to statutory and regulatory requirements"	TN
432	FR	389	1	Bullet b) is not easy to understand. In addition the end of the sentence is redundant with bullet a)	Stop the sentence of bullet b) after « including processes for continual improvement ».	TN
433	AU	390		Not always possible to 'continually' improve the quality management system	Delete 'continual'	TAF
434	DK	391	1	Delete "and applicable statutory and regulatory" as this requirement is already given in line 388.	Change 1b into "aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements."	TN
435	CA-19	392	1	The clause reads" All requirements of this International Standard are generic and are intended to be applicable to all organizations, regardless of type, size and product provided." Yet Annex A, clause A 5 states: " Where a requirement cannot be applied (for example where the relevant process is not carried out) the organization can determine that the requirement is not applicable." In our opinion nothing has changed and exclusions are still allowed only somewhat hidden now!!!! This will only bring many requests for interpretations to the table. It raises the same issues as before. Who decides if it is applicable?. Not all the requirements are applicable to all organizations. Without change, we can foresee possible problems between customers, suppliers and certification bodies	This definitely is confusing. It is necessary to clearly detail how exceptions to the standard are to be handled, similar to the 2008 version. If nothing else, the clause should be inserted into the Scope as it was before in clause 1.2 Application. Why hide the fact in the Annex??? Anything in an Annex that refers to scope should be delete.	TN
436	TC2 10	392 (move from line 959)	1 (move from 4.3)	There is no description about "Non-applicability" in "1. But in 4.3 and A5 It is necessary to clearly describe about the "non-applicability" in 1 not in 4.3.	Move line 959-963 to 1. (between line 391 and 392)	TN

437	INLA C	393	1	Be consistent throughout the standard of always using the term product and service	All requirements of this International Standard are generic and are intended to be applicable to all organizations, regardless of type, size and product or service provided.	EAP
438	ANS I	393	1 Scope	Since ISO 9001 consistently refers to "products and services," that concept should be applied here by adding "services."	Insert "or service" after "product."	EAP
439	RO	393	1	The standard is not mandatory to all organisations.	To replace "all" with "any".	EAF
440	IN	393	1.0	Only reference to 'product' is made.	Replace word 'product' with 'product and services'	EAF
441	MY	393	1	The term "product" should appear with "services"	To add the terms "and services" after "product"	EAF
442	EE	393	1	In ISO/DIS 9001, the sentence regarding applicability of the requirements is taken from ISO 9001:2008, Clause 1.2, without any amendment or addition and applies to "product provided". Instead of the expression "product provided" it is more relevant to use "product or service provided" as it will conform with subclause a) of Clause 1.	<i>Supplement existing wording of the sentence and use the following formulation:</i> All requirements of this International Standard are generic and are intended to be applicable to all organizations, regardless of type, size and product or service provided	EAP
443	AR	393	Scope	"size and product provided" is not consistent with other notations of product or service	Revise to "size and product and service provided"	EAP
444	CN	393	1	Add "service"	All requirements of this International Standard are generic and are intended to be applicable to all organizations, regardless to type, size and product and service provided.	EAP
445	TT	393	1	The text reads: "and product provided", which does not reflect the decision to use the term "product and service"	Change to "and product or service provided"	EAP
446	IT	393	1 Scope	The term "products" should be replaced by "products and services".	Modify sentence as follows: <i>All requirements of this International Standard are generic and are intended to be applicable to all organizations, regardless of type, size and products and services provided.</i>	EAP
447	GB	393	1	Consistent use of 'product or service'. Generally in the text, these are used in the plural.	Amend to All requirements of this International Standard are generic and are intended to be applicable to all organizations, regardless of type, size and products or services provided.	EAP
448	TC2 10	393	1	Consistent use of 'product or service'. Generally in the text, these are used in the plural.	Amend to All requirements of this International Standard are generic and are intended to be applicable to all organizations, regardless of type, size and products or services provided.	EAP
449	JP 14	393	1	Only product is mentioned, but service should also be addressed.	Change "product" to "products and services" and delete "provided."	EAP
450	AR	394 /395	Scope	Two issues: The definition of customer includes internal	Change Note as follows: NOTE 1	TN

				customer. However, ISO 9001 deals only with external customers. This is not stated in any part of the standard. The words "products or services" seem to provide an option. The word "or" should be replaced by "and"	In this IS the terms "product" or and "service" only apply to products and services intended to or required by a customer, and to any intended output resulting from the products and services realization processes; NOTE 2 In this IS the term "customer" applies only to external customers.	
451	RO	394	1	It is not an explanation. It is mandatory !!! Can not be a NOTE.	To delete "NOTE 1" and resize font to transform the sentence in paragraph 3.	TN
452	IE	394	1	The phrasing "only apply" is incorrect English.	Replace "only apply" with " apply only "	EN
453	SE	394	1	With this writing it seems like there are products and services excluded. Which products and services are excluded?	Delete NOTE 1	TN
454	FR	394	1	This note has no added value.	Remove note 1	TN
455	IAQ G	395 -396	0.4	May want to consider moving the Act block and arrow to the right side of PDC in order to support the logic of PDCA. Current example may raise questions as to APDC. Recognize that you should improve the process prior to ongoing output but this is an improvement model and not nonconformances management.	Revise diagram - improve Proposal: Move the arrow and text to the right of PCA.	TAP
456	JP 15	395	1	The "customer" should be in plural.	NOTE 1 In this International Standard, the terms "product" or "service" only apply to products and services intended for, or required by, a customer.	EN
457	RO	396	1	The first note was transform in paragraph.	"2" to be replaced with "1".	EN
458	ANS I	397 -399	2	The purpose of having ISO 9000 is to provide a normative reference to terms and definitions that are consistent across quality management standards. It is essential that ISO 9000 be cited as a normative reference as was done in previous editions of ISO 9001. Because ISO 9000 serves as the base vocabulary for other standards pertaining to quality management (e.g., ISO 10000 series), it is essential that ISO 9001 be consistent and cite ISO 9000 as a normative reference. ISO 9000 should be listed as a normative reference and the definitions removed from ISO 9001:2015. There were a substantial number of comments related to the ISO 9000 definitions being included in the DIS for ISO 9001:2015. While the text indicated that the definitions were being provided for commenting purposes, this has brought with it much confusion since WG24 only passes the comments on the definitions onto SC1.	Given that the inclusion of ISO 9000 as a normative reference is fundamental to this standard, list ISO 9000 as a normative reference	TAF

459	IT	397 -399	2	It is unacceptable to have no normative reference to ISO 9000! This is also in contradiction with clause 0.2, namely lines 225-226 <i>"These principles are not requirements in themselves, but they form the foundation of the requirements specified by this International Standard."</i> [CRITICAL COMMENT]	Make reference to ISO 9000 in clause 2 for the sake of continuity and complementarity between ISO 9000 family of standards, modifying clause as follows: <i>The following referenced documents are indispensable for the application of this document</i> <i>ISO 9000, Quality management systems - Fundamentals and vocabulary</i> <i>NOTE Refer also to Annex C, Table C.1 for other relevant standards.</i>	TAF
460	MY	397	2	Many terms and definitions are from ISO 9000	To consider including ISO 9000 as a normative reference	TAF
461	GB	397	2	The failure to reference ISO 9000 as a Normative reference is a big mistake. The whole point of having ISO 9000 as the Fundamentals and Vocabulary for Quality is simple. It allows one document to be the central control over definitions that relate to quality. This failure is evidenced where ISO 19011:2011 has also removed any Normative reference from its latest version. This has led to two different definition being introduced for auditor. QUOTE: - ISO 9000:2005 Auditor 3.9.9 person with the demonstrated personal attributes and competence too conduct an audit ISO 19011:2011 Auditor 3.8 Person who conducts an audit I will leave you to defend the removal of "Demonstrated Attributes" and "Competence" from the 2005 version. I guess from what takes place at present it is more truthful	Reinstate ISO 9000:2015 as a Normative reference to ISO 9001. You could then remove the majority of definitions from Clause 3 of ISO 9001:2015CD and only include specific definitions where changes have been needed or clarification required. Note 1: - There is no definition for Auditor, Observation or Audit Trail in the new ISO 9001 2015 all of which are critical to the effective use of the three "Core" standards. Note 2: - The definitions as presented are not in alphabetical order and there is no index.	TAF
462	FR	397	2	Add ISO 9000 as a normative reference	The introduction of the terms and definitions in the text of ISO 9001 is confusing. Not only it does not facilitate the reading of the text - 14 pages of terms and definitions before reaching the requirements chapters - it also raises the question of the reason to maintaining ISO 9000 as a standalone standard. In addition some terms do not have the same definition in ISO/DIS 9000 and in ISO/DIS 9001. Keep only the terms and definitions from the HLS in ISO 9001 and make a normative reference to ISO 9000 for the remaining definitions.	TAF

463	FR	397	2	Ensure consistency with terms and the general concepts in the field of the measure, where relevant, based on ISO/CEI GUIDE 99 (or JCGM VIM 200:2008)	"For the purpose of this document, the terms and definitions apply. When terms referred to measurement apply definitions given in International vocabulary of metrology (ISO/CEI GUIDE 99)"	TN
464	QS	398	2	Normative reference do not include any standards. ISO 9000 can be included as terms and definitions are based on that	Include ISO 9000 in normative reference	TAF
465	SE	398	2	As a consequence of the comment to lines 400-929, the text no longer applies.	Retain the introductory text in ISO 9001:2008, and introduce ISO 9000 as a normative reference.	TAF
466	CZ	399	2	A full stop at the end of the sentence instead of comma.	To be corrected.	EAF

Following a ballot in ISO/TC 176/SC2 (see documents SC2/N1235 and N1244), all the terms and definitions which had been included in ISO/DIS 9001 have been removed from ISO/FDIS 9001.

The comments numbered 467 to 1300 inclusively (and comment no. 400) were referred to ISO/TC 176/SC1 for the preparation of ISO/FDIS 9000. Members should refer to that FDIS when checking the actions taken against their comments.

467	TC4 6/SC 11 Liaison (FR)	400 -930	3 terms and definitions	Add the definition and reference to Records, Records management and RMSS	record(s) information created, received and maintained as evidence and as an asset by an organization or person, in pursuance of legal obligations or in the transaction of business NOTE 2 The term "evidence" is not limited to the legal sense NOTE 3 This applies to information in any medium, form or format. [ISO 30300:2011, definition 3.1.7 records management field of management responsible for the efficient and systematic control of the creation, receipt, maintenance, use and disposition of records, including processes for capturing and maintaining evidence of and information about business activities and transactions in the form of records [ISO 30300:2011, definition 3.4.3	TN
468	BR	400	3. Terms and definitions/ 3.48	There are notes on some definitions which reads: "note X to entry "xxxxx":", and some which just reads: "note X to entry:". Change accordingly for consistency of usage.	Change for consistency.	EAF

469	BW	400	3	Explain "to entry" used after each Note		EN
470	EOQ	400	3 New definition	The definition is not adequate: inserting the definition of "information" it amounts to "available collection of true, <i>meaningful data</i>" This is a very narrow concept and though using the way back definition framed by Plato, does not reflect the differences between information and knowledge, that is what happens within a human brain. A suggestion for a definition (cp. Davenport and Prusak 1998, p. 5) is given.	Knowledge: a mix of framed experience, contextual information, values and expert insight that provides a framework for evaluating and incorporating new experiences and information	TN
471	ISS/RS	400	3	Definition for term "outcome" is missed	Put in clause 3 definition for "outcome"	TN
472	NL	400	3	There is no clear, unambiguous description of the 'intended result' of the quality management system. Application of the standard would be simplified when all users have a clear understanding of the main purpose of a quality management system. (Expected result, objective, intended outcome, intended results (used in 4.1).....what is the clear/easy to understand explanation about its difference?)	Add as definition: Intended results Products or services that meet customer and applicable statutory and regulatory requirements and aims to enhance customer satisfaction	TN
473	IE	400	3	The term "adequacy" occurs six times in the requirements (lines 919, 1187, 1356, 1500, 1512, 1552), but is not defined in Clause 3 or in ISO/DIS 9000	Consider including the definition: "Adequacy: Capable of achieving a desired result" in Clause 3	TN
474	CA-21	400	3	A number of the Terms & Definitions really belong in ISO 9000 as there are several terms included in §3 <i>Terms and definitions</i> that are not used in the normative text of the Standard. For example: "business environment" only appears as an alternate term in the definition for "context of the organization" but nowhere in the text "defect" only appears as a definition "measuring equipment" only appears 1x in the Intro, and 2x in titles of referenced standards, but nowhere in normative text "object" appears 10x in various definitions, but nowhere in normative text. The term, "entity" only appears once, as an alternate term, in the definition for "object" "performance indicator" and the alternate term, "performance metric" only appear in the definition; nowhere in the normative text The term "strategy" only appears as a definition; nowhere in the normative text.	Include only those T&Ds which apply to ISO 9001; remove all that are not used in the normative text. In the case of "measuring equipment", check before considering deleting, as there are 2 comments, where we have suggested replacement of "measuring instrument" with "measuring equipment" Before considering this comment, refer to CA-22 which proposes an option to remove definitions from ISO 9001.	C

				What is the purpose of providing definitions for terms that are not used in the normative text?		
475	CZ	400	3	The term „applicability” as used for example in 4.3, table A.1 (amiss B.1), A.3, A.5 in the context of explaining „exclusion” should be added to clause 3.	“applicability – ability to be applied or used in a particular situation” (Source: Merriam-Webster Vocabulary (modified))	TN
476	GB	400	3	Please add definitions for: 'Issues' as used in clause 4.1 'Change' as used in clause 6.3 Can you please put the definitions in alphabetical order as it makes them easier to find in the document.	Proposed definition: Issue: any action that is likely to threaten the QMS. Change: any action that is taken from normal operational processes.	TN
477	GB	400	3	If Compliance Obligation is used, definition of compliance obligations needs to be inserted. See definition in 14k DIS.	Insert a definition for compliance obligation	TN
478	SE	400	3	The understanding of the meaning of “calibration” is necessary for the understanding of requirements in 7.1.5. A definition is missing.	Add a definition of calibration. Proposal of definition: “act of aligning the accuracy of a measuring equipment to a known standard”	TN
479	IAQ G	401	3.0	In the introduction section to definitions there would be value in adding a clarification statement related to any requirements that may be perceived.	Add text - improve Proposal: This definitions and associated notes should not be perceived as requirements. They are provided for clarification of intent and consistent interpretation.	TN
480	JP 17	402	3	Sub-cause numbering is not consistent with other part of the standard.	Change “3.01” to “3.1.” Review throughout the Clause 3 accordingly.	EAP
481	DE	402 to 471	3	In case terms and definitions are retained in ISO 9001, please correct numbering and start with 3.1.	Write 3.1, 3.2, ..., 3.9	EAP
482	MU R	402 to 930	3	Propose to define the terms in alphabetical order as it allows quick reference		EN
483	DE	402 to 930	3	In case terms and definitions are retained in ISO 9001, please check <u>all</u> the given sources. Some are false.	Please check and correct all given sources and correct where necessary.	EAP
484	RO	404	3.01	ISO 9000 has not defined “role”. 3.2.6 from ISO 9000 and 3.25 from ISO 9001 define “function”, but using “organization”, loop closed. ISO 9001, 5.3, uses “role”, not “function”.	To define “function” with out “organization” and to replace “role” with “function”.	TN
485	IQN et	406 and more 555 565 606 638	3.	Denomination of NOTES should be unified..e.g. 3.01, 3.10, 3.14, 3.16, 3.21, 3.36, 3.42 Note 1 to entry (but there isn't a 2nd Note) 3.18 Note 1 to term 3.20 Note 1 to definition 3.26 Note to entry (correctly without 1, but at the same time following the above logic, it could be Note to definition) 3.30 Note to entry (without numbering, which is	editorial review is necessary.	EAP

		743 763 774		correct) 3.46 Note 1 to entry "output" (It would be better Note 1 to term or to definition or just simply to entry) This is the case in Note 2. 3.47. 3.48: see 3.46.		
486	GB	406	3.0 3.01	The use of the term 'sole trader' is inappropriate as the vast majority of such businesses do not require a QMS to meet ISO 9001 as they operate on a very one to one direct customer basis e.g. window cleaners, shopkeepers, gardeners etc. Those that are plumbers, electricians, gas and heating engineers etc. as tradesmen are required to meet certified standards and this supports the quality of their workmanship. The very small percentage to whom the standard may be applicable will recognise the term micro business..	Remove the term sole trader and replace with small/micro businesses Leave sole trader – annex sl, but add note??	TN
487	ANS I	408	3	Two other possibilities for an organization existence added.	Note 1 to entry: The concept of organization includes, but is not limited to sole-trader, company, corporation, firm, enterprise, authority, partnership, association, charity or institution, or part or combination thereof, whether incorporated or not, public or private, physical (brick and mortar) or electronic (virtual) .	TN
488	FR	410	3.02	Pour moi les "parties prenantes" font partie du micro environnement de l'organisme (tels que les exemples donnés), quant aux "parties intéressées" elles se situent plus dans le macro environnement (tels que voisinage, associations, ... qui pourraient être impactés par l'activité de l'organisme.	Remplacer la définition par : Personne ou organisme (3.01) qui peut affecter, être affecté par, ou avoir la perception d'être affecté par une décision ou une activité de l'organisme (3.01) EXEMPLE <i>Clients</i> (3.26), propriétaires, personnel d'un <i>organisme</i> (3.01), <i>fournisseurs</i> (3.27), établissements financiers banques , syndicats, partenaires ou société qui peut inclure des concurrents ou des groupes de pression d'opposition. Add the following notes : Note 1 to entry: Interested parties can include person(s) and groups concerned with or affected by the QMS of an organization. Note 2 to entry: To "perceive itself to be affected" means the perception has been made known to the organization. Note 3 to entry: Interested parties can include	TN

					customers, communities, suppliers, regulators, nongovernment organizations, investors, employees.	
489	ANS I	412	3.02	Expanding the definition of "interested party" to include those who "perceive themselves to be affected by a decision or activity" opens up a potentially large can of worms. This is not practical to be responsible for identifying such groups/individuals let alone their requirements. Nor is it always worthwhile to try to address perceptions that are not reality or in the worst case manufactured perceptions.	Eliminate this part of the definition.	TN
490	MX	412	3.02	Include area in the text	Person, area or organization that can affect, be affected by.....	TN
491	SE	412 ,414	3.02	There are two formal references to "organization (3.01)" on the lines indicated. There is no requirement in ISO Directives or in ISO 10241-1 that italic font and term number is to be used every time a reference to a term defined elsewhere is made in an entry. It seems sufficient to have italic font and term number only at the first occurrence of another defined term. This seems to be applied in examples given in ISO 10241-1.	Make formal reference to "organization (3.01)" only once, i.e. on line 412 in this entry. If this principle is applied, the rest of clause 3 should be reviewed. Three other examples are given below.	EAP
492	QS	413	3.02	In the definition of "interested parties" ...a decision or activity" of whom? to be made clear	Change as follows a decision or activity of the organization	TN
493	ANS I	414	3.02	Definition of "interested party" does not explicitly include "employees" as a possible party. This would appear to defy Deming.	Consider adding to the list of examples: "employees or staff of the organization."	TN
494	IT	414	3.02	Editorial suggestion (there is more than one example).	Write "EXAMPLES" instead of "EXAMPLE".	EN
495	ANS I	414 , 415	3.02	This is not a financial or social accountability standard.	Delete opposing pressure groups, and bankers from example	TN
496	MY	414 , 415	3.02	In the context of a quality management system standard, "regulator" is also a significant interested party	To add "regulator" as another example of interested party	TAF
497	ANS I	415	3	Adding competitors and opposing pressure group to interested parties will be confusing to user community. EXAMPLE <i>Customers</i> (3.26), owners, people in an <i>organization</i> (3.01), <i>suppliers</i> (3.27), bankers,	EXAMPLE <i>Customers</i> (3.26), owners, people in an <i>organization</i> (3.01), <i>suppliers</i> (3.27), bankers, unions, partners or society.	TN

				unions, partners or society that may include competitors or opposing pressure groups.		
498	ANS I	415	3	Add regulators, legislative bodies.	EXAMPLE <i>Customers</i> (3.26), owners, people in an <i>organization</i> (3.01), <i>suppliers</i> (3.27), bankers, unions, partners or society. Regulators and applicable legislative bodies.	TAP
499	CH	415	3.02	... that may include competitors ... According to ISO/IEC Directives Part 2 Annex H, "may" means "is permitted", "is allowed", "is permissible". The use of "may" in this context is not appropriate therefore. Use "can" instead	... that can include competitors ...	EAF
500	SE	415	3.02	"...that may include competitors or opposing pressure groups". It seems unfortunate to mention these parties since it can imply that their needs and expectations could at least formally influence requirements in an unintended way. Adding "relevant" in front of "interested parties" does not necessarily solve the problem – a competitor or a pressure group can be very relevant! "relevant" is not added on lines 73, 421, 425, 942, 1260, 1627, 1710, 1712, 1756, 1759, 1760.	Add: "Note: for the purpose of this International Standard "competitors and opposing pressure groups" are not considered "interested parties" even if they could be influential or have an interest concerning the success of the organization." This would also eliminate the need for adding "relevant" in front of "interested parties" on lines 198, 276 (Figure 1), 268, 957, 1032, 1245, 1288, 1511.	TN
501	PH/ BPS	416	3.02	Source of definition of interested party is incorrect:	SOURCE: ISO DIS 9000:2014, 3.2.5	EAP
502	MX	416	3	incorrect reference to ISO 9000	Change 3.2.4 by 3.2.5	EAP
503	PT	416	3.02	ISO DIS 9000:2014, 3.2.4	ISO DIS 9000:2014, 3.2.5	EAP
504	SE	416	3.02	[SOURCE: ISO DIS 9000:2014, 3.2.4] Reference numbers have not been updated to the current version of ISO/DIS 9000 as indicated here and in the following.	[SOURCE: ISO DIS 9000:2014, 3.2.5]	EAP
505	JP 18	416	3.02	Cross-reference is incorrect.	3.2.4 should be 3.2.5.	EAP
506	FR	417	3.03	Remove the word « generally » from the definition	Remove the word « generally » from the definition	TN
507	LU	419	3.03	The term generally is confusing.	need or expectation that is stated, generally implied or obligatory	TN
508	CA-	419	3.03	Definition of "requirement" is confusing as it	Make the distinction between product/service	TN

	23			equates “needs” with “expectations” It would also help to make the distinction between product/service “requirements” (i.e. the attributes of the product/service); and the requirements of organizations and interested parties Further, the current definition indicates that “expectations” is a sub-set of “requirements”, which is in conflict with the definition for “customer satisfaction” see CA-30	“requirement” and requirements of organizations and interested parties. In the case of product/service, “requirements” are ultimately derived from customer expectations, as well as applicable statutory and regulatory requirements. NOTE – If the current definition of “customer satisfaction” is retained, it will be necessary to add a definition of “expectations”. Consult with SC1/WG1, but a suggested wording is: “hopes and desires, as stated and agreed between the customer and the organization”	
509	TT	419	3.03	Customers may have requirements which may not be necessary for achieving their organizational objectives (“wants” rather than “needs”), yet if those requirements are not fulfilled there may be a significant impact on the level of customer satisfaction. E.g. a customer may require a car to be painted to control corrosion (the “need”), and may want it to be painted green. If the supplier provides the car in a different colour it may lead to a lower level of customer satisfaction. Luxury goods and fashion items may be examples where the fulfilment of “wants” has a more significant impact on customer satisfaction than basic goods (e.g. staple foods)	Change to “need, want or expectation that is stated, generally implied or obligatory”	TN
510	SE	420 -421	3.03	Definition of “requirement”. Note 1 refers to “interested parties” and is not restricted to “relevant “ such. The customer and an opposing pressure group may have requirements that are contradictory and cannot be met together. The co-existence of the definition of “interested party” (3.02) and the definition of “requirement” (3.03) as they are stated can make it impossible for an organization to accept certain orders if all types of requirements have to be met.	Rewrite the definition 3.02 or 3.03 or both in order to eliminate the problem. Maybe it could sometimes be necessary to overlook certain requirements of certain interested parties. Amend to: “<i>Customers</i> (3.2.8), owners, people in an <i>organization</i> (3.2.1), <i>suppliers</i> (3.2.9), bankers, unions, partners or society. Note: For the purpose of this International Standard “competitors and opposing pressure groups” are not considered to be “interested parties” even if they could be influential or have an interest concerning the success of the organization”.	TN
511	SE	421 , 425	3.03	There are two formal references to “interested parties (3.02)” on the lines indicated.	Make formal reference to “interested parties (3.02)” only on line 421 in this entry.	EAP
512	FR	423	3.03	Add a reference to (3.37) and put the word	Add a reference to (3.37) and put the word	TN

				« Quality » in italic at the end of Note 3	« Quality » in italic at the end of Note 3	
513	CQI 15	425	3.03	Requirements can be generated by different interested parties (3.02). Requirements can be generated by customers and the organization as well.	Requirements can be generated by the organization (3.01), customers (3.26) and different interested parties (3.02).	TN
514	AU	431 -2	3.04		Change to policies (3.07), objectives (3.08) and processes'	EN
515	GB	429	3.04	"and" is not required.	3.04 management system set of interrelated or interacting elements of an organization (3.01) to establish policies (3.07), objectives (3.08), and processes (3.12) to achieve those objectives	EN
516	AU	431	3.04	Says elements not processes	Change 'elements' to 'processes' as per 436 and 464	TN
517	SE	432 , 436-437	3.04	There are two formal references to "processes (3.12)" on the lines indicated.	Make formal reference to "processes (3.12)" only on line 432 in this entry.	EAP
518	ANS I	433	3.04	"Quality" is a defined term, and therefore cross-reference to its definition should be provided for consistency with other terms.	Change to "...e.g. <i>quality</i> (3.3.7) <i>management</i> (3.30)..."	TN
519	AU	433		'disciplines' is not the correct terminology. Suggest 'function' or alternative		TN
520	AU	435		'elements' is not the correct terminology. Suggest 'processes'		TN
521	CH	438	3.04	The word 'may' means 'permission', which is incorrect in a NOTE.	<u>Change</u> to read: "...system CAN include ..."	EAF
522	IAQG	438 , 1220	Note 3 of 3.04, 4.3, 8.1, and 8.4	Based upon the description of how the scope of the management system may be applied (3.01, 4.3), and the requirements of 8.1, the same requirements are applied to outsourced providers as other parts of the organization considered external providers. It seems this needs to be more clearly defined.	IAQG Priority Comment Add definition – clarify Proposal: Expand definitions and have different, specific requirements applied to " <u>external providers</u> ", and "outsourced external providers", especially considering some external providers may still be within the organization per the definition.	TN
523	PH/BPS	441	3.04	Source of definition of management system is incorrect	SOURCE: ISO DIS 9000:2014, 3.4.3	EAP
524	MX	441	3	incorrect reference to ISO 9000	Change 3.4.2.1 by 3.4.3	EAP
525	PT	441	3.04	ISO DIS 9000:2014, 3.4.2.1	ISO DIS 9000:2014, 3.4. 3	EAP
526	SE	441	3.05	[SOURCE: ISO DIS 9000:2014, 3.4.2.1]	[SOURCE: ISO DIS 9000:2014, 3.4.3]	EAP
527	JP	441	3.04	The Note 2 is slightly different from DIS 9000.	Clarify that Note 2 has been modified.	EAP

	19			The “etc” is deleted.		
528	JP 20	441	3.04	Cross-reference is incorrect.	3.4.2.1 should be 3.4.3.	EAP
529	SE	444 -448	3.05	There are three formal references to “ <i>organization</i> (3.01)” on the lines indicated.	Make formal reference to “ <i>organization</i> (3.01)” only on line 444 in this entry.	EAP
530	ANS I	445	3.05	The current wording in the note implies that Top Management can delegate authority and responsibility to others within the Organization. While this is true, it's important that, during an audit, requirements indicating that Top Management shall ...be demonstrated by Top Management, as opposed to those they delegated to. Otherwise, Top Management could abdicate their responsibility and steer an auditor to whomever they delegated to.	Change note to: Top Management has the power to provide resources within the organization (3.01) and delegate authority. If authority is delegated, Top Management remains accountable and responsible.	TN
531	FR	450	3.06	The definition is unclear.	Replace by : Capacity to achieve defined objectives (or expected results) Remplacer par : Capacité à atteindre les objectifs définis (ou les résultats attendus).	TN
532	PH/ BPS	453	3.06	Source of definition of effectiveness is incorrect	SOURCE: ISO DIS 9000:2014, 3.7.11	EAP
533	MX	453	3	incorrect reference to ISO 9000	Change 3.7.7 by 3.7.11	EAP
534	PT	453	3.06	ISO DIS 9000:2014, 3.7.7	ISO DIS 9000:2014, 3.7.11	EAP
535	SE	453	3.06	[SOURCE: ISO DIS 9000:2014, 3.7.7]	[SOURCE: ISO DIS 9000:2014, 3.7.11]	EAP
536	JP 21	453	3.06	Cross-reference is incorrect.	3.7.7 should be 3.7.11.	EAP
537	FR	454	3.07	Add : to implement its strategy at the end of the definition	Policy : ... as formally expressed by its top management, to implement its strategy politique : intentions et orientations d'un organisme, telles qu'officiellement formulées par sa direction pour mettre en œuvre sa stratégie	TN
538	PH/ BPS	457	3.07	Source of definition of policy is incorrect	SOURCE: ISO DIS 9000:2014, 3.4.8	EAP
539	MX	457	3	incorrect reference to ISO 9000	Change 3.4.5 by 3.4.8	EAP
540	PT	457	3.07	DIS 9000:2014, 3.4.5	DIS 9000:2014, 3.4.8	EAP
541	IT	457	3.07	It is important to underline the consistency between the policy of the organization and its mission and vision. Information regarding policy should be clear and effective.	Note 1 to entry: The policy should be consistent with organization's mission and vision (see ISO 9000, 3.4.11 and 3.4.10) and it should be expressed in a concise, simple and	TN

					<i>essential manner.</i>	
542	SE	457	3.07	[SOURCE: ISO DIS 9000:2014, 3.4.5]	[SOURCE: ISO DIS 9000:2014, 3.4.8]	EAP
543	JP 22	457	3.07	Cross-reference is incorrect.	3.4.5 should be 3.4.8.	EAP
544	ANS I	460	3.08	I believe this is too brief. Expand it to be more able to determine if it is achieved.	'measurable result to be achieved over some finite time period.'	TN
545	ANS I	460	3.08	"Objective" should be specific, measurable, achievable, time specific and as a result, I would recommend that this definition be changed. More lofty goals should be just that such as "I want to achieve growth". Objectives should define what metric will be used to achieve growth.	Add "measureable" prior to "result to be achieved".	TN
546	ANS I	460	3.08	I believe that the explanation is too truncated and unspecific.	Stated , planned or documented results to be achieved	TN
547	GOS T R	461	3 Terms and definitions	"An objective can be strategic, tactical, or operational" – terms shall be explained further more		TN
548	BR	463	3.08	The expression "...and can apply at different levels" should be improved	Change to "...and can be applied at different levels"	TN
549	SE	465	3.08	"...as an intended outcome..." See also general comment	"...as an intended result..."	TN
550	ANS I	467	3	Add to the objective Note 3.	Objective can be short term or long term.	TN
551	ANS I	467		Change from "sometimes" to "generally" Note 5 to entry: The term "risk" is sometimes used when there is only the possibility of negative consequences	Note 5 to entry: The term "risk" is generally used when there is only the possibility of negative consequences	TAP
552	DK	468	3.08	Delete note 4 as the note relates to requirements which are not allowed within definitions. And the requirements are given elsewhere, so no need for the note.	Note 4 to entry: In the context of quality management systems (3.33), quality objectives are set by the organization (3.01), consistent with the quality policy (3.34), to achieve specific results.	TN
553	IAQ G	468	3.09	If risk is an "effect of uncertainty ..." (line 467) and " An effect is a deviation from the expected — positive or negative" (line 468), it can be deduced that a risk can be either negative or positive. This contradicts common sense, whereby risk has only and always the connotation of a threat to the achievement of objectives.	IAQG Priority Comment Add definition – clarify Proposal: Clarify that <u>risk</u> is the <u>negative effect</u> of uncertainty. <u>Opportunity</u> could be presented as the <u>positive effect</u> of uncertainty	TN
554	JP 23	470	3.08	The Note 2 is slightly different from DIS 9000.	Clarify that Note 2 has been modified.	EAP

				The cross-reference for the term "organization" is deleted.		
555	GB	471 -483	3.09	this definition of risk is different to that of ISO14001:2015 draft copy. If the two Standards are meant be more closely aligned then they should share the same definition of risk. Therefore, how can you integrate two different ISO systems if the meaning of a critical word means two different things? Especially, when ISO14001 is supposed to be based around the RISK of the activities, products and/or services of the organisation. AND "Note 1-4 to entry: ..." are identical, which only compounds the issue.	Find a definition of risk that is shared between ALL Standards, e.g. 27001, 9001, 45001, 14001, etc. The persons who define the terminology should meet to discuss the variations in terms that are going to be used, so that a consensus can be reached.	TN
556	MY	471 -482	3.09	Definition of "risk" is different from ISO 14001 and other MSSs, hence a note should be added to inform users that other definitions of the term exist.	To add Note 6 to this clause as follows: "Users of this standard should be aware that there are other definitions of "risk" in other management system standards published by ISO "	TN
557	CL	471 - 473	3.09	It says "risk effect of uncertainty on an expected result" The National Committee considers there is a difference between <i>expected results</i> and <i>expected objectives</i>. Furthermore ISO / DIS 14001 also mention the definition of ISO 31000, , that include "objectives".	We suggest to change to use definition of ISO 31000: "risk effect of uncertainty on objectives" To be consistent with ISO 31000:2009 and ISO/DIS14001.	TN
558	FR	471	3.09	Use the definition of risk as given in ISO 31000	Use the definition of risk as given in ISO 31000	TN
559	FR	471	3.09	The standard defines the term "risk", but not "opportunity"	Add a definition of the term « opportunity »	TN
560	NO	472 -473	3.09	We do not see any advantages in using the term "expected results". "Effect of uncertainty" should be linked to "objectives". Hence we prefer to use the same definition of risk as in ISO 31000 and ISO/DIS 14001. Alternatively use the same definition of risk as in ISO Directive 1, Annex SL	3.09 risk effect of uncertainty on objectives	TN
561	FI	472		The Risk -definition according to the standard ISO 31000 should be used in standard ISO 9001 (in ISO 9000 also) (not the modified Risk definition according to "Annex SL")	Use a Risk definition according the standard ISO 31000	TN

				In ISO 9001 it is referred to the standard ISO 31000, and it causes a remarkable confusion, if risk definitions are not similar in these both documents.		
562	TC2 10	472	3.09	In the medical device industry, the word "risk" has been long used in QS / QMS international standards, i.e. ISO 13485:1996 and ISO 13485:2003. The word "risk" is defined in ISO 14971 as "combination of the probability of occurrence of harm and the severity of the <u>harm</u>" and ISO 13485 share this definition. Then, the regulations for medical devices all over the world also share this definition for "risk" in their requirements. Currently ISO 13485 has been made based on ISO 9001 and in this standard. For ISO 13485, all requirements related to "risk" are very essential. Then, it would cause very big confusion that the next version of ISO 13485 starts to use the word "risk" differently. It will also mean that the definition of "risk" will not be harmonized between ISO and the regulations. If the "risk" will be started to be differently in ISO 9001, QMS requirements for medical devices may not be able to be based on ISO 9001 at least for this part.	Replace "risk" with "effect of uncertainty" (or "effect of uncertainty on an expected result") through the document.	TN
563	CQI 16	473	3.09	effect of uncertainty on an expected result The Oxford English Dictionary defines the word risk as "the possibility of loss, injury, or other adverse or unwelcome circumstance In every instance of the use of the term in this DIS it is used in this sense and never in the sense of a positive effect. The word opportunity has been used for that purpose.	the chance of not achieving the intended outcome or (result)	TN
564	IIOC	473	3	The definition of the term risk is too simplistic and not in accord with risk management terminology. A risk can be known to exist therefore an affect does not have to stem from uncertainty.	Redefine risk as "the combination of likelihood and the associated consequence (impact) upon the organisation and/or process	TN
565	BR	473	3/3.09	An effect is a deviation from the expected — positive or negative. A risk is not related only to a result. This makes the definition incompatible with Note 1.	Delete "on an expected result"	TAP
566	ANS I	473	3.09	This definition is different than the same definition	Please consider use of definition of "risk"	TN

				of “risk” contained in ISO 31000. Line 304 of Clause 0.5 makes a direct reference to ISO 3100 for risk-based thinking.	contained in ISO 31000 to maintain standardization of terms across all ISO Standards.	
567	DK	473	3.09	It should be made clear why the definition of “risk” is different to that given in ISO Guide 73. The introduction to “risk thinking” is not making this clear.	Explain in a note what the difference is between the definition of risk in risk Management and r in Quality Management.	TN
568	NL	473	3.09	We prefer to define ‘risk’ in the same wording as in ISO 31000 (and similar to ISO/DIS 14001, ISO 27001, ISO 55001 and ISO 22301). In our opinion the existing wording ‘effect on uncertainty on an expected result’ suggests a difference with 31000 that is not clear. Using ‘objectives’ instead of ‘expected result’ has also the advantage that the user is referred to a defined term with some notes that are very important to better understand the concept of risk.	Risk = effect of uncertainty on objectives	TN
569	IT	473	3.09	Since “objective” is, by definition (3.0.8), a “result to be achieved”, there seems to be no reason nor added value in modifying ISO Guide 73 definition of “risk”. An objectives can imply the achievement of more than one result. The term “objective(s)” is therefore broader than “an expected result”. Moreover, the use of term “objective(s)” highlights that uncertainty can affect the whole process of planning and achieving relevant expected result, including the following: - establish objective(s) and its targets; - determine all activities and actions necessary to achieve established objective(s); - carry out determined activities and actions in order to achieve expected results.	Modify definition as follows, assuring consistency with ISO Guide 73: <i>effect of uncertainty on an expected result</i> objectives	TN
570	JP 24	473	3.09	To be consistent with Annex SL.	Delete “on an expected result.”	TAF
571	ANS I	474	3 Terms and Definitions	474 “positive or negative” seem to conflict with 475 “of deficiency” how can a deficiency be a positive?	Remove the terms “positive or negative” from line 474	TN
572	ANS I	474	3.09	“positive” There is no positive risk. See line 482	Delete “positive” or negative”	TN
573	ANS I	474	3.09	An effect is a deviation from the expected – risk can be expected and is not necessarily a deviation	Risk is uncertainty including future events, caused by lack of or incomplete information. It is also the probability of a hazard or vulnerability in a product	C

					or service resulting in an adverse event	
574	QS	474	3.09	"An effect" is a result or outcome of an activity and not "deviation from the expected — positive or negative" as said in the standard	Change as below Note 1 to entry: An effect is an result where deviation from the expected can be either positive or negative	TN
575	IT	474	3.09	The effect of uncertainty can also be positive "and" negative, not necessarily only positive or negative.	Modify as follows, according to ISO Guide 73:2009: [...] <i>positive and/or negative</i> [...].	EN
576	CZ	474	3.09	A full stop at the end of the sentence is missing.	To be added.	EAP
577	GB	474	3.09	In every instance of the use of the term in this DIS the word risk is used in the negative sense and not once in the sense of a positive effect as the word opportunity has been used for this purpose. Use of the term opportunity in the title to 6.1 would be redundant if risk has a positive effect. When presented with a risk there is a choice of action as per the Note on line 1061. We weigh-up the potential benefits and harms of exercising one choice of action over another and if we decide to take a risk , this is sometimes referred to as "positive risk taking" It does not make a risk positive or the effect of risk positive but the effect of taking a risk may be positive either because the benefits out-weigh the losses or the likelihood of occurrence is very low.	Change to: Note 1 to entry: An effect is the result of an action.	TN
578	ANS I	475	3.09	No value added	Delete Note 2	TN
579	CA-24	475	3.09	Modify the current wording (copied below) to the wording shown in the column on the right. Note 2 to entry: Uncertainty is the state, even partial, of deficiency of <i>information</i> (3.50) related to, understanding or <i>knowledge</i> (3.53) of, an event, its consequence, or likelihood.	Note 2 to entry: <i>Uncertainty is the state, even partial, of deficiency of information</i> (3.50) <i>related to, the understanding or knowledge</i> (3.53) <i>of, an event, its consequences, or the likelihood of its occurrence.</i>	TN
580	ANS I	476	3.09	No value added	Delete Note 2	TN
581	IAQ G	476	3.09	The note suggests that the term "risk" is "used when there is only the possibility of negative consequences" not always, but only "sometimes". This contradicts the common use of the term risk, which always implies negative consequences.	Reword definition – Improve Proposal: Delete " <u>sometimes</u> " from Note 5	TN
582	ANS I	477	3.09	Typo. ISO Guide 73.209 is missing a zero. The guide is not included in the bibliography.	Correct typo. Add Guide 73.2009 to the bibliography. Most	EAP EN

					users will need all the help they can get on managing risk.	
583	ANS I	477	3.09	Redundant with Note 4	Delete note 3	TN
584	ANS I	477	3.09, Note 3	Add "the likelihood of" to sentence to comply with wording in ISO 31000: 2.1, Note 4	Risk is often characterized by reference to the likelihood of potential "events"...	TN
585	PT	477	3.09	ISO Guide 73:209	ISO Guide 73:2009	EAP
586	IQN et	477	3.09	wrong year number.	ISO Guide 73:2009	EAP
587	HU	477	3.09	The year of issue in the reference of ISO Guide 73 is not correct: a '0' is missing	Correctly: ISO Guide 73:2009	EAP
588	CZ	477	3.09	ISO Guide 73:209.	To be corrected – ISO Guide 73:2009	EAP
589	JP 25	477	3.09	The year of publication of Guide 73 is a typo.	Change "209" to "2009."	EAP
590	BR	482	3.09	The term risk is not used when there is only the possibility of negative consequences, but only to refer to this possibility, even when there are also positive consequences. Change note 5 for clarity	Change note 5: The term "risk" is sometimes used in this standard to refer only to negative consequences.	TN
591	ANS I	482	3.09	The Note 5 qualifier for the definition of risk appears to contradict the Note 1 as it pertains to whether risk is positive or negative, and will cause serious confusion for end users. If the standard itself is confused itself on this definition, users will be more so.	If Note 5 is to remain, then Note 1 should be removed. If Note 1 is to remain, then Note 5 should be removed.	TN
592	IAQ G	482	3.09	NOTE5 has been added for the definition of "risk", but the term "only" should be deleted because it can be interpreted as completely limited situation.	Reword - clarify Proposal: Change as follows. "The term "risk" is sometimes used when there is only the possibility of negative consequences"	TAP
593	IAQ G	482	3.09	Add NOTE as follows. "The possibility of positive consequences can be addressed by the term "opportunity"". That makes requirements in clause 6.1 much clearer.	Add note - clarify Proposal: Add NOTE as follows. "The possibility of positive consequences can be addressed by the term "opportunity".	TN
594	CO	482	3.09	Delete note 5 or move to guidance . This is not part of the definition. It is contrary to note 1.	Delete note 5 or move to guidance	TN
595	CO	482	3.09	Include note 5 of ISO Guide 73:2009 regarding Uncertainty, in order to clarify the term.	Uncertainty is the state, even partial, of deficiency of information related to understanding or knowledge of an event, its consequence or possibility	TAP
596	TC6 9	482	3.09	Contrarily to the other notes of the Standard, this note does ends with a point: "The term "risk" is sometimes used when there is only the possibility of negative consequences"	"The term "risk" is sometimes used when there is only the possibility of negative consequences."	EAP

597	GB	482	3.09	Regarding "Note 5 to entry: The term "risk" is sometimes used when there is only the possibility of negative consequences" The phrase: "risks and opportunities" is used throughout the standard implying that this standard itself only uses the term "risk" for negative consequences	Consider rewording the note to make the usage of risk in the standard consistent	TN
598	BY	483	3.9	incorrectly refer	We offer changed to: [SOURCE: ISO DIS 9000:2014, 3.7.8]	EAP
599	PH/ BPS	483	3.09	Source of definition of risk is incorrect	SOURCE: ISO DIS 9000:2014, 3.7.8	EAP
600	MX	483	3	incorrect reference to ISO 9000	Change 3.7.4 by 3.7.8	EAP
601	PT	483	3.09	ISO DIS 9000:2014, 3.7.4	ISO DIS 9000:2014, 3.7.8	EAP
602	TH	483	3.09	SOURCE is incorrect.	Replace "SOURCE: ISO DIS 9000:2014, 3.7.4" with "SOURCE: ISO DIS 9000:2014, 3.7.8"	EAP
603	SE	483	3.09	[SOURCE: ISO DIS 9000:2014, 3.7.4]	[SOURCE: ISO DIS 9000:2014, 3.7.8]	EAP
604	JP 26	483	3.09	Cross-reference is incorrect.	3.7.4 should be 3.7.8.	EAP
605	AT	484	3.10	The note leads to confusion because of inconsistent definitions. Qualification is now – since the definition of competence has changed - used in a different way: e.g. ISO 17024: qualification demonstrated education, training and work experience, where applicable Alternative suggestion: introduce definition of qualification consistently with other standards. This alternative should be done, if the term "qualification" is kept in chapter 8.	Note 1 to entry: Demonstrated competence is sometimes referred to as qualification.	TN
606	CA- 25	485	3.10	The definition of the term "competence" should also include expertise for the individuals and not only knowledge and skills. Expertise can be achieved through several means but should be an essential part of one's competence	Change to: "ability to apply knowledge (3.53), skills and expertise to achieve intended results"	TN
607	ANS I	487	3.10	"Demonstrated competence is sometimes referred to as qualification" This does not make sense.	Delete Note 1	TN

				Demonstration of knowledge and skills is competence		
608	EOQ	487	3.10	This note is inconsistent with current use of competence and qualification in ISO standards. There has been developed a specific standard on vocabulary regarding competence of persons, cp. ISO 17027 Currently the word “qualification” is used only in two instances in chapter 8, where it should be deleted for consistency. The whole of section 7.2 does not mention “qualification”.	Note 1 to entry: Demonstrated competence is sometimes referred to as qualification.	TN
609	AU	487	3.10	This is confusing and not correct. A qualification is a formal benchmark of achievement – it can involve theory, practical or a combination of the two.	Change to ‘Competence may be demonstrated by a relevant qualification’	TN
610	GB	487	3.10	Note 1 could lead to ambiguity as qualifications do not necessarily demonstrate competence and therefore this could lead to confusion	Remove Note 1	TN
611	PH/ BPS	488	3.10	Source of definition of competence is incorrect	SOURCE: ISO DIS 9000:2014, 3.6.10	EAP
612	MX	488	3	incorrect reference to ISO 9000	Change 3.6.6 by 3.6.10	EAP
613	PT	488	3.10	ISO DIS 9000:2014, 3.6.6	ISO DIS 9000:2014, 3.6.10	EAP
614	SE	488	3.10	[SOURCE: ISO DIS 9000:2014, 3.6.6]	[SOURCE: ISO DIS 9000:2014, 3.6.10]	EAP
615	JP 27	488	3.10	Cross-reference is incorrect.	3.6.6 should be 3.6.10.	EAP
616	TC4 6/SC 11 Liaison (SE)	489	3.11	The term “documented information” is confusing since its wording and definition seems both interchangeable and deviates to the term and definition of “document, noun” in 3.1.3 ISO 30300, the term and definition of “documentation” in 3.1.4 ISO 30300, the term and definition of “evidence” in 3.1.5 ISO 30300, and the term and definition of “record(s)” in 3.1.7 ISO 30300.	Remove the term “documented information”. Add the term “document, noun” and its definition from 3.1.3 ISO 30300. Add the term “documentation” and its definition from 3.1.4 ISO 30300. Add the term “record(s)” and its definition from 3.1.7 ISO 30300.	TN
617	ANS I	490	3.11	“documented information” The way this is defined, it disconnects with A.6, line 1669 and 1672. There is no retention component in the definition. According to A.6, the definition should contain both “retain” and “maintain” components	Redefine documented information considering line 1660 A.6	TN

618	ANS I	491	3.11	3.50 define "information" as "meaningful data". With this now the definition reads....Meaningful data required to be controlled" and maintained. The "maintained" word reference to documented procedure or document as per A.6. So retain, as per A.6 is not covered in this definition	Redefine documented information considering line 1660 A.6	TN
619	LU	491	3.11	Definition doesn't express the "documented" aspect. The definition have to remind the former notion of procedure and record	information (3.50) required to be controlled, <u>specified</u> , maintained and <u>kept</u> by an organization (3.01)...	TN
620	NO	494 - 498	3.11	"Procedure" should be used as an example of what documented Information can refer to.	Add a new bullet point (new line 498) in Note 2 - procedure	TN
621	GB	494	3.11	It is stated in Note 2 to 3.11 that Documented information can refer to: - the quality management system (3.33), including related processes (3.12) However, it is defined in 3.04 that management system is a set of interrelated or interacting elements of an organization (3.01) to establish policies (3.07) and objectives (3.08) and processes (3.12) to achieve those objectives. Hence, it is not appropriate to state that Documented information can refer to: - the quality management system (3.33), including related processes (3.12)	3.11 documented information (3.50) required to be controlled and maintained by an organization (3.01) and the medium on which it is contained Note 1 to entry: Documented information can be in any format and media and from any source. Note 2 to entry: Documented information can refer to: - the information of the quality management system (3.33), including related processes (3.12); - information (3.50) created in order for the organization (3.01) to operate (documentation); - evidence of results achieved (records).	TN
622	CQI 17	495 - 497	3.11	- the quality... - information... - evidence... The 3 bullets under Note 2 to entry are unordered. To improve identification these should be ordered (c.f. 3.65 Note 3 to entry).	a) the quality... b) information... c) evidence...	TN
623	ANS I	496	3.11	Since procedures are such a common and well known example of information that is used to operate, refer to procedures here to reinforce understanding	Add "such as procedures" to this line.	TAP
624	EE	497	3.11	It could be referred to term 3.8.11 (i.e. <i>record</i>) in ISO/DIS 9000, in the last subclause of note 2.	Replace existing wording of last subclause with	TN

					<i>following:</i>	
					– evidence of results achieved [records (3.8.11)].	
625	BY	498	3.11	incorrectly refer	We offer changed to: [SOURCE: ISO DIS 9000:2014, 3.8.3]	EAP
626	PH/BPS	498	3.11	Source of definition of documented information is incorrect	SOURCE: ISO DIS 9000:2014, 3.8.3	EAP
627	MX	498	3	incorrect reference to ISO 9000	Change 3.8.1.1.1 by 3.8.3	EAP
628	PT	498	3.11	ISO DIS 9000:2014, 3.8.1.1.1	ISO DIS 9000:2014, 3.8.3	EAP
629	SE	498	3.11	[SOURCE: ISO DIS 9000:2014, 3.8.1.1.1]	[SOURCE: ISO DIS 9000:2014, 3.8.3]	EAP
630	JP 28	498	3.11	Cross-reference is incorrect.	3.8.1.1.1 should be 3.8.3.	EAP
631	IT	501	3.12	"Interrelated" and "interacting" are not necessarily alternative one each other.	Change "or" to "and/or".	EN
632	GB	501	3.12	The definition of <process> is not generic, and is still based on a manufacturing mindset. A transformation is not necessary, but a trigger event and an objective is.	Change to: A set of related activities triggered by an event and intended to achieve an objective	TN
633	IT	503 -504	3.12	The note can be misleading, as it is not clear how a catalyst of a chemical process can be regarded as the output of the process.	Delete or modify accordingly, e.g. by means of a more comprehensible example.	TAP
634	SE	503 -504	3.12	"Note 2 to entry: In some processes, some inputs become outputs (3.46) without any transformation e.g. a blueprint used in a manufacturing process or a catalyst in a chemical process." The contents of the note seem to be in conflict with the definition. Moreover, to perform a process you would in general need various resources. Some resources will remain (such as equipment, blueprints and catalysts), others will be spent (such as fuel, cooling water, time). Some resources will be used for control of the process (again, such as blueprints and catalysts!)	Use the term "input" only to what actually is being acted on in the process, in line with the definition. Delete Note 2 to entry.	TAP
635	BR	503	3/3.12	Note 2 does is too confusing and does not add value, and is inconsistent with the definition of process which transforms inputs into outputs	Remove note 2	TAP
636	ANS I	503	3.1.2	The examples in Note 2 are confusing. E.g. a catalyst is not necessarily an output; it may stay in the process until the process is shut down.	Delete not 2 or find better examples that always hold true.	TAP
637	ANS I	504	3.12	"blueprint" is an old term	Suggest changing "blueprint" to "technical drawing"	TAP

638	ANS I	504	3	Note 2 to entry: In some processes, some inputs become <i>outputs</i> (3.46) without any transformation e.g. a blueprint used in a manufacturing process or a catalyst in a chemical process.	Note 2 to entry: In some processes, some inputs become <i>outputs</i> (3.46) without any physical transformation e.g. Output for a blueprint used in a manufacturing process is information or knowledge or a catalyst in a chemical process that helps with acceleration.	TN
639	AT	505 -506	3.12	This note doesn't add any value	Delete Note 3	TAP
640	SE	505 -506	3.12	"Processes in an <i>organization</i> (3.01) are generally planned and carried out under controlled conditions to add value." This seems self evident and hardly needs to be emphasized.	Self evident. Delete Note 3 to entry.	TN
641	DK	505	3.12	The content of note 3 seems to be self-evident and not needed. The text is: "Note 3 to entry: Processes in an organization (3.01) are generally planned and carried out under controlled conditions to add value."	Delete the note 3	TN
642	GB	506	3.12	The term <special process> is not used in ISO 9001 and is a hangover from pre 2000 versions of ISO 9001. In the service sector conformity of the resulting outputs is validated prior to the service being delivered to customers thus making most services special processes. The inclusion of this note therefore adds no value and is unnecessary.	Delete	TN
643	AT	507 -508	3.12	This note doesn't add any value and with "special process" even worse causes confusion	Delete Note 4	TN
644	IT	507 -508	3.12	In the current edition (2005) of ISO 9000 the wording is: <i>"A process where the conformity of the resulting product cannot be readily or economically verified is ..."</i> There is no clear the reason for changing from "verified" to "validated".	Keep the wording of ISO 9000:2005, 3.4.1, Note 3, i.e. do not change "verified" to "validated".	TAF
645	ANS I	507	3	The term "readily" may not be consistently interpreted. Note 4 to entry: A process where the <i>conformity</i> (3.18) of the resulting <i>output</i> (3.46) cannot be readily or economically validated is frequently referred to as a "special process".	Note 4 to entry: A process where the <i>conformity</i> (3.18) of the resulting <i>output</i> (3.46) cannot be subsequently verified or economically validated is frequently referred to as a "special process". (alignment with line 1374)	TN
646	CA- 26	508	3.12	The Note 4 to entry, for the term "process",	Leave the Note as was (i.e., using 'verified'), in	TN

				states: "A process where the <i>conformity</i> (3.18) of the resulting <i>output</i> (3.46) cannot be economically validated is frequently referred to as a "special process". The definition for "process" in ISO 9000:2005 (3.4.1) has the identical wording in it's Note 3, except the term "verified" was used, instead of "validated". Validation is checking that the requirements for a specific intended use (i.e., the customer's requirements) are fulfilled. Verification is checking that specified requirements (for that process) have been fulfilled. Verification is the more frequently applied check on the output of a process, before that output proceeds to the next process. On the other hand, validation is more frequently applied in checking the output of a system (of processes). It is more appropriate that process outputs are <u>verified</u> , rather than <u>validated</u> . What was the logic behind the change from 'verified' to 'validated'??	ISO 9000:2005	
647	AT	510	3.13	Discussion in Austria revealed different interpretations which lead to misunderstand and confusion. This definition needs to be clarified by terminology experts.	This definition needs to be clarified by terminology experts.	C
648	FR	510	3.13	The definition of the terms « performance » is very poor.	Performance : Achievement of mesurable and expected results in coherence with the issues and the context of the organization Performance : Atteinte des résultats mesurables et attendus en cohérence avec les enjeux et le contexte de l'organisme"	TN
649	SE	512 -513	3.13	"performance measurable result Note 1 to entry: Performance can relate either to quantitative or qualitative findings." Are "qualitative findings" measurable in the ordinary sense of the word? Or would e.g. "graded" be a more suitable word in this case. Add a note to this effect.	Add: "Note 3 to entry: For qualitative findings "measurable" could often be replaced with "graded" or similar word."	TAP
650	TC6 9	512 , 742	3.13, 3.46	The term "result" is not defined and some confusion may exist with the term "findings", for instance, used in the note 1 to entry 3.13. The new entry's definition is based on the definition of "measurement result" of the "ISO/IEC	New entry: "3.70 Result Set of characteristic values determined by a given process (3.12)"	TN

				Guide 99:2007 - International vocabulary of metrology"		
651	ANS I	513	3.13	"findings". This word can be confusing to the auditors	Delete "findings" or replace it with another word.	TN
652	TC69	513	3.13	The term "findings" is not clear enough for the note 1 to the entry 3.13: "Note 1 to entry: Performance can relate either to quantitative or qualitative findings."	New note 1 to the entry 3.13: "Note 1 to entry: Performance can relate either to quantitative or qualitative outputs (3.46)."	TN
653	PT	514	3.13	... activities, <i>processes</i> , <i>products</i> , <i>services</i> , ... not aligned with DIS 9000:2015	... activities, <i>processes</i> , <i>products</i> and <i>services</i> ...	EN
654	IT	514	3.13	Editorial suggestion.	Modify as follows: "[...] <i>products</i> (3.47), <i>services</i> (348) [...]"	C
655	JP 191	514	3.13	Different from 3.7.9 of DIS 9000. The "product" is changed to "products."	The definition in ISO 9000 and 9001 should be identical.	C
656	JP 192	514	3.13	Different from 3.7.9 of DIS 9000. The "and" is changed to a comma before "services."	The definition in ISO 9000 and 9001 should be identical.	C
657	AT	515	3.13	Quality Performance has been introduced to the standard as a term. It should be contained in the definition.	Ad ", or quality (3.37) to the Note in line 515.	TN
658	EOQ	515	3.13	"Quality Performance" is a new concept within the standard. Therefore also here in the definition of performance the term "quality performance" should be mentioned as one possibility.	", or quality (3.37) " should be added to the Note in line 515.	TN
659	PH/BPS	516	3.13	Source of definition of performance is incorrect	SOURCE: ISO DIS 9000:2014, 3.7.9	EAP
660	MX	516	3	incorrect reference to ISO 9000	Change 3.7.5 by 3.7.9	EAP
661	PT	516	3.13	ISO DIS 9000:2014, 3.7.5	ISO DIS 9000:2014, 3.7. 9	EAP
662	SE	516	3.13	[SOURCE: ISO DIS 9000:2014, 3.7.5]	[SOURCE: ISO DIS 9000:2014, 3.7.9]	EAP
663	JP 29	516	3.13	Cross-reference is incorrect.	3.7.5 should be 3.7.9.	EAP
664	HU	517-520	3.14	It is not clear why this term is defined as a verb,. E.g. 'monitoring' is defined as a noun, but is used several times as a verb.	"Outsourcing making an arrangement"	C
665	ANS I	519	3.14 Outsource	During the release of ISO 9001:2000, TC 176 simplified the value stream to mean Customer-Organization-Supplier. This rewording proved to be very effective over the past 14 years. The	Change the text to read: make an arrangement where a supplier (3.27) performs part of an organization's	TN

				word supplier can mean either internal-to-organization or external-of-the-organization supplier. In either case, the organization must ensure they monitor supplier performance in accordance with any related organizational requirements. I would propose replacing the language "external provision" and "external providers" with the term "supplier(s)", and include a definition for both external and internal suppliers under glossary term 3.27.		
666	CH	519	3.14	It is theoretically possible for an external organization to perform all of the organization's processes.	<u>Change</u> to read: "...performs part OR ALL of an organization's ..."	TN
667	CN	520 522	3.14	The sequence of this definition is "function or process" but in ISO9001,the sequence is "process or function" such as in line 1325,1341	The sequence should be aligned with each other by the sequence of "process or function"	EN
668	ANS I	521 -522		The use of the term 'external organization' in outsourcing and limiting to only 'external' may be avoided	Contradicts with current published guidelines on outsourcing where 'outsourcing' can be even within an organization where one process / part / division as long as it is not included in the scope of the QMS and even if there is no financial transaction involved	EN
669	ANS I	521	3.14 Outsource	During the release of ISO 9001:2000, TC 176 simplified the value stream to mean Customer-Organization-Supplier. This rewording proved to be very effective over the past 14 years. The word supplier can mean either internal-to-organization or external-of-the-organization supplier. In either case, the organization must ensure they monitor supplier performance in accordance with any related organizational requirements. I would propose replacing the language "external provision" and "external providers" with the term "supplier(s)", and include a definition for both external and internal suppliers under glossary term 3.27.	Change the text to read: Note 1 to entry: A supplier (3.27) is outside the scope of the management system (3.04) although	TN
670	ANS I	521 522	3.14	This Note 1 is not clear, and it implies all functions and processes for example, hiring process	Add another note to remove this implication. <u>THIS IS FOR SC2 CONSIDERATION, THE ISSUE RAISED IS NOT REALLY A TERMINOLOGY ISSUE....ANY LIMITS TO APPLICABILITY SHOULD BE A REQUIREMENT.</u>	TN

671	GB	521	3.14	This is very confusing – this difference between an external organisation and an outsourced function is not obvious. Secondly and more crucially this Note is actually a requirement in the standard (line 1341) and so should not be a note at all (or it should reference the relevant sections of the standard.	Delete	TN
672	ANS I	523	3	Additional clarification to the note.	External organization can be part of the same parent organization with a different scope of the management systems. (Outsourced to a sister organization)	TN
673	PH/ BPS	523	3.14	Source of definition of outsource is incorrect	SOURCE: ISO DIS 9000:2014, 3.6.7	EAP
674	MX	523	3	incorrect reference to ISO 9000	Change 3.6.3 by 3.6.7	EAP
675	PT	523	3.14	ISO DIS 9000:2014, 3.6.3	ISO DIS 9000:2014, 3.6.7	EAP
676	SE	523	3.14	[SOURCE: ISO DIS 9000:2014, 3.6.3]	[SOURCE: ISO DIS 9000:2014, 3.6.7]	EAP
677	JP 30	523	3.14	Cross-reference is incorrect.	3.6.3 should be 3.6.7.	EAP
678	FR	524	3.15	The term « determination » used in this definition is inappropriate. In addition, the term “determination” is unclear and is very difficult to translate in French. Explanation about the term and the concept of determination would greatly help translating the term.	Explanation about the term and the concept of determination would greatly help translating the term. We would appreciate if the liaison officer between WG24 and WG1 could help clarifying this issue.	C
679	CA- 27	526	3.15	This definition is missing a few items which would bring clarity to it and allow a better control over the action of monitoring. I would like to see the addition of the “State” of the system and also the addition and link back to the verification	Determining (3.67) the status and state of a system (3.31), a process (3.12) or an activity through proper verification (3.54)	TN
680	SE	526	3.15	“<i>determining</i> (3.67) the status...” The substitution principle does not work with the present wording.	“ <i>determination</i> (3.67) of the status...”	TN
681	SE	528 -529	3.15	“Monitoring is generally a determination (3.67) of the object (3.36) being monitored, carried out at different stages or at different times.” “Monitoring is...being monitored” seems close to a circularity.	“Monitoring is generally a determination (3.67) of the status of an object (3.36), carried out at different stages or at different times.”	TN
682	PE	528	3.15	In Note 2 it has been omitted to describe the characteristic to be determined (status) of the	It should say:	TAF

				object: <i>Monitoring is generally a determination (3.67) of the object (3.36) being monitored, carried out at different stages or at different times.</i>	<i>Monitoring is generally a determination (3.67) of the status of the object (3.36) being monitored, carried out at different stages or at different times.</i>	
683	PH/ BPS	530	3.15	Source of definition of monitoring is incorrect	SOURCE: ISO DIS 9000:2014, 3.13.3	EAP
684	MX	530	3	incorrect reference to ISO 9000	Change 3.13.1.2 by 3.13.3	EAP
685	PT	530	3.15	ISO DIS 9000:2014, 3.13.1.2	ISO DIS 9000:2014, 3.13. 3	EAP
686	SE	530	3.15	[SOURCE: ISO DIS 9000:2014, 3.13.1.2]	[SOURCE: ISO DIS 9000:2014, 3.13.3]	EAP
687	JP 31	530	3.15	Cross-reference is incorrect.	3.13.1.2 should be 3.13.3.	EAP
688	IQN ET	531	3.16 Section 3.	Measurement is defined as a process. Why? 9.1 does not require a process neither 4.4. I can have it as an activity within a process and not a process itself. For and organization to have a process for measuring will be dependent on the context. The definition is not compatible with 9.1. Dictionary definition is enough	Delete definition or revise to exclude process	TN
689	FR	531	3.16	Inaccurate definition	Measurement : Activity to determine a value representative of an object characteristic Mesure : activité visant à déterminer une valeur représentative d'une caractéristique d'un objet.	TN
690	FR	531	3.16	Replace process by activity	Replace process by activity	TN
691	FR	531	3.16	Remove the reference to 3.67	Remove the reference to 3.67	EAF
692	ANS I	533	3.16	"determine (3.67)" Inaccurate clause number. The verb is not defined	Define (3.67) as verb "determine"	TN
693	TC6 9	533	3.16	Coherently with the comment to the entry 3.67, the definition of the entry 3.16: "process (3.12) to determine (3.67) a value" should be updated	"process (3.12) to determine (3.67) one or more values"	TN
694	JP 32	533	3.16	3.67 is a definition of a noun "determination", not a verb "determine".	Delete the cross-reference "(3.67)."	EAF
695	DK	534	3.16	Even though the note is correct the added value for the reader is rather little. The text is: "Note 1 to entry: According to ISO 3534-2:2006 the value determined is generally the value of a quantity"	Delete the note.	TN

696	PH/BPS	535	3.16	Source of definition of measurement is incorrect	SOURCE: ISO DIS 9000:2014, 3.13.7	EAP
697	MX	535	3	incorrect reference to ISO 9000	Change 3.13.3 by 3.13.7	EAP
698	PT	535	3.16	ISO DIS 9000:2014, 3.13.3	ISO DIS 9000:2014, 3.13.7	EAP
699	SE	535	3.16	[SOURCE: ISO DIS 9000:2014, 3.13.3]	[SOURCE: ISO DIS 9000:2014, 3.13.7]	EAP
700	JP 33	535	3.16	Cross-reference is incorrect.	3.13.3 should be 3.13.7.	EAP
701	ANS I	536 -551	3.17	The changes made to the Annex SL definition of audit are in violation of the ISO directives, inconsistent with the other management system standards, not aligned with the definitions in ISO 19011 and the definitions developed by the experts who were charged with responsibility for developing these definitions. They are also not aligned with the definitions used within organizations that are driven by the U.S. government rules and regulations (e.g. GAO), or the definitions used by financial and internal auditors (IIA standards). The changes are also technically incorrect. An audit needs to be a documented process (as set out in the Annex SL definition). This is critical to the integrity of the audit process. The evidence used in an audit must be "audit evidence" as defined in ISO 19011. It needs to be verifiable and relevant. To change the term to "objective evidence" is incorrect using either the dictionary definition of "objective" or the definition set out in ISO 9000 – which is not the same as the definition 3.61 (lines 863 to 866) set out in this standard.	Retain Annex SL definition of audit. <u>THIS IS AN SC2/WG24 LEADERSHIP ISSUE</u>	TAP
702	SE	536 -551	3.17	The definition and Notes are not identical with those in ISO 9000 or in Annex SL.	The definition and notes should be discussed with SC1 to arrive at a generally accepted text.	C
703	GB	536	3.17	The revised definition of audit given in 3.17 should be conveyed to TC 176/SC1 for inclusion in ISO 9000, as it removes the meaningless term "documented process", which also causes confusion with the Annex SL defined term of "documented information". There is also a risk that "documented process" will be interpreted to mean "documented procedure", which is something that both Annex SL and DIS 9001 have tried to avoid referencing.		C

704	TC2 10	538 -551	3.17	This definition is not identical to ISO DIS 9000:201X	To fit the ISO9000:201X definition. See comment #5	TAP
705	ANS I	538 539	3.17	The word "documented" is missing. This deletion does not make any sense for defining audit. Audit should be documented to ensure evidence	Simply add "documented" to this definition 'audit'. Retain the exact definition of audit (3.17) with "documented"	TAP
706	SE	538	3.17	When you perform an audit you collect audit evidence. Objective evidence might be right but then we do not need audit evidence as an own term in 3.61.	Amend to audit evidence	TN
707	JP 195	538	3.17	Different from 3.10.1 of DIS 9000. The "and documented" is deleted and changed to "systematic, independent process."	The definition in ISO 9000 and 9001 should be identical.	TAP
708	CZ	542 -545	3.17	We recommend to specify „independence“, e.g. independence of auditors.	"In many cases, particularly in smaller <i>organizations</i> , independence of <u>auditors</u> can be demonstrated by the freedom from responsibility for the activity being audited."	TN
709	CH	543	3.17	... and may form the basis for an organization's declaration of conformity. Please check the correct use of "may" according to ISO/IEC Directives Part 2 Annex H. If the intention is to say that first party audits are permitted as a basis for declaration of conformity, the use of "may" appears to be correct. If it should indicate just an option, "can" is appropriate.	... and <u>can</u> form the basis ...	EAF
710	ANS I	544 - 545		Delete the sentence "In many cases, particularly in smaller organizations, independence can be demonstrated by the freedom from responsibility for the activity being audited." This is a description of how independence may be demonstrated. It should be replaced by a sentence describing a requirement or desired characteristic of internal audits.	Modify the sentence " In many cases, particularly in smaller organizations, Independence can be demonstrated by the freedom from responsibility for the activity being audited"	TAP
711	SE	544 & 545	3.17	The sentence "In many cases, particularly in smaller organizations, independence can be demonstrated by the freedom from responsibility for the activity being audited." is a description of how independence may be demonstrated. It should be replaced by a sentence describing a requirement or desired characteristic of internal audits or a mere reference to ISO 19011.	Add a reference to ISO 19011 for guidance as requirements are not possible to address in notes.	TN
712	GB	546	3.17	Note 3 to entry: External audits include	Note 3 to entry: External audits include	TAP

				those generally called second and third-party audits. <u>Second party</u> audits are conducted by parties having an interest in the <i>organization</i> (3.01), such as <i>customers</i> (3.26), or by other persons on their behalf. Third-party audits are conducted by external, independent auditing organizations such as those providing certification/registration of <i>conformity</i> (3.18) to <u>ISO 9001 or ISO 14001</u> . Ref to 9001 or 14001 is not necessary. Second party audit may be written as second-party audit to follow the convention used here.	those generally called second and third-party audits. Second-party audits are conducted by parties having an interest in the <i>organization</i> (3.01), such as <i>customers</i> (3.26), or by other persons on their behalf. Third-party audits are conducted by external, independent auditing organizations such as those providing certification/registration of <i>conformity</i> (3.18) to a management system.	
713	MA	548 - 549	3.17	The exclusive reference to ISO 9001/14001 may induce the reader astray even with the use of the phrase "such as"	The third-party audits ... such as granting the registration or certification of compliance with ISO 9001 or ISO 14001 management system standards (eg ISO 9001 ISO 14001)	TAP
714	ANS I	548	3.17	Third-party audits also include government/authority agents, such as FDA and FAA in the USA	Third-party audits are conducted by external, independent auditing organizations such as government agencies and those providing certification/registration of conformity(3.18) to ISO 9001 or ISO 14001.	TAP
715	AU	549	3.17	Not necessary to nominate particular Standards. Third party audit can apply to a wide variety of Standards, not just QMS and EMS.	Delete, 'to ISO 9001 or ISO 14001'.	TAP
716	ANS I	550 551	3.17	"modified—the definition has been modified and the original Note 1 to entry has been deleted " Deleting "documented" from this ISO DIS 9000:2014 (3.10.1) is not a good decision. Do not mess with this definition since this will assure evidence for auditing	Adapt audit (3.10.1) in ISO DIS 9000:2014 in totality. Do not modify it	TAP
717	ANS I	555	3.18	The Note gives different meanings for two different languages. This defies the ISO rule that standards be written in a method that allows them to be translated equally among all member nations, and the fact that the definition only addresses English and French thereby gives those language priority over others. This sets a bad precedent, opening the door to unlimited "notes" defining things differently in different languages.	Remove the note entirely.	TN
718	ANS I	555	3.18	"deprecated" not well understood	English "conformance" or French "compliance" are less acceptable synonyms for "conformity"	TN

719	PH/ BPS	557	3.18	Source of definition of conformity is incorrect	SOURCE: ISO DIS 9000:2014, 3.5.11	EAP
720	MX	557	3	incorrect reference to ISO 9000	Change 3.5.6 by 3.5.11	EAP
721	PT	557	3.18	ISO DIS 9000:2014, 3.5.6	ISO DIS 9000:2014, 3.5. 11	EAP
722	SE	557	3.18	[SOURCE: ISO DIS 9000:2014, 3.5.6]	[SOURCE: ISO DIS 9000:2014, 3.5.11]	EAP
723	JP 34	557	3.18	Cross-reference is incorrect.	3.5.6 should be 3.5.11.	EAP
724	BY	558	3.19-3.22	You can change the order of presentation of the definitions for a logical	We propose the following sequence of presentation of definitions: 3.19 nonconformity 3.20 correction 3.21 corrective action 3.22 continual improvement	TN
725	PH/ BPS	561	3.19	Source of definition of nonconformity is incorrect	SOURCE: ISO DIS 9000:2014, 3.5.9	EAP
726	MX	561	3	incorrect reference to ISO 9000	Change 3.5.5 by 3.5.9	EAP
727	PT	561	3.19	ISO DIS 9000:2014, 3.5.5	ISO DIS 9000:2014, 3.5. 9	EAP
728	SE	561	3.19	[SOURCE: ISO DIS 9000:2014, 3.5.5]	[SOURCE: ISO DIS 9000:2014, 3.5.9]	EAP
729	JP 35	561	3.19	Cross-reference is incorrect.	3.5.5 should be 3.5.9.	EAP
730	BY	562	3.20, 3.21	From the context of Note 2 to 3.20 and Note 1 to 3.21 is assumed that there definition of "preventive action"	Propose to introduce a definition of "preventive action"	TAF
731	DK	564	3.20	There can be more than one cause to a nonconformity.	Add "(s)" after "cause" in the definition. It will then read: corrective action action to eliminate the cause(s) of a nonconformity (3.19) and to prevent recurrence	TN
732	DK	565	3.20	In case "(s)" is added after "cause" to the definition of 3.20 this not can be deleted.	Delete note and add "(s)" after "cause" in the definition of nonconformity (3.20).	TN
733	CQI 18	566 - 567	3.20	With the removal of preventive action from the standard there is no reason to keep this distinction. Delete Note 2	Note 2 to entry: Corrective action is taken to prevent recurrence whereas preventive action is taken to prevent occurrence.	TN
734	CZ	566 -567	3.20	The term "preventive action" is no longer used in the body of the standard. One of the key purposes of a quality management system is to act as a preventive tool. Consequently, this International Standard does not have a separate clause or sub-clause titled 'Preventive action'.	We recommend to delete „whereas preventive action is taken to prevent occurrence" from the note text and replace it with "risk treatment to prevent occurrence".	TN

				The concept of preventive action is expressed through a risk-based approach to formulating quality management system requirements.		
735	BR	566	3.20	Preventive action is not present in the standard anymore. Note 2 makes no sense.	Delete Note 2	TN
736	ANS I	566	3.20	Recognizing that <i>preventive action</i> is actually part of risk management, Annex SL rightfully removed references to preventive action. Including it here only continues the opportunities to confuse <i>corrective</i> action with <i>preventive</i> action.	Remove Note 2.	TN
737	ANS I	566 567	3.20	This note 2 contains "preventive action" and has been deleted from section 10 line 1521, improvement.	Either delete the preventive action from this note or add preventive action under section 10.3 <u>DEFINITION IS STRAIGHT FROM 9000 – SC2/WG TO DISPOSITION AND SHARE WITH SC1</u>	TN
738	IQNet	566	3.20	The term of preventive action is not included in the standard. We recognized the concept is being abandoned as a clause in the but is still used in the explanation of explanation of preventive should be given	Make reference where to find the term of preventive action	TAF
739	CH	566	3.20	The term 'preventive action' is not defined, even though the concept is important, also in Annex A.4.	Add 1) Add a new term 'preventive action' to clause 3 and 2) after the words 'preventive action' on line 566, <u>add</u> the new term number in brackets.	TAP
740	TC2 10	566 , 575	3.20, 3.21	There is the term "preventive action" in these two definitions but there is no definition of "preventive action" in this DIS..	Add the definition of "preventive action" or remove these two occurrences.	TAP
420	PT	375 /376	3.21		Add: [SOURCE: ISO DIS 9000:2014, 3.3.2]	EAP
741	SE	569 -575	3.21	Reference to source is missing.	[SOURCE: ISO DIS 9000:2014, 3.3.2]	EAP
742	TR	569	3.21	It must be "improvement" not "continual improvement"	Erase "continual"	TN
743	GB	569	3.21	add reference.	3.21 (SOURCE: ISO DIS 9000:2014, 3.3.1.1)	EAP
744	IIOC	570	3.21	Term contains the word 'continual'	Remove 'continual' for consistency	TN
745	ANS I	571		The word "recurring activity" implies that the same activity is repeatedly taken.	"activities applied periodically to enhance performance"	TN
746	IT	572 -575	3.21	The process of establishing objectives and finding opportunities for improvement can be also carried	Modify note as follows:	TN

				out through Risk Management or, more precisely, risk assessment, typically followed by to risk treatment.	"[...] through the use of <i>audit findings</i> (3.62) and <i>audit conclusions</i> , analysis of data (3.49), <i>management</i> (3.29) <i>reviews</i> (3.68) or other means, <i>such as risk assessment</i> , and generally leads to <i>corrective action</i> (3.21) or <i>preventive action</i> or , in general terms, risk treatment. "	
747	CZ	572 -575	3.21	See comments to 3.20	We recommend to delete " or preventive action " from the note text.	TN
748	ANS I	573	3 Terms and Definitions	"analysis of data" – data is a subset of information per the definition in 350. 350 "information" is meaningful data. Meaningful data would seem more appropriate.	Replace "data (3.49)" with " data (3.49) information(3.50) ". Suggest macro replacing data with information everywhere as noted since it is used far less and seems to have less of a meaning	TN
749	PH/BPS	573	3.21	"Process" in italic font but not followed by its entry number	process (3.12)	EN
750	CQI 19	574 - 575	3.21	... leads to <i>corrective action</i> (3.21) or preventive action. With the removal of preventive action from the standard there is no reason to keep this.	... leads to <i>corrective action</i> (3.21) or preventive action .	TN
751	ANS I	574 575	3.21	Specification of "preventive action" in this note 1 as other means of continual improvement disconnects with section 10 lines 1515 and in specific lines 1554 through 1556.	Either delete the preventive action from this note or add preventive action under section 10.3 <u>SC2/WG TO DISPOSITION AND SHARE WITH SC1</u>	TN
752	PH/BPS	574	3.21	Incorrect entry number for "corrective action" is used	corrective action (3.20)	EAP
753	DK	574	3.21	Delete "preventive action" in the note.	Note 1 to entry: The process (3.12) of establishing objectives (3.08) and finding opportunities for improvement (3.28) is a continual process through the use of audit findings (3.62) and audit conclusions, analysis of data (3.49), management (3.29) reviews (3.68) or other means and generally leads to corrective action (3.21) or preventive action .	TN
754	IQN et	574	3.21	Wrong reference to corrective action	corrective action (3.20.)	EAP
755	HU	574	3.21	The clause number after 'corrective action' is not correct: (3.21)	Correctly: (3.20)	EAP
756	JP 36	574	3.21	Cross-reference is incorrect.	Change 3.21 to 3.20.	EAP
757	MX	575	3.21	Is missing	WRITE [SOURCE: ISO DIS 9000:2014, 3.3.2]	EAP
758	ANS	575	3.21	The reference to ISO 9000 is missing & replace	Add a line "[SOURCE: ISO DIS 9000:2014,	EAP

	I			"preventive action" with "action to prevent the occurrence of nonconformities"	3.3.2]". Also replace "preventive action" with "action to prevent the occurrence of nonconformities"	TN
					<u>SC2/WG TO DISPOSITION AND SHARE WITH SC1</u>	
759	ANS I	575	3.21	Recognizing that <i>preventive action</i> is actually part of risk management, Annex SL rightfully removed references to preventive action. Including it here only continues the opportunities to confuse <i>corrective</i> action with <i>preventive</i> action.	...generally leads to corrective action (3.21) –or preventive action.	TN
760	ANS I	575	3.21	At the heart of continual improvement are the many little changes that are made by workers and work teams every day. Continual Improvement is cultural, and it does the concept a dis-service not to include an employee involvement and employee motivation dimension in this definition.	At least add "employee suggestions" or "employee feedback" to the other examples under Note 1.	TN
761	IQN et	575	3.21	A.4. "The concept of preventive action is expressed through a risk-based approach to formulating quality management system requirements."	Make reference where to find the term of preventive action	EAP
762	GB	575	3.21	Add reference	Add: [SOURCE: ISO DIS 9000, 3.3.2]	EAP
763	JP 37	575	3.21	Source is missing. The term "continual improvement" is defined in DIS 9000.	Add a source.	EAP
764	AU	576	3.22	"Correction" is after "corrective action" (and CI) however "correction" is the first part of the process to address a nonconformity and so it would flow better if placed first.	Put "correction" before "corrective action".	TN
765	IIOC	578	3.22	The definition of correction is not always limited to elimination. Mitigation to prevent (further) negative impact can also be considered to be initial stage correction.	Consider amending to 'action to eliminate a detected nonconformity or to mitigate consequences to prevent further negative impact'.	TN
766	BR	579	3.22	There is an inconsistency between " corrective action" and the reference (3.21) which is actually 3.20.	Change for "Note 1 - A correction can be made in conjunction with a corrective action (3.21 3.20)."	EAP
767	ANS I	579	3		Correction is taken to address the effect of a nonconformity.	TN
768	PH/ BPS	579	3.22	Incorrect entry number for "corrective action" is used	corrective action (3.20)	EAP
769	5.	579	3.22	A Syntactical correction is required	Please replace: " ... with a corrective action (3.21) or preventive action.", with: " ... with a corrective action (3.20) or preventive action."	EAP

770	JP 38	579	3.22	The cross-reference is incorrect.	Change 3.21 to 3.20.	EAP
771	JP 39	582 -585	3.23	The term "involvement" is used in the requirements, but it is used with no more than dictionary meanings.	Delete the definition of the term "involvement."	TN
772	SE	585	3.23	[SOURCE: ISO 10018:2012, 3.5] Even if the source is correct the reference should be made to the corresponding ISO 9000 entry for consistency.	[SOURCE: ISO DIS 9000:2014, 3.1.2]	EAP
773	PL	586	3.24	Context of the organisation This term does not require definition because in the relevant clause of the standard it is really very clearly explained. On the other hand when you compare text of definition and text of the clause itself, you can easy see, that meaning of these two texts is the same. On the other hand – you can be confused, in one text it is used <u>factors</u> , in the text of the standard there is <u>issues</u> . Is this the same? Defintion: "combination of internal and external factors and conditions that can have an effect on an <i>organization's</i> (3.01) approach to its <i>products</i> (3.47), <i>services</i> (3.48) and investments and <i>interested parties</i> (3.02)" clause: <i>The organization shall determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system.</i> When you copare the above text you can see that "Intended results of the quality management system are products, services, investments and interested parties ?" Is it true? Defintion is ver confusing, does not clarify anything and we suggest to delete it from both	Delete this term and definiton also from ISO 9000	TN

				standards ISO 9001 and ISO 9000.		
774	GB	586	3.24	3.24 context of the organization business environment combination of internal and external factors and conditions that can have an effect on an <i>organization's</i> (3.01) approach to its <i>products</i> (3.47), <i>services</i> (3.48) <u>and investments and interested parties</u> (3.02) <i>'and investments and interested parties (3.02)' - two 'and' not appropriate. Better use one 'or' after investments. This will give more clarity to this definition.</i>	3.24 context of the organization business environment combination of internal and external factors and conditions that can have an effect on an <i>organization's</i> (3.01) approach to its <i>products</i> (3.47), <i>services</i> (3.48), and investments, and or <i>interested parties</i> (3.02)	EAP
775				Secretariat Note; comment no.775 was a repeat of comment no.774, so has been deleted		
776	ANS I	587	3.24	Context of the Organization sounds a lot like "Culture". How do these relate or differ?	Show a relationship or Note about how "Culture" maybe related to "Context of the Organization"	TN
777	PH/BPS	587	3.24	Source of definition of context of the organization is incorrect	SOURCE: ISO DIS 9000:2014, 3.2.4	EAP
778	CQI 20	588	3.24	business environment'. Not needed as covered in Note 2 (lines 594 to 595)	Delete line 588 business environment	TAF
779	DK	588	3.24		Make " business environment " in bold letters. Insert comma instead of "and" after "services (3,48)"	EN
780	QS	588	3.24	No link between the line 588 and 589. Are they different definition? To clarify	Delete Business Environment in Line 588 as it is already referred in Note 2	TAF
781	ZA	588	3.24	Use of the term "business environment" is out of place here. It is referenced in Note 2, line 594 correctly. The use here infers that this Standard is focused on businesses and runs the risk of alienating non-business environments such as government department, NGOs, charity organizations.	Remove "business environment" in ISO DIS 9001 and ask SC 1 to do the same in ISO DIS 9000.	TAF
782	SE	588	3.24	Other English phrases of the concept of context of the organization are mentioned in Note 2. The term "Business environment" is not used in this standard.	Delete line 588 business environment	TAF
783	ANS I	589	3.24	"effect" Impact fits better	Replace "effect" with "impact"	TN
784	ANS	590		See suggested rewording in "Proposed change"	Combination of internal and external factors and	TN

	I				conditions that can have an effect on an organization's (3.01) strategy towards its products (3.47), services (3.48), allocation of resources and relationships with interested parties (3.02)	
785	CA-28	590	3.24	Modify the current wording (copied below) to the wording shown in the column on the right. <i>organization's</i> (3.01) approach to its <i>products</i> (3.47), <i>services</i> (3.48) and investments and <i>interested parties</i> (3.02)	<i>organization's</i> (3.01) approach to its <i>products</i> (3.47), <i>services</i> (3.48), investments and <i>interested parties</i> (3.02)	EAP
786	SE	590	3.24	See suggested rewording in "Proposed change"	combination of internal and external factors and conditions that can have an effect on an organization's (3.01) strategy towards its products (3.47), services (3.48), allocation of resources and relationships with interested parties (3.02)	TN
787	JP 188	590	3.24	Different from 3.2.4 of DIS 9000. The "and" is added as below. Combination of internal and external factors and conditions that can have an effect on an organization's approach to its products (3.7.6), services (3.7.7) and investments and interested parties (3.2.5).	The definition in ISO 9000 and 9001 should be identical.	TAP
788	ANS I	591	3.24	Add the following to context of the organization: governance, compliance, social, environmental		TN
789	MX	596	3	incorrect reference to ISO 9000	Change 3.2.3 by 3.2.4	EAP
790	DK	596	3.23	Change source track	[SOURCE: ISO 10018:2012, 3.5 9000.3.1.2]	EAP
791	PT	596	3.24	ISO DIS 9000:2014, 3.2.3	ISO DIS 9000:2014, 3.2.4	EAP
792	ZA	596	3.24	Line 596 gives an incorrect reference	Change to 3.2.4	EAP
793	SE	596	3.24	[SOURCE: ISO DIS 9000:2014, 3.2.3]	[SOURCE: ISO DIS 9000:2014, 3.2.4]	EAP
794	JP 40	596	3.24	Cross-reference is incorrect.	3.2.3 should be 3.2.4.	EAP
795	CZ	597-599	3.25	We recommend to add the term "role"; the term 3.25 function has another meaning.	"role - a function or its part performed especially in a particular activity, operation or process" (Source: Merriam-Webster Vocabulary (modified))	TN
796	IQN ET	597	Section 3.	Definition of function is too narrow for what function means and is used. The definition relates to organizational function	Change term defined to organizational function and revise standard to explicit organizational function (6.2.2. objectives?) , if considered needed to define.	TN
797	BR	598	3/3.25	The definition of function should be consistent with de definition of organization (3.01)	Change de definition of function role to be carried out by a designated unit or person of the organization (3.01)	EAP

798	ANS I	599	3.25	The definition focuses too narrowly on a human organization. Other things also perform functions. Other definitions are useful and common, depending on the type of organization.	Add this as a second definition: defined objective or characteristic action of a system or component (ISO/IEC/IEEE 24765:2010 Systems and software engineering--Vocabulary)	TN
799	ANS I	599	3.25	This definition of function "role to be carried out" can be outsourced as per definition of outsource. This means external parties can provide services of role carrying.	Redefine based on usage of outsource	C
800	PH/ BPS	600	3.25	Source of definition of function is incorrect	SOURCE: ISO DIS 9000:2014, 3.2.6	EAP
801	MX	600	3	incorrect reference to ISO 9000	Change 3.2.5 by 3.2.6	EAP
802	PT	600	3.25	ISO DIS 9000:2014, 3.2.5	ISO DIS 9000:2014, 3.2.6	EAP
803	SE	600	3.26	[SOURCE: ISO DIS 9000:2014, 3.2.5]	[SOURCE: ISO DIS 9000:2014, 3.2.6]	EAP
804	JP 41	600	3.25	Cross-reference is incorrect.	3.2.5 should be 3.2.6.	EAP
805	ANS I	601 - 604		The definition does not match the definition contained within the ISO 9000:2015 DIS which states: "person or organization that could or does <u>not</u> receive a product (3.7.6) or a service (3.7.7) that is intended for or required by this person or organization."	Match the text within the ISO 9000:2015 DIS , which states: "person or organization that could or does receive a product (3.7.6) or a service (3.7.7) that is intended for or required by this person or organization."	EAP
806	BW	601 - 604	3	Re-look at the definition of "customer"	Person or organization (3.01) that directly or indirectly receives a product (3.47) or service (3.48)	EN
807	BR	601	customer	Definition has been wrongly copied from ISO/DIS 9000.	Do not include terms and definitions in Clause 3 but make a reference to ISO 9000.	TN
808	PE	601	3.26	It says " ... that could or does not receive ..." Whereas in DIS ISO 9000 says "...that could or does receive"	Eliminate the word not : <i>person or organization (3.01) that could receive a product (3.47) or a service (3.48) that is intended for or required by this person or organization</i>	TN
809	IQN ET	601	Section 3.	We do not understand the meaning of the sentence. Nevertheless we do not consider necessary to define customer	Revise or preferably delete	TN
810	PL	601	3.26	This definition of " customer" is not understood , not clear– it must be reworded. person or organization (3.01) that could or does not receive a product (3.47) or a service (3.48) is intended for or required by this person or organization ?????	Has to be developed in other way	C

811	AU	601	3.26	customer person or <i>organization</i> (3.01) that could or does not receive a <i>product</i> (3.47) or a <i>service</i> (3.48) is intended for or required by this person or <i>organization</i> Grammar? Perhaps missing word ...(3.48) that is intended... However the definition lacks clarity	Not sure.	C
812	ZA	601	customer	Definition has been incorrectly copied from ISO/DIS 9000.	Rather refer to the definition in ISO 9000.	EAP
813	ZA	601	customer	Definition has been wrongly copied from ISO/DIS 9000.	Rather refer to the definition in ISO 9000.	EAP
814	LC	601	3.26	In definition of 'customer' there is too much ambiguity which makes the definition unclear	Redefine 'customer'	TN
815	GB	601	3.26	wording of clause 3.26 appears clumsy. Surely the word 'not' should be deleted, and the word 'is' should perhaps be rendered as 'as'?	Review and re-do the clause totally. Perhaps as "Customer: A person or organisation that may receive a product or service as provided by the operations of this company."	TN
816	FR	601	3.26	"Customer person or organization (3.01) that could or does not receive a product (3.47) or a service (3.48) is intended for or required by this person or organization" ...or does not receive??? NOT should be deleted???	person or organization (3.01) that could or does receive a product (3.47) or a service (3.48) is intended for or required by this person or organization	TN
817	AU	602 /603	3.26	Defining statement for "customer" makes no sense and accordingly the words "not" and "is" should be deleted.	Delete words "not" and "is" for the paragraph to read "customer person or organization that could or does receive a product or a service intended for or required by this person or organization".	EAP
818	ANS I	603 -604	3.26	This is a very sloppy definition.	Change to "person or organization that receives or is intended to receive a product or service	TN
819	SE	603 -604	3.26	"person or <i>organization</i> (3.01) that could or does not receive a <i>product</i> (3.47) or a <i>service</i> (3.48) is intended for or required by this person or organization" This is not exactly the ISO 9000 wording.	ISO 9000 states: "person or organization that could or does receive a product (3.7.6) or a service (3.7.7) that is intended for or required by this person or organization"	EAP
820	CQI	603	3.26	person or organization (3.01) that could or does	person or organization (3.01) that could or does	EAP

	21			<u>not</u> receive a product - this is obviously a typographic error	not receive a product	
821	BR	603	3.26	The note is confusing. Customer who does not receive a product or service is not as customer. Change text for clarity.	Change text to: "person or organization (3.01) that could or does not receive a product (3.47) or a service (3.48) is intended for, or required by this person or organization."	EAP
822	ANS I	603	3.26	Organization (3.01) by definition already includes person. "person or organization" is redundant.	Change "person or organization" to "organization" only.	TN
823	AT	603	3.26	Very amusing! Delete "not"	Change "person or organization (3.01) that could or does not receive a product (3.47)..."	EAP
824	IN	603		... that could or does not receive ... Definition should be the same as given in ISO DIS 9001:2014	... that could or does receive	EAP
825	PH/BPS	603	3.26	The clause "that could or does not" is confusing	Suggest a change to "that receives or supposed to receive"...	EAP
826	6.	603	3.26	A Syntactical correction is required	Please replace: " ... or a service (3.48) is intended for or ...", with: " ... or a service (3.48) but is intended for or ..."	EAP
827	7.	603	3.26	A Syntactical correction is required	Please replace: " ... or information (350).", with: " ... or information (3.50)."	C
828	DK	603	3.26		Delete "is" so the definition reads: "person or organization (3.01) that could or does not receive a product (3.47) or a service (3.48) is intended for or required by this person or organization"	EAP
829	PT	603	3.26	... or a service (3.48) is ...	Not fully aligned with DIS 9000:2015, word "that" is missing to read ... or a service (3.48) that is intended ...	EAP
830	AU	603	3.26	States that "...could or does not receive..". Looks like "not" should not be in the sentence. Sentence is also lengthy and may read better if split.	Split sentence and remove "not".	EAP
831	CH	603	3.26	Person or organization (3.01) that could or does not receive a product (3.47) or a service (3.48) is intended for or required by this person or organization. This definition looks weird! Check against ISO/DIS 9000!	Person or organization (3.01) that could or does not receive a product (3.47) or a service (3.48) <i>that</i> is intended for or required by this person or organization.	EAP
832	IT	603	3.26	Editorial mistake.	Delete "not".	EAP

833	CZ	603	3.26	"person or organization (3.01) that <u>could or does not receive</u> a product (3.47) or a service (3.48) is intended for or required by this person or organization" The underlined text seems not to be correct and is not understandable especially for not English-speaking countries	To be corrected. See ISO 9000:2014, 3.2.8.	EAP
834	JP 42	603	3.26	The definition of DIS 9000 is wrongly modified.	Change to: Person or organization that could or <u>does receive</u> a product or a service <u>that</u> is intended for or required by this person or organization.	EAP
835	QS	603 and 604	3.36	Definition of customer is complicated and not clear as it includes, "does not receive a product".	Give general clear definition for customer and include in note about different types of customers.	EAP
836	PH/BPS	604	3.26	"Organization" in italic font but not followed by its entry number	organization (3.01)	EAP
837	SE	605	3.26	"...input to internal process (3.12)..." It seems somewhat unusual to designate "input" as a customer – and why only to an internal process?	"...the receiver in a process..."	EAP
838	CZ	606	3.26	Note to entry: Even one note is referred to as Note 1 to entry.	To be corrected.	EAP
839	GB	606	3.26	On line 401 it states: <For the purposes of this document, the following terms and definitions apply>: This implies that the term customer in every clause e.g. clause 5.1.2 <Customer focus> could be an <internal customer> but the term customer in ISO9001 is only used in the sense of a customer outside of the organization. Those who receive from a process within the organization are simply receivers. There is no need to ascribe special labels to them as it adds confusion.	Redraft to clarify or delete	TAP
840	ANS I	607	3.26	The statements, "The output (3.46) of each internal process (3.12) is the input of the next process" and "The next process is the internal customer of the preceding process" is not always true. For instance, the last process in a chain will not provide input for any other.	"When the output (3.46) of an internal process (3.12) is provides the input of the next process, this next process is the internal customer of the preceding process."	TAP
841	PH/BPS	607	3.26	"Organization" in italic font but not followed by its entry number	organization (3.01)	EAP

842	GB	607	3.26	That the output of each internal process is the input of the next process is not always true because: a) Processes may be linked in series and in parallel and they may have a number of inputs and outputs b) Outputs of external processes maybe inputs into internal processes. The statement is therefore not adding value in the context of the definition of customer.	Delete or Move to 3.12 on process	TAP
843	ANS I	608	3.26	If a process is the customer, would that process be a "person or organization" per 603-604?	Clarify the definition to include "organization or process" instead of "person or organization" in 603-604.	TN
844	PH/BPS	608	3.26	"Process" in italic font but not followed by its entry number	process (3.12)	EAP
845	GB	608	3.26	The customer is defined in 3.26 as person or organization and not a process so the statement that the next process is the internal customer of the preceding process is illogical.	Delete	TAP
846	SE	608	3.26	"The next process is the internal customer of the preceding process." It is not obvious what a customer of a process is. Instead, someone could be customer of the output of a process.	"The receiver is the customer of the output of the preceding process." Alternatively, delete the two last sentences in Note 1.	TN
847	PH/BPS	609	3.26	Source of definition of customer is incorrect	SOURCE: ISO DIS 9000:2014, 3.2.8	EAP
848	MX	609	3	incorrect reference to ISO 9000	Change 3.2.6 by 3.2.8	EAP
849	PT	609	3.26	ISO DIS 9000:2014, 3.2.6	ISO DIS 9000:2014, 3.2.8	EAP
850	SE	609	3.26	[SOURCE: ISO DIS 9000:2014, 3.2.6]	[SOURCE: ISO DIS 9000:2014, 3.2.8]	EAP
851	JP 43	609	3.26	Cross-reference is incorrect.	3.2.6 should be 3.2.8.	EAP
852	SE	610 -617	3.27	" supplier provider... " See comment to lines 400-929.	No specific meaning. Delete.	TAP
853	CZ	610 -612	3.27	It should be considered to amend the term and use only "external provider" as used for example in 8.4.1, 8.4.3 etc. The term "supplier" is mostly used in clause 3.	3.27 external provider – person or <i>organization</i> (3.01) that provides externally a <i>product</i> (3.47) or a <i>service</i> (3.48)	TAP

854	PL	610	3.27	Supplier/ provider We suggest to choose only one term. We prefer "supplier". For many years this term was used and this term is sufficiently broad to cover all situation. Text in Notes should be then adjusted and provider exchanged for supplier.	supplier	TN
855	GB	610	3.27	'information' may be added, as mentioned in the note and at other definitions. and 'or' to be shifted before information. Correct reference to 3.50	3.27 supplier provider person or <i>organization</i> (3.01) that provides a <i>product</i> (3.47), <i>service</i> (3.48), or information (3.50)	TN
856	CH	611 -613	3.27	There are 2 words in bold type. Only one term should be defined. The second word (provider) should be part of the definition.	<u>Change</u> to read: (bold type) "supplier" (Definition, not bold type) " <u>provider</u> , person or organization ..."	EAP
857	CQI 22	611 - 612	3.27	'Supplier Provider' . It is not clear if these two terms are synonymous. Supplier is no longer used in the standard. The first proposal is to delete Supplier. The second proposal is to put Provide first and Supplier should be second and indicate that Provider is the preferred term. In addition Note 2 needs to be changed.	Supplier Provider OR Provider (preferred term) Supplier (admitted term) AND Note 2 to entry: In a contractual situation, an external provider supplier is sometimes called a "contractor".	EAP
858	PH/ BPS	611 -612	3.27	Putting provider under supplier is confusing. Only 3.27 has this arrangement.	Suggest "supplier or provider". Or put a note saying "supplier may also be called provider"	TAP
859	IT	611 -612	3.27	ISO/DIS 9001 makes use of term "provider" rather than "supplier", specifically when "externally provided products and services" (8.4) are concerned.	Adopt "provider" as preferred term and "supplier" as admitted term (no labels required though).	TAP
860	AU	611	3.27	As "Supplier" (refer to line number 1582 Table B.1) has changed to "External provider" 3.27 should be amended accordingly.	Replace "Supplier" with "External (Supplier)".	TN
861	ANS I	611 , 612	3.27	Provider and supplier	Explain the relationship between the two. Are they synonymous?	C
862	ANS	612	3.27	The terminology used in Annex A, Line 1582,	Add "external provider" as a term in the definitions	TAP

	I			Table B.1, for supplier is “external provider.” The requirements in this document call out “external provider.” Just using a note in line 615 seems insufficient to highlight this major change in terminology as used in this particular standard.	section, either here or in another line entry that references back to this generic line.	
863	ANS I	612	3.27 Supplier	This line adds no additional value in defining a supplier.	Delete this line.	TN
864	QS	612 and 613	3.27	No link between 612 and 613	Link line 612 and 613 as below Person or <i>organization</i> (3.01) that provides a <i>product</i> (3.47) or a <i>service</i> (3.48). Also called Provider.	TAP
865	ANS I	613	3.27	Organization (3.01) by definition already includes person. “person or organization” is redundant.	Change “person or organization” to “organization” only.	TAP
866	PH/BPS	614	3.27	Incorrect entry number for “information” is used	information (3.50)	EAP
867	IT	614	3.27	Editorial suggestion (there is more than one example).	Write “EXAMPLES” instead of “EXAMPLE”.	EN
868	IT	614	3.27	Editorial mistake (dot missing).	Modify sentence as follows <i>EXAMPLE Producer, distributor, retailer or vendor of a product (3.47) or a service (3.48) or information (3.50).</i>	EAP
869	CZ	614	3.27	EXAMPLE Producer ... or <i>information (350)</i> .	To be corrected – (3.50).	EAP
870	SE	614	3.27	“...a <i>product</i> (3.47) or a <i>service</i> (3.48) or <i>information (350)</i> ” “information” can be regarded as the output of an information process, therefore a kind of immaterial product, i.e. covered by “product”.	If retained amend to “...a <i>product</i> (3.47) or a <i>service</i> (3.48). .”	EAP
871	JP 44	614	3.27	Cross-reference is incorrect.	“information (350)” should be “information (3.50).”	EAP
872	JP 45	615	3.27	The definition should be identical with the definition in DIS 9000.	Change “provider” to “supplier.”	TN
873	JP 189	615	3.27	Different from 3.2.9 of DIS 9000. The “supplier” is changed to “provider.”	The definition in ISO 9000 and 9001 should be identical.	EAP
874	ANS I	616	3.27	Contractor is mentioned but subcontractor is not.	Suggest adding “subcontractor” to this note as well.	TN
875	ANS I	616	3.27 Supplier	This line adds no additional value in defining a supplier.	Delete this line.	TN

876	ANS I	616	3.27	"Consultant" should also be considered and recognized. This a regulatory requirement in the "medical device industry"	After "Contractor" add "or "consutant""	TN
877	PH/ BPS	617	3.27	Source of definition of supplier is incorrect	SOURCE: ISO DIS 9000:2014, 3.2.9	EAP
878	MX	617	3	incorrect reference to ISO 9000	Change 3.2.5 by 3.2.6	EAP
879	PT	617	3.27	ISO DIS 9000:2014, 3.2.7	ISO DIS 9000:2014, 3.2.9	EAP
880	SE	617	3.27	[SOURCE: ISO DIS 9000:2014, 3.2.7]	If retained: [SOURCE: ISO DIS 9000:2014, 3.2.9]	EAP
881	JP 46	617	3.27	The Note 1 is slightly different from DIS 9000.	Clarify that Note 1 has been modified.	EAP
882	JP 47	617	3.27	Cross-reference is incorrect.	3.2.7 should be 3.2.9.	EAP
883	SE	618 -622	3.28	" improvement... "	No specific meaning. Delete.	TN
884	GB	618	3.28	3.28 Improvement should precede 3.21 Continual improvement	3.28 Improvement to be moved so it precedes 3.21 Continual improvement.	EAP
885	ANS I	621	3.28	Grammatically awkward	Change "singular" to "one-time" or rewrite sentence to read, "...achieved by multiple activities or a single activity."	EAP
886	PH/ BPS	627	3.29	"Objectives" in italic font but not followed by its entry number	objectives (3.08)	EN
887	PH/ BPS	634	3.29	Source of definition of management is incorrect	SOURCE: ISO DIS 9000:2014, 3.3.3	EAP
888	MX	634	3	incorrect reference to ISO 9000	Change 3.3.2 by 3.3.3	EAP
889	PT	634	3.29	ISO DIS 9000:2014, 3.3.2	ISO DIS 9000:2014, 3.3.3	EAP
890	SE	634	3.29	[SOURCE: ISO DIS 9000:2014, 3.3.2]	[SOURCE: ISO DIS 9000:2014, 3.3.3]	EAP
891	JP 48	634	3.29	Cross-reference is incorrect.	3.3.2 should be 3.3.3.	EAP
892	FR	635	3.30	Remove the term « generally » from the note	Remove the term « generally » from the note	EAP
893	ANS I	637	3.30	I have always felt QM should be applied to all processes that impact meeting customer requirements and the organizations requirements. I would add the text in the next column	<i>management</i> (3.29) of all processes with regard to <i>quality</i> (3.37)	TAP
894	QS	638	3.30	Remove "and" between quality policy and quality objectives	Replace "and" with ", (comma)"	EAP
895	PH/ BPS	640	3.30	Source of definition of quality management is incorrect	SOURCE: ISO DIS 9000:2014, 3.3.4	EAP

896	MX	640	3	incorrect reference to ISO 9000	Change 3.3.2.1. by 3.3.4	EAP
897	PT	640	3.30	ISO DIS 9000:2014, 3.3.2.1	ISO DIS 9000:2014, 3.3.4	EAP
898	QS	640	3.30	Reference to ISO DIS 9000: 2014 standard is wrong.	Replace SOURCE: ISO DIS 9000:2014, 3.3.2.1 — 3.3.4	EAP
899	SE	640	3.30	[SOURCE: ISO DIS 9000:2014, 3.3.2.1]	[SOURCE: ISO DIS 9000:2014, 3.3.4]	EAP
900	JP 49	640	3.30	Cross-reference is incorrect.	3.3.2.1 should be 3.3.4.	EAP
901	GB	641	3.31	The term system as used in ISO 9000 family relates to an organization as a dynamic entity and not a static system therefore there has to be interaction amongst the elements for it to function. The inclusion of the option (or) in this definition implies a management system can be simply a set of interrelated documents.	Change to: set of interrelated and interacting elements	TN
902	CQI 23	643	3.31	Description of a system as a set of interrelated or interacting elements; this is very vague and inherently weak as a description. There should be some expansion of what an element is.	EXAMPLE a process, function, organisational unit, outsourcing arrangement; otherwise people will always struggle with the reality of an 'element'.	TN
903	ANS I	643	3.31	I have always understood a system to be a relationship of processes, not elements.	"set of interrelated or interacting processes"	TN
904	IT	643	3.31	"Interrelated" and "interacting" are not necessarily alternative one each other.	Change "or" to "and/or".	TN
905	SE	645 -648	3.32	Reference to source is missing.	[SOURCE: ISO DIS 9000:2014, 3.4.2]	EAP
906	PL	645	3.32	Term "infrastructure " is really needed? This is common term and well understood , it is redundant term In the Note to 7.1.3 this term was really sufficiently explained. We do not need special definition of "infrastructure".	Delete this term from ISO 9001 and ISO 9000	TN
907	GB	645	3.32	Add reference.	3.32 (SOURCE: ISO DIS 9000:2014, 3.4.1.1)	EAP
908	FR	645	3.32	Add a note to precise that the information system is par of the infrastructure	Add a note to precise that the information system is par of the infrastructure	TN
909	JP 50	648	3.32	Source is missing. The term "infrastructure" is defined in IS 9000.	Add a source.	EAP
910	CA- 29	649 653 733	3.33 3.34 3.46	There is no value added by simply adding "quality" in front of terms like "objective" or	Remove them or expand them with their linked definition. Relative references are not helpful.	TN

				"policy" – and send the reader to look to other definitions. It is not helpful and borderline insulting to the reader to suggest that a "quality policy" is a "policy related to quality".	Perhaps look at the DIS 14001 definitions, as an example – they are more helpful, e.g' "environmental policy: intentions and direction of an <i>organization</i> as formally expressed by its <i>top management</i> related to <i>environmental performance</i> "	
911	PH/BPS	651	3.33	Incorrect entry number for "quality" is used	quality (3.37)	EAP
912	B.	651	3.33	A Syntactical correction is required	Please replace: " ... to quality (3.5.2).", with: " ... to quality (3.37)."	EAP
913	IQNet	651	3.33	wrong reference	with regard to quality (3.37)	EAP
914	HU	651	3.33	The clause number after 'quality' is not correct: (3.5.2)	Correctly: (3.37)	EAP
915	QS	651	3.33	Reference to quality definition is given as 3.5.2 instead of 3.37	Replace 3.5.2 with 3.37	EAP
916	SE	651	3.33	Incorrect reference.	Amend 3.5.2 to 3.37.	EAP
917	JP 51	651	3.33	Cross-reference is incorrect.	"quality (3.5.2)" should be "quality (3.37)."	EAP
918	PH/BPS	652	3.33	Source of definition of quality management system is incorrect	SOURCE: ISO DIS 9000:2014, 3.4.4	EAP
919	MX	652	3	incorrect reference to ISO 9000	Change 3.4.1.2.1 by 3.4.4	EAP
920	PT	652	3.33	ISO DIS 9000:2014, 3.4.1.2.1	ISO DIS 9000:2014, 3.4.4	EAP
921	QS	652	3.33	Reference to ISO DIS 9000: 2014 standard is wrong.	Replace SOURCE: ISO DIS 9000:2014, 3.4.1.2.1-3.4.4	EAP
922	SE	652	3.33	[SOURCE: ISO DIS 9000:2014, 3.4.1.2.1]	[SOURCE: ISO DIS 9000:2014, 3.4.4]	EAP
923	JP 52	652	3.33	Cross-reference is incorrect.	3.4.1.2.1 should be 3.4.4.	EAP
924	GB	653	3.3.4	While the definition of Quality Policy indicates it can be based on the quality management principles (in Note 2), nowhere does it make reference to the "context of the organization". ISO/TC 176/SC1 should be encouraged to amend the Notes to this definition to include such a reference	Add new Note 2 to entry: The context of the organization can influence the quality policy of the organization.	TN
925	FR	653	3.34	Remove the term « generally » from the note	Remove the term « generally » from the note	TN
926	IAQG	656 664	3.35	Strategy is defined in 3.35, but not used anywhere else in the standard.	Revise definition - improve Proposal: Change "strategy" definition to "strategic" to align with the use in the standard.	TN

927	SE	656	3.34	A company may have more than one policy or a collection of policies governing its operations.	Note 1 to entry: "Generally the quality policy is consistent with the overall policy or policies (3.07) of the organization (3.01)"	TN
928	ANS I	657	3.34	It says Quality Policy "can" be aligned with the organization's vision and mission, etc. The spirit of ISO 9001 is that the QP "IS" aligned with vision and mission.	"consistent with the overall policy (3.07) of the organization (3.01), is aligned with the organization's vision and mission....."	TN
929	AT	657	3.34	To avoid proliferation of new terms without any added value change as follows:	"can be aligned with the organization's vision and mission purpose and strategy and provides ..."	TAP
930	PH/ BPS	657	3.34	"Organization" in italic font but not followed by its entry number	organization (3.01)	EN
931	PT	659	3.34	... in this International Standard can form a ...	Insert a cross reference ... in this International Standard (see Annex B) can form a ...	TN
932	CZ	660	3.34	A full stop is missing at the end of the sentence.	To be added.	EAP
933	SE	660	3.34	"... <i>quality policy</i> (3.34)" Do not make a formal circular reference.	"...quality policy."	EAP
934	PH/ BPS	661	3.34	Source of definition of quality policy is incorrect	SOURCE: ISO DIS 9000:2014, 3.4.9	EAP
935	MX	661	3	incorrect reference to ISO 9000	Change 3.4.5.1 by 3.4.9	EAP
936	PT	661	3.34	ISO DIS 9000:2014, 3.4.5.1	ISO DIS 9000:2014, 3.4.9	EAP
937	QS	661	3.34	Reference to ISO DIS 9000: 2014 standard is wrong.	Replace SOURCE: ISO DIS 9000:2014, 3.4.5.1 –3.4.9	EAP
938	SE	661	3.34	[SOURCE: ISO DIS 9000:2014, 3.4.5.1]	[SOURCE: ISO DIS 9000:2014, 3.4.9]	EAP
939	JP 53	661	3.34	Cross-reference is incorrect.	3.4.5.1 should be 3.4.9.	EAP
940	TC4 6/SC 11 Liaison (AU)	662 -665	3.35	The term 'strategy' has not been used in this standard	Remove the entry for 'strategy'	TN
941	JP 54	662 -665	3.35	The term "strategy" is not used in DIS 9001.	Delete the definition of "strategy."	TN
942	SE	662 -664	3.35	" strategy planned activities to achieve an <i>objective</i> " The definition can apply to tactics and plans as well.	As worded there is no specific meaning. Delete. If retained, possibly: " strategy summarized description of planned high-level	TN

					activities to achieve an <i>objective</i> "	
943	IQNET	662	Section 3.	The definition is misleading as people could think that when they are planning in section 6 they are defining strategy, what can create a lot of confusion. Definition is not consistent with business use of the word strategy, nor with dictionary meaning. ISO 9001 does not require strategy, only alignment with strategic intent, so definition of strategy is not even needed.	Delete. Consider to define strategic intent	TN
944	FR	662	3.35	Wrong reference	The correct reference is : [SOURCE : ISO DIS 9000:2014, 3.4.12]	EAP
945	DK	664	3.35	The definition of "strategy" is: "planned activities to achieve an objective". This seems more to be definition of "planning" or a part of "quality planning" as defined in 3.3.6.	A new definitions could be established from the outset of this proposal: "organization's overall plan of development, describing the effective use of resources in support of the organization in its future activities". Or it shall be aligned with the "strategy" thinking in ISO 9004.	TN
946	CZ	664	3.35	A full stop at the end of the definition is not correct.	To be deleted.	EAP
947	PH/BPS	665	3.35	Source of definition of strategy is incorrect	SOURCE: ISO DIS 9000:2014,3.4.12	EAP
948	MX	665	3	incorrect reference to ISO 9000	Change 3.4.9 by 3.4.1	EAP
949	PT	665	3.35	ISO DIS 665 9000:2014, 3.4.8	ISO DIS 665 9000:2014, 3.4.12	EAP
950	QS	665	3.35	Reference to ISO DIS 9000: 2014 standard is wrong.	Replace SOURCE: ISO DIS 9000:2014, 3.4.8 3.4.12	EAP
951	SE	665	3.35	[SOURCE: ISO DIS 9000:2014, 3.4.8]	[SOURCE: ISO DIS 9000:2014, 3.4.12]	EAP
952	JP 55	665	3.35	Cross-reference is incorrect.	3.4.8 should be 3.4.12.	EAP
953	HU	666-675	3.36	Sometimes the use of this term could be acceptable (e. g. for buildings), but generally it is not a user friendly expression, it is confusing. The "entity" word generally is not used (in Hungarian), only in very special disciplines (e. g. in philosophy). Some examples listed in the Note seem to be unnatural (e. g. sheet of paper, conversion ratio, project plan, unicorn)	We suggest deleting this term. Instead of this word the use of proper part(s) of examples are suggested in relevant part of the standard.	TN
954	FR	666	3.36	Rework definition	Object : Anything concrete, perceivable by visual means or by touch	TN

					Objet : toute chose concrète, perceptible par la vue, le toucher	
955	FR	666	3.36	Remove « person » from the examples	Remove « person » from the examples	TN
956	ANS I	667 - 669		The definition of object is very unclear: object 668 entity 669 change "anything perceivable or conceivable" to "any perceived or conceived entity"	668, 669 change "entity" and "anything perceivable or conceivable" to "any perceived or conceived entity"	EN
957	CH	667 -669	3.36	On lines 667 and 668, there are 2 words ahead of the definition on line 669. Only one term should be defined. The second word (entity) should be part of the definition.	<u>Change</u> to read: (bold type) "object" (Definition, not bold type) "entity, anything perceivable or ..."	TN
958	IT	667 -669	3.36	The term "object" is confusing and misleading "entity" has a broader meaning. [CRITICAL COMMENT]	Modify as follows: 3.36 Entity (preferred term) Object (admitted term) Any concrete or abstract thing of interest, individually perceivable or conceivable. Add at the end of example(s): " ...resource, or a combination thereof " Replace "Objects" with "Entities" in Note 1 and in whole standard.	TN
959	ANS I	667	3.36	Comment: Application of the word "object" seems to contradict the word "objective" which is used extensively through- out the standard. The word "object" can also imply a negative impression, such as to reject something tangible or intangible. It somehow does not flow right with the standard, in my opinion.	Proposed change: Suggestion to eliminate this definition to reduce confusion. Or, elaborate the definition to include "item" as part of the definition; or the inclusion of "tangible" or "intangible" to the word "object" when used in the standard.	EAP
960	ANS I	668	3.36	Is entity part of the definition or is it synonymous with object?	Recommend clarifying the difference between object and entity.	TN
961	ANS I	669	3.36	"anything perceivable or conceivable" is too broad of a definition. http://dictionary.reference.com/browse/object defines object primarily as: "anything that is visible or tangible and is relatively stable in form" and lastly as "anything that may be apprehended intellectually: objects of thought."	Recommend a more finite and clearer definition such as; "something that is tangible or that may be conceived intellectually".	TN
962	ANS I	669	3.36	This definition is not needed; it does not add value	Delete definition 3.36	TN

963	AU	673	3.36	Objects may be material (e.g. an engine, a sheet of paper, a diamond), immaterial (e.g. conversion ratio, a project plan) or imagined (e.g. a unicorn). A service example would add value.	Add service example.	TN
964	AU	673	3.36	Not necessary and insulting to the intelligence of the reader (imagining unicorns....)	Delete note	EAP
965	CH	673	3.36	Objects may be material ... According to ISO/IEC Directives Part 2 Annex H, "may" means "is permitted", "is allowed", "is permissible". The use of "may" in this context is not appropriate therefore. Use "can" instead	Objects <i>can</i> be material ...	EAP
966	ANS I	674		The example given for "imagined" is somewhat childish and may be culturally limited	"or imagined (e.g., a concept or idea.)"	TAP
967	ANS I	674	3.36	Levity is appreciated, but should also have a meaningful example for imagined objects in phrase "Objects may be material (e.g. an engine, a sheet of paper, a diamond), immaterial (e.g. conversion ratio, a project plan) or imagined (e.g. a unicorn)." The inclusion of imagined object is unnecessary as falls within "immaterial" or intangible. Also, the term "immaterial" can mean "unimportant" or "insignificant".	Objects may be tangible (e.g. an engine, a sheet of paper, a diamond), intangible (e.g. conversion ratio, a project plan).	TAP
968	ZA	674	3.36	Use of the example "unicorn" is very euro-centric and may be difficult to translate	Delete example of unicorn	TAF
969	ANS I	677		Quality – "Degree to which a set of inherent characteristics of an object fulfils requirements" pl consider revising the def.	Quality is either zero or 100% - it is like jumping over a wall. This def. Dilutes the seriousness or importance – it may be O.K for CUSTOMER SATISFACTION Note – 1 may be deleted as it is highly subjective	TN
970	ANS I	678	3.3.7	<i>"degree to which a set of inherent characteristics (3.65) of an object (3.36) fulfils requirements (3.03)"</i> Comment: As commented for line item 666 above, the use of the word "object" in the definition for quality does not seem correct. It could be that I am not used to it – and I interpret object as a service, product, tangible or intangible.	Proposed change: Quality definition could be as follows: <i>"degree to which a set of inherent characteristics of an object, tangible or intangible fulfils requirements)"</i> Or - remove the word " object" to read: <i>"degree to which a set of inherent characteristics fulfils requirements"</i>	TN
971	SE	679	3.37	The statement that various adjectives can be	Self evident. Delete Note 1 to entry.	TN

				applied does not seem to add much value.		
972	ANS I	680	3.3.7	<i>"Note 2 to entry: 'Inherent', as opposed to 'assigned', means existing in the object (3.36)"</i> Comment: This note seems confusing	This note further demonstrates that the word "object" in the standard is somewhat of an afterthought. Proposed change: Suggest removing this note or modifying to read "...existing in the tangible or intangible object"	TN
973	IQN ET	682 and 686	Section 3.	Statutory and regulatory are hard to translate to other languages and in practice are referred as legal requirements, the ones an entity is enforced to comply with. Its use in the standard puts the document more heavy, difficult to read, creates problems to translation.	Add new definition definition of legal requirements Legal requirements: set of statutory and regulatory requirements, Revise all standard to use legal requirements	TN
974	PH/ BPS	685	3.38	Source of definition of statutory requirement is incorrect	SOURCE: ISO DIS 9000:2014, 3.5.6	EAP
975	MX	685	3	incorrect reference to ISO 9000	Change 3.5.4.2 by 3.5.6	EAP
976	PT	685	3.38	ISO DIS 9000:2014, 3.5.4.2	ISO DIS 9000:2014, 3.5.6	EAP
977	QS	685	3.38	Reference clause to ISO DIS 9000: 2014 standard is wrong. 3.5.4.2 does not exist	Replace SOURCE: ISO DIS 9000:2014, 3.5.4.2 3.5.6	EAP
978	SE	685	3.38	[SOURCE: ISO DIS 9000:2014, 3.5.4.2]	[SOURCE: ISO DIS 9000:2014, 3.5.6]	EAP
979	JP 56	685	3.38	Cross-reference is incorrect.	3.5.4.2 should be 3.5.6.	EAP
980	PH/ BPS	689	3.39	Source of definition of regulatory requirement is incorrect	SOURCE: ISO DIS 9000:2014, 3.5.7	EAP
981	MX	689	3	incorrect reference to ISO 9000	Change 3.5.4.3 by 3.5.7	EAP
982	PT	689	3.39	ISO DIS 9000:2014, 3.5.4.3	ISO DIS 9000:2014, 3.5.7	EAP
983	QS	689	3.39	Reference clause to ISO DIS 9000: 2014 standard is wrong. 3.5.4.3 does not exist	Replace SOURCE: ISO DIS 9000:2014, 3.5.4.3 3.5.7	EAP
984	SE	689	3.39	[SOURCE: ISO DIS 9000:2014, 3.5.4.3]	[SOURCE: ISO DIS 9000:2014, 3.5.7]	EAP
985	JP 57	689	3.39	Cross-reference is incorrect.	3.5.4.3 should be 3.5.7.	EAP
986	AU	690	3.40	Refers to defects however the Standard already has nonconformities included. Question the need to have defects included as well.	Delete the definition and reference to defects	TN
987	ANS I	691 - 694		The note indicates that there is a distinction between defect and nonconformity. A nonconformity is defined as "nonfulfillment of a requirement". A defect is defined as a "nonconformity related to an intended or specified	Defect "a lack of completeness or adequacy related to an intended or specified use".	TN

				use.” By extension, then the definition of a defect becomes: “nonfulfillment of a requirement related to an intended or specified use”, implying that defects are a subset of nonconformities. If intent is to make a distinction between defect and nonconformity because of legal reasons, then suggest that you do not use the word nonconformity within the definition of the word defect.		
988	SE	691-694	3.40	The note indicates that there is a distinction between defect and nonconformity. A nonconformity is defined as “nonfulfillment of a requirement”. A defect is defined as a “nonconformity related to an intended or specified use.” By extension, then the definition of a defect becomes: “nonfulfillment of a requirement related to an intended or specified use”, implying that defects are a subset of nonconformities. If you want to make a distinction between defect and nonconformity because of legal reasons, then I suggest that you do not use the word nonconformity within the definition of the word defect.	Defect “a lack of completeness or adequacy related to an intended or specified use”.	TN
989	ANS I	692	3.40	This definition implies that a “defect” also must be “nonconforming”. An item may conform to all specification, regulatory and other requirements, yet still not be suitable for its intended use.	A condition, whether conforming or nonconforming, which renders a product or service unsuitable for its intended or specified use.	TAP
990	PH/BPS	697	3.40	Source of definition of defect is incorrect	SOURCE: ISO DIS 9000:2014, 3.5.10	EAP
991	MX	697	3	incorrect reference to ISO 9000	Change 3.5.5.1 by 3.5.10	EAP
992	EE	697	3.40	Cross-references between ISO/DIS 9000 and ISO/DIS 9001 must be revised because of some mistakes (also in ISO/DIS 9000). E.g. in the end of term 3.40 in ISO/DIS 9001 the source is referred to be ISO DIS 9000:2014 3.5.5.1. Such numeration (i.e. 3.5.5.1) does not exist in ISO/DIS 9000 draft, instead term <i>defect</i> is under number 3.5.10.	<i>Replace existing wording in source reference with following:</i> ISO DIS 9000:2014, 3.5.10	EAP
993	PT	697	3.40	ISO DIS 9000:2014, 3.5.5.1	ISO DIS 9000:2014, 3.5.10	EAP
994	SE	697	3.40	[SOURCE: ISO DIS 9000:2014, 3.5.5.1]	[SOURCE: ISO DIS 9000:2014, 3.5.10]	EAP
995	JP 58	697	3.40	Cross-reference is incorrect.	3.5.5.1 should be 3.5.10.	EAP
996	ANS I	700	3.4.1	“ability to trace the history, application or location	Proposed change: ability to trace the history,	TN

				of an object (3.36)." Comment: In this case object is something tangible.	application or location of that which is being sought (3.36).	
997	ANS I	700	3.41	Uses Trace to define traceability; Trace is not defined; does not include the concept of objective evidence (or documented information)	Change to read: "...ability to know through documented information the history,"	TN
998	CQI 24	702 – 704	3.41	- the origin of... - the processing... - the distribution... The 3 bullets under Note 1 to entry are unordered. To improve identification these should be ordered (c.f. 3.65 Note 3 to entry).	a) the origin of... b) the processing... c) the distribution...	EN
999	IT	704 -705	3.41	It would be appropriate to include a note of support.	Add the following note: Note 3 to entry: The effectiveness of traceability should be assessed.	TN
1000	TC6 9	705	3.41	There are commas ill-located: "In the field of metrology the definition in ISO/IEC GUIDE 99: 2007, is the accepted definition."	"In the field of metrology, the definition, in ISO/IEC GUIDE 99: 2007 is the accepted definition."	EAP
1001	PH/BPS	706	3.41	Source of definition of traceability is incorrect	SOURCE: ISO DIS 9000:2014, 3.5.13	EAP
1002	MX	706	3	incorrect reference to ISO 9000	Change 3.5.8 by 3.5.13	EAP
1003	PT	706	3.41	ISO DIS 9000:2014, 3.5.8	ISO DIS 9000:2014, 3.5.13	EAP
1004	QS	706	3.41	Reference clause to ISO DIS 9000: 2014 standard is wrong.	Replace SOURCE: ISO DIS 9000:2014, 3.5.8 3.5.13	EAP
1005	SE	706	3.41	[SOURCE: ISO DIS 9000:2014, 3.5.8]	[SOURCE: ISO DIS 9000:2014, 3.5.13]	EAP
1006	JP 59	706	3.41	Cross-reference is incorrect.	3.5.8 should be 3.5.13.	EAP
1007	IQN ET	707	Section 3.	1. Innovation might not be a process. 2. TO put the word object and then define object is too far too complicate the terms and to force people to unnecessary reading. It does not clarify. 3. For innovation definition Oslo Manual 3 rd edition, would be a goont source to make a good definition. Alternatively, look closer at ISO/TC 279 or CEN TC 389	Example (from CEN TS 16 555) innovation implementation of a new or significantly improved product (good or service), or process, a new marketing method, or a new organizational method in business practices, workplace organization or external relations	TAP
1008	PL	707	3.42	Innovation – definition is not clear, What kind of process the author meant? This	Delete this term form ISO 9001 and ISO 9000	TN

				"process" has to be clarified. What is relation with "design and development" ? From the dictionary "innovation is something new or new way of doing something " Because the proposed definition does not add any value to this one from dictionary we suggest to delete it as redundant		
1009	FR	707	3.42	Use the proposed definition for the term innovation.	Innovation : process that leads to the implementation of one or more new or improved products, services, processes, organisational structures or business models that are likely to meet explicit or implied expectations and generate economic, environmental or social value for all stakeholders Note 1 to entry This definition includes the concepts of innovation value and processes, which are not mentioned in the Oslo Manual. Innovation: processus qui conduit à la mise en oeuvre d'un ou plusieurs produit, service, procédé, forme d'organisation, modèle d'affaires, nouveaux ou amélioré, susceptible de répondre à des attentes implicites ou explicites et de générer une valeur économique, environnementale ou sociétale pour toutes les parties prenantes Note 1 à l'article dans cette définition apparaissent les notions de processus et de valeur de l'innovation qui ne sont pas mentionnée dans le manuel d'Oslo.	TAP
1010	SE	708	3.42	The suggestion from TK532 Innovation Management, is taken directly from the OECD- Oslo manual and in the published CEN/TS 16555-1 Innovation Management System Source: OECD, Oslo Manual, GUIDES FOR COLLECTING AND INTERPRETING INNOVATION DATA, 3rd Edition Page: 46 Link: http://unstats.un.org/unsd/EconStatKB/Attachment336.aspx Section: 2.146	"implementation of a new or significantly improved product, service, or process, a new marketing method, or a new organizational method in business practices, workplace organization or external relations"	TAP

1011	ANS I	709	3.4.2	process (3.12) resulting in a new or substantially changed object (3.36).	Propose change: as follows: “ <i>process</i> resulting in a new or substantially changed <i>idea</i> or <i>methodology</i> ...”	TAP
1012	CQI 25	711	3.42	The <i>object</i> (3.36) for the purpose of innovation can be e.g. a <i>management system</i> (3.04), a... An organization can also be subject of innovation.	The <i>object</i> (3.36) for the purpose of innovation can be e.g. <i>an organization</i> (3.01), a <i>management system</i> (3.04), a...	TAP
1013	ANS I	711	3.42	<i>Note 1 to entry: The object (3.36) for the purpose of innovation can be e.g. a management system (3.04), a 712 process (3.12), a product (3.47), a service (3.48) or technology</i>	Same comment as above for line item 680. This note is attempting to clarify – but I think it adds further confusion.	TAP
1014	ANS I	712	3.42	Insert a space prior to “a product” as a typographical correction.	Change to “...a <i>process</i> (3.12), a <i>product</i> ...”	EAP
1015	PH/ BPS	713	3.42	Source of definition of innovation is incorrect	SOURCE: ISO DIS 9000:2014, 3.6.3	EAP
1016	MX	713	3	incorrect reference to ISO 9000	Change 3.6.1.2 by 3.6.3	EAP
1017	PT	713	3.42	ISO DIS 9000:2014, 3.6.1.2	ISO DIS 9000:2014, 3.6.8	EAP
1018	SE	713	3.42	[SOURCE: ISO DIS 9000:2014, 3.6.1.2]	[SOURCE: ISO DIS 9000:2014, 3.6.3]	EAP
1019	JP 60	713	3.42	Cross-reference is incorrect.	3.6.1.2 should be 3.6.3.	EAP
1020	JP 61	714 -717	3.43	The term “contract” is used with dictionary meanings in DIS 9001, and therefore, the definition is not necessary.	Delete 3.43, the definition of “contract.”	TN
1021	SE	714 -716	3.43	“ contract ...” See comment to lines 400-939.	No specific meaning. Delete.	TN
1022	PL	714	3.46	Term “contract”- really we need this term and definition? It is redundant. It is dictionary term	Delete it from ISO 9001 and ISO 9000	TN
1023	ANS I	716	4.43	Add “between two or more agreeing parties” to comply with universal legal definition presented in Blacks Law Dictionary	binding agreement <u>between two or more agreeing parties</u> .	TN
1024	PH/ BPS	717	3.43	Source of definition of contract is incorrect	SOURCE: ISO DIS 9000:2014, 3.6.8	EAP
1025	MX	717	3	incorrect reference to ISO 9000	Change 3.6.4 by 3.6.8	EAP
1026	PT	717	3.43	ISO DIS 9000:2014, 3.6.4	ISO DIS 9000:2014, 3.6.8	EAP
1027	SE	717	3.43	[SOURCE: ISO DIS 9000:2014, 3.6.4]	If retained: [SOURCE: ISO DIS 9000:2014, 3.6.8]	EAP
1028	JP 62	717	3.43	Cross-reference is incorrect.	3.6.4 should be 3.6.8.	EAP
1029	INLA	718	3.44	Use the definition of ISO 9000:2005 is more	design and development	TN

	C	- 721		appropriate and is technical correct. "Service" must be incorporated at the end of the definition.	set of processes that transforms requirements into specified characteristics or into the specification of a product, service , process or system	
1030	IQNET	718	Section 3.	This is a very strange (as it is so abstract and distant from the common dictionary) definition that might cause a lot of confusion in the users and that might prevent them from using design and development or might create unnecessary requirements. What is to detail more or less? In Cambridge dictionary design is the way in which something is planned and made: In Oxford A plan or drawing produced to show the look and function or workings of a building, garment, or other object before it is made The art or action of conceiving of and producing a plan or drawing of something before it is made: The arrangement of the features of an artefact, as produced from following a plan or drawing: On the other hand ISO 9000:2005 does not have a definition for this and it might not be necessary, as we do not define what is production, purchasing and so on.	Consider the need to define design and development. If considered needed use the most possible the common use (in the context of course) as defined in dictionary in a way people can understand.	TN
1031	ANSI	718 through 731	3.44	Should there not be a reference to "Research & Development", as well??	Add clarification that "research" is also a descriptor for this section.	TN
1032	ANSI	719 - 721		Do not understand this definition at all. The purpose of design and development processes is to transform identified requirements (whether broadly or specifically stated) for a product or service into the agreed arrangements necessary for the provisioning of a product or service meeting the requirements. If broadly stated requirements (as inputs to the processes) need to be further defined, that should be a part of the process.	Modify definition to more closely align with ISO 9000:2005 3.4.4 definition of "design and development" and include "object" as shown: "set of processes (3.12) that transforms requirements(3.0.3) for an object (3.36) into specified characteristics (3.65) or into the specifications of a product (3.47), process or system (3.31). "	TN
1033	SE	719 -721	3.44	"design and development set of processes (3.12) that transforms requirements (3.03) for an object (3.36) into more detailed requirements This definition may be formally correct but is	Suggestion: "design and development process (3.12) that transforms requirements (3.03) for an object (3.36) into more detailed requirements necessary for the next step in the realization of the object."	TN

				probably not comprehensible to the average reader. The terms “characteristics” and “specification” in ISO 9000:2005 were illustrative. Why “set of processes”?	Preferably define “design” and “development” as separate concepts. design arrangement of required features of an object and the creating process involved development extension of a design to detailed requirements necessary for the realization of an object	
1034	PL	719	3.44	Term design and development The problem with design and development is not only problem of English or French language, this is problem of many other languages, that is why the term and definition must be possible clearly translatable for other languages. WE suggest to delete this Note 2 as redundant, this note nothing explains. It is nearly tautology. We suggest to change the term into only “design” because if at all “development” is considered, it is part of design. This remark applies also to ISO 9000. Definition is also not clear as “the set of processes” are not defined, it is the same problem as in the case of innovation. In both cases definitions do not give explanation and understanding of the term,	3.44 design	TN
1035	IT	720 -721	3.44	The current definition (ISO 9000:2005, 3.4.4) is: “<i>Set of processes that transforms requirements into specified characteristics or into the specification of a product, process or system.</i>” There is no clear reason for substantially change the meaning of “design and development”. The current definition should be made simpler but in essence kept as it is.	Modify definition as follows: “<i>Set of processes that transforms requirements into specifications</i>”.	TN
1036	ANS I	720	3.44	<i>set of processes (3.12) that transforms requirements (3.03) for an object (3.36) into more detailed 721 requirements</i>	Propose change: “remove the word object: “<i>set of processes that transforms requirements into more detailed requirements</i>”	TN
1037	ANS I	720	3.44	requirements for an object into more detailed requirements	transforms requirements for an object into plans for actuation.	TN
1038	PH/ BPS	721	3.44	“Requirements” in italic font but not followed by its entry number	requirements (3.03)	EAP

1039	AU	722	3.44	Not clear what inputs to design could be.	Suggest some examples as std. as done for outputs.	TN
1040	AU	727	3.44	Question the need to include clarification of French terminology. Other countries may also have different relevant terminologies – put one country in, should include others.	Remove reference to French clarification.	TN
1041	PH/BPS	732	3.44	Source of definition of design and development is incorrect	SOURCE: ISO DIS 9000:2014, 3.6.9	EAP
1042	MX	732	3	incorrect reference to ISO 9000	Change 3.6.5 by 3.6.9	EAP
1043	PT	732	3.44	ISO DIS 9000:2014, 3.6.5	ISO DIS 9000:2014, 3.6.9	EAP
1044	SE	732	3.44	[SOURCE: ISO DIS 9000:2014, 3.6.5]	[SOURCE: ISO DIS 9000:2014, 3.6.9]	EAP
1045	JP 63	732	3.44	Cross-reference is incorrect.	3.6.5 should be 3.6.9.	EAP
1046	ANS I	734	1	The definition of “quality objective” is circular. Just a restatement of the words.	Quality objective – the intention or aim or goal of an individual to be achieved	TN
1047	ANS I	735	3.45	I would expand this definition to the one in the next column. “ <i>objective</i> (3.08) related to <i>quality</i> (3.37)”	<i>objective</i> (3.08) related to <i>quality</i> (3.37) that is measurable improvement over some time frame.	TN
1048	ANS I	735	3.45	The definition uses the very same words as the phrase being defined. This is breaking a basic rule of proper language usage, i.e. to never use a word in its own definition. To say “quality objectives” is “an objective related to quality” offers no help at all to readers. This is also redundant with line 468 under the definition of “objective” in 3.08.	Delete.	TN
1049	ANS I	736	3.45	Although it should be obvious, the words “and the needs of customers” should appear in Note 1.	“Quality objectives are generally based on the organization’s (3.01) quality policy (3.34) and the needs of its customers”	TN
1050	ANS I	736	4.1	Requirement is un-auditable without documented information.	Add a requirement for documented information on the issues defined.	TN
1051	MA	736	3.45	the word “generally” suggests that quality objectives could be set apart from the quality policy. 5.2 out according to the objectives as part of the quality policy and therefore, according to our understanding, either directly from the quality policy formulation, is established based on the framework provided	Quality objectives are generally based on the organization’s (3.01) <i>quality policy</i> (3.34).	TN
1052	CN	737-738	3.45	The note 2 mentioned that the Quality objectives are generally specified for relevant functions	The note 2 should be changed to	TAP

				(3.25) and levels in the organization (3.01). But the 6.2.1, requiring that The organization shall establish quality objectives at relevant functions, levels and processes. They are not align with each other	Quality objectives are generally specified for relevant functions (3.25) and levels and processes(3.12) in the organization (3.01).	
1053	PH/BPS	739	3.45	Source of definition of quality objective is incorrect	SOURCE: ISO DIS 9000:2014, 3.7.2	EAP
1054	MX	739	3	incorrect reference to ISO 9000	Change 3.7.1.1 by 3.7.2	EAP
1055	PT	739	3.45	ISO DIS 9000:2014, 3.7.1.1	ISO DIS 9000:2014, 3.7.2	EAP
1056	SE	739	3.45	[SOURCE: ISO DIS 9000:2014, 3.7.1.1]	[SOURCE: ISO DIS 9000:2014, 3.7.2]	EAP
1057	JP 64	739	3.45	Cross-reference is incorrect.	3.7.1.1 should be 3.7.2.	EAP
1058	HU	740 -781	3.46 – 3.48	The relationship between the terms 'output', 'product' and 'service' is not clear. Practically the former definition of 'product' is the same than the present definition of output. The former definition of 'product' contained every example, explanation of present definitions of 'product' and 'service'. The service is defined as definitely an intangible output, but the first example the car repairing, which typically contains tangible elements (products). Sometimes instead of output (or product) the 'outcome' is used, which is not defined.	The former definition of 'product' is suggested with some clarification and/or additional Notes, which can help in understanding the difference between the 'product' and 'service'. The use of 'result' is suggested instead of 'outcome'	TN
1059	IT	740 -757	3.46	According to ISO 704 “ <i>Substitution Principle shall be used to test the validity of a definition. Common types of deficient definitions are: circular, incomplete and negative definitions</i> ”. In this case there is a circularity between “Process”(3.6.1) and “Output” (3.7.5). In fact substitution of “Output” in “Process” definition provides the following circular definition: 3.6.1 Process: <i>set of interrelated or interacting activities which transforms inputs into result of a process (3.6.1)</i> while the substitution of Process in Output definition provides the following circular definition: 3.7.5 Output: <i>result of a set of interrelated or interacting activities which transforms inputs into outputs (3.7.5).</i> We propose to consider “output” as a primitive term/concept (as well as “input”) since it allows	Delete the whole term, definition and notes. Note 2 and part of Note 1 may be included in both definitions of “product” and “service”. [See also IT comments on “product” and “service”]	TAP

				term "Process" to remain unchanged for the sake of continuity with current ISO 9000:2005. [CRITICAL COMMENT]		
1060	GB	740	3.46	Space between 'the' and 'provider' not given.	the provider	EAP
1061	GB	740	3.46	Process defined in 3.12	result of a process (3.12)	EAP
1062	GB	741	3.46	The results of a process take different forms and not all are outputs. There are the results based on what the process produces when it is running which can be used to control a process directly such as the form, composition or condition of an object. There are also results which emerge long after the process that created them has stopped that indirectly impact or influence operational, social, environmental and financial conditions. These are often referred to as outcomes.	Change to: direct result of a process	TN
1063	PH/ BPS	742	3.46	Incorrect entry number for "process" is used	process (3.12)	EAP
1064	HU	742	3.46	The clause number after 'process' is not correct: (312)	Correctly: (3.12)	EAP
1065	CZ	742	3.46	"result of a <i>process</i> (312)"	To be corrected – (3.12)	EAP
1066	JP 65	742	3.46	Cross-reference is incorrect.	"process (312)" should be "process (3.12)."	EAP
1067	CQI 26	743 - 752	3.46	Nonsensical examples (as are many other Notes) Remove all examples in brackets	- services (e.g. transport); - software (e.g. computer program, dictionary); - hardware (e.g. engine 746 mechanical part); - processed materials (e.g. lubricant).	TAP
1068	GB	743 -752	3.46	These generic categories appear to create more uncertainty rather than less as they try to bridge the gap between concepts and the real world. Terms such as <processed material> with the example lubricants suggests that processed material cannot also be solid. Also a driver's manual would not be referred to as software but as documentation. Any note this long suggests the actual text against which it is written is not presented clearly to the reader. What the user needs is criteria for determining whether or not an object is an output that requires identification (8.5.2) and control (8.3.5, 8.5.1 & 8.7)	Change to: A direct result of a process is what it produces to meet an objective. Some outputs will be deliverable so can be termed conforming outputs, and the rest will be unsuitable for delivery so can be termed nonconforming outputs or waste. A conforming output ready for delivery to a customer is designated a product (3.47) or a service (3.48)	TAP
1069	GB	743 -752	3.46	These generic categories appear to create more uncertainty than less as they try to bridge the gap between concepts and the real world. Terms such	Change to: A direct result of a process is what it produces to	TAP

				as <processed material> with the example lubricants suggests that processed material cannot also be solid. Also a driver's manual would not be referred to as software but as documentation. Any note this long suggests the actual text against which it is written is not presented clearly to the reader. What the user needs is criteria for determining whether or not an object is an output that requires identification (8.5.2) and control (8.3.5, 8.5.1 & 8.7)	meet an objective. Some outputs will be deliverable so can be termed conforming outputs, and the rest will be unsuitable for delivery so can be termed nonconforming outputs or waste. A conforming output ready for delivery to a customer is designated a product (3.47) or a service (3.48)	
1070	SE	743 -752	3.46	"Note 1 to entry "output": There are four generic output categories, as follows: - services (e.g. transport); - software (e.g. computer program, dictionary); - hardware (e.g. engine mechanical part); - processed materials (e.g. lubricant). Many outputs comprise elements belonging to different generic output categories. Whether the output is then called service, product, software, hardware or processed material depends on the dominant element. For example, a car consists of hardware (e.g. tires), processed materials (e.g. fuel, cooling liquid), software (e.g. engine control software, driver's manual), and service (e.g. operating explanations given by the salesman)." There are not only four generic output categories! The example re a car seems unnecessary. The examples indicated for the various categories should be sufficient. It should be mentioned that the output can be intended and it can also be unintended.	"Note 1 to entry: The output can be material, immaterial or both."	TAP
1071	ANS I	743	3.46	Regarding the section 3.46 "output" definition; Documentation can also be an output	Recommend adding documentation as an output category.	TN
1072	ANS I	743	3.46	If documented information (3.11) and object (3.26) such as income statement, records, reports, or even this Standard can be an output, which output category do they belong?	If these four categories meant to be exhaustive and exclusive, then they should cover all potential outputs. If not, that needs to be clearly stated.	TAP
1073	9.	743	3.46	A Syntactical correction is required	Please replace: "results of a process (312).", with: "results of a process (3.12)."	EAP
1074	DK	743	3.46		Delete "output" in the "Note 1 to entry "output".	EAP

1075	CZ	743	3.46	Note 1 to entry "output":	„output“ – to be deleted, thus not used.	EAP
1076	AU	774 744	3.48	774 Note 1 to entry "service": Provision of a service can involve, for example, the following: Customers often participate in service delivery and supply inputs into service processes. An example is also "self-service" where customers do the work, e.g., on-line transactions like booking air tickets.	Include an example of a service in which customers actively participate in its production. Or modify the note on line 780 along the following lines: "A service is usually experienced by the customer who sometimes participates in its delivery."	TAP
1077	CQI 27	744 – 747	3.46	- services... - software... - hardware... - processed materials... The 4 bullets under Note 1 to entry are unordered. To improve identification these should be ordered (c.f. 3.65 Note 3 to entry).	a) services... b) software... c) hardware... d) processed material....	EN
1078	ANS I	749 - 752		Remove Note 1. There are no requirements in this standard that apply to one of these types of outputs to the exclusion of the others. The example is confusing. The sentence illustrates that a car is made up of different types of outputs, but never comes to the conclusion which element of the car is "dominant". The word "dominant" is not defined and how different characteristics are to be considered to determine dominance is not described. For example – by weight, then hardware is the dominant characteristic of a car. Without fuel, a car will not work, so that might be fuel may be considered to be dominant. Without software, the engine cannot be controlled, so the car will not work – in this case the software could be considered dominant.	Delete the following: "Whether the output is then called service, product, software, hardware or processed material depends on the dominant element. For example, a car consists of hardware (e.g. tires), processed materials (e.g. fuel, cooling liquid), software (e.g. engine control software, driver's manual), and service (e.g. operating explanations given by the salesman)."	TAP
1079	AU	749	3.46	Of what value is it to anyone to know that there are "four output categories"? This is meaningless and does not serve the purpose of the Standard. Unnecessarily labours the point. If the definition is worded correctly then there should be no need for any illustrative examples.	Delete note	TAP
1080	ZA	751	3.46	Spelling of the word "tires" is the American spelling.	Replace "tires" with "tyres"	EAP
1081	AU	752		SALESMAN – politically incorrect	e.g. customer service requirements provided by front-line service provider/person or at least Salesperson	EAP
1082	CQI	754	3.46	This does not add value and can be confusing.	Delete Note 2	TAF

	28	- 755				
1083	SE	754 -755	3.46	"Note 2 to entry output: The ownership of a product can usually be transferred. This is not necessarily the case for a service." Since the term "product" is used here for the first time in 3.46 a reference to 3.47 seems suitable if the changes to Note 1 are not accepted.	If changes to Note 1 are not accepted: "Note 2 to entry: The ownership of a <i>product</i> (3.47) can usually be transferred. This is not necessarily the case for a service."	EAP
1084	10.	754	3.46	A Syntactical correction is required	Please replace: "Note 1 to entry output :", with: "Note 1 to entry:"	EAP
1085	PH/ BPS	757	3.46	Source of definition of output is incorrect	SOURCE: ISO DIS 9000:2014, 3.7.5	EAP
1086	MX	757	3	incorrect reference to ISO 9000	Change 3.7.3 by 3.7.5	EAP
1087	PT	757	3.46	ISO DIS 9000:2014, 3.7.3	ISO DIS 9000:2014, 3.7. 5	EAP
1088	SE	757	3.46	[SOURCE: ISO DIS 9000:2014, 3.7.3]	[SOURCE: ISO DIS 9000:2014, 3.7.5]	EAP
1089	JP 66	757	3.46	Cross-reference is incorrect.	3.7.3 should be 3.7.5.	EAP
1090	INLA C	759 - 780	3.47 & 3.48	The proposed definition of product and service are not clear and creates confusion. Currently, the concept of product is understood as the result of the whole system or a process. "Product and service" should be defined as one concept. There is a risk that manufacturing organizations only consider the concept of product and the service organizations only the concept of service. The concept of "product and service" should make reference to the tangible and intangible elements of a product. Annex A.2 explains clearly this relationship. Therefore, the definition should be consistent with the intent of Annex A.2. The term "output" can be used to identify the intermediate "products". For example, an incoming inspection process may produce different outputs like approved materials, non conforming/suspect materials, inventory reports, etc.	Product and service output of the QMS aimed to satisfy applicable requirements that has intangible and tangible elements	TN
1091	IT	759 -768	3.47	The new definition has two critical issues according to ISO 704 guidelines: the substitution of <i>Output</i> in <i>Product</i> definition provides the repetition of word "result": <u>result</u> of a process that is a <u>result</u> of activities where none of them [...];	Restore current ISO 9000:2005 definition (3.4.2): result of a process (3.12) Modify Note 1 as follows: Note 1 to entry: There are three generic product categories, as follows:	TN

				2. the definition is an “inappropriate negative definition” with no added value, not clear and potentially misleading. [CRITICAL COMMENT]	- software (e.g. computer program, dictionary); - hardware (e.g. engine mechanical part); - processed materials (e.g. lubricant). <i>Hardware is generally tangible and its amount is a countable characteristic. Processed materials are generally tangible and their amount is a continuous characteristic. Hardware and processed materials often are referred to as goods.</i> <i>Software consists of information and is generally intangible and can be in the form of approaches, transactions or procedures.</i> Many products comprise elements belonging to different generic product categories. Whether the output is then called product, software, hardware or processed material depends on the dominant element. For example, a car consists of hardware (e.g. tires), processed materials (e.g. fuel, cooling liquid), software (e.g. engine control software, driver's manual), and it also includes service (3.48), e.g. operating explanations given by the salesman. Add the following notes: Note 2 to entry: The ownership of a product can usually be transferred. This is not necessarily the case for a service (3.48). Note 3 to entry: A product can be both intended (e.g. product offered to customers [3.26]) and unintended “by-product” (e.g. pollutant or other undesirable effects). Quality management (3.30) is mainly focused on intended product. [See also IT comments on “output” and “service”]	
1092	SE	759 -766	3.47	“product <i>output (3.46) that is a result of activities where none of them necessarily is performed at the interface between the provider (3.27) and the customer (3.26)</i> Note 1 to entry “product”: Hardware is generally tangible and its amount is a countable characteristic. Processed materials are generally tangible and their amount is a continuous characteristic. Hardware and processed materials often are referred to as goods. Software consists	“product <i>intended output (3.46) of a process (3.12)</i> Note 1 to entry: A product can be material or immaterial.”	TN

				of information and is generally intangible and can be in the form of approaches, transactions or <i>documented information</i> (3.11)." The definition above is quite long, somewhat difficult to understand and based on a negation connected to the definition of "service". From a logical point of view one should be careful and preferably not define an item as being not something. A simpler definition is given (as already previously suggested by Chris Cox if I am not mistaken). The words "material" and "immaterial" are preferred for translational reason; the words "tangible" and "intangible" are less suitable for translation in a standard context. There does not seem to be any reason to describe characteristics of "hardware " – it is a lexical word and has no special meaning in the standards. "Processed materials" likewise has no special meaning in the standards and need not be described. A search for "software" on the Internet gave 936 000 000 hits. In the many, but of course limited, number of cases looked at, "software" in general meant "computer program", in some cases "electronically archived files", i.e. in all cases immaterial.		
1093	ANS I	759 - 762		Do not understand this definition. There are many examples of joint development projects, and cooperative activities between the provider and the customer, e.g., interoperability testing, first office applications.	Delete the following: where none of them necessarily is performed at the interface 762 between the provider (3.27) and the customer (3.26).	TAP
1094	ANS I	760	1	The note states that software is generally intangible. This is at best misleading and at worst incorrect. Also the definition is 23 words long vs. 4 words in ISO 9000 2005.	Delete "...Software consists of information and is generally intangible..."	TN
1095	ANS I	761 -762	3.47	This definition needs clarification and contains repetitive/overlapping terms.	Change to: "output (3.46) of activities where none of them is necessarily performed at the interface between the provider (3.27) and the customer (3.26)	TAP
1096	ANS I	761	3.47	The new definition is not detailed enough.	Replace with "A <i>product</i> is the output of a process. <i>Products</i> can be tangible or intangible."	TN

1097	ANS I	762	3.47 Product	During the release of ISO 9001:2000, TC 176 simplified the value stream to mean Customer-Organization-Supplier. This rewording proved to be very effective over the past 14 years. The word supplier can mean either internal-to-organization or external-of-the-organization supplier. In either case, the organization must ensure they monitor supplier performance in accordance with any related organizational requirements. I would propose replacing the language "external provision" and "external providers" with the term "supplier(s)", and include a definition for both external and internal suppliers under glossary term 3.27.	Change the text to read: between the <i>supplier</i> (3.27) and the <i>customer</i> (3.26)	TN
1098	ANS I	763	3.47	Note 1 does not understand the nature of software. Software, while often intangible, is nevertheless a full product, and NOT "approaches, transactions or documented information." This definition defies the entire software industry. Entering into a debate about the tangibility of product is out of the scope of 9001, and clearly not understood by the authors.	Remove the Note 1 entirely.	TN
1099	11.	763	3.47	A Syntactical correction is required	Please replace: "Note 1 to entry product :", with: "Note 1 to entry:"	EAP
1100	AU	766	3.47	Computer software, or simply "software", is commonly known as "computer programs", where software is defined as the non-tangible component of computers.	"e.g. Software is the non-tangible component of computers, also known as computer programs".	TN
1101	JP 190	766	3.47	Different from 3.7.6 of DIS 9000. The "procedures" is changed to "documented information."	The definition in ISO 9000 and 9001 should be identical.	TAP
1102	PH/ BPS	768	3.47	Source of definition of product is incorrect	SOURCE: ISO DIS 9000:2014, 3.7.6	EAP
1103	MX	768	3	incorrect reference to ISO 9000	Change 3.7.3.1 by 3.7.6	EAP
1104	PT	768	3.47	ISO DIS 9000:2014, 3.7.3.1	ISO DIS 9000:2014, 3.7. 6	EAP
1105	ZA	768	3.4.7	Incorrect reference	Change the reference in 9001 to match 3.7.6 in ISO 9000.	EAP
1106	SE	768	3.47	[SOURCE: ISO DIS 9000:2014, 3.7.3.1 , modified – Note 1 to entry has been modified]	[SOURCE: ISO DIS 9000:2014, 3.7.5, modified – Note 1 to entry has been modified]	EAP
1107	JP	768	3.47	Cross-reference is incorrect.	3.7.3.1 should be 3.7.6.	EAP

	67					
1108	IT	770 -781	3.48	The substitution of “Output” in “Service” definition provides the repetition of word “result”: <i>result of a process that is a <u>result</u> of at least one activity [...]</i> Assuming that (see IT comments on “output” and product”): - “input” and “output” are considered as primitive terms/concepts; - definition of “product” should remain unchanged (i.e. “result of a process”) with reference to ISO 9000:2005; and considering that: - “service” can be not only seen as a result/output of activities, but can also include those activities. This is also confirmed referring to ISO concept database, as suggested by ISO/IEC Directives, Part 2, 2011 (Annex D, D.1.5) in order to avoid duplications and contradictions. There are definitions of “service” that describe it as process or number of processes or “action of an organization to meet a demand or need” (ISO 26000:2010, 2.16); - the main aim of a service is “to meet a demand or need” and we deem that it is important to highlight it in the definition, together with the other main characteristic of having “at least one activity necessarily performed at the interface between the provider and the customer”; - it is better to highlights that the activities at the interface between provider and customer affect Customer satisfaction (3.9.3); - it is not true that a service is always “intangible”, particularly referring to its own outcome(s). Examples: a repaired car is obviously tangible; the service of carry out an outsourced process can have as result a product, whether tangible or intangible. It is confusing, misleading and with no added value to consider a transport as intangible. We propose two possible - though slightly	Modify the definition as follows: <i>result of a process or system of processes carried out in order to meet customer needs, where at least one activity is necessarily performed at the interface between the provider and the customer</i> or: <i>process or system of processes carried out in order to meet customer needs, where least one activity is necessarily performed at the interface between the provider and the customer, including related result</i> Add the following notes: <i>Note 2 to entry: Provider and/or Customer can act in person or by means of apparatus at the interface.</i> <i>Note 3 to entry: Activities performed by customer at the interface can be essential to service provision.</i> <i>Note 4 to entry: A service can be relate to manufacturing and/or supplying of products, both tangible and intangible.</i> <i>Note 5 to entry: Some services come to the end of their life cycle at the conclusion of their own provision (e.g.: simultaneous interpreting).</i> <i>Note 6 to entry: The ownership of a product (3.7.6) can usually be transferred. This is not necessarily the case for a service.</i> <i>Note 7 to entry: Provider and customer can also be internal to the organization.</i> <i>Note 8: customer behaviour can influence the service provision result.</i>	TN

				different - solutions.		
				[CRITICAL COMMENT]		
1109	ANS I	771	1	Service is defined as "...intangible output...". Doctors, auto mechanics, waiters etc., would disagree that service is intangible. Also cannot find a definition of "record" in spite of the fact that according to A1 an organization can continue to use documents and records and ignore the term "documented information!!"	Delete "intangible..." Also, include text that states "organizations can ignore the use of documented information since it is not a requirement and continue to use documents and records in their QMS." Failure to include such text in the body of ISO 9001 is an absolute disservice to users and should be a reason for validation nonconformity for the entire document due to the implications for value-added compliance by users.	TAP
1110	ANS I	772 - 773	3.48	Many services include also the delivery of a product to the customer Not all services are intangible	Revise to show: intangible output (3.46) that is the result of at least one activity necessarily performed at the interface between the provider and the customer	TAP
1111	ANS I	772 -773	3.48	This definition needs clarification and contains repetitive/overlapping/unnecessary terms.	Change to: "intangible output (3.46) of at least one activity performed at the interface between the provider and the customer"	TAP
1112	BR	773	3. Terms and definitions/ 3.48	Lack of inclusion of item number of "Terms and definitions" and change the word form to italic.	Change to: "between the <i>provider</i> (3.27) and the <i>customer</i> (3.26)"	EAP
1113	CZ	773	3.48	...provider and the customer	To be corrected – use italics and reference to sub-clauses.	EAP
1114	12.	774	3.48	A Syntactical correction is required	Please replace: "Note 1 to entry "service" :", with: "Note 1 to entry:"	EAP
1115	CZ	774	3.48	Note 1 to entry "service":	„service“ – to be deleted, thus not used.	EAP
1116	CQI 29	775 - 779	3.48	- an activity performed... - an activity performed... - the delivery of... - the creation of... The 4 bullets under Note 1 to entry are unordered. To improve identification these should be ordered (c.f. 3.65 Note 3 to entry).	a) an activity performed... b) an activity performed... c) the delivery of... d) the creation of....	EN
1117	CZ	779	3.48	Semicolon at the end of the last bullet is not correct.	A full stop should be used.	EAP
1118	BR	780	3. Terms and definitions/ 3.48	Lack of inclusion of item number of "Terms and definitions" and change the word form to italic.	A service is usually experienced by the <i>customer</i> (3.26).	EAP

1119	PH/BPS	781	3.48	Source of definition of service is incorrect	SOURCE: ISO DIS 9000:2014, 3.7.7	EAP
1120	MX	781	3	incorrect reference to ISO 9000	Change 3.7.3.2 by 3.7.7	EAP
1121	PT	781	3.48	ISO DIS 9000:2014, 3.7.3.2	ISO DIS 9000:2014, 3.7.7	EAP
1122	SE	781	3.48	[SOURCE: ISO DIS 9000:2014, 3.7.3.2]	[SOURCE: ISO DIS 9000:2014, 3.7.7]	EAP
1123	JP 68	781	3.48	Cross-reference is incorrect.	3.7.3.2 should be 3.7.7.	EAP
1124	ANS I	785	3.49	Disagree with statement. "Data" can be taken for both an object or activity (intangible).	Add clarification that it can apply to either an object or intangible (activity).	TN
1125	ANS I	785		Information can be more than data. It can be emails, letters, SOPs, results of tests, etc. Information is knowledge derived from meaningful data rather than the meaningful data itself.	Knowledge derived from meaningful data.	TN
1126	ANS I	785		Information can be more than data. It can be emails, letters, SOPs, results of tests, etc. Information is knowledge derived from meaningful data rather than the meaningful data itself.	Knowledge derived from meaningful data.	TN
1127	ANS I	791-792	3.50	A note should be added to this definition to further explain how data is turned into meaningful information.	"Note 1: Data alone is not always meaningful. Data usually has to be analysed and interpreted in order to convert it into meaningful information that can be acted upon."	TN
1128	PH/BPS	792	3.50	Source of definition of information is incorrect	SOURCE: ISO DIS 9000:2014, 3.8.2	EAP
1129	MX	792	3	incorrect reference to ISO 9000	Change 3.8.1.1 by 3.8.2	EAP
1130	PT	792	3.50	ISO DIS 9000:2014, 3.8.1.1	ISO DIS 9000:2014, 3.8.2	EAP
1131	SE	792	3.50	[SOURCE: ISO DIS 9000:2014, 3.8.1.1]	[SOURCE: ISO DIS 9000:2014, 3.8.2]	EAP
1132	JP 69	792	3.50	Cross-reference is incorrect.	3.8.1.1 should be 3.8.2.	EAP
1133	TC4 6/SC 11 Liaison (FR)	793-800	3.51 objective evidence	Replace the definition with that of the ISO30300 standard. Remove the term "objective"	evidence documentation of a transaction NOTE This is proof of a business transaction which can be shown to have been created in the normal course of business activity and which is inviolate and complete. It is not limited to the legal sense of the term. [ISO 30300:2011, definition 3.1.5	TN
1134	ANS I	795	3 Terms	"data supporting"	Replace "data" with "data and information " and delete "or verify " replacing with "validity" so that it now reads: data (3.49) and information (3.50) supporting the verified existence or validity of	TN

					something	
1135	CH	796	3.51	Objective evidence may be obtained ... According to ISO/IEC Directives Part 2 Annex H, "may" means "is permitted", "is allowed", "is permissible". The use of "may" in this context is not appropriate therefore. Use "can" instead	Objective evidence <i>can</i> be obtained ...	EAP
1136	ANS I	798	3.51	The term "records" is not used in the standard	Replace "records" by " documented information "	TN
1137	GB	798	3.5.1	Replace "records" by "documented information" to be consistent with the Annex SL text	Replace "records" by "documented information"	TN
1138	CZ	799	3.51	A full stop is missing at the end of the sentence.	To be added.	EAP
1139	PH/ BPS	800	3.51	Source of definition of objective evidence is incorrect	SOURCE: ISO DIS 9000:2014, 3.8.4	EAP
1140	MX	800	3	incorrect reference to ISO 9000	Change 3.8.1.2 by 3.8.4	EAP
1141	PT	800	3.51	ISO DIS 9000:2014, 3.8.1.2	ISO DIS 9000:2014, 3.8.4	EAP
1142	SE	800	3.51	[SOURCE: ISO DIS 9000:2014, 3.8.1.2]	[SOURCE: ISO DIS 9000:2014, 3.8.4]	EAP
1143	JP 70	800	3.51	Cross-reference is incorrect.	3.8.1.2 should be 3.8.4.	EAP
1144	JP 71	801 -804	3.52	The tem "information system" is not used in other part of the standard.	Delete the definition of "information system."	TAF
1145	FR	801	3.52	Remove <QMS>	Remove <QMS>	EAF
1146	ANS I	803	3.52	The definition focuses too narrowly on a human organization.	an information processing system, together with associated organizational resources such as human, technical, and financial resources, that provides and distributes information (ISO/IEC 2382-1:1993 Information technology--Vocabulary--Part 1: Fundamental terms, 01.01.22)	TN
1147	ANS I	803	3.52	The term is not used in the standard.	Delete definition	TAF
1148	ANS I	803	3.52	The definition focuses too narrowly on a human organization.	an information processing system, together with associated organizational resources such as human, technical, and financial resources, that provides and distributes information (ISO/IEC 2382-1:1993 Information technology--Vocabulary--Part 1: Fundamental terms, 01.01.22)	TN
1149	13.	803	3.52	A Syntactical correction is required	Please replace: "<QMS> network of communication ...", with: "network of communication ..."	EAP

1150	SE	803	3.52	Why is <QMS> included in this definition? This looks like an editing error	Delete	EAF
1151	PH/ BPS	804	3.52	Source of definition of information system is incorrect	SOURCE: ISO DIS 9000:2014, 3.8.5	EAP
1152	MX	804	3	incorrect reference to ISO 9000	Change 3.8.2 by 3.8.5	EAP
1153	PT	804	3.52	ISO DIS 9000:2014, 3.8.2	ISO DIS 9000:2014, 3.8.5	EAP
1154	QS	804	3.52	Reference clause to ISO DIS 9000: 2014 standard is wrong.	Replace SOURCE: ISO DIS 9000:2014, 3.8.2 3.8.5	EAP
1155	SE	804	3.52	[SOURCE: ISO DIS 9000:2014, 3.8.2]	[SOURCE: ISO DIS 9000:2014, 3.8.5]	EAP
1156	JP 72	804	3.52	Cross-reference is incorrect.	3.8.2 should be 3.8.5.	EAP
1157	JP 73	805 -808	3.53	The definition of "knowledge" is not necessary. It is used with no more than dictionary meanings.	Delete the definition of "knowledge."	TAF
1158	AT	805	3.53	Incorrect definition of "Knowledge" still not altered, as proposed by ASI; knowledge is not an available collection of information!	Knowledge: tangible or intangible result of perception, learning, experience, reasoning or a combination of these	TN
1159	IQN ET	805	Section 3	The definition is very short for the purpose of the standard and also very far from its common use. There are common dictionary definitions more clear. Example form Cambridge Dictionary: understanding of or information about a subject that you get by experience or study , either known by one person or by people generally ; the state of knowing about or being familiar with something And Oxford Dictionary: Facts , information, and skills acquired through experience or education ; the theoretical or practical understanding of a subject;; The sum of what is known :	Redefine considering convergence with dictionary meaning and need to provide clarity to reader.	TN
1160	FR	805	3.53	Delete the end of the sentence after « information »	The definition reads : knowledge : available collection of information (3.50)	TAP
1161	MX	808	3	incorrect reference to ISO 9000	Change 3.8.3 by 3.8.6	EN
1162	PT	808	3.53	ISO DIS 9000:2014, 3.8.3	ISO DIS 9000:2014, 3.8.6	EN
1163	SE	808	3.53	[SOURCE: ISO DIS 9000:2014, 3.8.3]	[SOURCE: ISO DIS 9000:2014, 3.8.6]	EN

1164	JP 74	808	3.53	Cross-reference is incorrect.	3.8.3 should be 3.8.6.	EN
1165	ANS I	812	3.54 Verification	I recommend including the language that clarifies verification (intent to meet specified requirements) from validation (actual performance to specific requirements).	Change the text to read: Have been fulfilled prior to that realization of the good or service.	TN
1166	AU	812	3.54	Uses 'fulfilled' however may be useful to include word "implemented".	Replace, 'fulfilled' with, "implemented".	EN
1167	BR	813	3. Terms and definitions/ 3.54	Lack of inclusion of item number of "Terms and definitions" and change the word form to italic.	Note 1 to entry: The <i>objective evidence</i> (3.51) needed for a verification can be the result of an inspection or of other	EAP
1168	ANS I	813 & 821	3.54	Need to add "(3.51)" after "objective evidence" to be consistent.	Add "(3.51)" after "objective evidence."	EAP
1169	GB	814	3.54	ISO/TC 176/SC1 should consider the amendment to this note for ISO 9000, to be consistent with the Annex SL use of "documented information"		TN
1170	JP 193	814	3.54	Different from 3.8.13 of DIS 9000. The "documents" is changed to "documented information."	The definition in ISO 9000 and 9001 should be identical.	TAF
1171	CZ	816	3.54	A full stop is missing at the end of the sentence.	To be added	EAP
1172	PH/ BPS	818	3.54	Source of definition of verification is incorrect	SOURCE: ISO DIS 9000:2014, 3.8.13	EAP
1173	MX	818	3	incorrect reference to ISO 9000	Change 3.8.5 by 3.8.13	EAP
1174	PT	818	3.54	ISO DIS 9000:2014, 3.8.5	ISO DIS 9000:2014, 3.8.13	EAP
1175	SE	818	3.54	[SOURCE: ISO DIS 9000:2014, 3.8.5, modified – Note 1 to entry has been modified]	[SOURCE: ISO DIS 9000:2014, 3.8.13, modified – Note 1 to entry has been modified].	EAP
1176	JP 75	818	3.54	Cross-reference is incorrect.	3.8.5 should be 3.8.13.	EAP
1177	IQN ET	819	Section 3	As it is written it is still short for a quick and clear differentiation from verification to all kind of users, The common definition provides more clarity (although not enough to QMS purposes) Cambridge definition to make something officially acceptable or approved , especially after examining it:	Redefine considering convergence with dictionary meaning: Acceptance, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled	TN
1178	IAQ G	820	3.55	The definition for validation is focused on product design.	Add note - clarify Proposal: Include the following as a note: When validation is used in a design and development context, it is focused on a	TN

					determination of fulfilment of a product or service requirement. When validation is used in the context of a process its focus is on determining fulfilment of a specified process outcome.	
1179	BR	821	3. Terms and definitions/ 3.55	Lack of inclusion of item number of "Terms and definitions" and change the word form to italic.	confirmation, through the provision of <i>objective evidence</i> (3.51), that the <i>requirements</i> (3.03) for a specific	EAP
1180	ANS I	821	3 Terms and Definitions	"objective evidence, that" leaves out reference to where the term objective evidence is defined	Revise to "objective evidence (3.51), that"	EAP
1181	AU	822		Intended use	Should be intended function	TN
1182	ANS I	824	3.55	The words "such as performing alternative calculations or reviewing documented information (3.11)" are simply repeats of the same words in line 814 under verification. The words are valid for verification, BUT NOT OBJECTIVE EVIDENCE FOR VALIDATION, which requires evidence that intended use or application HAS BEEN FULFILLED.	Delete "such as performing alternative calculations or reviewing documented information (3.17)". An alternative wording could be "Where test results or other forms of direct objective evidence (such as installation and/or operation of the delivered product or service) cannot be obtained, <i>customer concurrence</i> to proposed documented information on validation methodology can be utilised."	TN
1183	JP 194.	824	3.55	Different from 3.8.14 of DIS 9000. The "document" is changed to "documented information."	The definition in ISO 9000 and 9001 should be identical.	TAF
1184	PH/ BPS	827	3.55	Source of definition of validation is incorrect	SOURCE: ISO DIS 9000:2014, 3.8.14	EAP
1185	MX	827	3	incorrect reference to ISO 9000	Change 3.8.6 by 3.8.14	EAP
1186	PT	827	3.55	ISO DIS 9000:2014, 3.8.6	ISO DIS 9000:2014, 3.8.14	EAP
1187	SE	827	3.55	[SOURCE: ISO DIS 9000:2014, 3.8.6, modified – Note 1 to entry has been modified]	[SOURCE: ISO DIS 9000:2014, 3.8.14, modified – Note 1 to entry has been modified]	EAP
1188	JP 76	827	3.55	Cross-reference is incorrect.	3.8.6 should be 3.8.14.	EAP
1189	GB	828	3.56	3.56 feedback opinions, comments and expressions of interest in a product, a service or a complaints-handling process a product, a service or a complaints-handling process - three 'a' not required. one before product is justified. complaints-handling process should be complaint-handling process.	3.56 feedback opinions, comments and expressions of interest in a product, a service or a complaints-handling process opinions, comments and expressions of interest in a product, service, or complaint-handling process	EN

1190	GB	828	3.56	Complaints are feedback, the complaints handling process is how we deal with feedback. Feedback can include positive or negative comments about the complaints handling process.	3.56 Feedback: positive or negative opinions and comments relating to a product or service, or to the complaints handling process.	TN
1191	GB	828	3.56	Improve readability by removing extra 'a' s.	opinions, comments and expressions of interest in a product, a service or a complaints-handling process	EN
1192	ANS I	830 - 831	3 Terms and Definitions	By specifying "in a product, a service or a complaint-handling process" you have a very limited definition of feedback. Other types of feedback are important to an organization – comments related to the relationship between parties (e.g., supplier/customer relationship),	Delete the following: in a product, a service or a complaints-handling process	TN
1193	ANS I	830 -831	3.56	Need to add clause # after defined terms (product, service, process) to be consistent.	Add clause # after each defined terms.	EAP
1194	ANS I	830	3 Terms and Definitions	"expressions of interest in" unsure what interest is intended to mean in this use	Revise to "opinions and comments of interested parties "	TN
1195	DK	830	3.56	A feedback can be to a process. Therefore add "process" into the definition.	Change the definition to read: feedback: opinions, comments and expressions of interest in a process , product, a service or a complaints-handling process	TN
1196	ANS I	831 / 832	3.56	The language is in the description for feedback is vague. I would suggest to add a Note to be more explicit about the meaning	Add "Note 1 Feedback can be positive, negative, or neutral."	TN
1197	FR	838	3.57	Delete « generally » from Note 1	Delete « generally » from Note 1	TN
1198	AU	834	3.57	Repeat of customer's – unless this is intentional.	835 <i>customer's</i> (3.26) perception of the degree to which the customer's their expectations have been fulfilled	EN
1199	CA-30	835	3.57	The DIS definition for 'customer satisfaction' is: " <i>customer's</i> perception of the degree to which the customer's expectations have been fulfilled". In ISO 9000:2005, the definition was: "customer's perception of the degree to which the customer's requirements have been fulfilled". The Annex SL & DIS definition for 'requirement' is " need or expectation that is stated, generally implied or obligatory " so, "expectation" is a part/sub-set of "requirement". Also, by replacing "requirements" with "expectations", but with no definition of "expectation", there is no longer an obligation that it has to be 'stated, generally implied or obligatory' i.e. it can be entirely in the mind of a	Since "requirements" was changed to "expectations" in the definition, then for consistency, the following change must be made in <i>Note 3 to entry</i> : "Even when customer (3.26) expectations have been agreed with the customer and subsequently fulfilled, this does not necessarily ensure a high level of customer satisfaction" See also, the comment on §9.1.2, <i>Customer satisfaction</i> , where it uses "requirements", not "expectations" CA-66	TN

				customer, and since it is that customer's perceptions about fulfillment of that expectation, this is a TOTALLY subjective situation. In this scenario, the organization is controlled by the customer. Certainly, customer focus is important, but being controlled by the customer would be an untenable position for an organization. Further, the DIS definition for 'customer satisfaction' has Note 3 to entry: "Even when <i>customer requirements</i> have been agreed with the <i>customer</i> and fulfilled, this does not necessarily ensure high customer satisfaction". Since, by the definition, 'requirements' can be replaced by 'needs or expectations', then, even if customer's needs or expectations have been fulfilled, this does not necessarily ensure high customer satisfaction. If the DIS definition for 'customer satisfaction' is to be retained, then for consistency, the Note 3 to entry must change to: "Even when <i>customer</i> (3.26) expectations have been agreed with the <i>customer</i> and fulfilled, this does not necessarily ensure high customer satisfaction." And if the expectations are agreed, then this would reduce the subjectivity level.		
1200	MA	836	3.61	There is redundancy with the definition 3.51	3.61 Audit evidence Objective evidence (3.51) obtained during the audit	TN
1201	PH/BPS	838	3.57	"Customer" in italic font but not followed by its entry number	customer (3.26)	EAP
1202	CA-31	840	3.57	The reference to complaints is out of sequence, and would be more appropriate at the end of this sub-clause	Move the text of current note 2 (re "Complaints") to the end of sub-clause 3.57, as a new "Note 5"	EN
1203	PH/BPS	842	3.57	"Customer" in italic font but not followed by its entry number	customer (3.26)	EAP
1204	CZ	847	3.58	We recommend to add an explanatory note to the term "complaint".	"Note 1 to entry The term "complaint" usually includes the appropriate complaint procedures, i.e. issue of the complaint protocol in order to claim the defective product or unsatisfactory service, as well as procedure for dealing with complaints, including negotiating a financial settlement."	TN
1205	GB	847	3.58	Missing space orservice	or service	EN

1206	FR	847	3.58	Delete <customer satisfaction> from the definition	Delete <customer satisfaction> from the definition	TN
1207	ANS I	849	3.58	This definition implies that a customer's expression of dissatisfaction is not a complaint if it can be shown that no response or resolution is explicitly nor implicitly expected.	"<customer satisfaction> expression of dissatisfaction made to an organization (3.01), related to its product (3.47) or service (3.48), or the complaints-handling process (3.12) itself."	TN
1208	14.	849	3.52	A Syntactical correction is required	Please replace: "<customer satisfaction> expression of dissatisfaction ...", with: "expression of dissatisfaction"	TN
1209	SE	849	3.58	Why is "<customer satisfaction> " included in the definition – this looks like an editing error	Delete	TN
1210	ANS I	851	3 Terms and Definitions	"where a response or resolution is explicitly or implicitly expected" – concern that this implies that an action is always required. As in a customer complaint that the price is too high or something is not immediately available where there is already information provided in advance but there is nothing to be done.	Revise to "where a response or resolution may is explicitly or implicitly be expected"	EN
1211	ANS I	853 -876	3.59 3.60 3.61 3.62	The source of these definitions is not ISO 9000. The source of these definitions is ISO 19011 and the experts responsible for that standard – which represent ALL management system TC's and should be the ones determining these definitions.	Source of definitions is ISO 19011.	TAP
1212	ANS I	856	3.59 Audit programme	The intent of all audits is to assess the current business management system performance as determined by establish criteria, i.e., customer, organizational and supplier requirements, and business management system objectives. I recommend adding language to this definition that includes these criteria.	Change the text to read: purpose and business management system processes and performance	TN
1213	AU	856		Purpose	That the suppliers' documented QMs and its policies and Processes and supporting documentation meets the requirements of ISO 9001:2014	TN
1214	PH/ BPS	857	3.59	Source of definition of audit programme is incorrect	SOURCE: ISO DIS 9000:2014, 3.10.11	EAP
1215	MX	857	3	incorrect reference to ISO 9000	Change 3.10.9 by 3.10.9	EAP
1216	PT	857	3.59	ISO DIS 9000:2014, 3.10.9	ISO DIS 9000:2014, 3.10. 11	EAP
1217	SE	857	3.59	[SOURCE: ISO DIS 9000:2014, 3.10.9]	[SOURCE: ISO DIS 9000:2014, 3.10.11]	EAP

1218	JP 77	857	3.59	Cross-reference is incorrect.	3.10.9 should be 3.10.11.	EAP
1219	GB	860	3.60	ISO/TC 176/SC1 should consider the amendment to this definition for ISO 9000, to be consistent with the Annex SL use of "documented information"		TN
1220	JP 196	860	3.60	Different from 3.10.14 of DIS 9000. The "procedure" is changed to "documented information."	The definition in ISO 9000 and 9001 should be identical.	TAF
1221	PH/ BPS	862	3.60	Source of definition of audit criteria is incorrect	SOURCE: ISO DIS 9000:2014, 3.10.14	EAP
1222	PT	862	3.60	ISO DIS 9000:2014, 3.10.12	ISO DIS 9000:2014, 3.10.14	EAP
1223	SE	862	3.60	[SOURCE: ISO DIS 9000:2014, 3.10.12, modified]	[SOURCE: ISO DIS 9000:2014, 3.10.14, modified]	EAP
1224	JP 78	862	3.60	Cross-reference is incorrect.	3.10.12 should be 3.10.14.	EAP
1225	SE	863 - 866	3.61	Why do we need Section 3.61 "objective/audit evidence" when we have Section 3.51 "objective evidence"? If a distinction needs to be made, then perhaps a note under Section 3.51 related to objective evidence related to audit should be included.	Delete 3.61	TAP
1226	LU	863	3.61	The difference between audit evidence and audit findings is quite low.	Remove the definition of audit evidence	TAP
1227	GR	863	3.61	The definition is superfluous. See 3.51, Note 2	Delete	TAP
1228	FR	863	3.61	Delete the definition, already defined in 3.51	Delete the definition, already defined in 3.51	TAP
1229	ANS I	864	3.61	The "objective / audit evidence" definition is confusing.	Remove slash mark "/"	TAP
1230	SE	864	3.61	"Objective evidence" is already defined under 3.51.	Remove objective from line 864	TAP
1231	IN	865	3.61	Objective /audit evidence Records, statements of fact or other information (3.50) ,which are relevant to the audit criteria (3.60) and verifiable Term objective evidence has its on definition (3.5.1) so word objective may be deleted as necessary	audit evidence Records, statements of fact or other information (3.50) ,which are relevant to the audit criteria (3.60) and verifiable	TAP
1232	PH/ BPS	867	3.61	Source of definition of objective/audit evidence is incorrect	SOURCE: ISO DIS 9000:2014, 3.10.15	EAP
1233	MX	867	3	incorrect reference to ISO 9000	Change 3.10.13 by 3.10.15	EAP

1234	PT	867	3.61	ISO DIS 9000:2014, 3.10.13	ISO DIS 9000:2014, 3.10.15	EAP
1235	SE	867	3.61	[SOURCE: ISO DIS 9000:2014, 3.10.13]	[SOURCE: ISO DIS 9000:2014, 3.10.15]	EAP
1236	JP 79	867	3.61	Cross-reference is incorrect.	3.10.13 should be 3.10.15.	EAP
1237	GB	872	3.62	Replace "recording" by "creating documented information on", to be consistent with Annex SL		TN
1238	QS	874	3.62	Note 3- starts with "in English" why used?	Clarify the use of "In English"	C
1239	ANS I	875	3.62	"Compliance/non-compliance" need to be clarified compared with conformity (3.18)/nonconformity (3.19).	If they are "synonymous but deprecated" (ref 3.18, Note 1, 555-556), or if they are interchangeable, state so to avoid confusion.	TN
1240	MX	876	3	incorrect reference to ISO 9000	Change 3.10.14 by 3.10.16	EAP
1241	PT	876	3.62	ISO DIS 9000:2014, 3.10.14	ISO DIS 9000:2014, 3.10.16	EAP
1242	SE	876	3.62	[SOURCE: ISO DIS 9000:2014, 3.10.14]	[SOURCE: ISO DIS 9000:2014, 3.10.16]	EAP
1243	JP 80	876	3.62	Cross-reference is incorrect.	3.10.14 should be 3.10.16.	EAP
1244	ANS I	878	3.63	A long standing equivalent term in the US for "concession" is "waiver".	Consider adding "Alternative definition: Waiver". Add reference to use in the US as appropriate.	TN
1245	ANS I	879 -880	3.63	In my experience, concessions can only be granted by customers. An organization cannot unilaterally grant itself a concession. Therefore, this should be added to the definition.	"permission, granted by a customer(s), to use or release (3.64) a product (3.47) or service (3.48) that does not conform to specified requirements (3.03)."	TN
1246	FR	885	3.64	Use the definition given in ISO/DIS 9000 :2014	Use the definition given in ISO/DIS 9000 :2014	TAF
1247	PH/ BPS	886	3.62	Source of definition of audit findings is incorrect	SOURCE: ISO DIS 9000:2014, 3.10.16	EAP
1248	ANS I	887 - 889	3 Terms and Definitions	"next stage of a process" – since a process is defined as input to output it would seem stage is incorrectly used here	Delete: "next stage" to show proceed to the next stage of a process (3.12). Also delete the Note as it is not applicable throughout the standard and adds complications. Note to entry: In English, in the context of software and documented information (3.11), the word "release" is frequently used to refer to a version of the software or the documented information itself.	TAP
1249	JP 197	888 889	3.64	Different from 3.11.7 of DIS 9000. The "document" is changed to "documented information" as below. In English, in the context of software and <u>documented information</u> , the word "release" is frequently used to refer to a version of the software or the <u>documented information</u> itself.	The definition in ISO 9000 and 9001 should be identical.	TAF
1250	BR	889	3. Terms and definitions/ 3.64	The word "software" is in italics, but it is not a term or definition.	Do not use italics for software	EAP
1251	PH/ BPS	889	3.64	"software" not needed to be in italic font	Software	EAP
1252	PH/ BPS	889	3.64	"Documented Information" in italic font but not followed by its entry number	documented information (3.11)	EAP

1253	FR	891	3.65	Definition needs to be completed	Characteristic : distinguishing feature of an object	TN
1254	FR	891	3.65	Add « intellectual » to the list under note 3	Add « intellectual » to the list under note 3	TN
1255	CZ	900	3.65	Semicolon should be used instead of a full stop at the end of the sentence.	To be corrected.	EAP
1256	FR	904	3.66	Add a precision to the definition	Add a note to precise that, depending on the context, performance indicators may be results or operational indicators Ajout d'une note exprimant le fait que les indicateurs de performance peuvent selon le contexte être des indicateurs de résultat ou de fonctionnement.	TN
1257	SE	905 - 908	3.66	Difficult to understand what term is being defined. Is it "performance indicator" or is it "performance metric." In either case the definition does not make sense. Citing only realization of output and customer satisfaction is limited. This definition needs work. Indicator could be, but is not limited to, metrics. Use only term <i>performance indicator</i> .	Delete line 906.	TAF
1258	CH	905 - 907	3.66	On lines 905 and 906 there are 2 words ahead of the definition on line 907. Only one term should be defined. The second term (performance metric) should be part of the definition.	<u>Change</u> to read: (bold type) "performance indicator" (Definition, not bold type) "performance metric, characteristic having ..."	TN
1259	ANS I	905 - 908 and 977		Do not understand what term is being defined. Is it "performance indicator" or is it "performance metric." In either case the definition does not make sense. Citing only realization of output and customer satisfaction is limited. This definition requires work.	Delete the definition and modify line 977 to show: the criteria, methods, including measurements and related performance indicators needed to ensure the effective operation, and control of these processes;	TAP
1260	ANS I	906	3.66 Performance indicator	Performance indicator and performance metric are the same. I recommend deleting performance metric	Change the text to read: Delete performance metric	TAP
1261	ANS I	906	3.66	Bold "performance metric" to be consistent.	Bold "performance metric."	EN
1262	JP 81	906	3.66	The term "performance metric" is not used in other part of the standard.	Delete the definition of "performance metric."	TAF
1263	LU	907	3.66	The definition of performance indicator is not relevant. An indicator is not a characteristic or a feature but the measure of it.	<u>Measure or value of</u> a characteristic (3.65) having significant impact on realization of the output (3.46) and customer	TN
1264	ANS I	910	3.66	I would expand this definition to the one in the next column. EXAMPLES <i>Nonconformities</i> (3.19) per million opportunities, first time capability, <i>nonconformities</i> per unit.	EXAMPLES <i>Nonconformities</i> (3.19) per million opportunities, first time capability, <i>nonconformities</i> per unit, infection rate, trend of procedures not being followed.	TN
1265	CZ	911	3.66	This note belongs to the term „characteristics“ (a full stop is missing).	To be deleted (or a full step should be added).	TAF
1266	SE	911	3.66	"The <i>characteristic</i> (3.65) can be quantitative or	Delete.	

				qualitative" This repeats Note 2 in 3.65.		TAP
1267	PH/ BPS	912	3.66	Source of definition of performance indicator is incorrect	SOURCE: ISO DIS 9000:2014, 3.12.3	EAP
1268	MX	912	3	incorrect reference to ISO 9000	Change 3.12.1.2 by 3.12.3	EAP
1269	PT	912	3.66	ISO DIS 9000:2014, 3.12.1.2	ISO DIS 9000:2014, 3.12.3	EAP
1270	SE	912	3.66	[SOURCE: ISO DIS 9000:2014, 3.12.1.2]	[SOURCE: ISO DIS 9000:2014, 3.12.3]	EAP
1271	JP 82	912	3.66	Cross-reference is incorrect.	3.12.1.2 should be 3.12.3.	EAP
1272	JP 83	913 -916	3.67	The definition of "determination" is not necessary. It is used with no more than dictionary meanings in DIS 9001.	Delete the definition of "determination."	TAP
1273	ANS I	914	3.67	Define determination so we can use it efficiently in section 3.15 and 3.16 in lines 526 through 533	Verify consistent use	TAP
1274	ANS I	915	3.68	The phrase, "activity to find out one or more characteristics (3.65) and their characteristic values" could be improved.	"activity to ascertain one or more <i>characteristics</i> (3.65) and their <i>characteristic</i> values"	TN
1275	PH/ BPS	915	3.67	"Characteristics" in italic font but not followed by its entry number	characteristic (3.65)	EAP
1276	TC6 9	915	3.67	The definition of the term "determination" is not clear enough: "activity to find out one or more characteristics (3.65) and their characteristic values" a) when the term is referred in the definition of the term "measurement" (3.16): "process (3.12) to <i>determine</i> (3.67) a value" b) when using the verb "find" that does not correspond to the current rationale of the "ISO/IEC Guide 99:2007 - International vocabulary of metrology", according to which "measurement" consists on "obtaining one or more values that can reasonably be attributed to a quantity"	New definition of the entry 3.67: "activity to obtain one or more characteristics (3.65) and, or, one or more values that can reasonably be attributed to"	TN
1277	CH	915	3.67	The inclusion and definition in 3.67 of the term 'determination' (from the verb 'determine') is very welcome. However, the verb 'determine' is used much more frequently than the word 'determination'. It would be preferable to have 'determine' as the basic defined term.	<u>Change</u> the term 'determination' (noun) to 'DETERMINE' (verb), and <u>change</u> its definition to "activity to FIND OUT ONE OR MORE ..." and <u>remove</u> the reference the source reference to ISO 9000.	TAP
1278	FR	917	3.68	Add process review to the examples	Add process review to the examples	TN
1279	FR	917	3.68	Concerns the french version 2ème alinéa : erreur de référence	2ème alinéa : remplacer "3.29" par "3.05"	EAP
1280	ANS I	919	3.68 Review	Business management system performance is based on effectiveness (compliance to customer specified requirements and satisfaction) and efficiency (organizational waste and variation	Change the text to read: <i>determination</i> (3.67) of the suitability, adequacy, effectiveness (3.06) and efficiency of an object (3.36) to achieve	TN

				reduction, i.e., Six Sigma). I recommend including language that addresses both effectiveness and efficiency.		
1281	JP 198	921	3.68	Different from 3.13.2 of DIS 9000. The "EXAMPLE" is changed to "EXAMPLES."	The definition in ISO 9000 and 9001 should be identical.	TAF
1282	CO	922	3.68	You do not determine the suitability, adequacy of effectiveness of nonconformities. (see review definition)	Delete nonconformity (3.19) from the example.	TAF
1283	SE	922	3.68	The example "nonconformity review" is not relevant. The meaning of "reviewing" a nonconformity in order to determine its "suitability, adequacy or effectiveness" is incomprehensible.	Delete the example "nonconformity review". Replacement by "review of corrective action" would make sense.	TAP
1284	AU	923	3.68	Better emphasises of the need to determine that people assigned/accepting responsible for undertakings are able to perform efficiently. ie. Are right for the job.	Add "of process and people" to the line.	TN
1285	PH/ BPS	924	3.68	Source of definition of review is incorrect	SOURCE: ISO DIS 9000:2014, 3.13.2	EAP
1286	MX	924	3	incorrect reference to ISO 9000	Change 3.13.1.1 by 3.12.2	EAP
1287	PT	924	3.68	ISO DIS 9000:2014, 3.13.1.1	ISO DIS 9000:2014, 3.13.2	EAP
1288	SE	924	3.68	[SOURCE: ISO DIS 9000:2014, 3.13.1.1]	[SOURCE: ISO DIS 9000:2014, 3.13.2]	EAP
1289	JP 84	924	3.68	Cross-reference is incorrect.	3.13.1.1 should be 3.13.2.	EAP
1290	JP 85	925 -929	3.69	WG24 has already decided to use the term "measurement resource" consistently in the standard.	Delete 3.69, the definition of "measuring equipment."	TAP
1291	IQN ET	925	Section 3	The standard now refers to resources	Change measuring equipment for measuring resource. Leave definition as is but remove reference to process	TN
1292	FR	925	3.69	Measurement is an activity not a process	Change the term « process » by « activity »	TN
1293	INLA C	929	New definition	Consider the development a definition of control and its inclusion in future ISO 9000. Is a term that is used in several parts of the standard and can have different interpretations in different contexts.	Current Guidance Document ISO/TC176/SC1/WG1/N318 includes a couple of meanings of control: - power to direct, restrain or regulate - means of restraining or regulating	TN
1294	INLA C	929	New definition	It is important to include the concept of "Business continuity" and some aspects in relation with this issue in the standard.	Include definition of "Business Continuity"	TN
1295	PH/ BPS	929	3.69	Source of definition of measuring equipment is incorrect	SOURCE: ISO DIS 9000:2014, 3.13.9	EAP
1296	MX	929	3	incorrect reference to ISO 9000	Change 3.13.5 by 3.13.9	EAP
1297	PT	929	3.69	ISO DIS 9000:2014, 3.13.5	ISO DIS 9000:2014, 3.13.9	EAP
1298	SE	929	3.69	[SOURCE: ISO DIS 9000:2014, 3.13.5]	[SOURCE: ISO DIS 9000:2014, 3.13.9]	EAP
1299	JP 86	929	3.69	Cross-reference is incorrect.	3.13.5 should be 3.13.9.	EAP
1300	CN	930	3.70	Add a definition of "issue" or replace with		TN

				"problem"		
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1301	GOS T R	931	4 Context of the organization	The term "Context" should be defined		TN
1302	ANS I	932 - 941		The title of this requirement is "Understanding the organization and its context". Use of the word "issues" indicates a negative situation – that something is a problem. Factors exist which represent opportunities to be pursued or exploited – a positive situation. Suggest that the word "factors" instead of the word "issues". The definition 3.24 context of the organization uses factors.	While no recommendation is being made at this time to change issues to factors, the fact that there is disagreement between the definition and the text has the potential to confuse users. This issue must be corrected in the common text.	TAP
1303	SE	932 - 941	4.1	The title of this requirement is "Understanding the organization and its context". Use of the word "issues" indicates a negative situation – that something is a problem. Factors exist which represent opportunities to be pursued or exploited – a positive situation. I would suggest that the word "factors" instead of the word "issues".	Issues to be replaced by <i>factors</i>	TAP
1304	BG	932	4.1	Change the wording of: 4.1 Understanding the organization and its context	To become: 4.1 Determining the organization's context	TN
1305	MU R	933 - 935	4.1	The term "sustainable development" has been mentioned in the introduction (Line 193) and the word sustainable has not been used in the text. We propose to add the term "sustainable at the end of the sentence.	The organization shall determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system <i>in a sustainable manner</i> .	TN
1306	IE	933 -934	4.1	The requirement "to determine" should be more specific.	Rephrase Line 934 as: "strategic direction and collect related information that affects its ability to achieve "	TN
1307	IIOC	933	4	The word 'issues' is used without context throughout the standard.	Include a definition of 'issues' in section 3.	TAP
1308	IIOC	933	4	The word 'issues' is used without context throughout the standard.	Include a definition of 'issues' in section 3.	TAP
1309	AT	933	4.1	1) The wording can be simplified by integrating "monitor and review" into the main sentence. The second sentence can be dropped,	The organization shall determine, monitor and review external and internal issues that are relevant to its purpose and its strategy and that	TN

				without change of meaning of the clause. 2) Instead of using the term “strategic direction” the word “strategy” should be used, as this is the word used in the definitions. Adding the word direction does not add value. The term “strategic direction” to be replaced by “strategy” in the whole document	affect its ability to achieve the intended result(s) of its quality management system. The organization shall monitor and review the information about these external and internal issues. << The term “strategic direction” to be replaced by “strategy” in the whole document >>	
1310	IAQ G	933	4.1 and 6.1.1 by ref	Not sure the term “issues” is the correct word here: Is: “The organization shall determine external and internal <u>issues</u> that are relevant to its purpose”	Add text – improve Proposal: “The organization shall determine external and internal <u>issues dependencies and needs</u> that are relevant to its purpose”	TN
1311	NL	933	4.1	Using “issues” could lead to misinterpretation. E.g. which detail is required (e.g. details or just subjects) Also applies to 9.3.1.b) Management review	The organisation shall determine (<u>internal and external</u>) <u>areas of concern</u> that are relevant to.....	TAP
1312	CA- 32	933	4.1	It would be essential that a definition for “issue” be added to the definition list or this will cause confusion on the intent. The concept of “issue” can vary from one individual to another. The Bible uses the term to mean ‘offspring’ and the Spanish translation will have ‘an issue’ with this. Dictionary.com provides 32 definitions of which 7 are nouns. None fit our usage well. If the term issue is not added, clarity should be brought into the text to clearly define the intent the standard has for the term “issue”. The term ‘issues’ is commonly used to refer to areas of concern. Perhaps the term “factors” could be considered, as it is neutral, and is more appropriate, as this is intended to consider enabling factors such as those mentioned in Note 2.	SC1 must be tasked to provide a clear definition for “issue” and be compatible also in ISO/TS 9002 OR Consider the possible use of “factors” as follows: (933) “The organization shall determine external and internal factors that are relevant to its purpose and ...” (936) “The organization shall monitor and review the information about these external and internal factors.” (940) “NOTE 2 Understanding the internal context can be facilitated by considering factors related to values, culture, knowledge ...”	TAP
1313	FI	933	4	Annex SL text must be respected. Additional text should not be added into the middle of the Annex SL text. The main purpose of the original Annex SL text is totally changed! Also the title 4.4 Quality Management system (delete: ... and its processes) Factually strategic direction is an issue of para 6	The purpose of Annex SL and its text must be respected	TAP
1314	SE	933	4.1	In line with the above	“The organization shall determine the external and internal factors that are relevant to its purpose...	TAP
1315	IAQ	933	4.1	As this clause is written, it suggests an	IAQG Priority Comment	TAP

	G	, 934, 935, 937, 956		organization should only be interested in external and internal issues which indicates problems. The word "issues" will cause confusion as it is used in this clause.	Reword – improve Proposal: Substitute the word "issues" with either "factors" or "elements", "aspects"...	
1316	IIOC	934	4.1	Line 934 - the amendment of "outcomes" to "results" is not allowed (HLS)	Change "results" back to "outcomes" this is a fundamental issue for correct application of the HLS as it relates to the intended outcomes of implementing the QMS which is defined within clause 1. Note 1 should also reference environmental issues some links to 4.2	TN
1317	RO	934	4.1	For consistency with 3.08.	To replace "intended result(s)" with "objective(s)".	TN T
1318	MY	934	4.1	The term "intended result(s)" is used throughout the standard in place of "intended outcome(s)", which is the term used in the common text of the HLS as well as in other new and revised MSS including ISO 14001.	If the use of the term is to be retained, there should be an explanation to justify its use and for the deviation from the common text of the HLS.	TN
1319	AU	934	4.1	The word 'result' is not used in relation to the purpose of the QMS. It would be better to stay with 'objectives'.	Replace, 'result(s)', with, 'objectives'	TN
1320	NG	934	4.1	"..... its strategic direction and that affects its ability achieve the intended result(s) of its QMS"	Change to "..... its purpose, strategic direction and that which affects its ability to achieve the intended result of its QMS"	EN
1321	JP 87	934	4.1	The justification for changing the Annex SL text from "outcome" to "result" is not strong enough, if it is only due to translational issue in Spanish. Other countries have translational issues more or less, too.	Back to the Annex SL, "outcome(s)."	TN
1322	MX	936	4.1	It is understands that they are all internal and external issues	Add "relevant" to read: The organization shall monitor and review the information about these relevant external and internal issues.	TN
1323	ANS I	936	4.1	The words monitor and review along with information implies documented information related to external and internal issues. This along with the requirement in Management Review 9.3.1 b) that requires that changes in external and internal issues that are relevant to the quality management system be considered as an input implies documented information. Since Management Review has a required "retain documented information" requirement, this would imply documented information here. Additionally, the determined internal and external issues are used as an input for determining the scope, which is documented information. Care should be given not to confuse users with	Revise to Option 1 The organization shall monitor and review the information about these external and internal issues <u>and shall retain documented information to the extent necessary.</u> Option 2 The organization shall monitor and review the information about these <u>determined</u> external and internal issues.	TN

				standard terminology. Two options are provided to resolve this issue		
1324	IAQ G	936	4.2	The “shall” requirements to determine interested parties, the requirements of these interested parties, and to “monitor and review the information about these interested parties” are very broad statements. An organization may have dozens, hundreds, or thousands of “interested parties” with each having hundreds of requirements. How is this auditable? The use of shall statements should be limited to things that are less subjective and more tangible. For example what constitutes “information” about these interested parties? Using this knowledge to help determine the scope of the QMS makes sense, but “monitoring it and reviewing it” is far too broad of a requirement to audit.	IAQG Priority Comment Reword – clarify Proposal: further define <u>interested parties</u> 4.2 Understanding the needs and expectations of interested parties Due to their impact or potential impact on the organisation’s ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, the organization should consider : a) the interested parties that are relevant to the quality management system; b) the requirements of these interested parties that are relevant to the quality management system.	TN
1325	PE	936	4.1	It says: “The organization shall monitor and review the information about these external and internal issues”. This requirement, as it is presented, does not request any evidence; which is contrary to all other <u>monitoring</u> requirements included in this DIS where the request “ <i>retain documented information</i> ” is always mentioned.	It should say: <i>The organization shall monitor and review the information about these external and internal issues and retain documented information</i> .”.	TN
1326	PE	936	4.2	This requirement, as it is presented, does not request any evidence; which is contrary to all other <u>monitoring</u> requirements included in this DIS where the request “ <i>retain documented information</i> ” is always mentioned.	It should say: <i>The organization shall monitor and review the information about these interested parties and their relevant requirements, and retain documented information</i> ”.	TN
1327	PT	936 1139 936	7.1.6 4.1	We agree with the requirement, but we remark that changing needs and trends is a concept that only appears in this section and is not supported elsewhere in the standard. How can an organization address this if it does not need to be addressed in the context, as it was in previous CD	Include in section 4.1 a reference to changing needs and trends The organization shall monitor and review the information about these external and internal issues, including changing needs and trends	TN
1328	IQN ET	936 1139	4.1 7.1.6 6.3 8.1, 8.5	Consideration of changing needs and trends in section 4.1 was explicit in CD 1 and disappeared in DIS, reappearing in section 7.1.6 Organizational knowledge. This reference to changing needs and trends is now “loose” in section 6.1 with no further support elsewhere in the standard, which may cause confusion On the other hand DIS 9001 proposes a	Include in section 4.1 reference to changing needs and trends. Proposal: The organization shall monitor and review the information about these external and internal issues, where relevant to determine changing needs and trends	TN

				consistent approach in dealing with change in several sections of the standard (6.3, 8.1 and 8.5, 10). By removing reference in section 4 to changing needs and trends, the standard is failing to recognize that one of the most important inputs of information to address change comes from analysing the context. Finally 4.1 requires to monitor and review the determined internal and external issues, linking to 9.3.1, but it does not provide a clear rationale for the need, which may lead to a less sound approach by organizations		
1329	PL	936	4.1	We suggest to add statement that organisation shall use results of external and internal issues monitoring in quality management system planning. The purpose of determination and later monitoring of external and internal issue is not defined.	After the sentence "The organization shall monitor and review the information about these external and internal issues." add "The organization shall take into consideration the results of the above monitoring in quality management system planning."	TN
1330	QS	936	4.1	"The organization shall monitor and review the information about these external and internal issues"- Why ? and When? These requirements are to be implemented is required for more clarity	Include the answer to the following as requirement: the objective of this monitoring and review what is the output of this monitoring and review? when this has to be addressed in QMS? Like during QMS planning stage or during implementation stage or to be considered during Management review?	TN
1331	TT	936	4.1	The level of monitoring and reviewing information of these external and internal issues has been weak, in the past. The intent and value of this exercise should be explicit to the users. The credibility of information must be treated with high importance as it impacts on the decision-making process and on the bottom line. Credibility needs to be emphasised. It is recommended that this is done in ISO 9002 draft standard (Implementation of 9001).		C
1332	IT	936	4.1	Line 936 states that "<i>The organization shall monitor and review the information about these external and internal issues.</i>" It is not clear how to fulfill this requirement without relevant documented information. A cross-reference to clause 9.3.1 should be proper too.	Modify 2nd paragraph as follows: <i>The organization shall monitor and review the information about these external and internal issues. The organization shall retain documented information to the extent necessary to effectively implement planning (see 6.1).</i> Consider to make a cross-reference to clause	TN

					9.3.1.	
1333	TC2 10	936	4.1	The inclusion of the indefinite article is confusing and implies that there is some specific information on internal and external issues.	Delete 'the' before information and amend to "The organization shall monitor and review information about these external and internal issues."	EAF
1334	SE	936	4.1	In line with the above	The organization shall monitor and review the information about these external and internal <i>factors</i> .	TAP
1335	IE	937 /938/939	4.1	As ISO 9001:2015 may be the first introduction to a risk based approach for many organisations, there is a risk that the users of the standard will limit external context issues to those listed in Note 1 and the list is currently not comprehensive although it is positive to see market included.	Possible additional issues to include would be: • Regulatory • Financial • Natural – physical or mishap • Reputation – bad publicity, environmental Another approach would be to take the external context items listed in ISO 31000 4.3.1 • Evaluating the organization's external context may include, but is not limited to: a) the social and cultural, political, legal, regulatory, financial, technological, economic, natural and competitive environment, whether international, national, regional or local; b) key drivers and trends having impact on the objectives of the organization; and c) relationships with, and perceptions and values of, external stakeholders.	TN
1336	NL	937	4.1	Demographic, political and ecological issues can also be relevant to the quality management system, and are well known aspects in determining a strategic direction for an organization.	Add (bold) Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social, demographic, political, ecological and economic environments, ...	TN
1337	ZA	937		Note 1 may be enhanced by including the consideration of 'political' issues along with the others already mentioned.	NOTE 1 Understanding the external context can be facilitated by considering issues arising from political, legal, technological, competitive, market, cultural, social, and economic environments, whether international, national, regional or local.	TN
1338	FR	937	4.1	Complete the note	Add to the list of external context : ecological environment and political Ajouter dans le contexte externe l'environnement écologique et politique	TN

1339	TBS	938	Sub clause 4.1	Organization need to monitor and review the information about external issues includes political	Add the word "Political" after the word "Legal"	TN
1340	ANS I	940 -941	4.1	The phrase performance of the organization is used here. There is confusion with how the word performance is used throughout the standard. For consistency, one approach should be used.	NOTE 2 Understanding the internal context can be facilitated by considering issues related to values, culture knowledge and performance of the <u>organization quality management system</u> .	TN
1341	CH	940 -941	4.1	A comma is missing between the words 'culture' and 'knowledge'.	<u>Add</u> a comma to read: "... values, CULTURE, KNOWLEDGE and ..."	EAF
1342	SE	940 -941	4.1	"Understanding the internal context can be facilitated by considering issues related to values, culture knowledge and performance of the organization" It is not obvious whether or not there should be a comma after "culture".	If there should be no comma, what does culture knowledge mean? Knowledge about the organization's culture among the organization's people? Please clarify.	EAF
1343	IE	940 /941	4.1	As ISO 9001:2015 may be the first introduction to a risk based approach for many organisations, there is a risk that the users of the standard will limit internal context issues to those listed in Note 2 and the list is currently no comprehensive.	Possible additional issues to include would be: • Replace "Knowledge" with "People (Knowledge, loss of key persons/talent, fraud)" • Add "Infrastructure, support" • Add "Product (launch, delays, R&D expenditure)" • Add "Financial (credit/funding availability, cashflow" Another approach would be to take the internal context items listed in ISO 31000 4.3.1 Evaluating the organization's internal context may include, but is not limited to: – governance, organizational structure, roles and accountabilities; – policies, objectives, and the strategies that are in place to achieve them; – capabilities, understood in terms of resources and knowledge (e.g. capital, time, people, processes, systems and technologies); – information systems, information flows and decision making processes (both formal and	TN

					informal); – relationships with, and perceptions and values of, internal stakeholders; – the organization's culture; – standards, guidelines and models adopted by the organization; and – the form and extent of contractual relationships.	
1344	ANS I	940	4 Context..., 4.1	Text is grammatically weak.	Insert "the" between "to" and "values."	EN
1345	BY	940	4.1	We offer a new version.	«NOTE 2 Understanding the internal context can be facilitated by considering issues related to values, culture knowledge, performance and other management system of the organization.»	TN
1346	MX	940	4.1	I ask you if it is necessary a comma at the end of the first line "culture, knowledge" or "culture knowledge" is a new concept	"Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge and performance of the organization."	EAF
1347	CA- 33	940	4.1	"NOTE 2 Understanding the internal context can be facilitated by considering issues related to values, culture knowledge and performance of the organization." It is uncertain if it is issues related to 'culture knowledge' or 'culture' and 'knowledge'. I believe that they are separate, so the terms should be separated by a comma.	Change to: "NOTE 2 Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge and performance of the organization."	EAF
1348	GB	940	4.1	NOTE 2 Understanding the internal context can be facilitated by considering issues related to values, culture knowledge and performance of the organization. separate culture and knowledge with a comma	NOTE 2 Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge and performance of the organization.	EAF
1349	JP 88	940	4.1	Add comma after "culture" in the text of Note 1, for correction.	Corrected text reads: ...by considering issues related to values, culture, knowledge and performance of the organisation.	EAF
1350	ES	942	4.2	Considering that the object of the standard is to specify requirements for a QMS where an organization a) needs to demonstrate its ability to consistently <u>provide product or service that meets customer and applicable statutory and regulatory requirements</u> , and... We propose to delete the connexion to interested parties.	Delete as follows: 4.2 Understanding the needs and expectations of interested parties Due to their impact or potential impact on the organisation's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, the organization shall determine: a) the interested parties that are relevant	TN

				With the proposal we follow the Annex SL structure and we focus on product and service objet of the QMS, being as well consistent with 8.3.1 General <i>"Where the detailed requirements of the organization's products and services are not already established or not defined by the customer or by other interested parties"</i>	to the quality management system; b) the requirements of these interested parties that are relevant to the quality management system that shall be incorporated as requirements of product and service. The organization shall monitor and review the information about these interested parties and their relevant requirements.	
1351	BG	942	4.2	4.2 Understanding the needs and expectations of interested parties	4.2 Determining the needs and expectations of the organization's interested parties	TN
1352	GOS T R	942	4.2 Understandi ng the needs and expectations of interested parties	Add " expectations"	Understanding the needs, requirements and expectations of interested parties	TN
1353	TN	942	4	The concept is used for other interested parties in other standards interact with the ISO 9001	Replace interested stakeholders to get closer to the ISO 26000 parts	TN
1354	FR	942	4.2	Add ISO 26000 in bibliography	Add ISO 26000 in bibliography	TN
1355	CH	942 , 947	4.2	While the title talks of ' <u>needs and expectations</u> of interested parties', the text body talks of ' <u>requirements</u> of these interested parties'. Recognizing that the definition in 3.03 defined 'requirements' as 'needs and expectations', it is however unclear whether (the other way round) 'needs and expectations' can be defined as 'requirements'. In order to avoid unproductive discussions with auditors, the use of these terms should be <u>consistent</u> .	<u>Change</u> title and/or text body to read < either > "4.2 Understanding the <u>needs and expectations</u> of interested parties the organization shall determine: b) the NEEDS AND EXPECTATIONS of these interested parties" < or > "4.2 Understanding the REQUIREMENTS of interested parties the organization shall determine: ... b) the <u>requirements</u> of these interested parties"	TN
1356	SE	943 -947	4.2	The logic of the requirement is difficult to understand. Some change needs to be made. An analysis of the possible impacts of the different interested parties listed as examples in 3.02 shows that they should not primarily be linked with the organization's quality management system but rather with the organization's operations (which could be understood as including its products and services). The requirement would make sense if "the quality	Replace "the quality management system" with "the organization".	TN

				management system” be replaced by “the organization....”.		
1357	ANS I	943 -945	4.2	The use of relevant interested parties is still difficult to understand related to application. The definition 3.02 indicates that an interested party can be someone that perceives themselves to be affected by a decision or an activity. For this reason, stronger clarification is needed to avoid confusion by users in the future.	NOTE <u>Relevant</u> interested parties can vary from organization to organization based on the products and services it provides and their ability to affect conformity to product requirements. It can include, but is not limited to, customers, bodies that specify statutory or regulatory requirements, owners, employees, unions, suppliers, investors, and/or competitors.	TN
1358	ANS I	943	4.2	Clarify that impact is current or potential.	Due to their <u>current</u> impact or potential impact	EN
1359	DK	943	4.2	The first two lines are a rationale and should be deleted.	Rewrite to: Due to their impact or potential impact on the organisation's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, <u>the organization shall determine</u>	TN
1360	NL	943	4.2	Relevant interested parties are those who 'Due to their impact or potential impact on the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements'. Bullet a) and this text have the same intention. Text is redundant.	Remove: 'Due to their impact or potential impact on the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements'	TN
1361	IE	943	4.2	The text is inelegant and hard to read	Start the sentence “As the impact or potential impact of interested parties on the organisation's ability”	EN
1362	SE	943	4.2	Recognized practice in ISO standards.	Spell “organization's” with “z”.	EAF
1363	INLA C	943 & 944	4.2	Remove the opening sentence: “Due to their impact or potential impact on the organisation's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements” Is redundant with the scope. Also, is not consistent with ISO/DIS 14001.	The organization shall determine:	EN
1364	RO	943 , 944	4.2	For clarity.	To replace “Due to their impact or potential impact” with “Due to their <u>existing</u> or potential impact” To replace “applicable statutory and regulatory requirements” with “ <u>related</u> applicable statutory and regulatory requirements”.	EN
1365	IAQ G	944	4.3	4.3 discusses requirement for documenting justifications where an ISO9001 requirement cannot be applied. This is further discussed in Annex A section A.5. Where this replaces the old	Add text - improve Proposal: Revise wording to add (see Annex A.5) to the end of the requirement in 4.3.	EN

				exclusion concept, there will be a need to strengthen the connection between the requirement and the clarification for better understanding by all stakeholders. There should be a cross reference between the requirement and the clarification. References seem to be used throughout the DIS for significant cross references.	Justification for any instance where a requirement of this International Standard cannot be met (see Annex A.5)	
1366	TC4 6/SC 11 Liais on (AU)	944	5.1.1	'taking accountability of the effectiveness...'	Change to 'taking accountability for the effectiveness...'	EAF
1367	BR	945	4.2	To streamline the clause and make it more clear change as suggested, and delete te last paragraph	Due to their... organization shall determine, monitor and review : And delete last paragraph (lines 948-949)	EN
1368	CA- 34	945	4.2	Lines 945-947 Modify the current wording (copied below) to the wording shown in the column on the right. (945) organization shall determine : (946) a) the interested parties that are relevant to the quality management system; (947) b) the requirements of these interested parties that are relevant to the quality management system.	(945) organization shall: (946) a) identify the interested parties that are relevant to the quality management system; (947) b) determine the requirements of these interested parties that are relevant to the quality management system.	EN
1369	AU	946 /947		To better describe that the main emphasis should be on the "organization" and not on the quality management system	Replace "to the quality management system" with "to the organization and its quality management system" for both lines.	TN
1370	MX	947	4.2	The requirements of these interested parties that are relevant to the quality management system	The requirements of these interested parties that are relevant to the quality of products and services RATIONALE: The requirements of interested parties affect mainly products and services. If the organization uses risk thinking then it is important to take into account the needs and expectations of interested parties that could affect the QMS	TN
1371	NL	947	4.2	QMP Customer focus (ISO/DIS 9000, line 172) requires the organization to take action on interested parties' needs and expectations that can affect customer satisfaction.	Add c) Determine and take actions on interested parties' requirements that can affect customer satisfaction	TN
1372	NL	947	4.2	Bullet b) 'that are relevant to the quality management system' is redundant since 'these' refers to bullet a ('the interested parties that are relevant to the quality management system'. User could be confused about two times 'relevant'.	Remove (bold) b) the requirements of these interested parties that are relevant to the quality management system .	TN

1373	NL	947	4.2	Not all requirements of 'these' interested parties are relevant to the products or services of the organization. User could think all requirements of relevant interested parties are relevant to the system. Bullet b) should be more specific to clarify to users.	Add (bold) b) the requirements, related to the products or service of the organization , of these interested parties.	TN
1374	QS	947	4.2	remove "that are relevant to the quality management system", as this is repeating..	the requirements of these interested parties that are relevant to the quality management system.	TN
1375	SE	947	4.2	"the requirements of these interested parties that are relevant to the quality management system" "these" implies that "interested parties" are the same as the ones mentioned in a). The words added in black are redundant. It seems somewhat odd that the title is about "needs and expectations" whereas "requirements" appears in b).	"the needs and expectations of these interested parties."	TN
1376	IR	947 and 949	4.2	Taking into account the title of this sub-clause a distinction may be needed to be made between "requirements" and "needs and expectations". Not all interested parties' needs and expectations can be considered as requirements.	Replace the word "requirements" by the word "needs and expectations" in item b) of Para 1 and Para 2 of the sub-clause 4.2	TN
1377	ANS I	948 -949	4.3	The words monitor and review along with information implies documented information related into interested parties and their relevant requirements. This along with the requirement in Management Review 9.3.1 c) 5) issues concerning external providers and other relevant interested parties as an input implies documented information. Since Management Review has a required "retain documented information" requirement, this would imply documented information here. Additionally, the determined interested parties are used as an input in determining the scope, which is documented information. Care should be given not to confuse users with standard terminology. Two options are provided to resolve this issue.	Revise to Option 1 The organization shall monitor and review the information about these interested parties and their relevant requirements <u>and shall retain documented information to the extent necessary.</u> Option 2 The organization shall monitor and review the information about these <u>determined</u> interested parties and their relevant requirements.	TN
1378	IT	948 -949	4.2	It is not clear how the essential requirement " <i>The organization shall monitor and review the information about these interested parties and their relevant requirements</i> " can be assessed without relevant documented information. [CRITICAL COMMENT]	Modify 2 nd paragraph as follows: <i>The organization shall monitor and review the information about these interested parties and their relevant requirements. The organization shall retain documented information to the extent necessary to effectively implement planning (see 6.1).</i>	TN
1379	SE	948 -949	4.2	"...about these interested parties and their relevant requirements." It seems somewhat odd that the title is about	"...about these interested parties and their relevant needs and expectations."	TN

				"needs and expectations" whereas "requirements" appears on line 949.		
1380	QS	948 and 949	4.2	"The organization shall monitor and review the information about these interested parties and their relevant requirements." Why ? and When? These requirement are to be implemented is required for more clarity	Same as above (4.1)	TN
1381	IT	949 -950	4.2	It would be appropriate to include a note of support.	Add the following note: Note 3 to entry: Interested parties can be internal or external to the organization.	TN
1382	ANS I	After 949	4.2	When considering the users, it's important to ensure that text is comprehensible to small (often less sophisticated) organizations – like small machine shops.	Consistent with the notes after 4.1, include a note at the end of 4.2 citing examples of interested parties.	TN
1383	SE	949	4.2	See general comment about requirements of interested parties.	Delete "relevant requirements" and insert" needs and expectations"	TN
1384	CH	950 -960	4.3	There is <u>inconsistent</u> use of words, leading to confusion. On line 950, the scope is to be 'determined', but on line 952, the scope is to be 'established'. The words 'determining/determined' are partly being used <u>differently</u> from 3.67. Sometimes these words are being used with the meaning 'deciding on/decided'.	Applying the definition in 3.67, <u>change</u> to read: " <u>Determining DECIDING ON the scope of the quality management system</u> <u>The organization shall determine the boundaries and applicability of the quality management system to establish its scope.</u> <u>When determining DECIDING ON this scope, the organization shall consider:.....</u> Where a requirement of this International Standard within the determined DECIDED scope can be applied, then it shall be applied by the organization."	TN
1385	IAQG	950	4.3	Concern - Less reliance on quality manual: Requirements addressed in DIS (Clause 4.3)	Add text – improve Proposal: Since now a "documented information" is required (line 965), to rename clause 4.3 (Determining the scope of the quality management system) to "Determining and documenting the scope of the quality management system".	TN
1386	FR	950	4.3	Shorten the title	Replace by "Scope of the QMS"	TN
1387	IAQG	951	4.2.2	Requirement for a Quality Manual will enable both the organization and ISO auditors to more easily locate and evaluate compliance requirements of the standard.	IAQG Priority Item Add text – improve Proposal: Recommend requirement for Quality Manual be maintained.	TN
1388	CQI 30	951 , 962 and 967 - 968	4.3	- products and services ... - justification for any... The two bullets are unordered; to be consistent with all other lists in the standard and to ensure sufficient unique identification of requirements the bullets should be ordered. AND for consistency with all other clauses with	4.3.1 The organization shall determine the boundaries and applicability... AND 4.3.2 The scope shall be available and be maintained as documented information stating the:	EN

				more than one ordered list clause 4.3 should be split into two: 4.3.1 and 4.3.2 at lines 951 and 962 respectively.	a) products and services covered by the quality management system; b) justification for any instance where a requirement of this International Standard cannot be applied.	
1389	LU	954	4.3	It could be meanfull to include Strategy and Policies as inputs to consider the scope	d) <u>the strategy and policies of the organisation.</u>	TN
1390	PL	956	4.3 a)	To be clear, to reflect the intent of the standard that what external and internal issues the organization shall consider it is only what is relevant to its QMS, we suggest to add: <u>the external and internal issues relevant to the quality management system referred to in 4.1;</u> It is not well, if we are able to understand requirements after reading informative Annex. Informative is not a requirement, it is only guidance.	a) <u>the external and internal issues</u> relevant to the quality management system <u>referred in 4.1;</u>	TN
1391	CA-35	956	4.3	Noting that the main purpose of the QMS is to ensure that it's customers obtain the quality of product/service they expect, bullet c) should be listed first, i.e " a) the products and services of the organization." In bullet a), which would then become bullet b), replace the word 'issues' with the word 'factors'.	Revise to read "" a) the products and services of the organization," Now b) changes to: "b) the external and internal factors referred to in 4.1;"	EN
1392	ES	957	4.3 b)	Interested parties should be removed from the requirement. Deletion fulfills the Annex SL structure and is consistent with 4.2	Delete interested parties: b) the requirements of relevant interested parties referred to in 4.2;	TN
1393	NL	957	4.3	'relevant' is redundant since this is determined in 4.2	Remove (bold) b) the requirements of relevant interested parties referred to in 4.2	EN
1394	MUR	958	4.3	Not to use the word organization twice in same sentence.	To restructure the sentence as follows: c) its products and services of the organization ;	EN
1395	INLAC	958	4.3 c)	The scopes that are defined in many of the QMS are more about processes than products or a mixture that includes processes and products in the text of the scope.	Add in bullet c): the products and services and the processes of the organization that allows its realization.	TN
1396	GOST R	958	4.3 Determining the scope of the quality management system	Add e) QMS processes	c) the products and services of the organization. e) QMS processes	TN
1397	CL	958	4.3 c)	It says: "products and services covered by the quality management system";	We suggest to add:	TN

				To be consistent with what is stated in 01, lines 210 and 211, "The quality management system requirements specified in this International Standard are complementary to requirements for products and services", and what is established in 4.4 Quality management system and its processes.	c) "the processes, products and services covered by the quality management system";	
1398	BG	959 - 968	4.3	The text provides for confusion. On one hand exclusions from the scope are not permitted, on the other hand requirements that cannot be applied are permitted unless conformity to product requirements is maintained.	If non-applicability of requirements is permitted than specify which clauses of the standard allow for non-applicability of requirements.	TN
1399	CQI 31	959 - 960	4.3	...then it shall be applied by the organization. Apply consistent use of the active voice throughout the standard.	...then it shall be applied by the organization the organization shall apply it.	TAP
1400	ANS I	959	4.3	Using 'applied' instead of 'applicable' is confusing and not consistent with other language in the standard. There are requirements that can be applied but are not applicable. For example a service organization may have a tape measure but accuracy and precession is not important.	Replace 'can be applied' to 'applicable.' Where a requirement of this International Standard within the determined scope can be applied <u>is applicable</u> , then it shall be applied by the organization. If any requirement(s) of this International Standard is not applicable cannot be applied , this shall not affect the organization's ability or responsibility to ensure conformity of products and services.	TAP
1401	BY	959	4.3	Suggest adding enumeration.	«d) processes, projects, and resources available to the organization and other stakeholders»	TN
1402	IAQ G	959 960	4.3	The sentence "Where a requirement of this International Standard within the determined scope can be applied, then it shall be applied by the organization" does not make sense. Suggest deleting this text entirely and adding a new bullet point d) in the text above.	Reword - clarify Proposal: Add a new bullet point d) "the requirements of this international standard" and delete the sentence "Where a requirement of this International Standard within the determined scope can be applied, then it shall be applied by the organization"	TAP
1403	QS	959 and 960	4.3	Change requirement for more clarity	Change as below: Where a requirement of this International Standard within the determined scope can be applied All the requirement of this International Standard shall be applied by the organization, if it is applicable within the determined scope.	TAP
1404	ANS I	962 -968	4.3	There is no link to process as there was in ISO 9001:2008. This information is consistent with the information that was previously maintained in the quality manual. Currently there is a	Add: The scope shall be available and be maintained	TN

				requirement in 4.4 related to maintaining and retaining documented information for processes. This requirement is currently written in a complex manner and does not provide clarity to users. Recommend that this requirement be included here for consistency with the past as well as simplifying text. This modification will also ease the transition of users who struggle with the removal of the concept of the quality manual.	as documented information stating the: Products and services covered by the quality management system, Justification for any instance where a requirement of this International Standard cannot be applied; and <u>A description of the interaction between the processes of the quality management system.</u>	
1405	BW	962-963	4.3	Meaning of Paragraph is not clear	Where any requirement(s) of this International Standard cannot be applied due to the nature of an organization and its products, this can be considered for exclusion.	TN
1406	CZ	962-963	4.3	If any requirement(s) of this International Standard cannot be applied, this shall not affect the organization's ability or responsibility to ensure conformity of products and services. The rules for possible "exclusions" are not sufficiently specified.	Clarify the scope of possible exclusions using a note with reference to explanation in A.5. or "Note The clauses 4, 5, 6, 9 and 10 shall be applicable without exception."	TN
1407	DE	962	4.3	If any requirement(s) ... cannot be applied, this shall not affect the organization's ability or responsibility to ensure conformity ... It appears to be reasonable to point out that is about such requirements, that the organization <i>believes</i> that they cannot be fulfilled. In addition, the plural of requirement(s) appears to be superfluous in the text.	If any requirement... is considered to be not applicable, this shall not affect the organization's ability or responsibility to ensure conformity ...	TN
1408	CH	962	4.3	If any requirement(s) ... cannot be applied, this shall not affect the organization's ability or responsibility to ensure conformity ... It appears to be reasonable to point out that is about such requirements, that the organization <i>believes</i> that they cannot be fulfilled. In addition, the plural of requirement(s) appears to be superfluous in the text.	If any requirement... cannot be applied <u>in the organization's opinion</u> , this shall not affect the organization's ability or responsibility to ensure conformity ...	TN
1409	QS	962 and 963	4.3	Change requirement for more clarity	Change as below: If any requirement(s) of this International Standard cannot be applied, justification that, this shall not	TN

					affect the organization's ability or responsibility to ensure conformity of products and services shall be provided by the organization.	
1410	RO	962 , 968	4.3	For clarity.	If any requirement(s) of this International Standard is (are) not applicable due to the nature of the organisation's activities , this shall not affect the organization's ability and / or responsibility to ensure conformity of its products and services.	TN
1411	DE	963	4.3	Please clarify "conformity" – to what?	...to ensure conformity to the requirements regarding the products and services.	TN
1412	BR	965	4.3	Suggested to specify whom the scope shall be available to.	The scope shall be available to relevant interested parties, as appropriate , and be...	TN
1413	DZ	965	4.3	To modify the following sentence : The scope shall be available and be maintained as documented information stating the	Replace : "available" with " be defined"	TN
1414	IAQ G	965	4.3	Provide an example in a NOTE to clarify the "scope of the QMS" and providing "documented information".	Add note – clarify Proposal: Add a NOTE: Documented information may be in the form of a "Quality Manual, Management System Handbook, Exposition etc."	TN
1415	IAQ G	965	4.3	4.3 discusses requirement for documenting justifications where an ISO9001 requirement cannot be applied. This is further discussed in Annex A section A.5. Where this replaces the old exclusion concept, there will be a need to strengthen the connection between the requirement and the clarification for better understanding by all stakeholders. There should be a cross reference between the requirement and the clarification. References seem to be used throughout the DIS for significant cross references.	Add text – improve Proposal: Revise wording to add (see Annex A.5) to the end of the requirement in 4.3. Justification for any instance where a requirement of this International Standard cannot be met (see Annex A.5)	TN
1416	BE	965	4.3	Scope does not only consist of products & services and exclusions, but also of involved sites and main processes (clarifying what is systematically outsourced). Notes: - ISO17021:2011 §5.1.2 requires a contractual agreement that can be enforced to <u>all sites</u> involved in the certification. - ISO 17021:2011 §8.2.3.a requires that the certification documents identify the geographical location of the headquarters and <u>any sites</u> within the scope of certification - ISO 17021:2011 §8.2.3.f requires that	- products and services covered by the quality management system; - involved sites of the organization; - main processes, including externalized process; - justification for any instance where a requirement of this International Standard cannot be applied.	TN

				certification documents contain the scope of certification with respect to product (including service), <u>process</u>, etc., as applicable at <u>each site</u>; ISO 17021:2011 §8.3 requires that the certification body keeps a directory of certified clients including the geographical location of the headquarters and <u>any sites</u> within the scope of certification		
1417	IE	965	4.3	The phrasing is awkward and does not read well	Change to: Documented information on the scope of the QMS shall be maintained and readily available. It shall state the:...	EN
1418	PL	965	4.3 Last paragraph	Determining scope of QMS, organisations should also define site or sites of its activity, not only products and services. We suggest to add also that site (s) , where organisation is performing its activity should be defined	The scope shall be available and be maintained as documented information stating the: products and services covered by the quality management system; - Site (s) where products and services are realized; justification for any instance where a requirement of this International Standard cannot be applied	TN
1419	QS	965	4.3	If scope is maintained as documented information then it ensures its availability. Hence delete "available"	Change as The scope shall be available and be maintained as documented information....	TN
1420	SE	965	4.3 Determining the scope of the quality management system	The addition to the Annex SL text i.e. "and be maintained" is superfluous. This since the definition in 3.11 states that documented information is " <i>information</i> required to be controlled and maintained by an <i>organization</i> "	Delete "and be maintained".	TN
1421	IR	967	4.3	When stating the QMS scope the finished products and services to be provided to customers are to be considered. The term "product and services" includes also the externally provided incoming as well as the intermediate products and services used in production of finished products and provision of services.	Read the second item of the third Paragraph as follows: The products and services to be provided to customers that are covered by the quality management system.	TN
1422	IT	967	4.3	It would be appropriate to add a reference to the processes covered by the QMS.	Modify bullet as follows: - products and services and processes covered by the quality management system;	TN

1423	INLA C	967 & 968	4.3	For consistency, it should be used bullets in letter format.	Change the bullet's format.	EAP
1424	CQI 32	968	4.3	justification for any instance where a requirement of this International Standard cannot be applied	justification for any instance where a requirement of this International Standard cannot be applied but shall not exclude products or services that could be covered by the application of this International Standard	TN
1425	IE	968	4.3 Line	If the justification for excluding a requirement is to be part of the Scope, that part of the ISO 9001 certificate could become very verbose.	Include any such exclusions in the Quality Policy statement (Clause 5.2)	TN
1426	GB	968	4.3	Replace "where", which is location dependent, by "when" which is time dependent		EN
1427	SE	968	4.3	The word "instance" can have several meanings e.g. authority. Due to that it is unclear what is meant.	Amend line 968 to: justification for any occurrence when a requirement of this International Standard cannot be applied.	TAP
1428	CN	969 -988	4.4	As for the description of the requirements to process, the first two paragraph are easily to lead confuse, because the organization should determine the process the first then they can manage them according to this standard but this requirement appear in the second paragraph not the first one.	The whole 4.4 should be separated into two clause according to this : 4.4 Quality management system and its processes 4.4.1 General The organization shall establish, implement, maintain and continually improve a quality management system, including the processes needed and their interactions, in accordance with the requirements of this International Standard. 4.4.2 Process approach The organization shall determine the processes needed for the quality management system and their application throughout the organization and shall determine: a) the inputs required and the outputs expected from these processes; b) the sequence and interaction of these processes;	EN
1429	DE	969	4.4	The bullets a) to h) actually mean that a procedure has to be in place for the processes determined as necessary for the quality management system	Please add note following the list: NOTE For the processes that were determined as necessary for the quality management system, a procedure has to be in place.	TN
1430	IAQ	969	4.4	The title "Quality management system and its	Reword - clarify	TN

	G			processes" is not clear.	Proposal: Change the title to "Quality management system and its processes."	
1431	BE	969	4.4	Order of points a to h not fully logic	Change order to: e, b, a, d, c, g, f, h	TAP
1432	BE	969	4.4	ISO 9001:2008 §4.1 contains some explaining notes that are quite useful. These notes are not present in ISO DIS 9001 §4.4.	Add notes from ISO 9001:2008 §4.1	TN
1433	PL	969	4.4	We suggest to delete "and its processes" from the title. From the definition of "quality management system" it is known that processes are part of the management system. Because this paragraph is <u>only</u> about processes, we suggest to add additional subclause 4.4.1 Processes	Add 4.4.1 Processes	TN
1434	SE	969	4.4 Quality management system and its processes	We see no added value of the addition of "and its processes" to the Annex SL text.	Delete "and its processes"	TN
1435	FR	969	4.4	Unclear: the related processes are those specific to the QMS (like QMS planning or continuous improvement) or all the processes within the boundaries of the QMS?	Remove the term "including" from line 971. The sentence becomes : The organization shall ... and continually improve a quality management system and its processes ..." Add to line 987: "the organization shall ... to support the operation of the QMS and its processes ..." Changer le premier paragraphe : L'organisme doit établir, mettre en oeuvre, tenir à jour et de manière continue améliorer un système de management de la qualité, et ses processus associés nécessaires Changer le dernier paragraphe : L'organisme doit tenir à jour les informations documentées juste nécessaires pour soutenir le fonctionnement du SMQ et de ses processus associés et doit les conserver pour avoir l'assurance que les processus sont mis en oeuvre comme prévu	TN
1436	IT	970-972	4.4	It would be appropriate to clarify that the QMS is related to products and services.	Modify sentence as follows: <i>The organization shall establish, implement,</i>	TN

					<i>maintain and continually improve a quality management system for all the products and services it provides, including the processes needed and their interactions, in accordance with the requirements of this International Standard.</i>	
1437	BR	970	4.4	Exclude the word continually to be consistent with the new QMP's and with the clause 10.	The organization shall establish, implement, maintain and continually improve ...	TN
1438	IAQ G	970 971 972	4.4	Clarify the term "processes" in this clause and remove duplication of the word "interaction" (covered in bullet b)	Reword – clarify Proposal: "The organization shall establish, implement, maintain and continually improve <u>the</u> quality management system, including the processes needed and their interactions <u>that have an impact on the conformity of the product and service and their interactions</u> , in accordance with the requirements of this International Standard".	TN
1439	NL	970	4.4	Users should understand that these processes are related to the intended result of the system, so 'these processes' need to have a direct relation to product conformity. The applicable requirements (incl. Statutory and regulatory) are to be considered when designing the operational processes. ISO/DIS 9000 (line 238) refers to 'key processes'.	Add (bold) The organization shall establish, implement, maintain and continually improve a quality management system, including the key processes needed to provide products and service conforming to all applicable requirements and their interactions.	TN
1440	AR	971	4.4	The concept of determination of "processes needed" is mentioned twice as if they were different actions.	Change 973 as follows: "The organization shall determine the process needed for the QMS and their the application of those processes throughout the organization and shall determine..."	TAP
1441	IAQ G	972 -984	4.4	The requirement of process approach was specified in CD, but it is described in clause 0.3 of DIS as "This International Standard promotes the adoption of a process approach when...". (See comments for clause 0.3) It should be described as NOTE that the bullets a) - h) requirements are considered as essential to the adoption of a process approach.	Add note - clarify Proposal: Add the following NOTE h). "NOTE The above a) – h) requirements are considered as essential to the adoption of a process approach described in clause 0.3."	TAP
1442	FI	973 -988	4.4	A question: Is it reasonable to have these lines, because all the issues are presented some other places. For example behind 8.1 (redundancy)	Check these lines; do they bring a real added value	TN
1443	CH	973 -974	4.4	While on line 973 the word 'determine' is used correctly according to the meaning in 3.67, the word on line 974 is used in a different sense	On line 974, <u>change</u> to read: "... and shall DECIDE ON THE FOLLOWING:"	TN

				from 3.67, and means 'decide on (a-h))'		
1444	IIOC	973	4.4	Line 973 - Reason for this is that in most modern environments processes are built within software systems or automated lines etc where deviation by users is often impractical or where mandatory failed sand records may be required before the system will allow the process to move to the next stage which is why documenting processes is no longer felt to be mandatory however it is important that the design of these processes is approved by suitably authorities within organisations and that the relevant stages and information required needs to be clearly defined.	Change to The organization shall determine, define and authorise the processes needed for the quality management system and their application throughout the organization and shall determine:	TN
1445	AT	973	4.4	In determining the processes needed, it is necessary to understand the context of the organisation and the requirements of customers and relevant interested parties. This is described in the introduction, but not reflected in this clause. In addition the risks and opportunities in accordance with the requirements of 6.1 need to be considered (so 981 can be deleted).	The organization shall consider the issues referred to in 4.1, the requirements referred to in 4.2 and the and risks and opportunities in accordance with the requirements of 6.1 and shall determine the processes needed for the quality management system and their application throughout the organization	TN
1446	EOQ	973	4.4	The process approach does not refer to the "context of the organisation". However it is necessary to consider the context for building effective processes.	The organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the processes needed for the quality management system and their application throughout the organization	TN
1447	IAQ G	973 974	4.4	The sentence has duplicated the term "shall determine". The organization <u>shall determine</u> the processes needed for the quality management system and their application throughout the organization and <u>shall determine</u> :	Reword - editorial Proposal: Split the clause and add a bullet to read: "The organization shall" a) determine the processes needed for the quality management system and their application throughout the organization and shall determine: (revert to style in ISO9001:2008 4.1 a)	EN
1448	AR	973	4.4	The word "the processes needed" is mentioned in the first sentences.	To improve redaction: The organization shall establish their application of those processes and shall determine:	EN
1449	NL	973	4.4	Organizations are part of a supply chain. This supply chain influences the conformity of products. The organization should understand these 'upstream' processes because they have an impact on the quality management system of the organization. Therefore the interaction with these processes (and their impact on its own processes) should be understood by the	Add (Bold) The organization shall identify the interaction with the processes of parties relevant to the supply chain and , shall determine the processes needed for the quality management system and their application throughout the organization and shall determine.	EN

				organization. Maybe even collaboration with supply chain partners could be considered to improve interaction, although that would be an ISO 9004 issue.		
1450	NL	973	4.4	It might be not clear to all users which processes are needed for the QMS. Since the intended result of the QMS is to realize products which conform to all relevant requirements, it is made clear which paradigm the organization should use determining which processes are to be determined.	Change The organization shall determine the processes needed to ensure the realization of the intended results of the quality management system	TN
1451	ZA	973	4.4	The ISO 9001 standard includes the principle of a Process Approach. The requirement in line 973 seeks to control the quality management system processes whereas the quality management system should seek to control the business processes. The wording is identical to the 2008 version of the standard and if retained will perpetuate the current high levels of confusion in the market.	The organization shall determine the processes needed to achieve its objectives and apply the controls of the quality management system to these processes.	TN
1452	NZ	973	4.4	This requirement still has the impression of a static QMS. Establishing the processes needed is often a stage by stage process depending on the style of organisation (eg rate of change to products and services) and the nature of the work (eg project by project). The current wording of the requirement does not meet the needs of all current business practices.	Modify P2 to: The organization shall determine the processes needed for the quality management system and their application throughout the organization. The organization shall ensure that processes needed to achieve intended results are established as necessary and shall determine:	TN
1453	SE	973	4.4	The organization shall determine the processes needed for the quality management system and	Delete "for the quality management system".	TN
1454	FR	973	4.4	Split the second paragraph into 2 separate paragraphs	The organization shall determine the processes needed for the QMS and their application throughout the organization. The determination of these processes shall include : "L'organisme doit déterminer les processus nécessaires au SMQ et leur application dans tout l'organisme. La détermination de ces processus doit comprendre :	EN
1455	ANS I	975	4.4.	This sentence is adding many different concepts into one requirement which makes the requirement very difficult to understand. Measurements and related performance indicators implies objectives on each processes.	Revise The criteria, and methods, including measurements and related performance indicators needed to ensure the effective operation and control of these processes.	TAP

				This will be specifically challenging to smaller organizations. In addition, the words “performance indicators” are not used anywhere else in the standard. What are these performance indicators used for?		
1456	JP 199	975	4.4	For clarification Otherwise, it can be misunderstood as “the inputs required from these processes.”	Change to: The inputs required to these processes and the outputs expected from these processes	TAF
1457	IAQ G	976 /982	4.4 c) & g)	4.4c) mentioned methods including measurements and related performance indicator, while 4.4g) mentioned methods for monitoring, measuring as appropriate of processes. This is redundant.	Delete text - improve Proposal: delete ‘including measurements and related performance indicator’. Covered in 4.4g) the methods for monitoring, measuring where applicable, including performance indicator, and evaluation of processes, etc.	TAP
1458	BE	976	4.4.b		the sequence and interactions of these processes	TN
1459	NL	976	4.4	The sequence and interaction are the ‘architecture’ of the QMS. This architecture is required to understand the coherence of all system elements. This architecture should be available as documented information to ensure a common understanding of the QMS.	Add b) the sequence and interaction of these processes, which will be available as documented information.	TN
1460	SP	977 -978, 983-984	4.4	The interaction and difference between c), g) and h) is not clear. If c) is operation and control, g) is measuring and evaluation and h) improvement, but there are some confusion.	Rewrite to simplify these fundamental requirements on Quality management systems and its processes.	C
1461	TC4 6/SC 11 Liais on (AU)	977 -978	4.4	This item is confusing, do ‘methods’ include ‘measurements’ or ‘measurements and related performance indicators’?	Reword to clarify this requirement	EAP
1462	TC2 10	977 -978	4.4	Unnecessary comma breaks up text incorrectly.	Delete commas and amend to “c) the criteria and methods, including measurements and related performance indicators needed to ensure the effective operation and control of these processes;”	EAP
1463	JP 200	977 -978	4.4	Continuity with 4.1 c) of ISO 9001:2008.	c) the criteria <u>and</u> methods, including measurements and related performance indicators <u>needed</u> to ensure the effective operation <u>and</u> control of these processes;	EAP
1464	PT	977 /978	4.4	Instead of ... the criteria, methods, including measurements and related performance indicators needed to	Read ... the criteria <u>and</u> methods, including measurements and related performance	EAP

				ensure the effective operation, and control of these processes	indicators, needed to ensure the effective operation and control of these processes	
1465	IQN et	977 /978 983/984	4.4	g) the methods for monitoring, measuring, as appropriate, and evaluation of processes and, if needed, the changes to processes to ensure that they achieve intended results overlaps with c) the criteria, methods, including measurements and related performance indicators needed to ensure the effective operation, and control of these processes; in some extent and introduces confusion	Change to c) the criteria, methods, including measurements , monitoring and related performance indicators needed to ensure the effective operation, and control of these processes; g) the analysis and evaluation of processes and, where needed, the changes to processes to ensure that they assure intended results	TAP
1466	BR	977	4.4 c) and g)	Suggested to adjust the texts of sub clauses c) and g) because the way they are they state virtually the same requirements.	Change bullets c) and g) to read: c) the criteria, methods for monitoring and measurement, as appropriate, and related performance indicators needed to ensure the effective operation, and control of these processes; g) the changes to processes to ensure that they achieve intended results, if needed;	TAP
1467	IAQ G	977 978 983 984	4.4.g	Two of the bullets in this clause appear to be in conflict in relation to measurement. Clause c) measurement is mandatory but in clause g) measurement is "as appropriate".	Delete text - clarify Proposal: Delete the term "as appropriate" in bullet g) the methods for monitoring, measuring, as appropriate , and evaluation of processes and, if needed, the changes to processes to ensure that they achieve intended results;	TN
1468	INLA C	977 & 983	4.4 c) & g)	Letters c) and g) have similar concepts and there is a redundancy between both bullets.	Review bullets c) and g) and decide how redundancy can be eliminated.	TAP
1469	IN	978	4.4	Delete ',' after operation	'...effective operation and control of these process...'	EAF
1470	IT	978	4.4	It would be appropriate to add a reference to the planning process.	Modify bullet as follows: <i>c) the criteria, methods, including measurements and related performance indicators needed to ensure the effective planning, operation, and control of these processes;</i>	TN
1471	IR	979	4.4	The wording of item d) of this sub-clause needs change to make the second part of the phrase compatible with the verb "determine".	Read item d) of this sub-clause as follows: d) the resources needed and measures to ensure their availability;	TN
1472	NL	979	4.4	Clause 7.1.1 also requires the organization to determine the needed resources. Users of the standard could be confused about this two (almost) similar requirements. Bullet d) is	Remove d) the resources needed and ensure their availability.	TN

				redundant.		
1473	IE	979	4.4 d)	As the other bullet points include the word "processes", add a similar reference to this sub-clause.	Text to read "the resources needed for these processes and to ensure their availability"	EAP
1474	QS	979 ,	4.4	Ensure availability of resource is management commitment hence should not part of the determining the process requirements. Also availability of resources is covered under 5.1.1 (See line 1001)	Change as: d) the resources needed and ensure their availability for effective operation of processes	TN
1475	QS	979	4.4	In the current ISO 9001:2008, under 4.2.2 Quality Manual at sub-section c), there is a requirement to document a description of the interactions between the processes of the QMS. This requirement implies visible mapping and alignment of processes. In a complex organisation, such as a Matrix structure, quality plans define the interactions between specific operational and project based activities. At the corporate level, the Quality Manual serves as the governing document that defines the interactions of the whole organisational QMS. The draft ISO 9001:2015 has not shifted this requirement for documenting the description of the interactions between systems and processes at the corporate level (governance), from the present 4.2.2 'Quality Manual' requirement to '4.4 Quality management system and its processes'. Interactions between processes are described at 0.1 General, 0.3 Process approach, 4.4 Quality management system and its processes, 7.5.1 General, 8.4.3 Information for external providers. None of these descriptions clearly define a requirement to document a description of the interactions between the processes (or systems) of the quality management system.	Amend lines 986, 987 and 988 to include a requirement to define the interactions between the processes of the QMS, and if appropriate other management systems.	TN
1476	NZ	979	4.4	Ensuring availability of resources duplicates 5.1.1 f) and 7.1.1. Also 'and ensure their availability' does not make grammatical sense after 'shall determine'.	Change to d) the resources needed	TN
1477	TC2 10	979	4.4	The text 'and ensure their availability' does not follow from the construction of the list that starts '... the organization shall determine: ' Furthermore the requirement to ensure availability of resources is a requirement of Top Management in 5.1.1 f) and it is unnecessary to break up the flow of the list and repeat the requirement here.	Delete 'and ensure their availability;'	TN

1478	SE	979	4.4 Quality management system and its processes	Insert text from ISO 9001:2008, 4.1 d): "ensure the availability of resources and <u>information</u> necessary to support the operation and monitoring of these processes", in 4.4 d). Beginning with "the resources needed and ensure their availability";	Change to: d) the resources <i>and information</i> needed and ensure their availability;	TN
1479	JP 89	979 981	4.4 d) and f)	The "ensure their availability" in item d) and "plan and implement" in item f) do not fit to the "shall determine" in L974 as a sentence. Retain 4.1 of 2008 version.	Change to: The organization shall determine the processes needed for the quality management system and their application throughout the organization and <u>shall</u> : a) <u>determine</u> the inputs required... b) <u>determine</u> the sequence and interaction... c) <u>determine</u> the criteria, methods, including... d) <u>determine</u> the resources needed and ensure their availability... e) <u>determine</u> the assignment of the responsibilities... f) <u>determine</u> the risks and opportunities ..., and plan and implement ... g) <u>determine</u> the methods for monitoring, h) <u>determine</u> opportunities for improvement...	TAP
1480	ANS I	981 -982	4.4	The use of the word risk has caused a large amount of comment from those who are experienced with the application of risk as well as those who are involved in ISO 31000. The term "opportunities" is not defined. Since the definition of "risk" is included, and contradicts those of other ISO standards which treat risk and opportunity as identical ("positive risk"), this must be corrected. Using this terminology as it is written in Annex SL is technically incorrect and has resulted in much feedback has the potential for lack of understanding and misinterpretation in the marketplace. Risks and its opportunities should be replaced by risks and its effects with some clarification added in the requirements related to terminology. The last part of the requirement in the sub-clause is redundant since clause 6.1 is all about planning and implementing the appropriate actions to	f) the risks and its effects opportunities in accordance with the requirements of 6.1, and plan and implement the appropriate actions to address them;	TN

				address risks and opportunities.		
1481	CZ	981-982	4.4	The requirement in contradiction with A.4 could not be audited. Interpretation of A.4: Although it is necessary to identify risks and opportunities and address them, there are no requirements to formal risk management or to a documented process of the risk management. The text explicitly does not imply that risks and opportunities are mandatorily included in documented information to support operation of processes. <i>It is not clear how an organization demonstrates that it identified risks and opportunities that needed to be addressed.</i> The requirement could not be verified by an audit.	To add to Clause 6.1.1: “The organization shall maintain documented information to the extent necessary to support the operation of processes and retain documented information to the extent necessary to consider risks and have confidence that the processes are being carried out as planned.”	TN
1482	TC2 10	981-982	4.4	The text ‘and plan and implement the appropriate actions to address them;’ does not follow from the construction of the list that starts ‘... the organization shall determine: ‘ Furthermore, there is a whole clause on Planning in 6 and it is unnecessary to break up the flow of the text and repeat part of those requirements here.	Delete ‘and plan and implement the appropriate actions to address them;’	EAF
1483	CQI 33	981	4.4	f) the risks and opportunities in accordance with... Change all instances of ‘risks and opportunities’ to ‘opportunities and risks’ to emphasize the positive nature of a Quality Management System. See CQI General comment.	f) the risks and opportunities and risks in accordance with...	EN
1484	AT	981	4.4	Can be deleted, see our comment on 973 above	Delete 4.4 f)	TAP
1485	DK	981	4.4	The requirement is covered by 6.1.2 and can be deleted	Delete 4.4.f)	TAP
1486	EOQ	981	4.4	It is not clear that the “risks and opportunites” here refer to those of the processes; an additional qualifier is needed	the risks and opportunities regarding these processes in accordance with the requirements of 6.1, and plan and implement the appropriate actions to address them	TN
1487	AR	981	4.4	The phrase “Risks and opportunities” is not correct. , since risk is a neutral term, that can be associated with threats and with opportunities.	Change (throughout all clauses of the document) : “risks and opportunities” by “risk associated with threats and opportunities”	TN
1488	NL	981	4.4	This clause is about determining (designing the system). The determination of risks and opportunities, and actions to is described in clause 6.1. This bullet is redundant.	Change into f) the method needed to address risks and to assess the potential impact on the conformity of products and services.	TN

				Like measuring methods (bullet c) the organization should determine a method to address and analyze risks.	(Also deleted 'opportunities', see overall comment)	
1489	NZ	981	4.4	Determining risks and opportunities for each process is unrealistic and also could reduce the focus on risks and opportunities associated with processes acting together in a QMS. Duplicates 6.1 unnecessarily.	Delete bullet f)	TN
1490	NZ	981	4.4	Planning and implementing actions duplicates 6.1.2	If bullet retained, delete 'and plan and implement the appropriate actions to address them'	TAF
1491	JP 90	981	4.4	Only item f) refers to another sub-clause. Here, the description should be limited to general considerations necessary for the establishment of QMS.	Delete "In accordance with the requirements of 6.1" and change f) to: Risk and opportunities <u>related to the quality management system, and plan and implement the appropriate actions to address them</u>	TN
1492	NO	981 – 982, 985	4.4.	The difference between f) and h) is not obvious, the clauses seem to cover the same topic. Bullet point f) is covered by 6.1. We propose to delete bullet point f).	Delete bullet point f).	TAP
1493	IR	981 and 985	4.4	As the items f) and h) both relate to the issue of risks and opportunities, it would be more appropriate to merge them into the single item f) and delete item h) accordingly.	Merge the items f) and h) into the single item f) and delete item h) as follows: f) the risks and opportunities <u>for improvement of the quality management system and its processes</u> in accordance with the requirements of 6.1, and plan and implement the appropriate actions to address them;	TN
1494	CH	982	4.4	The word 'appropriate' is not suitable in this context.	<u>Change</u> to read: "... implement the actions NECESSARY to address them;"	TN
1495	CH	982	4.4	Major goal of risk based thinking is not only to address the risks but also to minimize them. Clause 4.4.f) reads: "the risks and opportunities in accordance with the requirements of 6.1, and plan and implement the appropriate actions to address them;"	Read: "the risks and opportunities in accordance with the requirements of 6.1, and plan and implement the appropriate actions to address them, and if necessary to reduce them; "	TN
1496	ANS I	983 -984	4.4	This sentence is confusing because it combines changes to process along with the methods for monitoring and measuring. This concept overload may not provide emphasis on the change of processes. Especially in light of the emphasis of change in ISO 9001:2015.	Revise to g) the methods for monitoring, measuring, as <u>appropriate where applicable</u> and evaluation of processes. h) determining needed changes to processes to	TN

				The words "as appropriate" should be replaced with where applicable because if measuring is applicable, it should be applied.	ensure that they achieve intended results h) opportunities for improvement of the processes and the quality management system	
1497	NG	983 -984	4.4 f	Rephrase for better flow/presentation. Delete 'and' and 'the' in the sentence	"the risks and opportunities in accordance with the requirements of 6.1, plan and implement appropriate actions to address them;	TN
1498	BR	983	4.4	Monitoring shall be a requirement, measuring not always. Delete the comma between "measuring" and "as appropriate" to clarify.	g) the methods for monitoring, measuring, as appropriate, and evaluation of processes...	TAP
1499	DE	983 984	4.4 g)	the methods for monitoring, measuring, as ... Not all users will immediately understand what relates to what	Reword: ...of processes and, if needed, <u>of</u> the changes	TN
1500	IAQ G	983 984	4.4.g	Bullet g) has lost the need to implement actions when planned results are not being met (ref ISO9001:2008 clause 4.1 f).	Add Text - improve Proposal: Add additional text into bullet g) "the methods for monitoring, measuring as appropriate, and evaluation of processes and, if needed, the changes to processes <u>and implementation of actions</u> to ensure that they achieve intended results;"	TAP
1501	LU	983	4.4	Split the point g)	g) the methods for monitoring, measuring, as appropriate, and evaluation of processes h) opportunities for improvement of the processes and the quality management system and, <u>if needed, the changes to processes to ensure that they achieve intended results.</u>	TN
1502	PE	983	4.4	The standard says: <i>the methods for monitoring, measuring, as appropriate, and evaluation of processes and, if needed, the changes to processes to ensure that they achieve intended results;</i> The usage of the term "APPROPRIATE" does not match with the term "APPLICABLE" used in the requisite 9.1.1 b, it is recommended to use the same term.	It should say: <i>the methods for monitoring, measuring, as applicable, and evaluation of processes and, if needed, the changes to processes to ensure that they achieve intended results;</i>	TAP
1503	AR	983	4.4	This bullet is no clear and partially repetitive with bullet c) g) the methods for monitoring, measuring, as appropriate, and evaluation of processes and, if needed, the changes to processes to ensure that	g) the changes to realise in the processes to ensure that they achieve intended results	TAP

				they achieve intended results;		
1504	NL	983	4.4	Processes refer back to the processes determined before (line 973).	Add (bold) g) the methods for monitoring, measuring, as appropriate, and evaluation of these processes and, if needed, the changes to these processes ...	TAP
1505	NL	983	4.4	Consistent wording: the quality management system achieves an intended result, the processes achieve intended outputs. (See also bullet a).	Change (bold) g) the methods for determining .. to ensure the achieve intended outputs	EN
1506	NZ	983	4.4	'and, if needed, the changes to processes to ensure that they achieve intended results' is a separate concept to determining 'the methods for monitoring' etc. There is reference in 6.3 to 4.4 having determined the need for change to the QMS. This needs to be a separate bullet and needs to relate to processes and the QMS as is done in h).	In g) delete 'and, if needed, the changes to processes to ensure that they achieve intended results' Insert new h) the need for change to the quality management system and its processes in order to achieve intended results	TAP
1507	GB	983	4.4 g)	Redundant 'the' (2 off) and this clause duplicates clause 4.4 c)	propose deletion of methods in 4.4c	TAP
1508	SE	983	4.4	The measurements needed are defined in 4.4 c. There should be no reason to consider if they are appropriate at this stage.	Remove "as appropriate".	TAP
1509	FR	983	4.4	Clarify the section and the meaning of the term « as appropriate » in bullet g) Problem with translation : The term "as appropriate" is used in bullet g). Could SC2/WG24 clarify if this term is used to mean "in an appropriate manner" or if it is used in the meaning of "if necessary". Depending on the use of this term, the translation to French will be different and will have a significant impact on the requirement.	Split the list after bullet f). the paragraph reads : The organization shall determine the processes needed for the QMS and their application throughout the organization. The determination of these processes shall include : a) to f) and implement g) and h) ajouter une ligne avant le g : et mettre en œuvre g) et h)	TAP
1510	MX	983 & 984	4.4	The methods for monitoring, measuring, as appropriate, and evaluation of processes and, if needed, the changes to processes to ensure that they achieve intended	The methods for monitoring, measuring as appropriate, in order to assess processes and, if needed, make changes to processes to ensure that they achieve intended results;	TN

				results;	RATIONALE: The current writing of the sentence is confusing	
1511	JP 201	984	4.4	For clarification and continuity with the 2008 version which consistently uses the expression "these processes" in 4.1.	Change to: g) the methods for monitoring, measuring, as appropriate, and evaluation of <u>these</u> processes and, if needed, the changes to <u>the</u> processes to ensure that they achieve intended results;	EAP
1512	INLA C	985	4.4 h)	For consistency with the scope of the standard, also include the improvement of products and services	h) opportunities for improvement of the processes, product and services ,and the quality management system	TN
1513	IN	985	4.4	Include 'continual'	'opportunities for continual improvement'	TN
1514	NL	985	4.4	Determining opportunities for improvement are part of clause 6.1, 9.3.and chapter 10. This bullet h could confuse users.	Remove h) the opportunities for improvement of the processes and the quality management system.	TN
1515	NZ	985	4.4	Use phrase consistent with title throughout	h) opportunities for improvement <i>of the quality management system and its processes</i>	TN
1516	JP 91	985	4.4	The term "opportunities" is used. However, it is too close to "risk and opportunity" in L981 and is confusing.	Change "opportunities for improvement" to "need for improvement."	TAP
1517	ANS I	986 -988	4.4	The requirement for maintain and retaining of processes in the same clause is confusing and more prescriptive than necessary. Retain documented information to the extent necessary to have confidence that the processes are being carried out as planned seemed redundant. Most information related to the results of processes would be in the form of some type of metrics or goals. Most organizations would maintain this information, but not necessarily retain it as "record." Additionally, most of these processes would have some type of retained documented information as a part of another part of the standard if it has been determined to be relevant information. Therefore, this requirement is not needed. If the requirement is to be retained, the requirement should address control of processes and not operation of processes.	Option 1 Delete P3 (lines 986-988) and include requirement for documented information in clause 4.3. Option 2 The organization shall maintain documented information to the extent necessary to support the operation control of processes and retain documented information to the extent necessary <u>and</u> to have confidence that the processes are being carried out as planned.	TAP
1518	CN	986 -988	4.4	This paragraph is repeated in the line 1214-1216 which is the 8.1.e	Add "see 4.4 " in the 8.1.e	TN

1519	NO	986 -988	4.4	"To the extent necessary" is very vague. ISO 9001 will be more user friendly if it gives specific requirements on what needs to be established and maintained as documented information.	Add a new paragraph after line 988 The documented information shall include, as a minimum; - scope of the management system; - quality policy and objectives - processes, the sequence and interaction of these processes - other documented information in accordance with the requirements of this International Standard.	TN
1520	NL	986	4.4	The extent to which documented information is needed is related to the level of competence of staff, the technological level of infrastructure, the maturity of internal communication/information exchange. So documentation is not the only 'switch' a organization can use to improve process control. Users should understand the QMS has more 'control switches' which can be applied. Referring only to documentation could lead organizations to think documentation is the only 'switch'. One of the goals of the new standard was to reduce documentation.	Change (bold) The organization shall maintain documented information to the extent necessary to support the operation of processes, taking into account the fitness for use of resources, the available competence, the awareness of people and the effectiveness of internal communication , and retain documented information to the ...	TN
1521	QS	986 ,	4.4	Repeated information. Maintain and Retain? Is the requirement different for both?	Change as The organization shall maintain documented information to the extent necessary to support the operation of processes and retain documented information to the extent necessary to have confidence that the processes are being carried out as planned.	TN
1522	NZ	986	4,4	Long and confusing sentence used to differentiate between 'maintain' and 'retain'. The requirement can be clear without this lengthy construction.	The organization shall maintain documented information to the extent necessary to support the operation of processes and retain documented information to the extent necessary to have confidence <i>demonstrate</i> that the processes are being carried out as planned.	TN
1523	INLA C	986 & 987	4.4	There is no need to differentiate with a verb (maintain or retain) what documented information relates to documents and what relates to a record. Annex A.6 explains clearly the introduction of the term "documented information" that will help current users of ISO 9001. For the new users, a differentiation of documents and records does not add any value.	Change paragraph: The organization shall maintain documented information to the extent necessary to support the operation of processes and to have confidence that the processes are being carried out as planned.	TN

				In all references to "documented information" in the standard a consistent verb must be used: "maintain" is more appropriate.		
1524	QS	986 , 987 and 988	6.1.2	Bullet, b) 1 and 2 can be made bullet, b) and bullet, c) instead of new numbering	Change as: b) how to integrate and implement the actions into its quality management system processes c) how to evaluate the effectiveness of these actions	TN
1525	IR	987	4.4	The wording of the last paragraph of this sub-clause needs slight change to address the planning of processes besides their operation.	Add the words "planning and" before the word "operation" in the line 987 of the last paragraph of this sub-clause as follows: The organization shall maintain documented information to the extent necessary to support the planning and operation of processes and retain documented information to the extent necessary to have confidence that the processes are being carried out as planned.	TN
1526	IE	987	4.4 Line	The phrase "to have confidence" is subjective and unauditale.	Replace "to have confidence" with "to demonstrate"	TN
1527	QS	987	5.1.1	Integration QMS requirements with other MS requirements if any can also be added	Change as d) ensuring the integration of the quality management system requirements into the organization's business processes and other management system if any	TN
1528	IT	987	4.4	Technical/editorial suggestion.	Add "effective" before "operation".	EN
1529	QS	988	6.1.1 b)	Remove Comma ",",	b) prevent, or reduce, undesired effects;	EN
1530	CH	988	4.4	Retained 'documented information' gives confidence that processes <u>have been</u> carried out as planned,	<u>Change</u> to read: "... processes HAVE BEEN carried out as planned."	TN
1531	JP 202	988	4.4	For continuity with the 2008 version which consistently uses the expression "these processes" in 4.1.	Change "the processes" to "these processes."	EAF
1532	PH/BPS	989	5.1	The requirement that top management should demonstrate leadership and ensure that their quality policy and quality objectives are relevant to and supportive of their organizations' strategic		C

				direction is explicitly stated.		
1533	IE	989	5 leadership	No mention of Quality Management Principles	Include mention of quality management principles. e.g. a) promoting and adhering to quality management principles.	TN
1534	GB	990	5.1	This needed as Small/Micro business owners do not relate to top management, seeing such terms as applying only to large businesses. This as a result of being entrepreneurs running their own businesses with small teams of staff. Small/micro businesses do not have a hierarchical structure and each employee has to be responsible for a number of disciplines operating as a co-ordinated small team with the owner seen as the leader of that team. It is important to appreciate that a small business is 12 or less staff and micro 6 or less (unfortunately government figures do not recognise this quoting much higher numbers)	(Additional explanatory section 991a -992a or 991-992-etc.) Note: All references to Top Management are intended to be inclusive from small/micro business owners or partners to senior management, directors and CEO's in large companies, organisations.	TN
1535	IR	990 , 991, 1013, 1023 and 1033	5.1, 5.1.1 and 5.1.2, 5.2 and 5.3	Commitment with respect to the quality management system and with respect to the needs and expectations of customers along with other commitments to establish Quality Policy and assignment of the responsibilities and authorities for relevant roles within organization are requirements of this standard to be met by top management to demonstrate its leadership of organization. Commitment is a result of adhering to the Quality Management Principle "Leadership". Hence, as commitment is an aspect of leadership the two words "Leadership" and "Commitment" are not to be used at the same level and therefore the word commitment should not appear together with the term leadership on the same sub-clause title. There is a proposal to modify the titles and numbers of sub-clauses 5.1, 5.1.1 and 5.1.2 for sake of clarity. Besides that, the sub-clauses 5.2 and 5.3 are also to be re-numbered as proposed in the next column.	Delete the title and number of the sub-clause 5.1 and re-number the current sub-clauses 5.1.1 as 5.1, 5.1.2 as 5.2, 2.3 as 5.3 and 5.3 as 5.4 and list the Clause 5 and its sub-clauses in the contents page as follows: 5. Leadership 5.1 Commitment for the quality management system 5.2 Customer focus 5.3 Quality policy 5.4 Organizational roles, responsibilities and authorities	EN
1536	TC4 6/SC 11 Liai	991 -1009	5.1(a-k list)	as it is stated in 4.4 (QM processes) that the organization shall maintain documented information to the extent necessary to support the operation of processes and retain documented	Add a bullet point (in the currently a-k list) "ensuring that documented and accurate information is maintained and retained to the extent necessary to support the operation of	TN

	on (FR)			information to the extent necessary (...)it should be stated in 5.1 that top management should ensure that documented information is well maintained to the extent necessary	processes"	
1537	CZ	991 -1009	5.1.1	There should be a requirement for evidence of risk-based thinking of the management.	One bullet should be added between e) and f): "communicating of important risks and responsibilities for their treatment to relevant levels and roles;"	TAP
1538	ANS I	991	5.1.1	There is a laudable effort to require Leadership and commitment. However the vast majority of subclause (b thru k) is delegable thus negating the direct involvement of leaders in the QA process.	Reword the first sentence to state Top management shall demonstrate <u>their</u> leadership and commitment with respect to the quality management system by	EN
1539	IAQ G	991	5.1.1	The term "Leadership and commitment" has a duplicate in the title of line 990.	Reword - editorial Proposal: Change to Leadership and commitment for the "Quality management system".	EAP
1540	CO	991	5.1.1	Include new literal, in order to strength top management leadership and commitment	Holding the Management review in an effective way.	TN
1541	NL	991	5.1	In the interim draft of DIS 9001 there was a sentence with direct relation to annex B: <i>'ensuring the promotion of awareness of quality management principles throughout the organization.'</i> This was the strongest argument to include the QMP into ISO 9001.	Add following bullet point to 5.1.1: 'ensuring the promotion of awareness of quality management principles throughout the organization.	TN
1542	IE	991	5.1.1 Line	The heading is ungrammatical.	Replace with: 5.1.1 Leadership and commitment with respect to the quality management system	TN
1543	INLA C	991 & 1013	5.1.1 & 5.1.2	Some sub-clauses do not have any title (see 5.2.1 and 6.1.1, among others). The titles of sub-clauses 5.1.1 and 5.1.2 add little value and can be removed.	Remove titles in sub-clauses: 5.1.1 Top management shall demonstrate... 5.1.2 Top management shall demonstrate...	TN
1544	EE	992	5.1.1	Keeping the quality management system up-to-date is very important for its operation. Based on our experiences, many organizations, which have implemented the quality management system and passed the certification are not keeping the system up-to-date. There are several reasons, but in many cases it is caused by top management approach of reducing resources assigned to maintain the management system	<i>Replace existing wording of clause h) with following:</i> h) ensuring that the quality management system is up-to-date and achieves its intended results;	TN

				(and to keep it up-to-date)It is top management responsibility to keep management system up-to-date. Clear statement of this responsibility would help to prevent or at least reduce these problems in the future. Therefore, a subclause h) should be supplemented under Clause 5.1.1 indicating that top management should demonstrate its leadership and commitment by “ensuring that the quality management system is up-to-date”.		
1545	LC	992 Also applies to lines 1004; 1036 - 1038;	5.1.1 5.3	If “Top Management shall assign the responsibility and authority for ensuring that the QMS conforms to the requirements of this international standard” and “ Top management shall demonstrate leadership and commitment with respect to the QMS by ensuring that the QMS achieves its intended results”, who ultimately has responsibility ? It is recognized that the assignments in Lines 1037 to 1045, may well be distributed among a number of persons with the responsibility and authority. This is with the recognition that in Clauses 5.1.1 (i) to (k) or lines1005 -1008, top management shall engage, direct and support persons to contribute to the effectiveness of the QMS, and support other relevant management roles to demonstrate their leadership, as it applies to their areas of responsibility.		TN
1546	TT	992	5.1.1	Use of the phrase ‘with respect’ is weak. This sentence should be more definitive as it is becoming more challenging to gain Top Management’s support for the QMS. In many cases, the QMS has only seen partial success. Therefore, Top Management must demonstrate greater commitment to the success of the QMS.	Change to: Top management shall demonstrate leadership and commitment ‘to the success of’ the quality management system by:	TN
1547	CH	994 and 998-999	5.1.1	These requirements are <u>very important</u> for the repositioning of QM into the management system of organizations, and are <u>highly welcome</u> .	<u>Please retain these requirements !</u>	C
1548	CQI 34	994	5.1.1	‘ ..accountability <u>of</u> the effectiveness ...’ I believe there is a minor error, Top Management should be accountable FOR the effectiveness of the QMS.	‘ ...accountability ef for the effectiveness ...’	EAF
1549	ANS I	994	5.1.1	This requirement has been added to the Annex SL text. It is important that management	Option 1	TN

				commitment requirements be strong. However, where possible we should streamline them. A) is redundant to requirement i).	Delete a) Option 2 If the word accountability is specifically wanted, incorporate it into i)	
1550	ANS I	994		Suggest change "accountability of" to "accountability for"	"taking accountability of for the effectiveness of the quality management system"	EAF
1551	AR	994	5.1.1	Suggest change "accountability of" to "accountability for"	"taking accountability of for the effectiveness of the quality management system"	EAF
1552	IE	994	5.1.1 a)	Change "of" to "for" for readability	a) Taking accountability for the effectiveness ...	EAF
1553	IE	994	5.1.1 Line	Incorrect grammar.	Replace "accountability of" with ""accountability for "	EAF
1554	AU	994	5.1.1 a)	Incorrect use of English. There is no such phrase as, 'taking accountability'. Use of 'responsibility' is more consistent with organizational principles.	Reword to, 'being accountable for the effectiveness of the quality management system'	TN
1555	CA-36	994	5.1.1	Replace the word 'of' with 'for' – leadership must take accountability <u>for</u> , not 'of' a) taking accountability of the effectiveness of the quality management system	a) taking accountability for the effectiveness of the quality management system;	EAF
1556	GB	994	5.1.1 a)	Improve the English: 'taking accountability of the effectiveness of the quality management system;'	Reword: ' accepting accountability for the effectiveness of the quality management system;'	EAP
1557	SE	994	5.1.1	Suggest change "accountability of" to "accountability for"	"taking accountability for the effectiveness of the quality management system"	EAF
1558	ANS I	995-996	5.1.1	The US TAGs to 176 and 207 Liaison Group recommends alignment between the two standards with respect to the following: Revert to Annex SL text, without additions, in Leadership and commitment clause Rational: This clause represents significantly new requirements to both standards, and since it is targeted to Top Management, it will received scrutiny from users and require justification. There is no discipline-specific justification to have different requirements in 9001 and 14001. The additions are redundant, and in some cases inconsistent with, the corresponding sub-clause. For example, -9001 5.1.e is redundant with bullet g; -the term 'accountability' in 5.1.a is not used elsewhere in the standard, and is redundant with	For 9001: delete additions to Annex SL text 5.1.b: ensuring <u>establishing</u> the quality policy and ensuring the quality objectives are established for the QMS and are compatible with the strategic direction and the context of the organization OR 5.1.b: ensuring the quality policy and the quality objectives are established for the QMS and are compatible with the strategic direction and the context of the organization For 14001: delete additions to Annex SL text 5.1.b: ensuring <u>establishing</u> the environmental policy and ensuring the environmental objectives are established for the EMS and are compatible	TN

				fifth Annex SL bullet; -5.1.b is inconsistent and redundant causing confusion and misinterpretation by users. (Top management 'ensures the policy is established' in 5.1 (i.e., can be delegated) but must establish it themselves in 5.2? Both 5.2 & 6.2 already have a requirement for establishing a policy and objective, so it is redundant in 5.1. The 'context' is the as-is state, whereas the policy and objectives should represent the future state.	with the strategic direction and the context of the organization OR 5.1.b: ensuring the environmental policy and the environmental objectives are established for the EMS and are compatible with the strategic direction and the context of the organization	
1559	FR	995	5.1.1	Replace bullet b)	Replace bullet b as follows ; b) establishing the quality policy and quality objectives for the quality management system and ensure their compatibility with the strategic direction and the context of the organization Remplacer le texte par "en établissant une politique qualité et des objectifs qualité pour le système de management de la qualité compatibles avec l'orientation stratégique et le contexte de l'organisme"	TN
1560	IE	996	5.1.1 Line	The phrasing would be improved by moving from the general to the particular.	Rephrase as: ". . . compatible with the context of the organization and its strategic direction. "	TAF
1561	ANS I	997	5.1.1	The commitment of top management for communicating the quality objectives should also be included as this is an important part of the effectiveness of the quality management system.	c) ensuring that the <u>quality objectives</u> and quality policy is communicated, understood and applied within the organization.	TN
1562	MY	997	5.1.1 c)	The use of the word "understood" is not consistent with Subclause 7.3 which only requires persons doing work under the organization's control to be "aware" of the quality policy.	To use the term which shows consistency with Subclause 7.3	TN
1563	AU	997		Delete 'understood'	'communicated and applied throughout'	TN
1564	SE	997	5.1.1	Requirements in respect of communicating the quality policy are duplicated. There is overlap between 5.1.1 and 5.2.2. Requirement in 5.1.1: "Top management shall demonstrate leadership and commitment ... by: ... c) ensuring that the quality policy is communicated, understood and applied within the organization". Requirement in 5.2.2: "The quality policy shall: ... b) be communicated, understood and applied". It is quite sufficient that the requirement to	Delete 5.1.1 c).	TAF

				communicate (etc.) the policy is stated once. The most suitable place to keep the requirement is 5.2.2.		
1565	CQI 35	997 and 1031	5.1.1	c) ensuring that the quality policy is communicated, understood and applied within the organization; and The quality policy shall: ... b) be communicated, understood and applied within the organization; These two requirements are a duplicate. Top management has already met this requirement in 5.1.1, there is no need to repeat it in 5.2.2. Delete line 1031	b) be communicated, understood and applied within the organization;	TAP
1566	IAQ G	997 , 1031	5.1.1(c), 5.2.2(b)	How does an auditor verify with objective evidence that the quality policy has been "applied"? Seems to be audit trap or incorrect use of the term relative to the intent of the requirement.	Reword - improve Proposal: Suggest using "integral to the organization's strategic direction" instead of "applied"	TN
1567	ANS I	998 -999		The US TAGs to 176 and 207 Liaison Group recommends alignment between the two standards with respect to the following: The use of the word 'business'. Rational: The use of the word 'business' and associated explanatory note is causing confusion and misinterpretation. The users do not understand the difference between a business process and a MS process. The note is not helpful. Including this new requirement essentially elevates the QMS to the level of the entire management system of the organization as you could not integrate with all of the organization's business processes without doing so. In addition, this is the only place in the standard where the terminology business processes is used, which is not consistent with other requirements in the standard.	Option 1 Delete d Option 2 Ensuring the integration of the quality management system requirements into the <u>organization's business-quality management system</u> processes,;	TN
1568	IE	998 -999	5.1.1 Line	Emphasising the QMS principles would encourage the intention of these lines.	Rephrase as: " quality management system principles and requirements into"	TN
1569	CQI 36	998	5.1.1	d) ensuring the integration of the quality management system requirements into the organization's business processes.	Change to d) ensuring the integration of all elements of the quality management system into the	TN

				The intent is sound but the way it is expressed implies that requirements from ISO 9001 are integrated into business processes rather than the elements of the QMS. It also implies that QMS processes are not business processes which is at odds with clause 8.1 because 'process needed to meet requirements' can only be business processes	organization's business processes	
1570	CQI 37	998	5.1.1	Delighted that the ISO/TC176 committee has got it right - at last - after 2 decades. If they had put preventive action before corrective it would have saved years of hassle and debate.	None. Don't reinstate preventive action!!	C
1571	IAQ G	998	5.1.1d	This is a requirement to integrate QMS requirements into the company's business processes. This requirement could introduce confusion as to the difference between business process and quality processes. The definition of a business process starting on line 1010 should be changed to note that all quality system processes are part of the company's business processes and there are some business processes that are not QS processes. The current definition appears to exclude QS processes as being core business processes when in fact, many QS processes are core to the success of the business.	Reword - improve Proposal: Replace the existing note with the following: Note: All of a company's activities can be identified as business processes and a large percentage of these can be seen as quality system processes. There are other business processes, such as finance and employee safety, that are indirectly related to quality system processes that should be integrated with quality system processes.	TN
1572	IAQ G	998	5.1.1 (d)	Including this new requirement essentially elevates the QMS to the level of the entire management system of the organization as you could not integrate with all of the organization's business processes without doing so. Though it is a noble idea, it really exceeds the scope of a QMS. We should delete this clause (d) or add, "as determined by the organization"	Add text – improve Proposal: add "as determined by the organization"	TN
1573	VN	998	5.1.1	the requirement for the "integration" is too broad and need to be explained to ease the implementation and assessment	Insert a Note: "The purpose of the requirement for the integration of the quality management systems is to avoid the "parallel management", when, for example, one activity is controlled by differently in different documents, which can described as "QMS" and "non-QMS" documents."	TN
1574	QS	998 and 999,	7.1.4	Spacing between the lines to be adjusted	Change as: Adjust spacing between the lines 1112 and 1113	EAF
1575	INLA C	999 - 1011	5.1.1 d and Note	To avoid confusion with not for profit and public administration organizations, change the word "business" to "core" in bullet d) and the Note.	Change: d) ...into the organization's core processes;	TN

				Also, in the Note, the term “core” should be changed by “essential”.	Note: Reference to “core” in this International Standard can be interpreted broadly to mean those activities that are essential to the purposes of the organization's existence; whether the organization is public, private, for profit or not for profit.	
1576	CQI 38	1000	5.1.1	' promoting awareness of the process approach'. Delete this line – it is already covered by g) at lines 1002 – 1003	e) promoting awareness of the process approach;	TN
1577	ANS I	1000	5.1.1	The process approach is not a requirement that is mentioned in the standard. Process approach as used as in the introduction is foundation information and therefore, this terminology should not be used.	Revise to consistent language in 4.4. e) promoting the <u>understanding</u> and awareness of the process approach <u>quality management system and its processes</u>	TN
1578	LU	1000	5.1.1	Include the risks based approach	e) promoting awareness of the process <u>and risk based</u> approach	TAP
1579	NL	1000	5.1.1	Process Approach is just one of the QMP's (Annex B). These principles are the foundation of quality management. To ensure these foundations are considered they should be part of the standard, not just in an annex.	Change (bold) e) promoting awareness of the quality management principles .	TN
1580	NL	1000	5.1.1	Leadership and commitment with regard to risk based thinking as a fundamental concept in ISO9001 has not been addressed.	Change to: “e. promoting awareness of the process and risk based thinking approach”	TAP
1581	NZ	1000	5.1.1	'process approach' is used only in the Introduction and QMPs. It would be better to use simple language here (eg title of 4.4) rather than what could be seen as quality jargon.	Change to e) promoting awareness of the organization's quality management system and its processes	TN
1582	IT	1000	5.1.1	It would be better to include a specific requirement for promoting awareness of the Quality Management Principles globally, not only limited to the process approach. This is an important way for demonstrate leadership and commitment with respect to the QMS by the top management.	Modify 5.1.1.e) as follows: <i>e) promoting awareness of the process approach and quality management principles;</i>	TN
1583	SE	1000	5.1.1	“promoting awareness of the process approach”. It is not necessary that everybody is or should be aware of process approach as a concept, motivating auditors to ask employees if they know what it is. People may apply the process approach without having heard the words. Implementation by means of application of the requirements in ISO 9001 is more important.	Delete “awareness of the”.	TAP

1584	FR	1000	5.1.1	Precise bullet e)	Bullet e) reads : promoting awareness of the process approach and its deployment Promouvant l'approche processus en favorisant son déploiement	TAP
1585	MUR	1001	5.1.1 f)	This line refers as for ensuring the availability of resources for the quality management system but does not speak about the maintaining of resources. Addendum of words "and maintained" at end of the sentence. This word will ensure that the resources are available and maintained	f) ensuring that the resources needed for quality management system are available and maintained	EN
1586	IIOC	1001	5.1f	5.1f requires that resources are available but does not indicate that they should be 'made available' - i.e. resources could be available but not applied	Consider amending to ensuring that the resources needed for the quality management system are <i>made</i> available	EN
1587	NL	1001	5.1.1	Resources are needed to ensure processes can be executed. One of most important tasks of top management is creating optimal conditions for these processes. Not all users of the standard will understand the relation between resources and process conditions. Clarification is needed to enhance better understanding of the concept of the systemic approach to resources.	Add (bold): f) ensure that the resources needed for the quality management system are available to create optimal conditions to execute the operational processes.	TN
1588	SE	1001	5.1.1	The requirement is vague. What is the purpose of the resources? Resources for the development/maintenance of the QMS? Resources for the operation of the QMS and its included processes? Resources for reporting on the performance of the QMS?	"ensuring that the resources needed for the <i>development, operations (including reporting on performance) and maintenance</i> of the quality management system are available"	TN
1589	TR	1002	5.1.1	In this statement, what will be communicated is explicit but the answer of "with whom top management communicate importance of effective quality management and of conforming to the quality management system requirements" is missing.	g) communicating the importance of effective quality management and of conforming to the quality management system requirements with interested parties and employees.	TN
1590	IIOC	1004	5.1	Line 1004 - the amendment of "outcomes" to "results" is not allowed (HLS) Better clarity of expectation	Change "results" back to "outcomes" this is a fundamental issue for correct application of the HLS as it relates to the intended outcomes of implementing the QMS which is defined within clause 1	EN
1591	ANSI	1004	5.1.1 h	This clause is redundant to 6.1.1a) This clause is difficult to audit. If an organization	Option 1: Delete 5.1.1 h) as it is covered in 6.1	TN

				puts becoming profitable as its intended result, and for some external reason (out of their control) can't accomplish the goal. They will be marked non-compliant as per this clause, which should not be the intent.	Option 2: Change to: h) demonstrating ensuring that the quality management system is working to achieves its intended results;	
1592	JP 92	1004	5.1.1	Evaluating quality management system (e.g., management review) is another essential item for demonstrating leadership.	Change item h) to: h) <u>evaluating continuing sustainability, adequacy, and effectiveness of quality management system</u> and ensuring that the quality management system achieves its intended results;	TN
1593	ANS I	1005 -1006	5.1.1	This clause as written is broad and directly does not lead to what is needed which is persons of the organization having a focus on the effective of the quality management system.	Option 1 Delete i) Option 2: Engaging, directing and supporting persons <u>of the organization</u> to contribute <u>provide focus</u> to the effectiveness of the quality management system (9/16) Option 3: Engaging, directing and supporting persons to <u>Communicating to the organization how they</u> contribute to the effectiveness of the quality management system	TN
1594	TC2 10	1005 -1006	5.1.1	While part of the Quality Management Principles, the requirement engagement to be a measure of Top management commitment represents a heavy and unnecessary demand to demonstrate compliance with this requirement in an audit situation.	Delete 'engaging'	TN
1595	AT	1005	5.1.1	The word engage has two very distinct meanings in this context: one is to hire or appoint persons for QM, the other one would be to get them actively involved (involve, participate, etc.); here definitely the second issue should be addressed. In translations it has to be decided between the two meanings, therefore a clearer word should be used where this ambiguity does not occur. For example in the german translation the term has now the meaning now "appoint/deploy". Alternatively to "actively engage the word "motivate" could be used.	Actively involving, directing and supporting persons to contribute to the effectiveness of the quality management system	TN
1596	EOQ	1005	5.1.1	The word "engage" could be interpreted as "hire".	Motivating , directing and supporting persons to contribute to the effectiveness of the quality management system	TN

1597	IE	1005	5.1.1 i)	Add the word “motivating”	i) Engaging, directing, motivating and supporting	TN
1598	BR	1007	5.1.1	Exclude the word continual to be consistent with the new QMP’s and with the clause 10.	j) promoting continual improvement;	TN
1599	ANS I	1007	5.1.1	The word promoting is not results based.	i) Promoting <u>demonstrating commitment to continual improvement</u>	TN
1600	AT	1007	5.1.1	Leadership means not only managing the present but also introduce the necessary changes for the future. → Introduce a new k)	J) promoting continual improvement k) considering change and innovation, e.g. in order to satisfy predicted customer needs or to create customer value	TAP
1601	EOQ	1007	5.1.1	Leaders are responsible to consider all options to enhance sustumer satisfaction and fulfills needs and expectations of customers. It is not enough to only “improve the present”.	J) promoting continual improvement k) considering change and innovation in order to satisfy predicted customer needs or to create customer value	TAP
1602	CA-37	1007	5.1.1	“promoting continual improvement;” Need to add: innovation	Change to: “j) promoting continual improvement and innovation”	TN
1603	IT	1007	5.1.1	The promotion of innovation is as important as continual improvement, but it is missing in the DIS (while it was included in the CD).	Modify 5.1.1.j) as follows: j) promoting continual improvement and innovation ;	TN
1604	ES	1008-1009	5.1.1. k)	Difficult to understand and therefore to translate into Spanish. What does “other relevant management roles” refer to?	Please clarify	TN
1605	ANS I	1008-1009	5.1.1	This sentence “k)” makes no sense and is getting too detailed in how a top management team “manages”.	Delete k)	TN
1606	TC2 10	1008-1009	5.1.1	It is not clear how compliance with this vague requirement on Top Management commitment can be objectively demonstrated	Delete k)	TN
1607	CA-38	1008	5.1.1	Unclear what is really meant: “supporting other relevant management roles....” Who is demonstrating leadership – top management or ‘other management roles’??	Preferably remove complewtely or rewrite in clear words what is meant and ensure it is audit-able – how would top management demonstrate their support?	TN
1608	TR	1008	5.1.1	Statement is not clear how auditors will decide in audits what will be evaluated other relevant management roles	k) supporting all relevant management roles to demonstrate their leadership as it applies to their areas of responsibility	TN
1609	RO	1009	5.1	For consistency.	To add “and authority”	TN
1610	ANS I	1010 - 1012	5.1.1	The US TAGs to 176 and 207 Liaison Group recommends alignment between the two	Eliminate the NOTE.	TN

				standards with respect to the following: The use of the word 'business'. Rational: The use of the word 'business' and associated explanatory note is causing confusion and misinterpretation. The users do not understand the difference between a business process and a MS process. The note is not helpful. If business processes is eliminated, in 5.1.1, the NOTE becomes unnecessary.		
1611	CA-39	1010	5.1.1	The note seems oddly placed in the document. There is but one reference at all to the word "business" in that Leadership section. NOTE Reference to "business" in this International Standard can be interpreted broadly to mean those activities that are core to the purposes of the organization's existence ; whether the organization is public, private, for profit or not for profit. Conceptually, the word 'business' should appear initially in section 4.1 and therefore the Note would fit better in that section.	Move to section 4.1 (organizational context) or to <i>Introduction</i> .	TN
1612	BY	1013	5.1.2	We offer another section title.	Suggests the following revision: «Leadership and commitment for the customer focus»	TN
1613	PH/BPS	1013	5.1.2	The DIS clarifies an important requirement that in order for processes within the QMS are capable of delivering their intended outputs, these processes should be related to product conformity and customer satisfaction enhancement. This requirement will help focus the formulation of quality objectives of processes on these important items.		C
1614	IE	1013	5.1.2	Top management should also be responsible for improvements to the QMS	Change to Customer Focus and qms improvement Change d) to the focus on enhancing customer satisfaction is maintained and opportunities for improvement to the QMS are identified and acted on. Bullets a) & c) are similar - consider combining	TAP
1615	GB	1014	5.1.2	This clause does not adequately reflect leaders' roles under Quality Management Principle 2 for Leadership or Principle 1 for Customer Focus	Introduce additional requirements for top management (and other leaders) to set examples for the organisation in directing efforts to	TAP

					understanding and satisfying customer requirements. Example: e) communicating the linkage between organizational objectives and satisfying customer requirements f) encouraging improved understanding of customers and their requirements	
1616	SE	1016-1017	5.1.2	5.1.2 a) and c) are duplicating each other. In addition a) is duplicating the requirement in 8.2.2 a).	Delete "and met"	TAP
1617	ANS I	1016	5.1.2	The expression "statutory and regulatory requirements" is not sufficiently contained to those related to the product.	Add an entry to clause 3 that uniformly defines that the expression "statutory and regulatory requirements" are intended to mean "statutory and regulatory requirements related to the product".	TN
1618	NL	1016	5.1.2	QMP Customer focus (ISO/DIS 9000, line 168) states as action to communicate customer needs and expectations to the organisation.	Add (bold) 5.1.2a) Customer requirements and applicable statutory and regulatory requirements are determined, communicated throughout the organization and met.	TN
1619	NL	1016	5.1.2	To adapt to the requirements of customers the organisation should understand the origin of these requirements. Therefore an organisation should understand the (business) context of its customers.	Add as a first bullet a) the context of customers is understood	TN
1620	ANS I	1018-1019	5.1.2	The use of the word risk has caused a large amount of comment from those who are experienced with the application of risk as well as those who are involved in ISO 31000. The term "opportunities" is not defined. Since the definition of "risk" is included, and contradicts those of other ISO standards which treat risk and opportunity as identical ("positive risk"), this must be corrected. Using this terminology as it is written in Annex SL is technically incorrect and has resulted in much feedback has the potential for lack of understanding and misinterpretation in the marketplace. Risks and its opportunities should be replaced by	5.1.2 b) the risks and its effects opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;	TN

				risks and its effects with some clarification added in the requirements related to terminology.		
1621	CQI 39	1018	5.1.2	f) the risks and opportunities in accordance with... Change all instances of 'risks and opportunities' to 'opportunities and risks' to emphasize the positive nature of a Quality Management System. See CQI General comment.	f) the risks and opportunities and risks in accordance with...	TAP
1622	NL	1018	5.1.2	Determination and addressing of risks (..) is required in 6.1.1. More important is that organizations focus on risk that have most impact on customer satisfaction.	Change (bold) b)are determined and addressed managed	TN
1623	FI	1018	5.1.2, 8.2.	Title is customer focus: Product requirements shall be considered only from the viewpoints of customer requirements and satisfaction, and statutory and regulatory requirements. Broader view points (organizations strategic focus, technological requirements etc..) are not in the scope of this standard	For example line 1018. Delete conformity of product and services and	TN
1624	TT	1018	5.1.2	The phrase 'risks and opportunities' do not always compliment each as it appears in b). Opportunities are intended to have a positive impact. Use of 'and opportunities that can affect conformity' seems ambiguous and opposing. Risks can affect conformity, but opportunities should not.	Omit: 'and opportunities' from sentence.	TAP
1625	CH	1019	5.1.2	Major goal of risk based thinking is not only to address the risks but also to treat the risk. Clause 5.1.2 b) reads: "the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;"	Read: "the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined, and addressed and treated ;"	TN
1626	ES	1020 -1022	5.1.2 c) and d)	Items c) and d) seem redundant and not necessary. If on one hand the customer and legal and statutory requirements are met (a), and on the other hand risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed (b), then there is no need to add c) and d)	Delete requirements c) and d)	TAP

1627	INLA C	1024	5.2	For consistency with ISO/DIS 14001, remove the number of the two sub-clauses.	Change: Top management shall establish, review... The quality policy shall:...	EN
1628	ANS I	1024	5.2.1	The US TAGs to 176 and 207 Liaison Group recommends alignment between the two standards with respect to the following: Top management shall establish, <u>implement</u> review and maintain a quality policy... Rational: The concept of review is embedded in the term 'maintain', therefore is redundant. The proposed alignment is consistent with the phrase and terms used in 4.4.	For 9001: Top management shall establish, <u>implement</u> review and maintain an environmental policy... No change to 14001	TAP
1629	DE	1024	5.2.1 and further clauses	Please do not "mix" application of headline rules. If there is a numbered headline as 5.1.1 and 5.1.2 keep system. Numbering + title are good practice so there can be references in accordance to the regulations.	Please act similar as noted beside and rephrase where ever necessary. e. g. Line 1190, 1481, 1487, 1500, 1516, 1533, 1548	TAP
1630	CA-40	1024	5.2.1	5.2.1 <u>Top management shall establish, review and maintain a quality policy that:...</u> - There is no title for paragraph.	Add sub-title Developing the Quality Policy	TAF
1631	TR	1024	5.2.1	The Supplier is not required to prepare the Quality Manual in new ISO 9001:2015. So it is not necessary for the supplier in order to establish effective and economical QMS according to new ISO 9001:2015. However, instead of a detailed Quality Manual, the Supplier should prepare a cross references list or a reference table which indicates quality policy and all the processes implemented by the supplier in order to facilitate auditor's activities.	Just before the sentence of "Top management shall establish a quality policy that:", following sentence should be added; The Supplier shall prepare the Framework Document indicates both the quality policy and all the processes implemented by the supplier in order to facilitate all audit activities (see 9.2).	TN
1632	IT	1024 1029	5.2.1 5.2.2	Editorial suggestion.	It would be appropriate to indicate a title for sub-clauses 5.2.1 and 5.2.2, for editorial consistency within the text.	TAP
1633	IT	1025	5.2.1	Quality policy should be not only appropriate to the purpose of the organization, but also be consistent with its strategies and its overall objectives, in a short and medium-long term perspective. It is very important to ensure the integration of quality policy into the strategic planning process and business planning of the organization.	Modify 5.2.1 a) as follow: <i>a) is appropriate to the purpose and context of the organization and is consistent with its strategies and the overall objectives, in a short and medium-long term perspective</i>	TAP

1634	ANS I	1026	5.2.1	Providing a framework to review Quality objectives is technically incorrect since this would imply the need to include requirements or mention of the establishment and review of quality objectives, which could be a little too detailed for most policies. This text does not add value and is not needed.	b) provides a framework for setting and reviewing quality objectives	TAF
1635	BR	1027	5.2.1	Replace the verb "to satisfy" by "to meet" to maintain the uniformity of the entire text of the DIS 9001, related to "requirements", as an example: lines 214, 253, 261, 387, 944, 1020.	c) includes a commitment to <u>meet</u> satisfy applicable requirements;	TN
1636	ANS I	1027	5.2.1	The expression "applicable requirements" is unclear. Just what applicable requirements are intended here?	Revise to "...requirements applicable to the product"	TN
1637	CA-41	1027	5.2.1	In ISO 9001:2008, §5.3, it states: "Top management shall ensure that the quality policy....includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system". In the 9001 DIS, it states: "<u>Top management shall establish</u>, review and maintain <u>a quality policy that...</u>" c) <u>includes a commitment to satisfy applicable requirements;</u> d) <u>includes a commitment to continual improvement of the quality management system."</u> There are 2 points here: - the change from 'comply with requirements' to 'satisfy requirements'. What is the difference between 'comply' and 'satisfy'? Elsewhere, 'comply' (or variants) is used. If they mean the same thing, why use two different words – we should be consistent. If they have a different meaning, then define both terms, so that it is clear to the user. - bullet d) indicates that the focus is just on improving the QMS, not improving <u>the effectiveness</u> of the QMS. One might argue that any improvement of the QMS will improve its effectiveness, but if so, then why	If we take the current definition of "continual improvement" (3.21), supplemented by the definition for "performance" (3.13), it states: "recurring activity to enhance measurable result". When applied as 'continual improvement of the quality management system', this does not address the 'extent to which planned activities (on the QMS) are realized and planned results (expected in the QMS) achieved.' An improvement may <u>enhance measurable results</u> but not necessarily <u>achieve expected results</u>, so 'effectiveness', as defined in §3.06, is not inherent in 'continual improvement' Therefore, §5.2.1 d) of 9001 DIS should be changed to: <u>"includes a commitment to continual improvement of the effectiveness of the quality management system."</u> If they have different meanings, then define "satisfy" and "comply", in the context of this Standard. Otherwise, change §5.2.1 c) to: <u>"includes a commitment to comply with applicable requirements;"</u>	TN

				does the standard elsewhere (9x) keep emphasizing 'effectiveness of the QMS'? If 'effectiveness' is inherent in 'continual improvement' then why not be consistent, and just focus on improving the QMS. But, based on definitions, 'effectiveness' is not inherent in 'continual improvement', so the standard should revert to: "...continual improvement of the effectiveness of the quality management system..."		
1638	NL	1028	5.2.1	The quality policy should also require a statement with regard to risk based thinking/approach	Add e) includes a commitment to risk based approach	TN
1639	IE	1028	5.2.1 After line	Include in the Quality Policy statement the justification for excluding any requirements of the Standard (to avoid the danger of the ISO 9001 certificate becoming very verbose - see Clause 4.3 Line 968).	Include an additional requirement for the Quality Policy: (e) includes the justification for excluding any requirements of the Standard	TN
1640	DK	1029	5.2	And that the policy shall support the strategic direction of the organization	Add: "policy shall support the strategic direction of the organization" as a new indent.	TAP
1641	CA-42	1029	5.2.2	5.2.2 <u>The quality policy shall...</u> : - There is no title for paragraph.	Add sub-title Communicating the Quality Policy	TAF
1642	INLA C	1030	5.2.2 a)	For consistency with other references to documented information, include "be maintained". See line 965: The scope shall be available and be maintained as documented information	Change: a) be available and be maintained as documented information	TAF
1643	ANS I	1030	5.2.2	ISO 9001 has indicated through its own annex and notes that the use of maintain and retain will be used to clarify what type of documented information is being identified in a requirement. This clause does not provide that clarify.	a) Be available <u>Maintain</u> as documented information	TAP
1644	ISS/RS	1030	5.2.2	According to A.6 par.2 it is not clear if quality policy shall be retained/or maintained as documented information	a) be maintained as documented information	TAP
1645	MY	1031	5.2.2 b)	The use of the word "understood" is not consistent with Subclause 7.3 which only requires persons doing work under the organization's control to be "aware" of the quality policy.	To use the term which shows consistency with Subclause 7.3	TAP
1646	IT	1032-1033	5.2	It would be appropriate to include a note of support.	Add the following note: NOTE The policy should be consistent with organization's mission and vision (see ISO 9000, 3.4.11 and 3.4.10) and it should be expressed in a concise, simple and essential	TN

					<i>manner.</i>	
1647	NL	1032	5.2.2	'relevant' is redundant. As appropriate (HLS-text) is enough to leave room for a customized approach.	Remove (bold) c) be available to relevant interested parties, as appropriate.	TN
1648	CA-43	1032	5.2.2)	Delete the words 'as appropriate' – this is an ambiguous term and cannot be objectively audited. c) be available to relevant interested parties, as appropriate.	c) be available to relevant interested parties, as appropriate. (A 'Note' may be added to explain and give examples of the 'relevant interested parties' to whom the policy should be made available.)	TN
1649	SE	1032	5.2.2	The addition to the Annex SL text in c) i.e. "relevant" is superfluous. It is already covered by "as appropriate".	Delete: "relevant" and explain in 4.2 what is relevant (see ISO/DIS 14001)	TN
1650	TR	1033-1045	5.3	"The assigned authority/personnel by top management" definition in ISO 9001:2015 para.5.3 should be called the management representative. The management representative should have the necessary organisational authority and freedom to resolve matters pertaining to quality in order to ensure <i>that the quality management system conforms to the requirements of ISO 9001:2015, the processes interact and are delivering their intended outputs and to report on the performance of the quality management system to top management and any need for improvement (para 5.3 a),b), and c))</i> . Thus, when top management assign an authority as the management representative, it will facilitate the audit activities of second/third party auditors. Otherwise auditors may have difficulty to find a direct point of contact. In other words, as the second/third party auditors, we will probably have trouble in our audits with finding the right person as a communication interface between us and other employees about QMS issues.	<i>The statement of "Top management shall be accountable for the effectiveness of the quality management system and shall assign the responsibility and authority for:"</i> <i>Should be changed as "Top management shall be accountable for the effectiveness of the quality management system and shall assign the responsibility and authority (can be called the Management Representative if there is a customer requirement in the contract) for:"</i>	TN
1651	TR	1033-1045	5.3	We are not very clear about the following para. "c) reporting on the performance of the quality management system, on opportunities for improvement and on the need for change or innovation, and especially for reporting to top management"	Option 1: deletion the "especially for reporting to top management" Option 2: Add a new bullet as following: "especially for reporting to top management"	EAP
1652	ES	1033	5.3	The current requirement 5.5.2 a) in ISO 9001:2008 says:	Add text to 5.3 b) as follows: 5.3 Organizational roles, responsibilities and authorities	TN

				5.5.2 Management representative Top management shall appoint a member of the organization's management who, irrespective of other responsibilities, shall have responsibility and authority that includes: a) ensuring that processes needed for the quality management system are established, implemented and maintained, This requirement is partially missed in ISO/DIS 9001:2014 since it is not explicitly included in either 5.1.1 Leadership and commitment for the quality management system or 5.3 Organizational roles, responsibilities and authorities	<i>Top management shall ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization.</i> <i>Top management shall assign the responsibility and authority for:</i> a) <i>ensuring that the quality management system conforms to the requirements of this International Standard;</i> b) <i>ensuring that the processes needed for the quality management system are established, implemented and maintained, and delivering their intended outputs.</i>	
1653	CO	1033	5.3	Function and roles are both used within the standard.	Include a note clarifying the term role. ISO DIS 9000 includes a definition of functions but not roles	TN
1654	FR	1034	5.3	Complete the sentence	Complete the sentence by adding "identified" before "assigned" and by replacing "relevant roles" by "key roles". Top management shall ensure that the responsibilities and authorities for key roles are defined, assigned ...	TN
1655	ANS I	1035	5.3	The word "throughout is better than the "within"	Replace "within" with "throughout"	EN
1656	KE	1036	5.3	Top management need to assign a member of top management the responsibility and authority	Top management shall assign a member of top management the responsibility and authority	TN
1657	FR	1036	5.3	Remove the second paragraph. Redundant with the first one.	Top management shall ensure that the responsibilities and authorities for key roles are defined, assigned, communicated and understood within the organization for : a) to e)	TN
1658	IE	1037	5.3	Change the text in the bullet points by adding "ensuring that" to line 1036.	Add "ensuring that" to line 1036. Delete "ensuring that" from a), b) and e). c) the performance of the quality management system is reported and includes opportunities for improvement d) customer focus is promoted throughout the organisation	EN
1659	JP 93	1037	5.3	To ensure continuity with 2008 version.	Insert 5.5.2 a) of 2008 version "ensuring that processes needed for the quality management	EN

					system are established" before item a).	
1660	ANS I	1039	5.3	Changing the word outputs to results will align it better with line 1051.	Change the word "outputs" to "results".	EN
1661	IT	1039	5.3	Technical suggestion.	Modify bullet as follows: <i>b) ensuring that processes of the quality management system are established, implemented, maintained and are delivering their planned outputs;</i>	EN
1662	ANS I	1040 -1042	5.3	Remove the word "especially" because that adds no value and implies that is more important than the other items. What is being "reported to top management". The sentence needs to be re-worded to be specific on what information is reported to top management. The word innovation is not used as a requirement in ISO 9001:2015, therefore, requiring top management to report on it is technically incorrect. Furthermore, it has been agreed by the WG experts that the term innovation should not be used. At the Belo Horizonte meeting, a decision was made related to the use of innovation. That decision stated "The standard shall accommodate innovation. It may even mention innovation. It will not require accidentally or otherwise the organization to innovate or be seen to be innovative. Neither will it imply the above. The use of innovation does not meet this criteria. It was further discussed in a general session of the WG plenary in Versailles and agreed by the WG experts that the word innovation was not to be used. The statement "especially for reporting to top management" can be written in more simpler terms.	C) reporting on the performance of the quality management system <u>to top management</u> , on opportunities for improvement and on the need for change or innovation , and especially for reporting to top management .	TAP
1663	IE	1040 -1042	5.3c Lines	The phrasing is cumbersome here.	Rephrase 5.3c as follows: "Reporting, especially to top management , on the performance of . . . or innovation".	EAP
1664	CO	1040	5.3	Rewrite literal c. Last sentence "and especially for reporting to top management" is not clear.	reporting to the organization and top management on the performance of the quality management system, on opportunities for	EAP

				What is the thing that has to be report to the top management?	improvement and on the need for change or innovation	
1665	AR	1040	5.3	Bullet c) is not clear "Innovation" is one of the many examples of "improvement" (See Note to 10.1).	Change to: Reporting on the performance of the QMS to top management and other relevant management levels, on the opportunities for improvement (including the need for change or innovation)	TN
1666	TC2 10	1041 -1042	5.3	The inclusion of four points within this one element of the list is excessive, and the final element including 'especially' is confusing and unnecessary	Delete 'and especially for reporting to top Management'	EAP
1667	AU	1041	5.3	"need for change or innovation" seems out of context. Delete 'innovation'.	Change to 'improvement and recommendations for change'	EN
1668	AU	1041	5.3 c)	It is unclear why it is felt necessary to include a superlative when the clause is normative anyway.	Delete, 'especially'.	EAF
1669	GB	1041	5.3 c	Use of the word 'especially' is not good practice	Delete term	EAF
1670	SE	1041	5,3	"... and especially for reporting to top management. " The word especially does not add anything. Are the other things to report on of less importance?	Remove "especially"	EAF
1671	JP 94	1041	5.3	"Improvement" is a comprehensive term that broadly includes "innovation" as explained in Note 1 to Clause 10.1. Do not use "innovation" in requirement texts of the standard to avoid confusion. Stay unchanged according to the intent of Design Specification.	Delete "or innovation" from L1041.	TAP
1672	JP 95	1041	5.3	The "and especially for reporting" can weaken the intent of the text of Annex SL.	Delete "and especially for reporting."	TAP
1673	IAQ G	1042 Et al	3. 6.1.1 (main occurrence)	Clause 6.1.1 requires to address risks and opportunities. While risk is defined in 3.09, no definition is provided for opportunity . In absence of an ISO definition, one has to refer to definitions given in dictionaries. This is considered unsatisfactory, because it would give the way to different interpretations, problematic implementation and subjective assessment of compliance	IAQG Priority Comment Add definition – clarify Proposal: Define <u>opportunity</u> . What is the interpretation of this term within the context of ISO 9001 requirements?	C
1674	NL	1043	5.3	Promotion of customer throughout the whole organization can only be done by the top management.	Move to 5.1.1 d) ensuring the promotion of customer focus throughout the organization.	TN

1675	IT	1043	5.3	It would be appropriate to include a reference to clause 4.2.	Modify bullet as follows: <i>d) ensuring the promotion of customer focus throughout the organization (see 4.2);</i>	TN
1676	SE	1044 -1045	5.3	Integrity is not easily translated to Swedish. What is the meaning in this sentence? The effect of the quality management system? Consider use of another term or explain integrity for translational purposes.	Change to: ""ensuring that the effectiveness and the scope of the QMS are maintained when changes are planned and implemented"	EN
1677	NL	1044	5.3	These 'changes' are the same as in 6.3. Make a reference since this is a different chapter	Add (bold) e) ensuring that the integrity ... are planned and implemented. (See 6.3)	EN
1678	TN	1045		Add at the end: "f) trigger actions address the risks and opportunities identified"		TN
1679	DE	1046	6		Please align risk related wording with ISO/DIS 14001 („risk related to threats and opportunities")	TN
1680	MUR	1046	6	It is understood that the clause on planning is for the quality management system. We are thus proposing to delete "for the quality management system".	To write the title as follows: 6 Planning for the quality management system	TAF
1681	PL	1046	6	Instead of ".Planning <u>for</u> the quality management system" we propose to change " Planning <u>of</u> the quality management system" As the intent is that the quality management system is planned	Planning <u>of</u> the quality management system	TN
1682	SG	1046	6	To indicate that risk must be addressed on many factors other than products and services.	Action to address risk and opportunity should emphasize on the following factors: - Products and services (already addressed) - People - Processes - Infrastructure - Environmental - Legal requirements - Other interested parties - Financial	TN

1683	SE	1046	6	The standard only talks about risks. There are different kinds of risks, they could be graded into different groups of risks.	Consider if the standard TS 9002 should talk about grading risk into different groups of risks, for example, financial, security for the society etc.	C
1684	PL	1047-1063	6.1	Actions to address risk and opportunities do not entirely replace preventive actions, especially in everyday operation. At the same time if there are not requirements concerning preventive actions – there is no need to document them.		TN
1685	IT	1047-1063	6.1	We deem that the risk-based approach expressed in clause 6.1, which requires the integration of “<i>actions to address risks and opportunities</i>” with the basic “<i>quality management system processes</i> (4.4)” is one of the key innovations of future ISO 9001. In this sense, it is strange to see that: - no documented information regarding risks and opportunities and related actions is currently required; - very few references and/or requirements to risks, opportunities and actions are provided in the following clauses (i.e. from 8 to 10) of the draft. We deem that the above mentioned innovation is still too implicit in the current draft. This is one of the very few step back with respect to the CD. [CRITICAL COMMENT]	Add a requirement regarding documented information related to risk and opportunities and related actions as expressed in 6.1. For instance add the following new sub-clause: 6.1.3 The organization shall retain documented information related to identified risks and opportunities and related actions, including the adopted methods and techniques for their identification and assessment. Modify clauses from 8 to 10 making explicit reference to risk and opportunities and related actions.	TN
1686	CQI 40	1047	6.1	6.1 Actions to address risks and opportunities Change all instances of ‘risks and opportunities’ to ‘opportunities and risks’ to emphasize the positive nature of a Quality Management System. See CQI General comment.	6.1 Actions to address risks and opportunities and risks	EN
1687	ANS I	1047	6.1	The use of the word risk has caused a large amount of comment from those who are experienced with the application of risk as well as those who are involved in ISO 31000. The term “opportunities” is not defined. Since the definition of “risk” is included, and contradicts those of other ISO standards which treat risk and opportunity as identical (“positive risk”), this must be corrected. Using this terminology as it is written in Annex SL is technically incorrect and has resulted in much feedback has the potential for lack of	6.1 Actions to address risks and <u>its effects</u> opportunities	TN

				understanding and misinterpretation in the marketplace. Risks and its opportunities should be replaced by risks and its effects with some clarification added in the requirements related to terminology.		
1688	PH/ BPS	1047	6.1	Risk and Opportunities derived from issues. In what context and situation would this relate,	A note would help clarify this.	C
1689	PH/ BPS	1047	6.1	The requirements in the ISO DIS, if retained in the final standard, will push for meaningful planning, use and improvement of the QMS because of the requirement that organizations understand and identify their context, along with their risks and opportunities.		C
1690	FR	1047	6.1	Tha standard focuses on risk management but much less on opportunities.	Add a definition of the term « opportunity » and add a note or examples on what can be considered as an opportunity	TN
1691	ANS I	1048 -1050	6.1.1	The use of the word risk has caused a large amount of comment from those who are experienced with the application of risk as well as those who are involved in ISO 31000. The term "opportunities" is not defined. Since the definition of "risk" is included, and contradicts those of other ISO standards which treat risk and opportunity as identical ("positive risk"), this must be corrected. Using this terminology as it is written in Annex SL is technically incorrect and has resulted in much feedback has the potential for lack of understanding and misinterpretation in the marketplace. Risks and its opportunities should be replaced by risks and its effects with some clarification added in the requirements related to terminology.	6.1.1 When planning for the quality management system, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and <u>its effects of those uncertainties</u> opportunities that need to be addressed to:	TN
1692	MU R	1048	6	We are proposing to add titles to the sub-clauses in clause 6. This would make the document user friendly. To be consistent with other management standards	6.1.1 Risks and opportunities 6.1.2 Planning to take action 6.2.1 Quality objectives 6.2.2 Planning actions to achieve quality objectives.	TN
1693	NL	1048	6.1.1	For an improved application of the concept of risk	When planning for the quality management system, the organization shall consider the issues	TN

				management in its complete we propose to add some small changes in the text to make the risk management concept at a more satisfactory level. (see 6.1.1, 6.1.2 and 6.3) Add bold text	referred to in 4.1 and the requirements referred to in 4.2 and determine the impact and likelihood of the risks that need to be addressed to:	
1694	CA-44	1048	6.1.1	6.1.1 When planning for the quality management system ... - There is no title for paragraph.	Add sub-title Planning for risks and opportunities	TN
1695	TH	1048	6.1.1	Clarification and example for undesired effects should be added as a NOTE.		TN
1696	IT	1048 1054	6.1.1 6.1.2	Editorial suggestion.	It would be appropriate to indicate a title for sub-clauses 6.1.1 and 6.1.2, for editorial consistency within the text.	EN
1697	FR	1048	6.1.1	Add ISO 31000 to the bibliography	Add ISO 31000 to the bibliography	TAF
1698	FR	1048	6.1.1	Precise that risks and opportunities are related to the QMS	Add to 6.1.1 : When planning for the QMS ... and determine the risks and opportunities related to the product or service and to customer satisfaction that need to be addressed :	TN
1699	CQI 41	1049	6.1.1	...and determine the risks and opportunities that... Change all instances of 'risks and opportunities' to 'opportunities and risks' to emphasize the positive nature of a Quality Management System. See CQI General comment.	...and determine the risks and opportunities and risks that...	EN
1700	INLA C	1049	6.1	TC 207/SC 1/WG 5 in this clause of ISO/DIS 14001 includes the term "threat". "Threat" is to identify the negative side of the risk; "opportunity", for the positive side. ISO/DIS 9000, 3.7.8, Note 1 to entry, states: An effect is a deviation of the expected - positive or negative. The term "opportunity" in clause 6 is not technical correct because a risk can result in a positive or negative effect, therefore, the intent of the word "opportunity" is covered in the definition of risk and there is no need to be included in the content of this clause and other parts of the standard. Clause 6.1 in current DIS of 9001 and 14001 are not consistent and an effort must be pursued by both WGs to ensure consistency in this clause that is key in the future standards.	There are three options to consider for change: Remove "opportunity" in the clause (ISO 14001 should proceed in the same way). Include the term "threat" and add a Note in the definition of Risk that clarify the terms "opportunity" and "threat". Keep the concepts of risk and opportunity as is now in the DIS and develop a definition of "opportunity" in ISO 9000. It can be included as a "Note to entry" to 3.7.8. Option 1 is the best way to proceed, in our opinion.	TN
1701	Lu	1049	6.1.1	The term determines could be completed by identify and evaluate.	... determine, <i>i.e. identify and evaluate</i> , the risks and opportunities	TN

1702	IIOC	1051	6.1	Line 1051 - the amendment of "outcomes" to "results" is not allowed (HLS)	Change "results" back to "outcomes" this is a fundamental issue for correct application of the HLS as it relates to the intended outcomes of implementing the QMS which is defined within clause 1	TN
1703	BG	1051	6.1.1	Quality management system should provide for the achievement of objectives.	Replace intended result(s) with objectives.	TN
1704	AR	1051	6.1.1	Keep "outcomes" from the HLS. "outcomes" is not a clear synonymous of "results" as used in the standard	Change "results" by "outcomes"	TN
1705	CH	1051	6.1.1	"assurance", means to "give confidence that" rather than to "make sure that". Users <u>need to be sure</u> that "give confidence" (to someone) is intended, as in clause 1.b).	<u>Check</u> that the first meaning ("give confidence") is really what is intended. <u>If, however</u> , the meaning 'make sure that' is intended, <u>change</u> line 1051 to read " a) ENSURE that the quality ... "	C
1706	FR	1051	6.1.1	Complete bullet a)	Complete bullet a so it reads : a) give assurance that the quality management system and its processes can achieve their intended results	TN
1707	ANS I	1052 -1053	6.1.1	Revise to include opportunities and clarify language in alignment with terminology.	c) create or increase positive opportunities; d) achieve continual improvement	TAP
1708	CA-45	1052	6.1.1	b) prevent, or reduce, undesired effects; The phrase 'undesired effects' is vague – perhaps re-word as per the definition of "corrective action"	Change to: " b) prevent, or reduce , nonconformities or other undesirable situations;" OR, re-phrase without using the word "undesired" or derivatives.	TN
1709	JP 96	1052	6.1.1	It is not clear that nonconformities are included in the "undesired effects."	Change to: b) prevent, or reduce, undesired effects <u>including nonconformities</u>	TN
1710	FR	1052	6.1.1	replace [...] prevent or reduce adverse effects [...] by [...] prevent or reduce the risks and adverse effects [...]	replace [...] prevent or reduce adverse effects [...] by [...] prevent or reduce the risks and adverse effects [...]	TN
1711	BR	1053	6.1.1	Exclude the word continual to be consistent with the new QMP's and with the clause 10.	c) achieve continual improvement	TAF
1712	NL	1053	6.1.1	Risks are the foundation of the quality management system. To ensure the organization can demonstrate it has serious considered all relevant risks this should be available as documented information.	Add The identified risks shall be available as documented information.	TN
1713	IT	1053	6.1.1	It would be appropriate to address also	Add the following bullet: d) identify needs for innovation.	TN

				"innovation".		
1714	FR	1053	6.1.1	Change bullet c) to extend it to other types of improvement	Bullet c) reads : Achieve improvement	TAF
1715	IE	1053 , 1093, et al	6.1.1	The document uses the words "continual improvement" in many places other than clause 10.3. Since Clause 10 and the principles refer only to "Improvement", continual should be reserved for clause 10.3 only/	Remove the word "continual" from improvement except in clause 10.3	TAF
1716	MUR	1054	7.3	This clause talks about awareness. The persons of the organisation should also be aware about the changes effected in the quality management system.	to add a sentence as (e) which will read as follows:- e) any changes effected in the quality management system.	TN
1717	BR	1054	6.1.2	Possible inclusion of one more phrase, about the revision of the risk and opportunities analysis, because can change over time	The organization shall review the definition of risks and opportunities at planned intervals	TN
1718	CA-46	1054	6.1.2	6.1.2 The organization shall plan ... - There is no title for paragraph.	Add sub-title Action for risks and opportunities	TN
1719	FR	1054	6.1.2	Need precision. Actions must be planned and implemented and shall concern also customer satisfaction.	Add : Actions taken to address risks and opportunities shall be planned and implemented and be proportionate to the potential impact on the conformity of products and services and customer satisfaction. Les actions relatives aux risques et opportunités doivent être planifiées et mises en oeuvre d'une manière adaptée au regard de leur impact potentiel sur la conformité des produits et des services et sur la satisfaction des clients.	TN
1720	CQI 42	1055	6.1.2	a) actions to address these risks and opportunities; Change all instances of 'risks and opportunities' to 'opportunities and risks' to emphasize the positive nature of a Quality Management System. See CQI General comment.	a) actions to address these risks and opportunities and risks ;	EN
1721	ANSI	1055	6.1.1	The use of the word risk has caused a large amount of comment from those who are experienced with the application of risk as well as those who are involved in ISO 31000. The term "opportunities" is not defined. Since the definition of "risk" is included, and contradicts those of other ISO standards which treat risk and opportunity as identical ("positive risk"), this must be corrected. Using this terminology as it is written in Annex SL	a) actions to address these risks and opportunities , i.e. uncertainties which can result in positive and negative consequences;	TN

				is technically incorrect and has resulted in much feedback has the potential for lack of understanding and misinterpretation in the marketplace. Risks and its opportunities should be replaced by risks and its effects with some clarification added in the requirements related to terminology.		
1722	TT	1055	6.1.2	In addressing risks and opportunities, the organization should also ensure that actions taken to address risks and opportunities must have the right combination of qualitative and quantitative risk inputs. Consider those actions necessary to build or improve customer confidence.	Add: new point under 6.1.2 : b) actions with the right combination of qualitative and quantitative risk inputs.	TN
1723	ANS I	1056 - 1058	6.1.2	"b) how to " is not item	Change to: b) how to integrate and implement the actions into its quality management system processes (see 4.4); and c) how to evaluate the effectiveness of these actions.	TN
1724	AR	1056	6.1.2	"b) how to " is not item	Change to: b) how to integrate and implement the actions into its quality management system processes (see 4.4); and c) how to evaluate the effectiveness of these actions.	TN
1725	QS	1056 , 1057 and 1058	8.5.4	What about preservation of Raw materials received from external parties?	Change "process outputs" to "goods"	TN
1726	NL	1058	6.1.2	For an improved application of the concept of risk management in its complete we propose to add some small changes in the text to make the risk management concept at a more satisfactory level. (see 6.1.1, 6.1.2 and 6.3) Add bold text	2) evaluate the effectiveness of these actions and the impact of these actions on the mitigated risks.	TN
1727	ANS I	1059 -1063	6.1.2	The use of the word risk has caused a large amount of comment from those who are experienced with the application of risk as well as those who are involved in ISO 31000. The term "opportunities" is not defined. Since the definition of "risk" is included, and contradicts those of other ISO standards which treat risk and opportunity as identical ("positive risk"), this must be corrected. Using this terminology as it is written in Annex SL is technically incorrect and has resulted in much	Actions taken to address risks and <u>their effects</u> opportunities shall be proportionate to the potential impact on the conformity of products and services. Note: Option to address risks and opportunities <u>Actions to be taken</u> can include avoiding or minimizing risks associated with negative consequences; taking or increasing risks associated with positive consequences, and assuming risk(s), by informed consent, without	TN

				feedback has the potential for lack of understanding and misinterpretation in the marketplace. Risks and its opportunities should be replaced by risks and its effects with some clarification added in the requirements related to terminology. Revise the note to be technically correct.	implementing additional controls.	
1728	NO	1059 - 1060	6.1.2	When reading line 1059 – 1060 carefully the text does not make any sense for us. It will be difficult to translate to meaningful text.	Delete lines 1059 – 1060 (or redraft).	TN
1729	CQI 43	1059	6.1.2	Actions taken to address risks and opportunities shall be... Change all instances of 'risks and opportunities' to 'opportunities and risks' to emphasize the positive nature of a Quality Management System. See CQI General comment.	Actions taken to address risks and opportunities and risks shall be...	TAF
1730	BW	1059	6.1.2	The word "proportionate" is not common	Use "appropriate" instead	TN
1731	LU	1059	6.1.2	Sentence no clear enough	Actions taken to address risks and opportunities shall be proportionate to <i>their</i> potential impact on the conformity of products and services	TN
1732	AR	1059	6.1.2	There should be documented information about the actions for addressing the identified risks and about the effectiveness of these actions	Change to: The organization shall retain documented information on the determined risks the actions taken to address risks and opportunities, proportionate to the potential impact on the conformity of products and services.	TN
1733	KE	1059	6.1.2	"Proportionate" is subjective	Replace with "appropriate"	TN
1734	NL	1060	6.1.2	Not all 'preventive' actions guarantee a risk will not occur. The organization should be aware of that. Therefore actions should be planned to reduce 'damage'. These actions only need to be executed when unforeseen events happen. (contingency actions?) These planned actions are the same as the 'corrective actions' as part of 8.7.	Add ... impact on the product conformity of products and services. The organization shall also consider to plan repressive and/or corrective actions to reduce the impact when risks do occur despite of taken actions.	TN
1735	NL	1060	6.1.2	One of the goals of ISO 9001:2015 is to create more flexibility into applying the standard. Therefore it is necessary to leave room to organisations the accept risks (or opportunities) 'as is'. On the other hand it is important – when reviewing the effectiveness of the system - to know why no action is taken.	Add (bold) ... impact on the product conformity of products and services. Where the organization determines not to take direct action to address a risk or opportunity, the organization shall retain information about the decision and the person or authority that made the decision.	TN

1736	IE	1060	6.1.2	Documented information on actions taken to address risk and opportunities should be available	Add: documented information on actions taken to address risk shall be retained	TN
1737	CQI 44	1061 - 1063	6.1.2	Options to address risks and opportunities can include: avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision. All the examples cited are risk. The exception is also risk to address a generic opportunity, This demonstrates bias towards risk. Split the Note into two and add examples of opportunities.	NOTE 1 Options to address opportunities can include: inventing new products, seeking new markets, joint ventures, adopting new technologies, restructuring the organization. NOTE 2 Options to address risks can include: avoiding risk, taking risk in order to pursue an opportunity , eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.	TN
1738	ANS I	1061 -1063	6.1.2	The note is correctly difficult to understand and not technically correct.	Note: Option to address risks and opportunities <u>Actions to be taken</u> can include avoiding or minimizing risks associated with negative consequences; taking or increasing risks associated with positive consequences, and assuming risk(s), by informed consent, without implementing additional controls.	TN
1739	JP 97	1061 -63	6.1.2	Applying ISO 31000 is not a requirement. The Note is not necessary.	Delete Note.	TN
1740	JP 98	1061 -62	6.1.2	The meaning of "opportunity" in L1061 is different from the meaning of "opportunities" of "risks and opportunities" in L1059.	Delete "in order to pursue an opportunity."	TN
1741	IAQG	1061	6.1.2	The NOTE is biased towards risk examples only.	Add text - clarify Proposal: Add examples to the NOTE of options to address "opportunities".	TN
1742	CO	1061	6.1.2	Provide reference for risk based and preventive approach	Include reference to Annex A-4;	TN
1743	TN	1061		Note: Replace "take the risk in order to seize an opportunity" to "be prepared to seize the opportunity"		TN
1744	AR	1061	6.1.2	Add a new note to consider quality emergency	NOTE 2 The organization may need to develop contingency plans to respond to emergency situations to can have impact on the conformity of products and services or on customer satisfaction	TN
1745	INLA C	1061 a 1063	6.1 Note	Change the Note. In clause 0.5, a reference to ISO 31000 is included as a potential option to address risk based thinking. The content of this Note in 6.1 is not consistent with the guidance provided in ISO 31000 and can create confusion for those organizations that decide to use ISO 31000 as a reference. Also, it can be of value to make reference to ISO	Change: Note: see ISO 31000 and ISO 31010 for guidance	TN

				31010		
1746	MX	1061 , 1062 and 1063	5.1.1	NOTE Options to address risks and opportunities can include: avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.	NOTE Options to address risks and opportunities can include: avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, minimizing the effects of risks, when possible , or retaining risk by informed decision. RATIONALE: The effects of some risks can also be minimized	TN
1747	INLA C	1063	6.1 New Note	Include a new Note to improve consistency with ISO/DIS 14001 highlighting the consideration of emergency situations	Include a new Note: Note: The organization may need to develop contingency plans to respond to emergency situations.	TN
1748	MY	1063	6.1.2	In businesses, actions are also taken to reduce risk.	To rephrase the note as follows: ".....taking risk in order to pursue an opportunity, reducing risk , eliminating the risk source,....."	TN
1749	NZ	1063	6.1.2	Extend "retaining" risk to include managing and monitoring of retained risk	End of sentence ", retaining, <i>managing and monitoring of risk</i> by informed decision"	TN
1750	BE	1064	6.2	There is a difference between the words "goals" and "objectives". Objectives are generally expressed in "SMART terms" (specific, measurable, adapted, realistic, timely). Goals are in general expressed for the longer time or expressed in a permanent way. The term "quality objectives" has been used for many years in the meaning of "quality goal". As long as the quality policy did not change, the frame work to define the quality objectives did not change neither. In consequence: the quality goals did not change. The risk exists that by requiring (in ISO DIS 9001 §6.2.2) the SMART definition of quality objectives, users might think that definition of quality goals are no authorised anymore.	Consider to clarify "quality goals" and "quality objectives" and coordinate with ISO/TC176 SC1 as appropriate.	TN
1751	TT	1064	6.2	Grammar: The heading: 'Quality objectives and planning to achieve them' is ambiguous - 'to achieve them' is implied and is therefore unnecessary.	Omit: 'to achieve them' from heading in 6.2	TN
1752	ANS I	1065 -1073	6.2.1	This requirement has been made very prescriptive which is in disagreement with the	The Organization shall ensure that quality objectives, including those needed to meet	TN

				overall philosophy of ISO 9001:2015. Specifically, 1. Sections (6.2.1) and (6.2.2) are too prescriptive and look like a guidance document section, and also dissimilar to many other parts of this DIS. 2. These sections being too prescriptive in nature, may pose potential for misinterpretation and lead to unnecessary and non-value added nonconformities during audits, especially third party audits. 3. Section 6.2.2 in specific, could be misinterpreted that organizations will have to documented information for all the prescriptive clauses a) thru e).	applicable statutory and regulatory requirements for products and services are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy, with the aim of enhancing customer satisfaction.	
1753	CZ	1065-1073	6.2.1	Risk-based thinking should appear in the process of planning.	One bullet should be added between d) and e): "be relevant to minimize the significant risks;"	TN
1754	MUR	1065	7.4	It is important to document all communication relevant to quality management system for traceability.	To add the following sentence as at line 1172 and shift the rest of the text as appropriate. The organization shall retain documented information as evidence of its communication, as appropriate.	TN
1755	BR	1065	6.2.1	Risk analysis and the identification of opportunities is an important factor for setting quality objectives.	h) Consider identified risks and opportunities	TN
1756	ANSI	1065	6.2.1	The word processes changes the focus of quality objectives from organizational objectives to specific process objectives. Objectives set at the function and level would most likely be "process" objectives."The word processes broadens this requirement. The standard text does not prevent organizations to identify objectives at the process level.	Delete "and processes" The organization shall establish quality objectives at relevant functions and levels and processes	TN
1757	GOST R	1065	6.2 Quality objectives and planning to achieve them	What are the differences between performance indicators and processes objectives?? Shall be clarified		C
1758	DZ	1065	6.2.1	The modify the following sentence : "The organization shall establish quality objectives at relevant functions, levels and processes."	"The organization shall establish quality objectives at relevant functions, appropriate levels and	TN

					processes.”	
1759	IAQ G	1065	6.2.1	6.2.1 states that “The organization shall establish quality objectives at relevant functions, levels and processes.” This could be misinterpreted as requiring each process to have a quality objective.	Add text - Improve Proposal: Add qualifiers to the requirement as noted below: The organization shall establish quality objectives at relevant functions, levels <u>and key processes</u> .	TN
1760	KE	1065	6.2.1	Functions, level s are sufficiently cover processes	Delete “ processes ”	TN
1761	CN	1065 1075	6.2	Should add title to the 6.2.1 and 6.2.2 The 4.4 mentioned the performance indicators of process, but there is not any further description about the relationship between the quality objectives of a process and the performance indicators of a process. This will arouse difficulty of using this standard. So, strongly recommend in 6.2.1, add relevant content about the performance indicators. 增加标题	Add “quality objectives and performance indicators” to 6.2.1 Add “h) be supported by performance indicators relevant” to 6.2.1 Add “Planning to achieve quality objectives” to 6.2.2	TN
1762	CA- 47	1065	6.2.1	6.2.1 The organization shall establish quality ... - There is no title for paragraph.	Add sub-title Quality objectives	EN
1763	IT	1065 1075	6.2.1 6.2.2	Editorial suggestion.	It would be appropriate to indicate a title for sub-clauses 6.2.1 and 6.2.2, for editorial consistency within the text.	EN
1764	GB	1065	6.2.1	It is not clear that it is possible to establish quality objectives at processes as stated here. Text needs to be consistent to the use of ‘processes’ in 4.4.	Either Delete “and processes” and include “and” between “functions” and “levels” Or revise to: “The organization shall establish quality objectives at relevant functions and levels in the organization and for processes needed for the quality management system”	TAP
1765	TC2 10	1065	6.2.1	It is not clear that it is possible to establish quality objectives at processes as stated here. Text needs to be consistent to the use of ‘processes’ in 4.4.	Either Delete ‘and processes’ and include ‘and’ between ‘functions’ and ‘levels’ Or revise to The organization shall establish quality objectives at relevant functions and levels in the organization and for processes needed for the quality management system’.	TN

1766	FR	1065	6.2.1	Need clarification	What is the difference between « levels » and « functions ». Clarification is necessary for translating the requirement.	C
1767	TC69	1067	6.2.1	The sentence should end with a semicolon, like the other intermediate sentences, not a comma: "a) be consistent with the quality policy,"	"a) be consistent with the quality policy;"	EAF
1768	IT	1067	6.2.1	Quality objectives should be consistent not only with the quality policy, but also with the strategies of the organization and its overall objectives, in a short and medium long term perspective. It is necessary to clarify this important concept to ensure the effective integration of quality into the strategic direction of the organization.	Modify 6.2.1 a) as follow: <i>a) be consistent with the quality policy, the strategies of the organization and its overall objectives, in a short and medium long term perspective;</i>	TN
1769	SE	1068	6.2.1	The objectives are to be set up and not to be measured. Their fulfilment is to be measured.	Replace "be measurable" with "be expressed in measurable terms".	TN
1770	INLAC	1068 & 1070	6.2.1	Switch the order of the letters to give consistency	bullet b) should be bullet d); bullet d), bullet b)	TN
1771	ANSI	1069	6.2.1	The expression "applicable requirements" is unclear. Just what applicable requirements are intended here?	Revise to "...requirements applicable to the product"	TN
1772	RO	1070	6.2.1	Reformulation	be relevant to conformity of products and services and to the enhancement of customer satisfaction;	TAF
1773	ANSI	1074	6.2.1	The US TAGs to 176 and 207 Liaison Group recommends alignment between the two standards with respect to the following: The organization shall maintain retain documented information om the XXX objectives. Rational: XXX objectives are a 'living' document, subject to review and revision. The standard should be consistent throughout by using verb 'maintain' to indicate a document (as explained in Annex). TAG 176 Comment - The reference to retain documented information is not correct. Most organizations maintain information about quality objectives since they update them on some level of frequency. This is a new record requirement. Management review (9.3.1) includes change as an input. Since this information is retained, this requirement is redundant, could be conflicting,	Revise to The organization shall retain maintain documented information on the quality objectives.	TAF

				and is not needed. Managers may also interpret this prescriptive requirement of making change of their quality management system more bureaucratic.		
1774	IAQ G	1074	6.2.2	bullets “a) to e)” are not applicable to quality objectives at all levels, e.g. the overall objectives	Add text - Improve Proposal: Add “as appropriate”	TN
1775	TT	1074	6.2.1	“The organization shall retain documented information on the quality objectives” does not correspond with Annex A.6, lines 1671 and 1672 as 6.2.1 (e) requires monitoring of quality objectives	Change to read “The organization shall maintain documented information on the quality objectives.”	TAF
1776	ANS I	1075 -1080	6.2.2	This requirement has been made very prescriptive which is in disagreement with the overall philosophy of ISO 9001:2015. Specifically, 1. Sections (6.2.1) and (6.2.2) are too prescriptive and look like a guidance document section, and also dissimilar to many other parts of this DIS. 2. These sections being too prescriptive in nature, may pose potential for misinterpretation and lead to unnecessary and non-value added nonconformities during audits, especially third party audits. 3. Section 6.2.2 in specific, could be misinterpreted that organizations will have to documented information for all the prescriptive clauses a) thru e).	6.2.2 Planning to achieve quality objectives The organization shall plan and determine defined <u>assign</u> responsibilities and resources required to achieve established quality objectives	TN
1777	SE	1075 -1080	6.2.2	“a) what will be done; b) what resources will be required; c) who will be responsible; d) when it will be completed; e) how the results will be evaluated.” As previously declared more than once the verb “will” to denote a requirement is not in line with ISO Directives Part 2 Table H.1. To avoid repetition of “shall” from the introductory line 1075 in bullets a) through e) Table H.1 gives several possibilities. Two are presented.	“a) what has to be done; b) what resources have to be required; c) who has to be responsible; d) when it has to be completed; e) how the results have to be evaluated.” or, retaining “will”: “a) what will have to be done; b) what resources will have to be required; c) who will have to be responsible; d) when it will have to be completed; e) how the results will have to be evaluated.”	TN
1778	IAQ G	1075	6.2.2	Using “shall” determine...a) – e). Makes this an auditable requirement. If a company has an	Reword – improve Proposal: Change “shall determine” to “shall	TN

				“objective” to reduce defects by 10% throughout the company, there may be dozens of activities in work to accomplish just that one objective. Some activities may be very complex and require planning as outlined in a) - e) and others may be very simply following daily routine work instructions, not requiring any “determination” of a) – e) at all.	consider”.	
1779	CA-48	1075	6.2.2	6.2.2 <i>When planning how to achieve its quality objectives ...</i> - There is no title for paragraph.	Add sub-title Achieving quality objectives	EN
1780	ES	1076 - 1080	6.2.2	The style of 6.2.2 seems not to be appropriate to the standard drafting. Use substantives for indicate each bullet a) to e)	6.2.2 When planning how to achieve its quality objectives, the organization shall determine: a) what will be done the actions to be performed; b) what resources will be required the resources required; c) who will be responsible the responsible; d) when it will be completed the deadlines for the completion; e) how the results will be evaluated the criteria for evaluate the results	TN
1781	AU	1079	6.22	Replace “it” with “they”	d) when they will be completed;	EN
1782	IT	1080	6.2.2	It would be better to clarify that the evaluation of results should be done at planned intermediate steps, so that the organization can effectively monitor the progress in the achievement of its objectives as planned.	Modify 6.2.2 e) as follows: e) <i>how the intermediate and final results will be evaluated;</i>	TN
1783	IAQ G	1081	6.3	To show that this clause does not cover all the requirements regarding the planning and control of changes	Add note - clarify Proposal: keep the note of the CD : “Specific requirements on control of changes are included in clause 8”	TN
1784	TN	1081	6	Added: the organization shall retain documented information on the planning changes		TN
1785	FR	1081	6.3	Add a note to give information about what kind of change should be taken into account	Note : Changes can include: organisation changes, information technology changes, etc.	TN
1786	ANS I	1082 -1083	6.3	The reference to (see 4.4) is not needed and could imply that this would be the only place where changes are determined. This reference should be eliminated to clarify that this clause refers to any change and just not those in 4.4.	Where the organization determines the need for change to the quality management system (see 4.4.) the change shall be carried out in a planned and systematic manner.	TN
1787	DK	1082	6.3	Any change – even not needed – shall fulfil the requirement.	Change the text into: “Where the organization determines the need for  change to the quality	TN

					management system (see 4.4) the change shall be carried out in a planned and systematic manner."	
1788	AR	1082	6.3	This clause should be applicable to any change that may affect the QMS. The term "systematic" is new to the document. Does it mean that in needs a procedure?, or a process, or what??	Change first line as follows: "... the need for change that affects the QMS (see 4.4) shall be carried out in a planned and systematic manner.	TAP
1789	GB	1082	6.3	Replace "where", which is location dependent, by "when" which is time dependent		EAF
1790	SE	1082	6.3	Does the reference to 4.4 ensure that the process for change is determined in every aspect?	Delete reference to 4.4.	TN
1791	TC6 9	1082 , 1083	6.3	The clause beginning with "where" should be separated by a comma from the main clause: "Where the organization determines the need for change to the quality management system (see 4.4) the change shall be carried out in..."	"Where the organization determines the need for change to the quality management system (see 4.4), the change shall be carried out in..."	EAF
1792	NL	1083 -1084	6.3	For an improved application of the concept of risk management in its complete we propose to add some small changes in the text to make the risk management concept at a more satisfactory level. (see 6.1.1, 6.1.2 and 6.3) Add par.	The organisation shall determine and mitigate the risks associated with the intended change.	TN
1793	ANS I	1083	6.3	What is the difference between "planned" and "systematic"?	Remove the word "systematic".	TN
1794	AT	1083	6.3	Simplify:	"... change shall be carried out in a planned and systematic manner ..."	TN
1795	LU	1084	6.3	Sentence no clear enough	<u>To plan the change</u> , the organization shall consider	EN
1796	AT	1085	6.3	"Any" means that every on, each single consequence has to be determined. This cannot be achieved. The qualifier any should be dropped, because this cannot be achieved by organisations. In the german translation the word "any" has been translated with "every single one", causing irritation.	the purpose of the change and any of its potential consequences;	TAF
1797	EOQ	1085	6.3	"Any" induce documentation creep – auditors could correctly interpret it as every single one.	the purpose of the change and any of its potential consequences;	TAF

1798	CO	1085	6.3	Include related risks.	a) the purpose of the change, the related risks and any of its potential consequences	TN
1799	PT	1085	6.3	c) the purpose of the change and any of its potential consequences;" Vague, potential consequences, can be misleading	a) the purpose of the change and any of its potential consequences including the determination of risks and opportunities (see 6.1)	TN
1800	IQNet	1085	6.3	a) the purpose of the change and any of its potential consequences;" Harmonize language and reinforce application of requirements as standard refers to address risks and opportunities	b) the purpose of the change and potential consequences in terms of risks and opportunities.	TN
1801	NL	1085	6.3	During a change may be special actions are needed. The organization should ensure it has a clear image of the step it needs to take. No 'action plan' will lead to chaos. Therefore we propose to split a) into two bullets a) and b) add the aspect of risk. And add bullet f).	a) the purpose of the change b) the risks and its potential consequences c) the integrity of the qms d) the availability of resources e) the allocation or reallocation of responsibilities and authorities f) the actions to be taken	TN
1802	CA-49	1085	6.3	Where the organization determines the need for change to the QMS,' the organization shall consider the purpose of the change and any of its potential consequences." Later in the standard (8.3.6 and 8.5.6) there are requirements for documented information on changes to be retained. It is equally important here, in regard to "potential consequences". Despite the best efforts of all involved, there are many cases where the potential consequences become more significant than originally estimated. Risk-based thinking would suggest that assumptions and constraints be retained as documented information, for periodic re-evaluation, to verify that the risk level has not become more critical. Why is there no requirement for retention of documented information on the changes to the QMS? This is not necessarily a benefit for the customer, but certainly is, for the organization.	Add a third paragraph: "Documented information on the purpose of any change to the quality management system, and any potential consequences, shall be retained."	TN

1803	CA-50	1085	6.3	Include specific reference to 'risk' - Modify this as shown in the column on the right a) the purpose of the change and any of its potential consequences;	a) the purpose of the change and its potential risks, opportunities and other consequences;	TN
1804	CH	1085	6.3	Risk based thinking should be also addressed when planning changes. Risk and opportunities of changes has been deleted compared to the CD. The risk evaluation should be included. 6.3) reads: "a) the purpose of the change and any of its potential consequences"	Read: "a) the purpose of the change and any of its risks and potential consequences"	TN
1805	TR	1085	6.3	Insert a new clause (b)	b) risks and opportunities	TN
1806	NL	1086	6.3	During a change special or temporary risks can occur. Part of planning changes should be that these risks are addressed to ensure no negative impact on conformity of products and services.	Change into b) the risks related the intended results of the quality management system	TN
1807	SE	1086	6.3	What is meant by "integrity of the quality management system"? Is it robustness etc...?	Clarify the meaning of "integrity" relative to this specific case.	TN
1808	CO	1088	6.3	It is important to document the planning.	The organization shall retain appropriate documented information as evidence of the planning change	TN
1809	TN	1088		Add at the end: e) than the risk associated with change "		TN
1810	TN	1088		Add the following note: "Note: Changes may include organizational structure, key responsibilities of the organization, the management system, providers of significant impact on product compliance and achievement of goals"		TN
1811	PT	1088	6.3	Instead of the allocation or reallocation of responsibilities and authorities	Read the assignment or reassignment of responsibilities and authorities [Responsibilities are assigned, not allocated!]	TN
1812	IE	1088	6.3	No reference to retaining documented information	Add "The organisation shall retain documented information relating to all changes in the quality management system"	TN
1813	NZ	1088	6.3	Add a requirement to ensure timeliness is considered	Add text: <i>"e) the timeline and milestones necessary to effect the change."</i>	TN
1814	TT	1088	6.3	Planning systematically for change, the time needed to execute the change and the impact of	Two criteria should be included when planning change:	TN

				this change (if it is long term) on the QMS should be considered.	a) the time required to execute the change b) the establishment of new/revised performance indicator(s) to substantiate the change as appropriate.	
1815	FR	1089	7	Structure of this § is highly unsatisfactory and "old fashion"	Consider restructuring this chapter to have a logical grouping of the clauses. Also, liaise with the ISO TMB MSS task force to provide feedback on the difficulty of implementing the clauses of chapter 7 in this sequence. New structure (deviation of high level structure): -7.1 General (internal and external resources) -7.2 Human resources (with 7.2.1 Competences & 7.2.2 Communication) -7.3 Knowledge -7.4 Infrastructure -7.5 Equipment (with 7.5.1 Process equipment & 7.5.2 Monitoring and measuring devices) -7.6 Logistics means -7.7 Information and telecom system -7.8 Documented information -7.9 Process environment	TN
1816	PT	1091	7.1.1	7.1.1 refers to resources needed for the QMS but 7.1.3 to 7.1.5 refer resources for product and service conformity. On the other hand it does not address requirements defined for resources, which in services are very frequent. Requirements associated with different types of resources are not balanced, some providing documented information, others legal requirements.	Read in 7.1.1 The organization shall determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system, and to consistently provide products and services that meet customer, and applicable statutory and regulatory requirements and enhance customer satisfaction, including the requirements applicable to resources by themselves. The organization shall retain appropriate documented information as evidence of fitness for purpose of resources	TN
1817	PT	1091 1097	7.1.1 and 7.1.2	There is no consistency between 7.1.1. and 7.1.2. Why do people need to meet requirements and other resources not? Why is there a separate section for people, as it does not add value to	Change 7.1.1 to include reference to people The organization shall determine and provide the	TN

				7.1.1 and neither adds requirements and may create confusion	resources, including people , needed for the ... Delete 7.1.2	
1818	IQNet	1091	7.1.1 And section 7.1 in general	7.1.1 Refers resources needed for the QMS but 7.1.3 to 7.1.5 refer resources for product and service conformity. The subclauses are repetitive and increase the length of the clause with little added value Resources related to product and service conformity (equipment, layout, measuring equipment, infrastructure, qualification of personnel) can have associated applicable requirements, which is frequently the case in services, and also in products, where a significant portion of requirements is associated with resource requirements (example: accessibility to an infrastructure, type of materials in a building, etc.). Attention to the need to correctly identify requirements associated with resources must be reinforced in this section to provide adequate support to section 8 (resources for operation) and 9.3.1 and 10 improvement and consideration of resources needed Reading all section 7.1 we notice that there is a failure on a systematic approach to definition of requirements for different kind of resources and on the language used We consider approach should be harmonized and if possible simplified and condensed in general to avoid unnecessary repetition in all subclauses and different interpretations	"The organization shall determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system, and to consistently provide products and services that meet customer, and applicable statutory and regulatory requirements and enhance customer satisfaction. The determination of resources shall include, consideration of the following resources and the determination of any applicable associated requirements: People Infrastructure, Work environment; Monitoring and measurement resources; and Organizational knowledge The organization shall retain appropriate documented information as evidence of fitness for purpose of resources." Delete sections 7.1.2,3,4 as they are repetitive Delete notes in 7.1.2 and 7.1.4 and revise definitions in section 3. 7.1.5 M&M resources and 7.1.6 need to be revised to delete repetition from generic clause but keeping specific requirements and applicable notes	EN
1819	IQNet	1091 1097	7.1.1 and 7.1.2	There is no consistency between 7.1.1. and 7.1.2.. 7.1.2 creates confusion and in some degree repetition with 7.1.1. We do not see added value in this subsection, although we acknowledge the importance to refer to people instead of "resources in abstract terms.	Change 7.1.1 to include reference to people See generic comment and proposal on 7.1.	TN
1820	ZA	1091	7.1.1	Heading of subclause ("General") is meaningless unless related to main clause This is particularly frustrating when reference is made to this subclause to describe how these	Change heading of subclause to read: .."General information relating to resources".. OR	EN

				requirements are met in an organisation, e.g. in context of integrated management systems	.."Introduction to resources"	
1821	DZ	1092	7.1.1	The modify the following sentence : « The organization shall determine and provide the resources needed for the establishment,"	To remove "for the establishment"	TN
1822	BR	1093	7.1.1	Exclude the word continual to be consistent with the new QMP's and with the clause 10.	The organization shall determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system.	TN
1823	ANS I	1095	7.1.1	By expressing "the capabilities of, and constraints on...", we are automatically dropping out facets such as: 1. Availability 2. Affordability 3. Reliability 4. Etc. Using other language would also simplify the requirement.	Revise a) The capabilities of, and constraints on, <u>the availability of</u> existing resources;	TN
1824	KE	1096	7.1.1	Address how the organization can obtain from external providers	Add to b) and how to obtain what is needed	TN
1825	NZ	1096	7.1.1	External should be interpreted as groups or personnel external to the quality management system, thereby including groups internal to the whole business but outside the QMS. This can be an important point in practice and a definition of external provider might be needed. This issue also applies to 8.4 but does not apply only to operational processes. Preferable to have only one Note.	Add Note External providers can be inside or outside the wider organizational structure but are outside the scope of the organization's quality management system. Consider requesting a definition of 'external provider' in ISO 9000 since same issue applies to 8.4.	TAP Remit to SC1
1826	IT	1096	7.1.1	Financial resources are necessary to ensure the effectiveness of the QMS and its continual improvement. When the organization determines and provides the resources needed for the QMS it should consider financial aspects appropriately as well as the expected returns.	Add the follow new bullet: c) the financial resources needed and the expected economic and financial returns of the quality management system;	TN
1827	IT	1097-1100	7.1.2	The overall performance of a QMS and its processes ultimately depends on the involvement of competent people (see ISO 10018:2102). The content of this sub-clause is definitely insufficient in order to fulfil QMP 3 - <i>Engagement of People</i> .	Modify sub-clause 7.1.2 as follows, extending contents and requirements regarding the engagement of people: <i>7.1.2 People</i> <i>To ensure that the organization can consistently meet customer and applicable statutory and</i>	TN

				This aspect seems to be missing in the other clauses of the standard too. [CRITICAL COMMENT]	<i>regulatory requirements, the organization shall:</i> a) provide the persons necessary for the effective operation of the quality management system, including the processes needed; b) have a process to promote people involvement, competence, attitude and motivation. Consider adding such requirements and cross-references in other clauses in order to implement QMP3 within the QMS.	
1828	DE	1097	7.1.2	Please put justification at the end of the sentence	Please reword: The organization shall provide the persons necessary for the effective operation of the quality management system, including the processes needed, to ensure that the organization can consistently meet customer and applicable statutory and regulatory requirements,	TN
1829	ANS I	1097	7 Support, 7.1 Resources	The use of "people" in this sub-clause is inconsistent with the text in the standard. The term "persons" is more generic with regard to resources and more consistent.	Change title to read: 7.1.2 People <u>Persons of the organization</u>	EN
1830	RO	1097	7.1.2	Term people is too general	Change "People" with "Personnel"	EN
1831	BW	1097	7.1.2 onwards	Use a word consistently throughout the standard, e.g. "people" should be used throughout instead of using it interchangeably with person(s)		EN
1832	KE	1097	7.1.2	7.1.2 is part of 7.2 competence	More 7.1.2 text to be opening text of 7.2	TN
1833	LC	1097	7.1.2	People – reference should be made to elaborate the point.	Insert - 'see also(7.2 and 7.3)' Should read: - <i>7.1.2 People (see also 7.2 and 7.3)</i>	TN
1834	GB	1097	7.1.2	Redundant wording 'that' and 'the' (twice). Tautological 'including the processes needed'	Remove redundant wording: 'To ensure the organization can consistently meet customer and applicable statutory and regulatory requirements, the organization shall provide persons necessary for effective operation of the quality management system.'	EN
1835	JP 99	1097	7.1.2	The term "people" is only used in the title of 7.2. For consistency of the use of terms, the term "people" should be replaced by "human resources."	Change "People" to "Human resources."	EN

1836	TC2 10	1098 -1100	7.1.2	Consistent with 7.1.3 and 7.1.4. It is necessary to indicate what the processes are needed for	Amend to To ensure that the organization can consistently meet customer and applicable statutory and regulatory requirements, the organization shall provide the persons necessary for the effective operation of the quality management system, including the processes needed <u>to achieve conformity of products and services.</u>	TN
1837	AT	1098	7.1.2	People are not be treated as resources. Also the organisation should provide people does not fit as term – it would provide them to itself! However, it is a known point that people are the essential success factor for a QMS. The clause cannot be dropped but should be re-written.	... regulatory requirements, the organization shall provide the personal resources necessary for the effective ...	TN
1838	EOQ	1098	7.1.2	People should not be treated as ressources. The clause is essential but should be improved.	To ensure that the organization can consistently meet customer and applicable statutory and regulatory requirements, the organization shall provide to the people, working under its control, the necessary time, authority and resources for the effective operation of the quality management system, including the processes needed	TN
1839	BE	1098	7.1.2	Review sequence of phrase.	The organization shall provide the persons necessary for the effective operation of the quality management system, including the processes needed, to ensure that the organization can consistently meet customer and applicable statutory and regulatory requirements.	TN
1840	IE	1098	7.1.2	Change order of text to start the sentence with "The organisation ... ". Better clarity.	The organisation shall provide the persons necessary for the effective operation of the QMS, including the processes needed, to ensure that the organisation can consistently meet customer and applicable statutory and regulatory requirements.	TN
1841	JP 100	1098	7.1.2	To be consistent with the descriptions in Clause 1 and 4.2.	Change to: To ensure that the organization can consistently <u>provide products or services that</u> meet customer... and applicable statutory...	TN
1842	IE	1099	7.1.2 Line	The phrasing "provide the persons" is awkward here	Rephrase as: ". . . ensure the availability of the persons . . ." Or .. the organization shall provide sufficient personnel for the effective...	TN

1843	NZ	1099	7.1.2	For consistency the organization should determine the personnel necessary as per the other clauses 7.1.3 & 7.1.4	Change to read: "the organization shall <i>determine and provide</i> the persons ..."	TAP
1844	ANS I	1100	7.1.2	This clause is about the resource of people. The text "including the processes needed" implies you are provisioning processes.	Revise To ensure that the organization can consistently meet customer and applicable statutory and regulatory requirements, the organization shall provide the persons necessary for the effective operation of the quality management system, including the processes needed.	TN
1845	MY	1100	7.1.2	To rephrase Line 1100 for consistency with 4.4 c)	To rephrase as "...for the effective implementation of the quality management system and the operation and control of its processes."	TAF
1846	GOST R	1100	7.1 Resources	"including the processes needed" should be changed on "and its processes".	operation of the quality management system and its processes.	TAF
1847	CO	1100	7.1.2	Improve user understanding. Rewrite the paragraph. Including the processes needs is not well connected with the text before. Processes are included in the quality management system.	Delete "including the processes needed".	TAF
1848	PL	1100	7.1.2	From the definition of "quality management system" results, that management system includes processes. That is why it is not necessary writing "the quality management system, including the processes needed" We suggest to delete ".... Including the processes needed".	To ensure that the organization can consistently meet customer and applicable statutory and regulatory requirements, the organization shall provide the persons necessary for the effective operation of the quality management system, including the processes needed.	TAF
1849	NZ	1100	7.1.2	Consistent language with 4.4	... necessary for the effective operation of <i>the quality management system and its processes</i>	TAF
1850	JP 101	1100	7.1.2	The ", including the processes needed" is not necessary.	Delete "including the processes needed."	TAF
1851	JP 102	1100 1102 1111 1136	7.1.2 7.1.3 7.1.4 7.1.6	Among Clauses 7.1.2, 7.1.3, 7.1.4 and 7.1.6, the wording expressing the purpose of applicable resources are inconsistent and must be corrected (i.e., "for the operation of its processes to achieve conformity of products and services").	- Corrected text of 7.1.2 reads: The organization shall provide the persons necessary for the effective operation of <u>its processes to achieve conformity of products and services</u> - Corrected text of 7.1.3 reads: The organisation shall determine, provide and maintain the infrastructure <u>necessary</u> for the operation of its processes to achieve conformity of	TAP

					products and services. • Corrected text of 7.1.4 reads: The organisation shall determine, provide and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services. • Corrected text of 7.1.6, Para 1 reads: The organisation shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services.	
1852	BW	1101 , 1114	7.1.3 and 7.1.5	Clause 7.1.5 should form part of clause 7.1.3	7.1.3 Infrastructure 7.1.3.1 General The organization shall determine, provide andServices. a) b) c) d) 7.1.3.2 Monitoring and measurement resources	TN
1853	PT	1101	7.1.3	This clause remains too vague and with few requirements related to availability of infrastructures and the role of maintenance, lay-out, etc. It is basically equal to 2008 and does not reinforce the need for adequate performance of infrastructure On the other hand in service industries a lot of requirements are defined for the infrastructure and process environment and this needs to be addressed in the standard. See our proposal for change in 7.1.1 generic and applicable to the whole chapter on resources	See our comment on 7.1.1. Align the text	TN
1854	IQNet	1101	7.1.3	This clause remains too vague and with few requirements related to availability of infrastructures and the role of maintenance, lay out, etc. It is basically equal to 2008 and does not reinforce the need for adequate performance of infrastructure	See generic comment and proposal on 7.1.	TN
1855	GB	1101 – 3	7.1.3	Suggest reword for clarity	The organization shall determine, provide and maintain infrastructure required for operation of its	TN

					processes to achieve conformity of products and services.	
1856	ES	1102 -1103	7.1.3	Text should be consistent with 7.1.4 <i>Environment for the operation of processes</i> Besides “determine and provide”, the organization shall also maintain the infrastructure necessary for the operation of its processes, etc.	Align with 7.4: The organization shall determine, provide <u>and maintain</u> the infrastructure <u>necessary</u> for the operation of its processes and to achieve conformity of products and services.	C
1857	NL	1102	7.1.3	Determination and provision of resources is already mentioned in 7.1.1. It's more important to ensure the infrastructure is 'available' (fitness for use) when needed for operation.	Change into: The organization shall ensure operationality of infrastructure necessary for the operation of its processes to achieve conformity of products.	TN
1858	CH	1102	7.1.3	The wording needs to be consistent with that in 7.1.2 and 7.1.4.	Add to read: "... infrastructure WHICH IS NECESSARY for the operation of its processes to achieve conformity of products and services."	TAP
1859	GB	1102	7.1.3	<i>Adding 'control' to 'operation' will bring relevance to cover all control-related infrastructure. The note/examples are not necessary – delete.</i>	Replace with: 7.1.3 Infrastructure The organization shall determine, provide and maintain the infrastructure for the operation <u>and control</u> of its processes to achieve conformity of products and services.	TN
1860	RO	1102 & 1103	7.1.3	Consistency of formulation (see 7.1.4)	The organization shall determine, provide and maintain the infrastructure necessary for the operation of its processes to achieve conformity of products and services.	TAF
1861	ANS I	1103	7 Support, 7.1 Resources	The text does not identify to what conformity refers. Some additional clarity is needed.	The organization shall determine, provide and maintain the infrastructure for the operation of its processes to achieve conformity of products and services <u>to requirements</u> .	TN
1862	ANS I	1105	7.1.3	The note longer includes workspace which was part of the requirement for infrastructure in 6.3 ISO 9001:2008. This has the potential for confusing users, and therefore should be added back in.	a) Buildings, <u>workspace</u> and associated utilities.	TN
1863	AR	1105	7.1.3	Information and communication technology is at the heart of today's business and its criticality should be reflected in the order of the examples	a) Buildings and associated utilities b) Equipment including hardware and software c) Information and communication technology d) transportation	TAF
1864	SE	1107	7.1.3	“Transportation” is an activity but the other listed components of infrastructure are either hardware or software. Create consistency!	Replace “transportation “ with “facilities for transportation” or the like.	TAP

1865	RO	1108	7.1.3	ISO 9001:2000, 6.3 clauses, was more generally.	To add “e) other supporting services.”	TN
1866	RO	1108	7.1.3	For clarity.	To replace with “information technology and communication (IT&C);”	TN
1867	IT	1108	7.1.3	Information System is an important resource for the effective operation of the QMS. It has a different meaning from “information and communication technology” (cf. bullet d in the note). It would be better to include the Information System in the note, as a specific bullet.	Add a new bullet: e) information system	TN
1868	PT	1109	7.1.4	See comment above to 7.1.2 and 7.1.1.	See comment above to 7.1.2 and 7.1.1.	TN
1869	IQN et	1109	7.1.4	See generic comment and proposal on 7.1.	See generic comment and proposal on 7.1.	TN
1870	BE	1109	7.1.4	Definition of ISO DIS 9000 §3.4.5 Work environment is not respected. ISO DIS 9000 §3.4.5 defines the term “work environment” in the same way as ISO DIS 9001 defines “Environment for the operation of processes”. <i>See also line 1582 –Table B.1 — Major differences in terminology between ISO 9001:2008 and ISO 9001:2015) that clarifies that the ISO 9001:2008 §6.4 title “Work environment” has been replaced by “ Environment for the operation of processes”.</i> In ISO DIS 9000, the definition of “work environment” is consistent with ISO DIS 9000 §2.4.1.3 Activity makes clear the relation between “human” and “activity”.	Change title to “work environment”.	TN
1871	TR	1109	7.1.4	As the notes are informative clauses better to take this sentence from note and put it directly in the paragraph	Put this sentence directly in the main paragraph	TN
1872	NL	1110 - 1112	7.1.4	To avoid misunderstanding and conflicts with ISO14001 underline the purpose of req 7.1.4	Add the bold words: The organisation shall determine, provide and maintain the process environment necessary for the operation of..... NOTE: Environment for the operation of processes can include physical, social, psychological, process environmental and others....	TN
1873	NL	1110	7.1.4	Determination and provision of resources is already mentioned in 7.1.1. It's more important to	Change The organization shall determine, provide and	TN

				ensure the work environment is 'suitable (fitness for use) when needed for operation.	maintain maintain the suitability of the environment necessary for the operation of its processes and to achieve conformity of products and services.	
1874	DK	1111	7.1.4		Delete "and" in 2. Line: "The organization shall determine, provide and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services."	EAF
1875	GOS T R	1111	7.1 Resources	To exclude the first word "and". See line 1103 of Standard	its processes to achieve conformity of products and services.	EAF
1876	CN	1111	7.1.4	Delete the "and"	The organization shall determine, provide and maintain the environment necessary for the operation of its processes to achieve conformity of products and services.	EAF
1877	IN	1112	7.1.4	The Note has made reference to "social and psychological factors". These are subjective and cannot be assessed, as well as they are entirely out of the scope of the QMS. It is not possible to standardize "social and psychological factors" and thus no way to assess them.	Change to: "NOTE Environment for the operation of processes can include physical, environmental and other factors such as temperature, humidity, noise, ergonomics, cleanliness etc.	TN
1878	PT	1112	7.1.4	The inclusion of social and psychological factors in the note creates confusion and may create unnecessary noise in QMs application and external audit. It may extend applicability of the standard beyond scope of standard	Delete reference to social and psychological, and keep note as in 2008 edition	TN
1879	IQN et	1112	7.1.4	The inclusion of social and psychological factors is confusing and may create unnecessary noise in QMs application and external audit. It may extend applicability of the standard beyond scope of standard	Delete reference to social and psychological, and keep note as in 2008 edition See generic comment on 7.1 to delete all not and put it in definitions	TN
1880	KE	1112 1113	7.1.3	" (such as temperature, humidity, ergonomics and cleanliness)" not placed appropriately	Delete "and other" and also the brackets().	TAP
1881	NL	1112	7.1.4	Social and psychological factors have little impact on (physical) products. Even services are hardly impacted by social or psychological factors of the environment. Users could think this note refers to OSH-factor (ISO45001). To prevent misconception, this factors should be removed. Environmental factors are temperature, humidity	Remove (bold), move (bold) Environment for the operation of processes can include, physical, social, psychological, environmental (such as temperature and humidity and cleanliness) and other factors (such as ergonomics)	TN

				and cleanliness; move these.		
1882	NO	1112	7.1.4	We propose to replace Note 2 with the note in 6.4 in ISO 9001:2008, to prevent the impression that clause 7.1.4 also covers occupation health and safety requirements.	Change the text in Note NOTE The term “environment” relates to those conditions under which work is performed including physical, environmental and other factors (such as noise, temperature, humidity, lighting or weather).	TAP
1883	QS	1112 and 1113	8.5.5	Post Delivery activities includes Installations in some cases, which is addressed in Note	Change as: Post-delivery activities can include installations, actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal	TN
1884	MX	1113	7.1.4 Environment for the operation of processes	High noise levels are important for the welfare of people, include in the example.	... and other factors (such as temperature, noise , humidity, ergonomics and cleanliness).	TAF
1885	NL	1113	7.1.4	Work of hi-tech companies are not bound by time or place, such as in the industrial age. They work in a virtual environment. This virtual environment should however – likewise - be well designed and protected to ensure effective operation of processes.	Add NOTE: Note 2: The environment for the operation of processes may consist of tangible and visible elements, but also from non-tangible and non-visible elements, such as digital environments.	TN
1886	HU	1114 -1134	7.1.5	It is not clear why the ‘resource’ (that is unusual in the context of measuring) is used instead of the standard expression ‘equipment’. There is no any explanation (at least in form of Note or Examples) what means the resource, what is the difference between ‘resource’ and “equipment” or ‘device’. There is no definition even among the terms (only on ‘measuring equipment’). It is not enough some explanation in the Annex, because this clause is an important requirement.	Suggested title of Clause: ‘Monitoring and measuring equipment’ A Note is suggested about the ‘resources’ e.g. Measuring and monitoring resources can also include the human sense organs, the measuring and monitoring software. Or among the terms is suggested defining the ‘measuring resources’	TN
1887	ES	1114	7.1.5	Last paragraph of Clause 7 in ISO 9001:2008 was deleted. There are organizations using software for monitoring and measuring that found that deleted paragraph very necessary.	Reinstate last paragraph of Clause 7 in ISO 9001:2008 or a revision of it.	TN
1888	CO	1114	7.1.5		Improve the numbering for better understanding. There are paragraph without identification, literals again paragraphs and bullets.	EAF
1889	CO	1114	7.1.5	7.1.5 makes reference to monitoring and measuring resources, while in 3.69 makes	Align 7.1.5 and 3.69 to measuring resources.	TN

				reference to measuring equipment. En el requisito 7.1.5 y su desarrollo se habla de "Recursos de seguimiento y medición"; sin embargo, En el capítulo 3 se habla de equipo de medición.		
1890	CO	1114	7.1.5	Include additional information for computer software. See current ISO 9001	Include the note of 7.6 current version of ISO 9001: Confirmation of the ability of computer software to satisfy the intended application would typically include its verification and configuration management to maintain its suitability for use.	TN
1891	CO	1114	7.1.5		Include guidance regarding verification and calibration in order to difference them.	TN
1892	IQNet	1114	7.1.5	Why is it better to use resources instead of equipment or devices or instruments? What do <i>resources</i> include?	An explanatory note on use of term resources is needed, here, in the definition or in annex A	TN
1893	ANSI	1115-1134		This clause uses a confusing set of dashes, letters, and paragraphs which makes the clause very difficult to follow and will make referencing difficult.	Edit so that each subclause/paragraph is properly numbered. This could be done by combining lines 1118-1120 into one paragraph and eliminating the letters and using letters for the dashes later on in the clause.	EAF
1894	IT	1115-1134		We suggest to modify and expand the wording of the sub-clause, splitting it in two different parts.	Modify sub-clause as follows: 7.1.5.1 General <i>Where The organization is required to take a risk-based approach to determine the type and extent of controls appropriate to the monitoring and measuring resources. The monitoring or measuring is resources, used for evidence of conformity of products and services to specified requirements the organization, shall determine the resources needed to ensure valid and reliable monitoring and measuring results.</i> 7.1.5.2 Measurement traceability Where measurement traceability is: a) a statutory or regulatory requirement; b) a customer or relevant interested party expectation; or c) considered by the organization to be an essential part of providing confidence in the validity of measurement results; <i>measuring instruments shall be:</i>	TAP

					- <i>verified or calibrated at specified intervals or prior to use against measurement standards traceable to international measurement standards. Where no such standards exist, the basis used for calibration or verification shall be retained as documented information;</i> - <i>identified in order to determine their calibration status;</i> - <i>safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.</i> <i>The organization shall determine if the validity of previous measurement results has been adversely affected when an instrument is found to be defective during its planned verification or calibration, or during its use, and take appropriate corrective action as necessary.</i>	
1895	CQI 45	1115 - 1129	7.1.5	'verified or Calibrated' - This clause still continues to be very vague, I have audited companies that use Calibration 'labs' that are clearly inadequate and incompetent (e.g. no knowledge of measurement uncertainty) but the standard does not allow me to raise it as a Non-conformance. A reference to ISO 17025 should be made	Add to the Bibliography ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories	EN
1896	TC2 10	1115 - 1120	7.1.5	Clarify that the subclause is conditional rather than location-specific Correct punctuation. Shorten text and simplify	Amend to <u>If</u> monitoring or measuring is used for evidence of conformity of products and services to specified requirements, the organization shall determine the resources needed to obtain valid and reliable monitoring and measuring results. The organization shall ensure that such resources are: a) suitable for the monitoring and measurement activities undertaken; b) maintained to ensure their continued fitness for their purpose.	EAP
1897	CN	1115 -1117	7.1.5	1. This requirement is just limited to the scope of providing evidence of conformity of products and service, it is too limited. This requirement should also include the control of process	Change the "Where monitoring or measuring is used for evidence of conformity of products and services to specified requirements the organization shall determine the resources needed to ensure valid and reliable monitoring and measuring results."	TAP

				2. "Where" should be changed to "When"; 3. should add a "," between the "requirements" and "the organization";	Into When the monitoring or measuring is used for evidence of conformity of products and services and processes to specified requirements, the organization shall determine the resources needed to ensure valid and reliable monitoring and measuring results."	
1898	KE	1115	7.1.5	Measurement and monitoring can be carried out independently or both .therefore "Or " is exclusive	Add "and / "	TN
1899	BE	1115	7.1.5	Review is text is grammatically correct.	Where monitoring or measuring is used for evidence of conformity of products and services to specified requirements, the organization shall determine the resources needed to ensure valid and reliable monitoring and measuring results.	EAP
1900	IE	1115	7.1.5	Change order of text to start the sentence with "The organisation ... ". Better clarity.	The organisation shall determine the resources needed to ensure valid and reliable monitoring and measuring results where monitoring or measuring is used for evidence of conformity of products and services to specified requirements.	EAP
1901	JP 103	1115	7.1.5	Monitoring or measurement is not used primarily "for evidence of conformity" but it is used "to verify conformity." Paying due respect to the intent of this conditional text that defines a situation where "the organization shall determine the resources needed to ensure valid and reliable results," it is recommended to include both two conditions (i.e., verifying conformity and providing evidence) to facilitate better understanding of requirements.	Change to: Where monitoring or measuring is used <u>to verify</u> conformity of products and services <u>or where it is required to provide evidence of conformity</u> to specified requirements measuring	TAP
1902	JP 104	1115 1123 1126 1129 1130	7.1.5	To improve readability.	Add a sub-clause number 7.1.5.1 before "Where monitoring or measuring is used..." in L1115. Add a sub-clause number 7.1.5.2 before "Where measurement traceability is..." in L1123. Change bullets in L1126, 1129 and 1130 to items a), b) and c) respectively.	EAP
1903	TC6 9	1115 , 1116	7.1.5	The clause beginning with "where" should be separated by a comma from the main clause: "Where monitoring or measuring is used for evidence of conformity of products and services to specified requirements the organization shall	"Where monitoring or measuring is used for evidence of conformity of products and services to specified requirements, the organization shall determine the resources..."	EAP

				determine the resources...”		
1904	CQI 46	1115 , 1123 and 1126 - 1131	7.1.5	- verified or calibrated at... - identified in order to determine ... - safeguarded from adjustments.... The three bullets are unordered; to be consistent with all other lists in the standard and to ensure sufficient unique identification of requirements the bullets should be ordered. AND for consistency with all other clauses with more than one ordered list clause 7.1.5 should be split into two: 7.1.5.1 and 7.1.5.2 at lines 1115 and 1123 respectively.	7.1.5.1 Where monitoring or measuring is used for evidence of conformity of products and services to... AND 7.1.5.2 Where measurement traceability is... measuring instruments shall be: a) verified or calibrated at ... b) identified in order to determine ... c) safeguarded from adjustments....	EAP
1905	MX	1116	7.1.5	Specified requirements the organization shall	Specified requirements, the organization shall RATIONALE: A comma is missing	EAP
1906	MX	1116	7.1.5	Determining the resources needed to ensure valid and reliable monitoring and measuring results alone is no sufficient for the purpose, it is needed to state that those resources are provided as well.	Modify to: ... the organization shall determine and provide the resources needed to ensure valid and reliable monitoring and measuring results.	TAF
1907	NG	1116		Specified requirements	Introduction of “comma” after “specified requirements,”	EAP
1908	SE	1116	7.1.5	“the organization shall determine the resources needed”. In other corresponding cases in the draft the phrase also includes “and provide”, which is also motivated here.	After “determine”, insert “and provide”.	TAF
1909	SE	1116	7.1.5 Monitoring and measuring resources	Insert text from ISO 9001:2008, 4.1 d): “ensure the availability of resources and <u>information</u> necessary to support the operation and monitoring of these processes”, in the first sentence in 7.1.5.	Change to: Where monitoring or measuring is used for evidence of conformity of products and services to specified requirements the organization shall determine the resources <i>and information</i> needed to ensure valid and reliable monitoring and measuring results.	TN
1910	RO	1118	7.1.5	Consistency of formulation	The organization shall ensure that the monitoring and measuring resources provided:	TN
1911	BR	1119		There are variations in the use of the words “adequate” and “suitable” throughout the standard. Sometimes they are used as synonymous, e.g. lines 1217 and 1302. There is some translations issues regarding the use of these words. In Portuguese, for instance, suitable means “adequado” and adequate means “suficiente”. There are value in using both words together. It makes the requirements complete and, at the	Use together the words “adequate and suitable” throughout the standard. This should happen in lines: 1119, 1192, 1217, 1260, 1289, 1302, 1370, 1371, 1378.	TN

				same time, solve the translation issues.		
1912	ANS I	1119	7.1.5	This clause is confusing. It refers to monitoring and measurement activities. In most places in the standard, monitoring and measurement is referred to along with the phrase criteria or methods. This language along with the phrase "being undertaken" is confusing.	a) Are suitable for the specific type of monitoring and measurement <u>methods</u> activities being undertaken .	TN
1913	ANS I	1120	7.1.5	"...continued fitness" Definition of continued fitness does not support intent within context used.	b) Are maintained to ensure their continued <u>capability</u> fitness for their purpose	TN
1914	IR	1120	7.1.5	The required metrological characteristics of Monitoring and measuring resources are to be taken into account while dealing with the requirement for their continued fitness for purpose.	Add a phrasal part at the end of item b) as follows: b) are maintained to ensure their continued fitness for their purpose <u>with respect to their required metrological characteristics</u> .	TN
1915	JP 203	1120	7.1.5	For clarification and better understanding of the text.	Change to: The organization shall retain appropriate documented information as evidence of fitness <u>of monitoring and measuring resources for their purpose</u> .	TN
1916	ES	1121 -1122	7.1.5	Sentence using a bit strange not usual wording "fitness for purpose of"	Simplify wording for easier translation	TN
1917	PT	1121 / 1122	7.1.5	Instead of ... evidence of fitness for purpose of monitoring and measurement resources	Read ... evidence of fitness for purpose of monitoring and measuring resources {Coherence with paragraph title}	EN
1918	BR	1121	7 Support/ 7.1 Resources/ 7.1.5 Monitoring and measuring resources	The paragraph on documented information is misplaced (1121). Where it stands now it seems not to be applicable to the measuring instruments. Furthermore, there is not such difference between monitoring and measuring for evidence of conformity and when it is a legal requirement. It is assumed that an instrument is a type of measuring resource. It deserves a note as explanation, if there is any difference. Reorder the paragraphs in this clause to clarify that it is applicable to the whole clause.	Rephrase the whole paragraph to read: (1115) Where monitoring or measuring is used for evidence ... requirements <u>or</u> (1123) where measurement traceability is: a statutory or regulatory ... confidence in the validity or measurement, (1116) the organization shall determine the resources needed to ensure valid and reliable monitoring and measuring results. (1132) The organization shall determine if the validity of previous...action as necessary. (1118) The organization shall ensure that the resources provided: a) Are suitable for ... being undertaking; b) Are maintained ... their purpose.	TN

					(1125) The measuring instruments shall be: • Verified or calibrated at... • Identified in order to ... • Safeguarded from adjustments... (1121) The organization shall retain appropriate documented information as ... resources.	
1919	ANS I	1121	7.1.5	There is inconsistency with how documented information is referred to. Sometimes it is appropriate and others it is to the extent necessary. To the extent necessary provides a better framework of when documented information would be required.	The organization shall retain appropriate documented information <u>to the extent necessary</u> as evidence of <u>continued capability</u> fitness for purpose of monitoring and measuring resources.	TN
1920	ANS I	1121	7.1.5	"...fitness for purpose of monitoring and measurement resources" Definition of fitness does not support intent within context used.	The organization shall retain appropriate documented information as evidence of <u>continued capability</u> fitness for purpose of monitoring and measuring resources.	TN
1921	ANS I	1123 -1125	7.1.5	"Where measurement traceability is: a statutory or regulatory requirement; a customer or measuring instruments shall be:" This sentence with two ":" s and imprecise words resulted into confusing to understand the total intent The word instruments in the text of the clause is confusing in relation to the clause title. There should be consistency in terms.	Where measurement traceability is a statutory or regulatory requirement, a customer or relevant interested party expectation, or considered by the organization to be an essential part of providing confidence in the validity of measurement results, measuring <u>resources</u> instruments shall be	TAP
1922	IE	1123 - 1125	7.1.5 Lines	Better formatting would enhance the legibility of these lines.	Reformat as follows: Where measurement traceability is: - a statutory or regulatory requirement, - a customer expectation or - an essential part of providing confidence . . . results measuring instruments shall be: (a) verified (b) identified . . . (c) safeguarded . . .	EAP
1923	TR	1123 -1125	7.1.5	Records of calibration and verification must be	The organization shall maintain the calibration and	TN

				requirement directly	verification records	
1924	SE	1123 -1124	7.1.5	"Where measurement traceability is: a statutory or regulatory requirement, a customer or relevant interested party expectation". It is most likely that the customer has stated a requirement in such a case and that the organization does not have to guess what kind of expectations the customer might have. Expectations of "interested parties" need not to be considered here.	Replace with "Where measurement traceability is: a customer or a statutory or regulatory requirement";	TAP
1925	ANS I	1123		While this covers the measurement resources, it ignores measurement processes. Both need to be included.	Add sentence from 9001:2008 to the effect that : "The organization shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements."	TN
1926	IE	1123	7.1.5	This paragraph could be improved for legibility by placing the requirements (currently delineated by ;) as bullet points	Change text to bullet points.	EAP
1927	ZA	1123	7.1.5	The reference to "measurement traceability" is confusing and has no definition under Clause 3. If the intention is to make the distinction between measurements that need to be traceable to either National or International Standards or the SI (System International) then it is highly desirable that reference to ISO/IEC Guide 99:2007 is considered. Definitions 2.41, 2.42 and 2.43 all refer to " metrological traceability ".	Ask SC 1 to define "measurement traceability"	TN
1928	IE	1124	7.1.5 Line	The phrase " . . . considered by the organization to be . . ." is subjective and unauditable.	Omit " considered by the organization to be "	TN
1929	ANS I	1125	7.1.5	The term "measurement resources" was used previously, but in this line it returns to "measurement instruments." This is inconsistent.	Select a term and use it consistently throughout clause 7.1.5.	TAP
1930	AT	1125	7.1.5	"measuring instruments" is not defined but "measuring equipment"	Replace "measuring instruments" by "measuring equipment" in the whole document	TAF
1931	RO	1125	7.1.5	For consistency with 3.69.	To replace "instruments" with "equipments".	TAP
1932	CA- 51	1125	7.1.5	"Where measurement traceability.....confidence in the validity of measurement results, measuring instruments shall be:" The term "measuring instruments" is inappropriate here. According to	Change to: "Where measurement traceability.....confidence in the validity of measurement results, measuring equipment shall	TAP

				the definition of "measuring equipment" (3.69), 'measuring instrument' is just one type of 'measuring equipment'. It is equally important that other types of 'measuring equipment' (e.g., 'software', 'reference material', etc.) must be verified or calibrated, in order to have "confidence in the validity of measurement results".	be:"	
1933	JP 105	1125	7.1.5	For consistency, "instruments" should be replaced with "resources."	Change to: measuring <u>resources</u> shall be	TAP
1934	RO	1126	7.1.5	Must be more generally.	To replace "verified or calibrated" with "verified and/or calibrated".	TN
1935	TC2 10	1126	7.1.5	It is not sufficient to simply verify or calibrate prior to use, but the measurement equipment must also be verified after use to ensure the confidence in the results	Add "and after" to revise text to read, "...at specified intervals or prior to and after use against measurement standards..."	TN
1936	SE	1126 1129 1131	7.1.5	The three indents make a reference to the paragraphs/requirements unclear during an audit.	Add a new sub clause before line 1115: 7.1.5.1 General Add a new sub clause before line 1123: 7.1.5.2 Measurement traceability. Change the three indents on lines 1126, 1129 and 1130 to a), b) and c)	EAP
1937	JP 106	1126	7.1.5	For continuity of 2008 version.	Change to: Verified or calibrated, <u>or both</u> at specified...	TAF
1938	JP 107	1126 1128 1133	7.1.5	The order of "verification" and "calibration" is not consistent, for example: - L1126: "verified or calibrated" - L1128: "calibration or verification" - L1133: "verification or calibration"	Use the expression "calibration or verification" consistently for continuity of 2008 version.	EAF
1939	TC2 10	1127	7.1.5	Evidence of traceability is needed as documented information.	Add between first and second sentences "The organization shall retain documented information as evidence of such traceability."	TN
1940	RO	1128	7.1.5	Must be more generally.	To replace "calibration or verification" with "calibration and/or verification".	TN
1941	ES	1129 -1131	7.1.5	Verification status should also be identified and Monitoring and measuring resources should be safeguarded from adjustments, damage or deterioration that would invalidate the verification status.	Add "verification" status: - identified in order to determine their calibration <u>or verification</u> status; - safeguarded from adjustments, damage	TAP

					or deterioration that would invalidate the calibration or verification status and subsequent measurement results.	
1942	ANS I	1136-7		This requirement is so unclear that it is hard to imagine what it would take to conform, how such conformity could be demonstrated or audited.	Edit the section to clarify what is intended and what is intended to be determined and maintained. I do not understand well enough what is intended to make a specific recommendation.	C
1943	PE	1129	7.1.5	The standard states that monitoring devices shall be verified or calibrated; however, the calibration is not always applicable.	It should say: identified in order to determine their calibration status, when applicable;	TAP
1944	IE	1129	7.1.5 Line	". . . in order to determine . . . " is inappropriate here.	Replace ". . . in order to determine . . . " with ". . . in relation to . . . "	TN
1945	SE	1129	7.1.5	"identified in order to determine their calibration status". The meaning of the expression is not clear. What you aim at is that when somebody encounters a measuring instrument he/she shall be able to determine its calibration status. The wording used in ISO 9001:2008, 7.6 c) was, at least, a little better.	Replace with "provided with an identification that enables determination of their calibration status".	TN
1946	IE	1130	7.1.5 Line	The word "would" is deterministic and narrower than the intention of this clause	Replace ". . . would invalidate . . . " With ". . . could invalidate . . . "	EN
1947	ANS I	1132 -1134	7.1.5	There is no need to qualify the instances when an instrument is found to be defective.	Revise The organization shall determine if the validity of previous measurement results has been adversely affected when an instrument is found to be defective during its planned verification or calibration, or during its use, and take appropriate corrective action as necessary.	TAP
1948	ANS I	1132 -1134	7.1.5	The word "defective" is not consistent with other language in ISO 9001 where language such as does not meet requirements is used. Consistency is important especially for translation purposes. Previous versions of the standard required action, not corrective action. While corrective action might be required sometimes, it would not be required every time. The word instrument is not used anywhere else in this clause. For clarification purposes the word resource or instrument or resource should be used.	Revise The organization shall determine if the validity of the previous measurement results has been adversely affected when an instrument <u>a resource</u> is found to be defective during its planned verification or calibration, or during its use, and take appropriate corrective action as necessary Alternative Instrument or resource	TAP

1949	IE	1132 - 1134	7.1.5	The meaning of this paragraph would be clearer if its component parts were re-ordered.	Re-phrase as follows: "When an instrument . . . or during its use, the organization shall determine if . . . adversely affected and take appropriate . . . necessary"	EN
1950	GB	1132 -1134	7.1.5	In addition to taking appropriate corrective action as necessary, other action, such as product recall, etc. should also be considered when an instrument is found to be defective during its planned verification or calibration, or during its use.	Amend to: The organization shall determine if the validity of previous measurement results has been adversely affected when an instrument is found to be defective during its planned verification or calibration, or during its use, and take appropriate corrective action and other action as necessary to deal with the consequences of any non-conformity.	TN
1951	DE	1132	7.1.5	The organization shall determine if the validity of previous measurement results has been adversely affected when ... This sentence is unclear and ambiguous to translate. What is meant? The organization shall examine whether the validity ... has been affected, or, the organization shall make a formal decision whether the previous measurements have been (in acceptably) affected?	Proposal: The organization shall determine <i>whether</i> the validity of previous measurements has been adversely affected ...	TAP
1952	CH	1132	7.1.5	The organization shall determine if the validity of previous measurement results has been adversely affected when ... This sentence is unclear and ambiguous to translate. What is meant? The organization shall examine whether the validity ... has been affected, or, the organization shall make a formal decision whether the previous measurements have been (in acceptably) affected?	Proposal: The organization shall determine <i>whether</i> the validity of previous measurements has been adversely affected ...	EN
1953	AT	1133	7.1.5	"instrument" to be replaced by "equipment"	"instrument" to be replaced by "equipment"	TAF
1954	BE	1133	7.1.5	By mentioning "is found to be defective", users might not link this to "out of tolerances" and might limit to "out of use" (= defective).	../. when an instrument is found to be defective or out of tolerance during its planned verification or calibration ../.	TN
1955	CA-52	1133	7.1.5	"...measurement results has been adversely affected when an instrument is found to be defective...". It is not always a case of an "instrument". There are a variety of types of 'measuring equipment' besides 'instruments' (e.g.	Change to: "The organization shall determine if the validity of previous measurement results has been adversely affected when any measuring equipment is found to be non-compliant or in an un-calibrated state, during its planned verification	TN

				software, measurement standard, etc.) that may be found to be non-compliant. Also, is it necessarily a case of being 'defective'? 'Defective' implies that it is not operational – it could still operate, but give inaccurate measurements/results, due to a calibration malfunction. Further, as indicated in the definition for "defect", in ISO 9000:2005 (3.6.3) the term "defect" (and by extension: "defective") has legal connotations and should be used with extreme caution.	or calibration, ...".	
1956	JP 108	1133	7.1.5	The term defined in 3.69 should be used. Same with L1125.	Change "instrument" to "measurement resource."	TN
1957	RO	1134	7.1.5	Not only corrective actions must be done.	To add "correction" before "Corrective action"	TN
1958	PE	1134	7.1.5	The standard uses the technical term "calibration" which is not referenced neither in ISO 9001 nor in ISO 9000	Include at the end: NOTE: See ISO 10012 as guidance	TN
1959	NZ	1134	7.1.5	Extend the appropriate "corrective action" to include "correction" otherwise there is only the requirement for the future, not a look back at tests which may have been wrong.	Amend last part of sentence ", and take appropriate <i>correction and</i> corrective action"	TN
1960	RSB	1135 -1148	7.1.6	The concept of Organisational Knowledge is already covered in clause 7.2(competence) because competence usually encompasses a knowledge aspect as well.	Delete Clause 7.1.6	TN
1961	TBS	1135 -1146	7.1.6	Knowledge is a subset of competence and it is covered well in clause 7.2	Delete 7.1.6	TN
1962	SE	1135 -1146	7.1.6	Many users of the standard will have problems with understanding the difference between the requirements in 7.1.6 and the requirements in 7.2.	Include 7.1.6 with 7.2.	TN
1963	IAQ G	1135	7.1.6, 3.0	The use of the term "knowledge" relative to the requirement is vague.	IAQG Priority Comment Add definition - clarify Proposal: Suggest adding definition for "organizational knowledge". Note 1 is inadequate since there are requirements that require action.	TN
1964	TN	1135		Useless same content as that of Chapters 7.1.2, 7.1.6 and 7.2		TN
1965	PL	1135	7.1.6	Title "organisational knowledge" - could be changed for „knowledge assurance"		TN
1966	CN	1135	7.1.6	It is not easy to understand "organizational knowledge".	7.1.6 organizational knowledge 改为 knowledge	TN

1967	TR	1135	7.1.6	This is a new area for this standard so expectations and requirements and criteria should be more explicit.	There may be some addition to this topic. In CMMI there is a generic goal (GP 3.2) it can be modified and transform to ISO. Collect process, product and service related experiences and best practices derived from planning and performing to support to determine what is the current knowledge of organization. Planning, risk management, performance measures for process, product or service are main areas for collecting information about organizational knowledge.	TN
1968	FR	1135	7.1.6	Why "organizational"?	Change the title to : knowledge management Enlever le terme "organisationnelles" de la note 1 dans la version française.	TN
1969	ANS I	1136 -1146	7.1.6	This clause as written does not add value. The difference in this clause and 7.2 competence is not clear. This confusion is compounded by the fact that the annex discussing organizational knowledge indicates that the knowledge needed can be based on competent persons in the organization. In addition, the current text indicates that the knowledge should be maintained and be made available which implies documented information. The focus should be on the process for organizational knowledge. Additional consideration should be given as to whether this should be a management review requirement. This clause needs to be completely rewritten or deleted.	Option 1 The organization shall establish, implement, and maintain a process to determine the knowledge necessary to achieve and sustain conformity of products and services to requirements and to disseminate this knowledge to those who need it throughout the organization and its supply chain . When making changes to the organization or introducing new products or services, the organization shall determine how to acquire or access any additionally needed knowledge. Note 1: Maintaining the necessary knowledge can include sharing and knowledge transfer between employees, education and training programs, documenting processes and best practices, and/or obtaining the necessary knowledge from an outside source. Option 2: Delete 7.1.6	TN
1970	IT	1136 -1137	7.1.6	The sentence should be completed with an explicit reference to customer satisfaction.	Modify sentence as follows: <i>The organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services and enhance customer satisfaction.</i>	TN
1971	RO	1136 to1145	7.1.6	Knowledge is defined in 3.53 but also means the range of a person's information, perception, or understanding.	To replace "knowledge" with "information".	TN

1972	PT	1136	7.1.6	Wording of clause is not consistent with wording in other resources	The organization shall determine and provide ...	TN
1973	IQNet	1136	7.1.6	Wording of clause is not consistent with wording in other resources	See generic comment and proposal on 7.1.	TN
1974	NL	1136	7.1.6	Determination and provision of resources is already mentioned in 7.1.1. It's more important to ensure the knowledge is 'available (fitness for use)' when needed for operation.	Change The organization shall determine maintain the accessibility of the knowledge necessary for the operation of its processes and to achieve conformity of products and services.	TN
1975	CN	1136	7.1.6	Delete the "and"	Change the "The organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services." Into "The organization shall determine the knowledge necessary for the operation of its processes to achieve conformity of products and services."	TN
1976	GB	1136	7.1.6	The organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services. This knowledge shall be maintained, and made available to the extent necessary. Improvement related knowledge, and sharing of knowledge could be added.	The organization shall determine the knowledge necessary for the operation and improvement of its processes and to achieve conformity of products and services. This knowledge shall be maintained, shared or made available to the people as necessary.	TN
1977	JP 109	1136	7.1.6	The "knowledge necessary" is too broad. In general, the knowledge to be intentionally controlled is the essential knowledge, and can be controlled effectively when recognized as essential.	Replace "necessary" by "essential" to read: The organization shall determine the knowledge <u>essential</u> for the operation of its processes...	TN
1978	FR	1136	7.1.6	Change « processes » by « QMS »	The sentence reads : the organization shall ... for the operation of its quality management system ... »	TN
1979	JP 110	1137	7.1.6	It needs to be required to update knowledge based on the result of improvement of the processes, and products and services.	Add the following to the end of L1138: The organization shall update the knowledge based on the result of the improvement on the processes, and products and services.	TN
1980	ANS I	1138	7.1.6	The current language in this requirement implies that information be maintained since the definition of knowledge (3.5.3) states "available collection	Delete this sentence. This knowledge shall be maintained, and made	TN

				of information (3.50) being a justified belief and having a high certainty to be true. The follow-on sentence adequately addresses the fact that knowledge shall be updated when changes are made.	available to the extent necessary.	
1981	IAQ G	1138	7.1.6	Concern on new DIS text – 7.1.6 Organizational knowledge. Not all knowledge need to be documented but there a need to enhance the importance of documenting appropriate knowledge accordingly.	Reword – improve Proposal: add to Line 1138 – This knowledge shall be maintained, documented as documented information when appropriate, and made available to the necessary extent.	TN
1982	IAQ G	1138	7.1.6	7.1.6 Seems like an Orphan requirement and not fully integrated into the QMS. The wording is focused on gaining knowledge, not what to do with it. 'Made available to the extent necessary' is only requirement stated on what to do with the knowledge. Needs statement for integrating knowledge into other applicable QMS sections	Reword – improve Proposal: Suggested Wording This knowledge shall be maintained; made available to the extent necessary, and be considered as inputs to applicable quality management system processes.	TN
1983	IE	1138	7.1.5 Line	"To the extent necessary" implies (but does not state) a purpose .	Add the purpose: " . . . to the extent necessary to ensure the integrity of the quality management system "	TN
1984	IT	1138	7.1.6	Line 1138 states that "knowledge shall be maintained and made available to the extent necessary". As such, the organization should also review it periodically, in order to assess whether the current level of knowledge is enough or has to be enhanced. Then, there should be a clear linkage to management review (9.3).	Modify clauses 7.1.6 and 9.3 accordingly, adding a reference to the need of reviewing the level of organizational knowledge.	TN
1985	TT	1139	7.1.6	When addressing changing needs and trends, the organization also needs to look at the associated risks that would negatively impact on these changes.	Add: 'and their associated risks,' after the word 'trends'.	TN
1986	BR	1141	7 Support/ 7.1 Resources/ 7.1.6 Organizatio n Knowledge	Both notes 1 and 2 just give arbitrary and redundant examples, they have not the purpose of clarify the requirement. They could cover any other array of examples. They don't add real value and are unnecessary.	Delete notes 1 and 2	TN
1987	NL	1141	7.1.6	An organization should at least have access to applicable legal and regulatory requirements.	Add (bold) Organizational knowledge can include information such as intellectual property, lessons learned and applicable laws and regulations.	TN/
1988	IE	1141	7.1.6	Experience, historical data, forecasting etc are all	Add to the note: historical date, experience, forecasting	TN

				part of knowledge gathering		
1989	CH	1141	7.1.6	On this new topic in ISO 9001, many users need guidance on what typically constitutes 'organizational knowledge' within the context of ISO 9001.	Expand NOTE 1 to read: "... GUIDANCE ON WHAT TYPICALLY CONSTITUTES 'ORGANIZATIONAL KNOWLEDGE' WITHIN THE CONTEXT OF ISO 9001 IS PROVIDED IN ANNEX A.7"	TN
1990	NL	1143	7.1.6	Research is a method to acquire (unique) knowledge.	Add (bold) a) Internal sources (e.g. learning from failures and successful projects, capturing undocumented knowledge and experience of topical experts within the organization and research undertaken)	TN
1991	JP 111	1143	7.1.6	"and" in the expression "learning from failures and successful projects" should be replaced with "or" because these are examples and selective.	Change to "learning from failures <u>or</u> successful projects."	TN
1992	CQI 47	1144	7.1.6	topical experts - I have an issue with this description of a person because it may be interpreted as that person being up to date not having a full and rounded understanding of the topic in question (expert)	amend topical expert to read 'subject matter expert'	TAP
1993	CQI 48	1144	7.1.6	'...experience of topical experts...' Typographical error.	'...experience of topical topic experts...'	TAP
1994	IN	1144	7.1.6	To bring more clarity	Topical / subject may be used	TN
1995	RO	1145	7.1.6	"academia" is not in English.	To replace "academia" with "academy".	TN
1996	IE	1145	7.1.6	Competitors and market needs are a key external source that should be considered	Add competitors to note.	TN
1997	CN	1145	7.1.6 b)	Add "external" to providers	Change the "external sources (e.g. standards, academia, conferences, gathering knowledge with customers or providers)." Into external sources (e.g. standards, academia, conferences, gathering knowledge with customers or external providers).	TN
1998	TT	1145	7.1.6	In acquiring current or additional knowledge, the organization must ensure that the external sources are credible. Great attention should be paid to sources of external risk information. For example, placing over-independence on credit rating agencies, organizations can be misguided	Change b) to: 'Credible' external sources.....providers), 'paying careful attention to sources of external risk information.'	TN

				on their level of limitations and could be subject to biases.		
1999	GB	1146	7.1.6	This requirement seems to focus on the need to determine and acquire knowledge for current operations. To have that knowledge there is a need to have a system and culture of accumulating knowledge at the end a process or a project. For example Note 2 (a) seems to indicate that a new project need to "obtain" the knowledge from sources such as learnings from past failures and successes. To have that knowledge available, the organization need to document the knowledge at the end of a process or project.	ADD the following after NOTE 2: NOTE 3 Organization shall consider documenting the learnings from its operations on an ongoing basis , and use that knowledge to continually improve the quality management system.	TN
2000	ANS I	1147 -1157	7.2	A note was added to the ISO 9001:2008 amendment to clarify that competence could be affected directly or indirectly. This clarification is important to retain.	Add Note: Conformity to product and service requirements can be affected directly or indirectly by personnel performing any task within the quality management system.	TN
2001	CQI 49	1148 - 1155	7.2	Determination, ensuring, taking actions and retain records of competence could be interpreted as a one-off for functions or individuals. Perhaps into point c), insert 'and continuously develop', so that competence remains something that's evolving, not static.	c) where applicable, take actions to acquire and continuously develop the necessary competence, and evaluate the effectiveness of the actions taken;	TN
2002	TBS	1148	7.2	Competence clause it misses general opening statement	Add "The organization shall ensure that people who perform work affecting conformity to products or service requirements shall be competent on the basis of appropriate knowledge, skills experience and attitude"	TN
2003	ANS I	1149 -1150	7.2	Language in this section of standard has reverted to the use of the term "quality" which, as with other revisions of ISO 9001, has never been defined. The expression "quality performance" can easily be construed as a number of unrelated issues, such as financial, OHS, environmental, etc. The 2008 revision of standard changed "quality" to "conformity to product requirements" because organization were, as touted in periodicals of the time, excluding individuals from training because they did not affect product quality directly even though their functions within the organizations did have an effect on meeting customer product or service requirements at time	a) Determine the necessary competence of person(s) doing work under its control that affects <u>conformity to product and service requirements</u> its quality performance .	TAP

				of delivery. Because of the use of the phrase quality performance, the experts on quality auditing from the United States believe the word competent would need to be added to the word auditor in 9.2 since they do not believe they would be covered by quality performance.		
2004	BR	1149	7.2	To maintain consistency with the topic "b", related to word "persons".	a) determine the necessary competence of person(s) persons doing work under its control that affects its	TN
2005	LU	1150	7.2	The term Quality performance has to be focused on the delivered product or service.	determine the necessary competence of person(s) doing work under its control that affects the quality performance <i>of the delivered product or service</i>	TN
2006	AU	1150	7.2 a)	Poorly worded sentence. Introduces a new term, 'quality performance' which is not necessary in order to convey the intent of this sentence.	Replace with, 'define the necessary competence required by persons under the organization's control who perform work affecting the quality of its products or services.'	TN
2007	INLA C	1151	7.2 b)	Add "skills" to maintain consistency with the definition of competence and current ISO 9001, clause 6.2.1 that is still valid. Also, change "or" by "and". The elements of competence complement each other, are not to be considered in isolation.	b) ...appropriate education, training, skills and experience	TN
2008	ANS I	1151	7.2.b	Add the word "Skills" which can be a key component of competence. The definition in 3.10 includes skills in the definition.	... b) <u>ensure that these persons are competent on the basis of appropriate education, training, skills, or experience;</u>	TN
2009	CO	1151	7.2.	Although competence definition includes skills, it is important to emphasize it explicitly in this literal. See current ISO 9001.	ensure that these persons are competent on the basis of appropriate education, training, skills or experience	TN
2010	ZA	1151	7.2	Education, training experience can be inclusive to each other or exclusive	Add "and" ... training <u>and</u> /or experience ...	TN
2011	ZA	1151	7.2	Persons are competent on "the basis of appropriate education, training, or experience". The word competent is defined in clause 3.10 as "ability to apply knowledge and skills to achieve intended results". It is important to add "skill" to competence since knowledge can be gained from education, training and experience.	Replace "(b) ensure that persons are competent on the basis of appropriate education, training, or experience" with "b) ensure that persons are competent on the basis of appropriate education, training, skill, and/or experience"	TN
2012	LC	1151	7.2 (b)	Is it that competence is no longer influenced by skills, which may be inherent and not just acquired through experience, training or	Include 'skills' Should read: -	TN

				education? Competence may well be originating from talent. While I agree that the "or" should be used in 7.2 (b), as competence can be due to a combination of any of the three i.e. education, training or, experience; "skills" should also be included as in Version 2008, 6.2.1.	'...appropriate education, training, skills or experience'	
2013	AU	1152	7.2 b)	Need to add "or a combination thereof" in the sentence as it currently reads that it is one or the other whereas it could be a combination of two or more items listed (or include other information).	Add "or a combination thereof" to the sentence.	TN
2014	NG	1153	7.2 c	'Where appropriate, take actions.....'	Change to: Where appropriate, take action(s).....'	TN
2015	TBS	1153	7.2	monitoring is missing in the sentence	Add the word "monitoring" before the word "evaluation"	TN
2016	IAQ G	1154	7.3.a 7.3.b	There seems to be a slight inconsistency between 5.2.2.b in 7.3.a regarding the Quality Policy. Where 5.2.2.b requires it to be understood and applied, 7.3.a only requires awareness of the policy. Note - The Awareness focus on the Quality Policy in 7.3.a could bring back bad industry habits 'Can you tell me what your quality policy is'. Versus the more appropriate focus on 5.2.2 to understand how it applies to an individual's job	Reword – improve Proposal: Revise 7.3.a & b - Suggested Combined Wording Persons doing work under the organization's control shall be aware of: a) The application of the quality policies & Relevant objectives to the individuals roles & responsibilities	TN
2017	IT	1155 -1156	7.2	No mention is provided to ISO 10018:2012, whereas, according to Table C.3, it affects all clauses of future ISO 9001.	Add a reference to ISO 10018 or to Annex A.	TN
2018	ES	1156 -1157	7.2	Clarify that the applicable actions are related with bullet c)	Move note below item c) or rewrite the note to clarify NOTE: Actions taken to acquire the necessary competence can include, for example, the provision of training to, the mentoring of, or the re-assignment of currently employed persons; or the hiring or contracting of competent persons.	TN
2019	IAQ G	1157 -1163	7.3.(e)	It is essential for all business processes related to management system including QMS to be aware of importance of compliance/ethics. Therefore, it should be explicitly specified for awareness of personnel.	Add text - Improve Proposal: Add the following. e) the importance of compliance/ethics and safety relating to products and services	TN
2020	SG	1158	7.3	Staff needs to know how their good performance is contributing to the quality performance of the organisation.	To include person doing work under the organisation's control shall be aware of their job performance in relation to the provision of goods and services.	TN

2021	CZ	1159 -1164	7.3	The evidence of risk based thinking should be demonstrated within awareness.	One bullet should be added between c) and d): "risks relevant for their processes and controls to minimize them;"	TN
2022	ANS I	1159	7.3	The expression "Persons doing work under the organization's control..." automatically includes internal building maintenance (cleaning/janitorial services), grounds work (mowing)	Revise to Persons doing work under the organization's control that affect conformity to product requirements shall be aware of:	TN
2023	IE	1159	7.3 Line	The phrase "shall be aware of" describes an aspiration rather than a requirement of a management system	Rephrase as follows: "The organization shall ensure that persons doing work . . . control are aware of . . ."	EAF
2024	IAQ G	1160 -1161	7.3.a 7.3.b	There seems to be a slight inconsistency between 5.2.2.b in 7.3.a regarding the Quality Policy. Where 5.2.2.b requires it to be understood and applied, 7.3.a only requires awareness of the policy.	Reword – improve Proposal: Revise 7.3.a & b - Suggested Combined Wording - "Persons doing work under the organization's control shall be aware of: b) The application of the quality policies & Relevant objectives to the individuals roles & responsibilities"	TN
2025	CQI 50	1161	7.3	b) relevant quality objectives; . Personnel need to be aware of the processes established for achieving the objectives and their role in those processes so that they work harmoniously with others	b) relevant quality objectives and the processes by which they are achieved.	TN
2026	CN	1162 -1163	7.3 c)	As for the effectiveness of the quality management system has different meaning to the benefits of improved quality performance, so it can not including it. Add a note to understand "quality performance".	Change the "c) their contribution to the effectiveness of the quality management system, including the benefits of improved quality performance;" Into "c) their contribution to the effectiveness of the quality management system; e) the benefits of improved quality performance"	TN
2027	ANS I	1162 1163	7.3	There appears to be confusion between the terms "quality performance" and "performance of the quality management system" which implies that these are two distinctly different things. In some cases, both terms have been used together, "The organization shall evaluate the quality performance and the effectiveness of the quality management system" while in other places within ISO 9001:2015, only 1 term has been used. In ISO 9001:2008 instead of quality performance,	c) Their contribution to the effectiveness of the quality management system, including the benefits of improved quality performance. Option 2 Their contribution to the effectiveness <u>and the performance</u> of the quality management system, including the benefits of improved quality performance.	TN

				the term consistently used was "performance of the quality management system". However, ISO 9001:2015 implies that quality performance is related to "affecting conformity to product requirements" as in ISO 9001:2008. We propose consistency and alignment throughout ISO 9001:2015		
2028	ZA	1162	7.3	"their contribution to the effectiveness of the quality management system..." is too general and does not clearly state how the persons are to be engaged in accordance with the Quality Management Principle "Engagement of People". Also the proposed change was part of ISO 9001:2008.	Add...c) " the relevance and importance of their activities and how they contribute to. the effectiveness of the quality management system..."	TN
2029	IT	1164 -1165	7.3	The sentence should be completed with a reference to customer satisfaction and innovation.	Add the following bullets: e) the opportunities of enhancing customer satisfaction; f) the opportunities resulting from continuous innovation.	TN
2030	IAQ G	1164	7.3.e	There is no reference to awareness of documented information in the list of items to be aware of.	Add text - Improve Proposal: Add: e) applicable documented information and work instructions	TN
2031	ANS I	1164	7.3	This is a negative statement and could imply some type of discipline for employees who do not conform. D) is not needed with c). If this is not an option, revise d) to be a positive statement.	Option 1: delete d) Option 2: d) the implications of not <u>meeting customer requirement</u> or conforming with the quality management system requirements. Option 3: d) the implications of not importance of conforming with the quality management system requirements.	TN
2032	JP 112	1164	7.3	To be consistent with the requirements to top management in Clause 5.	Add "and product requirements" to read: d) the implications of not conforming to the quality management system requirements <u>and product requirements</u>.	TN
2033	VN	1165 -1171	7.4	Communication is important to achieve the required results and inappropriate communication can have negative impacts on the performance. Thus it is necessary to evaluate the effectiveness of the communication.	Make additional provision: "Effectiveness of communication shall be evaluated and actions shall be implemented as appropriate to improve the communication".	TN
2034	PT	1165	7.4	The section requires determining the relevant communication needed but it does not refer legal requirements applicable to communication nor	The organization shall determine the need for internal and external communications relevant to	TN

				relevant interested parties. This kind of requirements may be relevant to certain sectors. On the other hand, it is too short defining requirements for reliability of communication (as in 14001) and retention of documented information	the quality management system including: b) on what it will communicate; c) when to communicate; d) with whom to communicate; and e) how to communicate, f) who will communicate. The organization shall consider a) Relevant communication requirements from relevant interested parties, b) Any communication requirements defined elsewhere in this standard c) Any restrictions to communication d) Documented information to be retained in the extent necessary to demonstrate that communication has occurred according to its determinations	
2035	IQNet	1165	7.4	The section requires to determine the relevant communication needed but it does not refer applicable requirements, including legal ones applicable to communication . Nothing is add to the HLS text which is short to ensure consistency of communication and does not reflect communication required in several sections of 9001. As a proposal for improvement consider further alignment with 14001 text as be a good solution	The organization shall determine the need for internal and external communication relevant to the quality management system including: The organization shall consider e) Relevant communication requirements from relevant interested parties, f) Any communication requirements defined elsewhere in this standard g) Any restrictions to communication h) Documented information to be retained in the extent necessary to demonstrate that communication has occurred according to its determinations	TN
2036	BE	1165	7.4	Functioning mechanisms like meetings between departments are not incorporated in an explicit way in the standard. Neither chapter 8.1 Internal	Add in a more explicit way requirement to organize coordination mechanisms (as applicable).	TN

				and external communication is		
2037	BE	1165	7.4	The topic "communication" is wider then in ISO 9001:2008 where it was limited to the internal communication on the efficiency of the QMS. However, communication and coordination mechanisms like meetings are not the same. Nor §4 Communication, nor other § in ISO DIS 9001 deal (clearly) with the topic of "coordination mechanisms".	Add requirements for internal and external coordination mechanisms.	TN
2038	ANS I	1166 -1167	7.4	The current text refers to determining internal and external communication relevant to the quality management system. The focus on communication in the past has been related to the effectiveness of the quality management system. This focus should be retained.	The organization shall determine the internal and external communications relevant to <u>the effectiveness of</u> the quality management system including.	TN
2039	TR	1166 -1167	7.4	Communication with interested party must be added to the clause		TN
2040	IT	1166 -1167	7.4	The sentence should be completed.	Modify sentence as follows: <i>The organization shall determine and implement the internal and external communications relevant to the quality management system including:</i>	TN
2041	INLA C	1166	7.4	To improve consistency with ISO 14001. Include the reference to a process.	Change: The organization shall determine the internal and external communication processes relevant	TN
2042	IE	1166	7.4 Line	This line does not focus clearly on the organization's needs.	Replace "... external communications relevant to ..." with: "... external communication needs relevant to ..."	TN
2043	CH	1166	7.4	The plural of 'communication' is not needed.	<u>Change</u> to read: "... COMMUNICATION ..."	EN
2044	CH	1166	7.4	The wording needs to be consistent with that in 7.1.2 and 7.1.4.	<u>Add</u> to read: "... internal and external communication WHICH IS NECESSARY AND relevant to the quality management system ..."	TN
2045	EE	1167	7.4	Assignment of responsibilities related to the communication is significant aspect and may constitute a risk factor when not settled. Therefore, it would be rational to determine in this clause who will communicate to this clause.	<i>Add following clause directly after clause a):</i> b) who will communicate;	TAF
2046	IE	1168	7.4a Line	The grammer in point a) is not consistent with the grammar in points b), c) and d)	Replace a) with: "On what issues to communicate;"	TN

2047	QS	1168	7.4 a)	"on what it will communicate;" is not clear	Replace "on what it will communicate;" with "what to communicate"	EN
2048	TN	1171	7	Add "e" why communicate		TN
2049	IQN et	1171	7.4	Assigned responsibilities for communication is a relevant requirement not addressed in this section	Add new bullet: who communicates	TAF
2050	NL	1171	7.4	Building upon the requirements in 4.2, it would be an omission in 7.4 to not make the link to the needs and expectations of external parties. Therefore we propose a requirement specific for external communication.	Add a paragraph: The organization shall externally communicate information relevant to the quality management system, as determined by its communication process and taking into account the needs and expectations of its relevant stakeholders (4.2)	TN
2051	FI	1171	7.4	7.4. Communication	Add: e) who communicates	TAF
2052	FI	1172 -1177	7.5	The concept "documented information" should be deleted from ISO 9000 and the text of ISO 9001 edited accordingly replacing "documented information" by "document". See our (Finland) comments on DIS 9000. The definition of "documented information" as it is now defined in DIS 9000 can be tested using substitution rule. This is what we get for example: DIS 9001 clause 7.5.1 a) The organization's quality management system shall include information required to be controlled and maintained by an organization ... required by this International Standard 7.5.3.1 information required to be controlled and maintained by an organization ... required by the quality management system and by this International Standard shall be controlled to ensure: ... In addition to the strange concept and its faulty definition the text should be edited. Now there is a requirement that "QMS shall include documented information". As we all know,	Delete the concept "documented information" Use "document" as defined in DIS 9000 (3.8.7) 7.5 Documents 7.5.1 General The organization's quality management system documentation shall include, in addition to the documents specifically required in other clauses of this standard, documents determined by the organization as being necessary for the effectiveness of the quality management system. .	TN

				the QMS is not a system of documents. Para a) requires "shall include documented information required by this international standard". Why do we have to say, that this standard requires what it requires? And in addition to that we say in para b) that it requires also something else than what it requires.		
2053	ANS I	1172	7.5	Since this is a deviation from past well understood terminology it would be very helpful to the reader to provide additional information to facilitate adapting to this terminology	Add a note related to Maintain and retain.	TN
2054	LU	1172	7.5	The merge of documentation and record requirements of the former ISO 9001 is confusing and will lead to mistake and heaviness for its deployment. By ex. Why it's necessary to ensure the review and approval of a record? PLEASE KEEP THE DISCRIMINATION OF DOCUMENTATION AND RECORD		TN
2055	TC4 6/SC 11 Liaison (SE)	1172	7.5-7.5.3.2	The requirements concerning "documented information" is confusing since it can consist of documents, documentation or records according to terms and definitions of 3.1.3-3.1.4 and 3.1.7 in ISO 30300.	Change "documented information" to "documents, documentation or records".	TN
2056	HU	1173 -1182	7.5.1	The use of these requirements could cause some disturbance in practice. An additional NOTE would be useful clarifying the use of present documentation (no need to modify the structure, the identification of present documents)	Additional NOTE is suggested about the use of present documentation.	TN
2057	MA	1173	7.5.1	<i>The quality management system should also include information documented references to applicable laws and regulations. Either the organization has the physical documents constituting the applicable laws and regulations, or it has documented references to them.</i>	Add bullet : c) documented information applicable laws and regulations or reference thereto.	TN
2058	ZA	1173	7.5.1	Heading of subclause ("General") is meaningless unless related to main clause This is particularly frustrating when reference is made to this subclause to describe how these requirements are met in an organisation, e.g. in context of integrated management systems	Change heading of subclause to read: .."General information relating to documented information". OR .."Introduction to documented information"	TN

2059	TC4 6/SC 11 Liaison (FR)	1174 -1177	7.5. Documente d Info – 7.5.1 general	Mention and refer to ISO15489, and ISO30300's series, to allow organizations to know how to manage documented and accurate information and evidence about business processes	"records management is the field of management responsible for the efficient and systematic control of the creation, receipt, maintenance, use and disposition of records, including processes for capturing and maintaining evidence of and information about business activities and transactions in the form of records ([ISO 30300:2011, definition 3.4.3]. "The management of records as evidence and information asset is standardized by the ISO records management standards particularly ISO15489 and ISO30300 series (ISO30300, ISO30301, ISO30302) . The latter series are management system standards , developed by SC11 as complementary to ISO 9000, 9001 and other management system standards. You may refer to these standards and implement these, to develop a management system for records, part of uour QMS, and to determine which records, information and data is needed in your QMS context.	TN
2060	MX	1174	7.5.1 general	There is not colon before the bullets.	The organization's quality management system shall include:	EAF
2061	TC6 9	1174	7.5.1	The clause should end with a colon: "The organization's quality management system shall include"	"The organization's quality management system shall include:"	EAF
2062	BE	1174	7.5.1	Improve phrasing.	The organization's quality management system shall include documented information: a) required by this International Standard; b) determined by the organization as being necessary for the effectiveness of the quality management system.	EN
2063	CN	1174	7.5.1	Should add “:.”	Change the “The organization's quality management system shall include” Into “The organization's quality management system shall include:”	EAF
2064	LC	1175	7.5.1 (a)	The standard should require documented information on an overview of the QMS. This would provide the Big Picture within the organisation.	Documented information providing an overview of the QMS should be available for understanding the QMS within the context of the organisation, It should capture the mission, quality policy, organisation structure, processes (core, support and outsourced), documentation structure, etc. This document can be similar to a business plan, strategic plan etc.	TN

2065	IE	1176 -1177	7.5.1b Line	This phrasing compromises the fundamental principle behind ISO 9001 - that a QMS should be demonstrably effective.	Replace " . . . necessary for the effectiveness of the . . . system" With " . . . necessary for the demonstrable effectiveness of the . . . system"	TN
2066	GOS T R	1176	7.5 Documente d information	Add "assuring of the"	documented information determined by the organization as being necessary for the assuring of the effectiveness	TN
2067	CH	1176	7.5.1	In the context of this sentence, the meaning of the word 'determine' does not match the definition in 3.67.	<u>Change</u> to read: "... documented information DECIDED by the organization as being ..."	TN
2068	TC2 10	1177 -1178	7.5.1	There is no requirement about the "Quality Manual" but for the user	Add c) Quality Manual.	Note to TC210, a requirement for a quality manual was specifically discuss and regarded as not needed.
2069	BG	1178 -1182	7.5.1	In addition to the factors provided, the extent of documented information is influenced by the culture of the organization.	Add d) – culture of the organization	TN
2070	ANS I	1178	7.5.1	<u>The note should refer to the context of the organization.</u> Current: NOTE The extent of documented information for a quality management system can differ from one organization to another due to: 1180 a) the size of organization and its type of activities, processes, products and services; 1181 b) the complexity of processes and their interactions; 1182 c) the competence of persons.	Delete existing note and replace. : NOTE The extent of documented information for a quality management system can differ from one organization to another due to <u>the context of the organization (4.1).</u>	TN
2071	GOS T R	1180	7.5 Documente d information	Add "and structure"	a) the size and structure of organization and its type of activities, processes, products and services;	TN
2072	CA- 53	1183	7.5.2	The section heading is incomplete – Modify the current wording (copied below) to the wording shown in the column on the right. 7.5.2 Creating and updating	7.5.2 Creating and updating documented information	TN
2073	CZ	1183	7.5.2	"Creating and updating" ... what?	To be added: "Creating and updating documented information"	TN
2074	TC4	1184	7.5.2 ;	Add refs to ISO15489 and ISO30300's	At the beginning at each clause, add "As	EN

	6/SC 11 Liaison (FR)	-1204	7.5.3.1 and 7.5.3.2		recommended by ISO15489 and ISO30300 series (...)"	
2075	ANS I	1184	7.5.2	Implies that one can "change" documented information of any type so long as version control is maintained. What we used to call records (i.e. attestations of fact) can be "corrected" but not "changed." This would be of great concern and against the law for legal documents.	when creating and updating <u>maintained</u> documented information, the organization shall ensure appropriate	TN
2076	TC6 9	1184	7.5.2	The clause beginning with "when" should be separated by a comma from the main clause: "When creating and updating documented information the organization shall ensure appropriate:"	"When creating and updating documented information, the organization shall ensure appropriate:"	EAF
2077	BE	1185	7.5.2.	Point a.: On one hand the ISO DIS 9001 will not impose documented procedures but on the other hand it has additional details compared to ISO 9001:2008 §4.2.3 requiring "identification and description" by means of (e. g.) a title, date, author, or reference number. What does "description" mean? Point b.: Remove examples that are evident.	Remove "description" and examples a. Identification b. Format	TN
2078	GOS TR	1186	7.5 Documented information	b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic); Should be excluded as obvious requirement. Documented information can not be presented without any format		TN
2079	ANS I	1187	7.5.2.c	Add the word "update" to reflect that documents can and should be periodically updated to ensure continued relevance. The current text does not include the concept of prior to issue as is included in 9001:2008.	c) <u>review, update and approval for suitability and adequacy prior to issue.</u>	TN
2080	IAQ G	1187	7.5.2.(c)	Review and approval for suitability and adequacy must be down before release of documentation	Add text - Improve Proposal: add at the end of the sentence : c) review and approval for suitability and adequacy <u>prior to release for use</u> "	TN
2081	IR	1187	7.5.3.2	In the item c) it would be more appropriate to use the word "revision" instead of the word "version"	Replace the word "version" by the word the "revision" in the item c) of this sub-clause.	TN

				which is mostly in use in the field of software.		
2082	NL	1187	7.5.2	Evaluation of communication process is missing. In relation with line 1010 (understood), this is very critical part of communication activities.	Add: e) how to evaluate effectiveness of communication	TN
2083	JP 113	1188	7.5.3	Editorial	Change "information" to "Information."	EAF
2084	CA- 54	1190	7.5.3.1	7.5.3.1 Documented information required by the quality ... - There is no title for paragraph.	Remove numbering	EN
2085	IAQ G	1193 -1198	7.5.3.2	It is essential/important for many industries to comply with statutory and regulatory requirements and/or customer requirements related to documented information (especially traditional "records").	Add text - Improve Proposal: Add the following. ..., the organization shall address ..., as applicable, <u>with consideration of applicable statutory and regulatory requirements and customer requirements</u> ;	TN
2086	NL	1194	7.5.3.2	7.1.6 This knowledge shall be maintained, and made available to the extent necessary. This doubles with par 2 of 7.5.3.2 "Documented information of...."	Delete par 2 of 7.5.3.2: 'Documented information of external origin determined by the organization to be necessary for the planning and the operation of the quality management system shall be identified as appropriate, and controlled'	TN
2087	CA- 55	1194	7.5.3.2	7.5.3.2 For the control of documented information ... - There is no title for paragraph.	Remove numbering	TN
2088	ANS I	1198	7.5.3.2	Implies that one can "change" documented information of any type so long as version control is maintained. What we used to call records (i.e. attestations of fact) can be 'corrected' but not "changed." This would be of great concern and against the law for legal documents.	c) control of changes for maintained documented information (e.g. version control);	TN
2089	BE	1198	7.5.3.2.c.	Remove example that is evident.	c. Control of changes	TN
2090	IE	1198	7.5.3.2c Line	The use of "e.g." is inappropriate in an ISO 9001 standard (except in a NOTE) as it confuses the distinction between a requirement and a clarification.	Expand the NOTE in Lines 1203-1204 to include the example of version control or Rephrase point c) as follows: "c) clarity of revision status"	TN
2091	ANS I	1199	7.5.3.2	The requirement for what was referred to in legacy terms as a record and that it can be corrected but not changes is not clear.	Add 7.4.3.2 d) correcting retained documented information.	TN
2092	NL	1200 -1202	7.5.3.2	Seen the text in 7.1.6 par 2 line 1138, the text in 7.5.3.2 is redundant.	Delete par.	TN

				Especially in the light of NOTE 2b of 7.1.6: external sources, eg standards		
2093	CH	1200	7.5.3.2	In the context of this requirement, the meaning of the word 'determine' does not match the definition in 3.67.	<u>Change</u> to read: "... of external origin DECIDED by the organization to be ..."	TN
2094	ANS I	1201	7.5.3.2	Making external documented information available is often lacking in organisations. (Eg. ASTM, SAE standards etc.) It is also not practicable to require an organization that does not own the document to control it. We would like to add a requirement to ensure that that external information determined by the organization to be necessary be identified and made available to the organization while deleting the control element.	<u>Documented information of external origin determined by the organization to be necessary for the planning and operation of the quality management system shall be identified and made available for use, as appropriate. ,and-controlled</u>	TN
2095	IAQ G	1201	7.5.3.2	Making external documented information available is often lacking in organisations. (Eg. ASTM, SAE standards etc.) It is also not practicable to require an organization that does not own the document to control it. We would like to add a requirement to ensure that that external information determined by the organization to be necessary be identified and made available to the organization while deleting the control element.	IAQG Priority Comment Add text – improve Proposal: Documented information of external origin determined by the organization to be necessary for the planning and operation of the quality management system shall be identified <u>and made available for use,</u> as appropriate. ,and controlled	TN
2096	DE	1205	8	„Operation“ does not fully capture the content of Clause 8	Please amend title 8 Operation (realization of products and services)	TN
2097	FR	1205	8	Paragrpahs 8.5 to 8.7 are not in a logical sequence.	Keep the same sequence from 8.5 to 8.5.4, then 8.5.5 becomes "Control of changes", 8.5.6 becomes "Control of nonconforming process outputs, products and services". 8.6 becomes Release of products and services 8.7 becomes Post delivery activities	TAP
2098	AU	1206 - 1216	8.1	Although the guidelines suggest that reference to risk management should go in either section 6 or section 8 this is actually poor risk management practice The quality management system should be planned taking into account risks but at an operational level operational planning and control should be based on an assessment of risks at a more detailed and specific level. The current wording of section 8 is very reactive and prescriptive	Insert a new point in 8.1 c) determining risks that might affect the quality of products and services and defining and implementing procedures to treat those risks Change all subsequent numbers	TN
2099		1206	8.1		Improve the numbering for better understanding.	EN

	CO				There are paragraph without identification.	
2100	BE	1206	8.1	See comment for line 1165 in regard to "functioning mechanisms" like meetings.	Add in a more explicit way requirement to organize coordination mechanisms (if necessary).	TN
2101	TR	1206	8.1	Operational planning and control can be incompatible with process focus approach and interpreted wrongly. Title may change.	New title is as follows; Process planning and control	TAP
2102	JP 114	1207 -1209	8.1	Clause 8.1 only makes reference to 6.1 "Actions to address risks and opportunities." No reference to 6.2 "Quality objectives and planning" will cause the same trouble as we have with the 2008 version, i.e., the planning of QMS based on quality objectives is isolated and has no links to implementation. This linkage is a matter of interest and essential for organizations to achieve quality objectives.	Revised text reads: The organization shall plan, implement and control the processes, as outlined in 4.4, needed to meet requirements for the provision of products and services and to implement the plans determined in 6.1 <u>and</u> 6.2 by:	TAP
2103	NZ	1207	8.1	'as outlined in 4.4' is incorrect – 4.4 defines requirements. The requirements of 4.4 apply to all processes not just 8. Including this statement implies some special applicability of 4.4 here.	Delete 'as outlined in 4.4'	TN
2104	IT	1208	8.1	The sentence should be completed.	Modify sentence as follows: <i>The organization shall plan, implement and control the processes, as outlined in 4.4, needed to meet requirements for the consistent provision of products and services and [...]</i>	TN
2105	SE	1210 -1211	8.1	The requirement in b) "establishing criteria for ... for the acceptance of products" is covered by the requirement in a) "determining requirements for the product and services" and it should not be mixed with criteria for the processes.	To be considered if 8.1 is not deleted: Rewrite a) and b) in the following way: a) determining requirements for the product and services including acceptance criteria; b) establishing criteria for the processes	EAP
2106	15.	1210	8.1	A Syntactical correction is required	Please replace: " ... for the product and services;"; with: " ... for the products and services;"	EAF
2107	EE	1210	8.1	Instead of the expression "the product and services" it is more relevant to use the new term "the products and services".	<i>Replace existing wording of clause a) with following:</i> a) determining requirements for the products and services;	EAF
2108	NL	1210	8.1	(General) requirements are determined in 4.2. Customer specific requirements are to be determined in 8.2. This bullet is redundant and will lead to misunderstanding.	Remove a) Determining requirements for the product and services.	TN

2109	CZ	1210	8.1	„determining requirements for the product and services;“	To be corrected: „determining requirements for <u>products</u> and services;“	EAF
2110	TC210	1210	8.1	Consistency in use of singular and plural terms	a) determining requirements for products and services;	EAF
2111	BR	1211	8.1	In addition to criteria, that are the basis for decision, processes need methods to be performed in the specified way	Change bullets b) and d) accordingly: b) establishing criteria and methods for the processes and for the acceptance of products and services; d) implementing control of the processes in accordance with the criteria and methods ;	TN
2112	MX	1211	8.1	Establishing criteria for the processes and for the acceptance of products and services;	Establishing performance indicators for processes and criteria for the acceptance of products and services; RATIONALE: The sentence “establishing criteria for the processes” is ambiguous. Processes are usually measured against established performance indicators	TN
2113	GOST R	1211	8.1 Operational planning and control	“criteria for the processes” should be excluded as doubling of line 977. Otherwise need to be clarified additionally .		TAP
2114	CO	1211	8.1	La expresión “estableciendo criterios para los procesos y para la aceptación de los productos y servicios” al hablar de productos y servicios es clara la expresión como criterios de aceptación, aplicado a procesos no es claro.	Include example of criteria for the process as guidance. (For example control, performance, operational requirements, among others)	TN
2115	LU	1211	8.1	Precise which criteria...	establishing criteria for the processes <u>performance</u> and for the acceptance of products and services	TN
2116	IE	1211	8.1b Line	“Criteria for the processes” is unclear.	Replace “Criteria for the processes” with “Criteria for the effectiveness of the processes”	TN
2117	NL	1212	8.1	General determination of resources is already done in chapter 7. (7.1.1). In this paragraph the organization shall allocate specific resources to perform operations.	Change (bold) c) allocating the resources needed to achieve conformity of product and service requirements	TN
2118	SE	1212	8.1	Insert text from ISO 9001:2008, 4.1 d): “ensure the availability of resources and <u>information</u> necessary to support the operation	Change to: c) determining the resources and information needed to achieve conformity to product and	TN

				and monitoring of these processes", in 8.1 c). Beginning with "determining the....."	service requirements;	
2119	ANS I	1213	8 Operation, 8.1 Operational Control	It is unclear which criteria apply and further clarity is needed.	Replace "the criteria" with "established criteria" for improved clarity.	TN
2120	MX	1213	8.1	implementing control of the processes in accordance with the criteria;	Implementing actions in order to control of the processes in accordance with their performance indicators ; RATIONALE: The wording of the sentence is ambiguous. In order to control processes, actions should be taken.	TN
2121	CO	1213	8.1	For better understanding	implementing control of the processes in accordance with the defined criteria;	TN
2122	NL	1213	8.1	Risk based thinking has not sufficiently been incorporated in the PDCA cycle	Change 8.1.d to: "determining control of the processes in accordance with the criteria and the determined risks"	TN
2123	CA- 56	1213	8.1	d) implementing control of the processes in accordance with the criteria ; Need to add "identify risks"	Change to: "d) identify risks and implement control of the processes"	TN
2124	NG	1213	8.1d	Reference to the 'criteria' being referred to, should be provided	'.....with the criteria (8.1b),	EN
2125	ANS I	1214 -1216	8.1	Using retaining documented information is not consistent language that allows for easy understanding by users. In this clause, the requirement should be focused on determining similar to the other requirements in this clause.	e) retaining <u>determining</u> documented information <u>to retain</u> to the extent necessary to have confidence that the processes have been carried out as planned and to demonstrate conformity of products and services to requirements.	TN
2126	IE	1214 -1216	8.1e Lines	The phrase ". . . to have confidence . . ." is subjective and unauditabile.	Replace "to have confidence that the processes . . . as planned and to demonstrate conformity . . . to requirements" with "to demonstrate that the processes . . . as planned and the conformity . . . to requirements"	TN
2127	CN	1214 -1216	8.1	It is the same as the last paragraph of 4.4(986-988)	Add "see 4.4"	TN
2128	IAQ G	1214	8.1.e	Confidence level is subjective. Leaving it could encourage debate versus actual results as to how the organization had confidence that the results	Reword – improve Proposal: retaining documented information <u>to the extent necessary to have confidence</u> <u>ensure</u>	TN

				would be achieved. Recommend that we simplify the verbage to "ensure"	that the processes have been carried out as planned	
2129	BR	1217	8.1	For clarity, change the text, including "and suitable" and "method of "	The output of this planning shall be adequate and suitable for the organization's method of operations ,	TN
2130	BR	1217	8.1	Ensure the completeness of planning	The output planning shall be suitable and adequate for the organization's operations	TN
2131	MY	1217	8.1	A note on quality plan should be added for guidance.	To add a note as follows : "A document specifying the processes of the quality management system and the resources to be applied to a specific product, service, project or contract can be referred to as a quality plan."	TN
2132	JP 187	1217	8.1	The organizational knowledge determined as resources in 7.1.6 has to be utilized. Its utilization will be needed especially in the operational planning stage in 8.1.	Add new line as 1217 The organization shall utilize the organizational knowledge determined in 7.1.6 for the above operational planning and control.	TN
2133	IT	1218 -1219	8.1	The sentence should be completed with a reference to clause 6.2 for a more in-depth understanding of the importance of the "actions to address risks and opportunities".	Modify sentence as follows: <i>The organization shall control planned changes and review the consequences of unintended changes, taking actions (see 6.1) to mitigate any adverse effects, as necessary.</i>	TN
2134	AR	1218 /1219	8.1	These two lines apply to changes in all processes of clause 8.1 However, there is a specific reference to changes in: - requirements (section 8.2, lines 1253 to 1255) - design and development (section 8.3.6) - production and service provision (clause 8.5.6). It may be convenient to gather all these requirements in one new clause 8.8.	Delete lines 1253 to 1255, subclause 8.3.6 and 8.5.6 Add new subclause : 8.8 Control of change The organization shall control planned changes and review the consequences of unplanned changes taking action to mitigate any adverse effects, as necessary. In particular, the organization shall review and control changes to: - requirements for products and services (see 8.2), ensuring that relevant documented information is amended and that relevant personnel are made aware of the changed requirements, - design inputs and design outputs (see 8.3) during the design and development of products and services or subsequently, to the extent that there is no adverse impact on conformity to requirements. - production and service provision processes (see 8.5) to the extent necessary to ensure continuing conformity with specified requirements.	TAP

					The organization shall retain documented information describing the changes, the personnel authorizing the change, and any necessary actions.	
2135	ZA	1218	8.1	Clause 6.3 deals with the management arrangements associated with control	The organization shall control planned changes in accordance with 6.3 and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.	TAP
2136	TT	1218	8.1	Since there is a clause for planned changes, reference should be made of 6.3 so as to maintain consistency with the syntax of the Std.	Add: planned changes 'as outlined in 6.3'.....	TAP
2137	IAQG	1218, 1412	8.1, 8.5.6	How does an organization review and control "unplanned" changes? Does this refer to emergency planning, such as how to react to environmental events (earthquake, tornado, flood, etc)? How is control of unplanned changes different than the change management requirements mentioned in clauses 4.4(g), 5.3 (c,e), 6.3, 7.5.3.2, 8.1, 8.2.1, 8.2.3, 8.3.6, 9.2.2, 9.3.1(b), 9.3.2(b), and 10.2.1(e)? How is the term "unplanned changes" different from the term "unintended changes" used in clause 8.1?	IAQG Priority Comment Add definition -clarify Proposal: Add a definition for " <u>unplanned changes</u> " and/or "unintended changes", or use the same term in both places if the usage and intent is meant to be the same.	TN
2138	DK	1220	8.1		Change "outsourced" to "external provided"	EN
2139	CH	1220	8.1	Presently, outsourcing addresses <u>only</u> 'processes'. This does not match 8.4.c) or A.8.	<u>Change</u> to read: "... outsourced process OR FUNCTIONS are ..."	TN
2140	TR	1221	8.2	"Determination of" should be removed from title.	New title is as follows; Requirements for products and services	TAF
2141	TT	1221	8.2	The proposed heading: Determination of requirements for products and services is conflicting with the intent of this overall Clause. The focus in the Clause is on the Customer and by extension all those processes that directly relate to customer interaction, example: communication, determining the requirements/specifications for the product and service, a review of these requirements / specifications and relevant documented information. Determination of requirements is just one element of the overall Clause 8.2. In addition, it also conflicts with the exact sub-heading of 8.2.2. As such, the previous heading of ' Customer-related Processes ' should revert.	Revert old heading title: ' <i>Customer-related Processes</i> ' replacing proposed heading title of 8.2 - Determination of requirements for products and services.	TN

2142	JP 115	1221	8.2	To be consistent with 4.3.	Change to "Determining."	TN
2143	FR	1221	8.2	Simplify – see proposed change	In 8.2.1 : delete « shall establish the processes », the first sentence reads : The organization shall take measures to communicate with customers in relation to. In French 8.2.1 L'organisme doit mettre en place les dispositions pour communiquer avec les clients à propos. In 8.2.2 The organization shall implement the measures taken to determine ... In French : 8.2.2 L'organisme doit mettre en œuvre les dispositions permettant In 8.5 : The organization shall establish, implement and update processes, under controlled conditions ... In French : 8.5 : L'organisme doit établir, mettre en œuvre et mettre à jour des processus pour ... (garder la notion de conditions maîtrisées)	TAP
2144	IAQ G	1222	8.2.1 – 3.0	8.2.1.e has a requirement for communicating with the customer in relation to 'specific requirements for contingency actions, when relevant'. Section 3 does not have any definition on the meaning of 'contingency action'.	Add definition -clarify Proposal: Create definition of 'Contingency Action' for better understanding of the stakeholders when applying and auditing the standard.	TN
2145	ES	1223	8.2.1	In order to be consistent with others clauses of the standard, 8.2.1 should indicate "establish, implement and maintain..."	Add the following: The organization shall establish, implement and maintain the processes for communicating with customers in relation to:	TAP
2146	AR	1223	8.2.1	When requiring process or procedures, the words used are not always consistent throughout the document, (see lines 1207, 1230, 1261, 1360	Change to: The organization shall establish plan, implement and control the processes for communication	TAP
2147	IE	1223	8.2	It should not be a requirement that customer communication is a process – what is needed is a mechanism to communicate with the customer to	Reword – the organization shall establish a customer communication mechanism to ensure: - product and service information is readily available	TN

				ensure the bullets in this section are addressed E,g information about products can be a product brochure or information available on the web – this is not necessarily a process.	- customer enquiries, contracts and order processing including any changes are adequately handled - customer view and feedback, including complaints are addressed - adequate handling of customer property, if applicable	
2148	SE	1223	8.2.1	In 8.2.1 the organization is required to "establish" the processes for communicating with customers. Requirements for establishing processes in specific cases are also stated in 8.2.2 Determination of requirements related to products and services and 8.3.1 Design and development of products and services. In the latter cases the organization is also required to "implement" and "maintain" the processes. It must be assumed that it is as important in 8.2.1 to "implement" and "maintain" as it is in 8.2.2 and 8.3.1.	If 8.2.1 shall contain a requirement for "establishing" a process it should also include that the process shall be "implemented" and "maintained". However, there is no need at all specifically to require a process to be established in this case, so the requirement for establishing a processes should preferably be deleted. Then the 1st sentence in 8.2.1 would read: "The organization shall communicate with customers in relation to".	TAP
2149	ANS I	1224	8.2.1	While product information was used in ISO 9001:2008, the fact that documented information is used in ISO 9001:2015 is confusing everytime the word information is used in the current draft.	a) Information <u>data</u> relating to products and services.	TN
2150	ANS I	1226	8.2.1	The current text is unclear and should refer to customer feedback on products and services, which is the subject of the sub-clause, in order to be consistent with other clauses in the standard. This is also the language that is used in ISO 9001:2008	d) Obtaining customer views and perceptions <u>customer feedback on products and services</u> , including customer complaints.	TAP
2151	MX	1226	8.2.1	Obtain the customers' point of view and perception This change is proposed considering the implementation of this requirement.	Replace the word "and" for "or" between view and perception	TAP
2152	CO	1226	8.2.1	3.56, 3.58 make reference to complaints-handling process but in the document there is not information or requirements regarding complaints- handling process. 8.2 should provide some requirements regarding complaints-handling process.	Include requirements or guidance for complaints-handling process (or make reference to ISO 10002). For example: • The organization shall establish a process for complaints handling. • The process shall include reception, validation, investigation, actions taken, communication and monitoring • Others	TN
2153	JP 116	1226	8.2.1	To be consistent with the "customer view and opinion" in L1462.	Revised text reads: c) obtaining customer views and <u>opinions</u> , including customer complaints;	TAP

2154	JP 117	1227 -1228	8.2.1	Items d) and e) are generally included in items a) and b).	Remove Items d) and e) from the listing.	TN
2155	ANS I	1227	8.2.1	It is not clear what the word treatment means beyond handling for customer property. Control is consistent with other language in the standard	d) the handling or <u>control</u> treatment of customer property, if applicable	TAP
2156	PT	1227	8.2.1	Usually the term applicable when used in the standard to emphasise that it may not be applicable is used like "Where applicable" and not if applicable	Harmonize expression and change from "if applicable" to "where applicable"	TAP
2157	NL	1227	8.2.1	If handling of customer property contains a significant risk, this will be identified at 6.1. Customer communication will be part of planned actions to reduce undesired effect.	Remove d) the handling treatment of customer	TN
2158	JP 204	1227	8.2.1	The expression "if applicable" is used only here in the text. For consistency with the rest of the text.	Change "if applicable" to "as applicable."	EAP
2159	RO	1228	8.2.1	The term contingency is not defined and it is not used anywhere else.	specific requirements for actions needed to address risks and opportunities , when relevant	TN
2160	NL	1228	8.2.2	Consistency in wording is needed. Users will be disoriented when reading several times 'requirements'. And several times with a different meaning. There should be a clear difference between 'general' product requirements and customer specific (individual) requirements General proposition: Requirements are 'general' needs and expectations of customer audience. Customer demands are specific requirements of a individual customer.	Change (bold) 8.2.2 Determination of customer demands The organization shall establish (..) maintain a process to determine and understand demands of potential customers for the products and services offered. The organization shall ensure that: a) offered products en services conform with customer demands and that applicable statutory and regulatory requirements are identified; b) it has the ability to meet the defined demands and ...	TN
2161	IE	1228	8.2.1 e)	This requirement would be better places in clause 8.1 as it is general.	Move to 8.1	TN
2162	NL	1229 -1244	8.2.2 and 8.2.3	In 8.2.2 a generic approach has been chosen to determine the requirements. The review in 8.2.3 should be in the same line of wording.	Combine 8.2.2 and 8.2.3: The organization shall establish, implement and maintain a process to determine <u>and review</u> the requirements for the products and services to be offered to (potential) customers. The organization shall ensure that:	TN

					a) product and service requirements (including those considered necessary by the organization), and applicable statutory and regulatory requirements, are defined; b) it has the ability to meet the defined requirements and substantiate the claims for the products and services it offers. The organization shall review, as applicable: a) requirements specified by the customer, including the requirements for delivery and post-delivery activities; b) requirements not stated by the customer, but necessary for the customers' specified or intended c) use, when known; d) additional statutory and regulatory requirements applicable to the products and services; e) contract or order requirements differing from those previously expressed. NOTE Requirements can also include those arising from relevant interested parties. This review shall be conducted prior to the organization's commitment to supply products and services to the customer and shall ensure contract or order requirements differing from those previously defined are resolved. Where the customer does not provide a documented statement of their requirements, the customer requirements shall be confirmed by the organization before acceptance. Documented information describing the results of the review, including any new or changed requirements for the products and services, shall be retained. Where requirements for products and services are changed, the organization shall ensure that relevant documented information is amended and that relevant personnel are made aware of the changed requirements.	
2163	IE	1229-1231	8.2.2	The title of this subclause is similar to the main clause title 8.2 – is this good standard writing practice?	Change to determination of product and service requirements	EAP
2164	AT	1229	8.2.2 and 8.2.3	There is no need to differentiate between determination and review in 8.2.2 and 8.2.3, this is an artificial boundary and to simplify the text those two sub-clauses can be merged!	Combine 8.2.2 and 8.2.3 to 8.2.2 with the title "Requirements related to products and services"	TN

2165	PT	1229	8.2.2 and 8.2.3	The section does not address the need for documented requirements, On the other hand, it requires that review of requirements is documented which may not always be possible (example: client on a restaurant changes the order). The issue on documenting requirements of products and services should apply either to determination or to review in a way appropriate to subsequent stages of the applicable processes	Create subsection 8.2.3 applicable either to 8.2.2 and 8.2.3 stating Documented information describing the outputs of products and services requirements determination process and results of any review, including any new or changed requirements for the products and services, shall be retained. Where requirements for products and services are changed, the organization shall ensure that relevant documented information is amended and that relevant personnel are made aware of the changed requirements Subsequently delete 1251 to 1255 in 8.2.3	TAP
2166	IQNet	1229	8.2.2 and 8.2.3	Section 8.2.2 does not require documentation but 8.2.3 requires which is confusing. Requirements have to be documented and documentation on the revision is often not practicable nor useful, that is not applicable nor relevant in all situations	Introduce 8.2.4, applicable either to 8.2.3 and 8.2.3 stating Documented information describing the outputs of products and services requirements determination process and results of any review, including any new or changed requirements for the products and services, shall be retained. Where requirements for products and services are changed, the organization shall ensure that relevant documented information is amended and that relevant personnel are made aware of the changed requirements Subsequently delete 1251 to 1255 in 8.2.3	TAP
2167	AR	1229	8.2.2	To align the title with the requirements of this sub clause.	Change title to: "Determination of requirements related to products and services to be offered to potential customers"	TAP
2168	KE	1229	8.2.2	Existing customers are excluded	Add " existing customers and "	TN
2169	JP 118	1229	8.2.2	To be consistent with 4.3.	Change to "Determining."	EAF
2170	INLAC	1229 a 1245	8.2.2 & 8.2.3	Combine 8.2.2 and 8.2.3 in one clause and change title. This will provide users with a more flexible approach to their interactions with customers, either the traditional way (quotation - p.o. approach) or the modern way (interface through Internet means). Also change in line 1230 the reference to processes. Normally, during the interface with	One clause with new title: 8.2.2 Determination and review of requirements related to products and services The organization shall establish, implement and maintain processes to determine... ... The organization shall review, as applicable...	TN

				customers several processes may take place (product/service introduction, quotation, acquisition, amendment).		
2171	TR	1230-1231	8.2.2	By only using potential customers, can be interpreted as disregarding current customer for this statement.	The organization shall establish, implement and maintain a process to determine the requirements for the products and services to be offered to current and potential customers.	TAP
2172	IT	1230-1231	8.2.2	Determination of requirements should include current customers.	Modify sentence as follows: <i>The organization shall establish, implement and maintain a process to determine the requirements for the products and services to be offered to customers, including potential ones.</i>	TAP
2173	BR	1230	8.2.2	Use "processes" instead "a process" because it's possible that the organizations use more than one process to determine the requirements for the products and services to be offered to potential customers	The organization shall establish, implement and maintain a process processes to determine the requirements for...	TAP
2174	AR	1230	8.2.2	When requiring process or procedures, the words used are not always consistent throughout the document,	Change to: The organization shall establish, implement and maintain plan, implement and control a process ...	TAP
2175	GB	1230	8.2.2	Requirement refers to a process. An organization may have more than one process for determining product and service requirements.	Reword 'and maintain process(es) for ... '	TAP
2176	ANS I	1231		The words "potential customers" implies that there is no existing relationship between the supplier and the customer. A new product or service may be offered to an existing customer of a suppliers other products or services.	Revise The organization shall establish, implement and maintain a process to determine the requirements for the products and services to be offered to <u>customers</u> or potential customers.	TAP
2177	MX	1231	8.2.2	The document is devoted to address issues about customer, not about potential customers. Actually there is the only one occurrence of such an expression. There is no apparent reason to use the expression "potential customers". Otherwise, this expression should be used in all of the situations where the potential customer has not strictly become a customer like in 8.2.3 a) and b).	Delete "potential" to read: ...products and services to be offered to customers.	TAF
2178	PT	1231	8.2.2	"... to be offered to potential customers" maybe misleading as the process is for the products and services be offered by the organization independently if they already have the clients or not.	Replace by: ... the products and services offered by the organization.	TAP

2179	IQN et	1231	8.2.2	"... to be offered to potential customers" is misleading as the process is for the products and services be offered by the organization independently if they already have the clients or not.	Replace by: ... the products and services offered by the organization.	TAP
2180	CN	1231	8.2.2	Should use "provided" not "offered"	Change the "the products and services to be offered to potential customers" Into the products and services to be provided to potential customers	TN
	FI	1231	8.2.2	to potential customers customer could be <i>potential</i> , but also <i>actual</i>	replace a concept <i>potential customer</i> with a concept <i>actual or potential customers</i>	TAP
2182	IT	1231	8.2.2	The reference to " <i>potential customers</i> " is appreciated but there could be also a reference to market analysis and clauses 4.1 and 4.2 as well.	Consider to modify the paragraph, adding reference to market analysis and clauses 4.1 and 4.2.	C
2183	SE	1231	8.2.2	The words "potential customers" implies that there is no existing relationship between the supplier and the customer. A new product or service may be offered to an existing customer of a suppliers other products or services.	Change to: "The organization shall determine the requirements for the products and services to be offered."	TAP
2184	JP 119	1231	8.2.2	According to the definition in 3.26, the "potential customers" is originally included in customers.	Replace potential customers by <i>customers</i> .	TAF
2185	IE	1232 -1236	8.2.2 Lines	1. These lines identify review criteria and so belong more appropriately to the review clause 8.2.3 2. The phrasing of point a) does not address the risk of ambiguity in the requirements	Move the content of Lines 1232-1236 to Clause 8.2.3 and rephrase Lines 1246-1248 of Clause 8.2.3 as follows: "This review shall be conducted prior to . . . and shall ensure that: a) product and service requirements . . . are clearly defined; b) it has the ability to meet . . . it offers; c) contract or order requirements differing . . . are resolved"	TN
2186	TC2 10	1233 -1234	8.2.2	Clarify that both requirements considered necessary by the organization and applicable regulatory requirements are included in product	Change to a) product and service requirements, including those considered necessary by the organization	EAP

				and service requirements	and applicable statutory and regulatory requirements, are defined;	
2187	CO	1233	8.2.2.	Include delivery and post delivery activities as current ISO 9000.	product and service requirements (including those considered necessary by the organization like delivery and post delivery activities)	TN
2188	CN	1233	8.2.2 a)	It should be "organization", not "organisation"	Change the "product and service requirements (including those considered necessary by the organisation)," Into product and service requirements (including those considered necessary by the organization),	EAF
2189	JP 120	1233	8.2.2	Editorial	Change to "organization."	EAF
2190	CN	1235 -1236	8.2.2.b)	The whole paragraph should be moved into 8.2.3	Move the whole 8.2.2.b into 8.2.3	TAP
2191	ES	1235	8.2.2	As written it is not clear "substantiate the claims for the products and services it offers." Why talking about claims here? Are they claims for inadequacy of the requirements to the needs of potential users? Or to possible not conformity of those requirements subsequent to the product production or service delivery?	Delete item b), because it is not applicable talking about claims in this subclause.	TAP
2192	ES	1235	8.2.2 b)	Issue b) seems to be appropriate to 8.2.3	Move this bullet to 8.2.3	TAP
2193	ES	1235	8.2.2 b)	Please, avoid the term "substantiate". It is difficult for translation. Consider the use of "address", "verify", ...	Change "substantiate" for "address"	TAP
2194	ANS I	1235 1236	8.2.2	Substantiate the claims has the strong possibility for getting into legal issues. The standard should not include requirements that provides this possibility.	b) It has the ability to meet the defined requirements and substantiate the claims for the products and services it offers.	TAP
2195	EOQ	1235	8.2.2/8.2.3	In order to know that the organisation has "the ability to meet the defined requirements" it has to carry out the review. Move this part of the caluse to section 8.2.3	b) it has the ability to meet the defined requirements and substantiate the claims for the products and services it offers	TAP
2196	ZA	1235	8.2.2	b) is unclear as to which or whose claims	Replace "the" with "it's" – "substantiate it's claims ..."	TAP
2197	SE	1235	8.2.2	To have the ability to "meet the defined requirements" and to "substantiate the claims" means more or less the same thing.	Delete "and substantiate the claims".	TAP

2198	IT	1236 -1237	8.2.2	We suggest to add a new specification.	Add a new bullet as follows: <i>c) the requirements related to products and services are clear and complete for the design and development, control of externally provided products and service and provision processes.</i>	TN
2199	GOS T R	1236	8.2 Determinati on of requirement s for products and services	Add as c) risks (e.g., new technology, short delivery time frame) have been identified	b) it has the ability to meet the defined requirements and substantiate the claims for the products and services it offers. c) risks (e.g., new technology, short delivery time frame) have been identified	TN
2200	ZA	1236	8.2.2	It is important for the determination of requirements to introduce risk assessment since new customers and requirements for the provision of products and services are introduced.	Add "c) the risks and opportunities for providing products and services have been determined and addressed (see 6.1)."	TN
2201	SE	1237 -1255	8.2.3	How does the requirements in 8.2.3 apply to i.e. webshops, catalogues etc. where the organization has no direct contact with the customer? Availability of correct information on product and services for the customers. To assure that the given information is understood by the customer may in some cases serve as a review.	Consider including a paragraph describing how review of requirement can be performed a different way to understanding of requirements. Eg. "Where the organization has no direct contact with customers (eg. Internet sales) this review can be done by ensuring the customers access to correct information on products and services and promoting the customers understanding of information prior to ordering. "	TAP
2202	CO	1237	8.2.3		Improve the numbering for better understanding. There are paragraph without identification.	C
2203	AR	1237	8.2.3	To align the title with the requirements of this sub clause.	Change title to: "Review of requirements related to products and services expressed by the customers"	TN
2204	FR	1237	8.2.3	Delete the term « as applicable »	Delete the term « as applicable » Add the note from ISO 9001 :2008 chapter 7.2.2 : NOTE In some situations, such as internet sales, a formal review is impractical for each order. Instead the review can cover relevant product information such as catalogues or advertising material.	TN TAF
2205	CQI 51	1238 - 1252	8.2.3	'The organisation shall review...' 'Documented information describing the results of the review... shall be retained.' The Note to ISO 9001:2008 clause 7.2.2 regarding the impracticality of such a review for situations such as Internet sales was very	Add new NOTE In some situations, such as internet sales, a formal review is impractical for each order. Instead the review can cover relevant product information such as catalogues or advertising material.	TAF

				helpful in qualifying this requirement. It may be considered that this review is now covered by clause 8.2.2 in the DIS but there is nothing specific in clause 8.2.3 allowing for the possibility that the further 'review of requirements related to products and services' might not take place. Is this now hidden away in Annex A.5 (which is only stated to be 'Informative')? Some restatement here of the Note from the 2008 standard would be helpful to ordinary users of the new standard.		
2206	EOQ	1238	8.2.2/8.2.3	It is not explained to what scope the organisation shall carry out review activities. The introductory phrase should be improved.	<u>In order to evaluate its ability to meet the defined requirements and substantiate the claims for the products and services it offers,</u> the organization shall review, as applicable	TAP
2207	CO	1238	8.2.3	All requirements shall be review. .	The organization shall review. Delete " as applicable"	TAP
2208	ES	1239 -1244	8.2.3	In general, the clause is describing the different types of requirements that have to be considered in the review. This core information could be more adequate in chapter 8.2.2	Move bullets a, b, c, d to 8.2.2	TN
2209	NL	1239	8.2.3	Users of the standard could be confused about the inconsistent use of the term 'requirements'. To make a clear distinction between requirement of the group of customers and the 'requirements' of individual customers, change the requirement into 'demand'.	Change (bold) a) demands of the customer, including demands for delivery and post-delivery	TN
2210	CQI 52	1241	8.2.3	Requirements specified by the organization (for example invention of a new product) should be included in the list . [Reference ISO 9001:2008 7.2.1 d)]	b) requirements specified by the organization;	TAF
2211	IN	1241	8.2.3	In many cases the product or service is not used by the customer himself, but by another 3 rd party, e.g. end user, consumer, etc. Example: A manufacturer sells his product, a ticket vending machine, to a railway company, but the user of the product will not be the railway company, but the passenger.	b) requirements not stated by the customer, but necessary for the customer's specified or intended use, where known;	TAF
2212	DE	1241	8.2.3	In many cases the product or service is not used by the customer himself, but by another 3 rd party, e.g. end user, consumer, etc. Example: A manufacturer sells his product, a ticket vending machine, to a railway company, but	b) requirements not stated by the customer, but necessary for the customer's specified or intended use, where known;	TAF

				the user of the product will not be the railway company, but the passenger.		
2213	CH	1241	8.2.3	In many cases the product or service is not used by the customer himself, but by another 3 rd party, e.g. end user, consumer, etc. Example: A manufacturer sells his product, a ticket vending machine, to a railway company, but the user of the product will not be the railway company, but the passenger.	b) requirements not stated by the customer, but necessary for the customer's specified or intended use, where known;	TAF
2214	GOST R/R U	1243	8.2.3	Status of "additional" requirements in the context is not clear .	Delete "additional"	TAF
2215	BE	1243	8.2.3	What is meant by "additional"? Additionally expressed by the customer?	Clarify "additional"	TAP
2216	ES	1244 1246- 1248	8.2.3	Line 1244 refers to "requirements <u>previously expressed</u> ". But line 1247 refers to "requirements differing from those <u>previously defined</u> ". It should be clarified where the requirements have been: <u>previously expressed</u> and <u>previously defined</u> , and if we are referent to the same concept "expressed, defined"	Clarify	TN
2217	ANSI	1245	8.2.3	These are requirements related to customer orders and reviewing these requirements. This note does not add clarification and is not needed because the types of requirements that would be coming from relevant interested parties are covered by b) and c).	Delete Note.	TAF
2218	DK	1245		The note is not needed.	Delete the note: "NOTE Requirements can also include those arising from relevant interested parties"	TAF
2219	CH	1245	8.2.3	The NOTE would be better at the end of 8.2.3	<u>Move</u> the NOTE to the end of 8.2.3.	TN
2220	SE	1245	8.2.3	It seems not motivated to refer to requirements arising from "interested parties" specifically in connection with review of requirements.	Delete the NOTE.	TAF
2221	IE	1246 -1248	8.2.3 Lines	These lines identify criteria for the review of requirements but do not include the criteria a) and b) in Clause 8.2.2.	Move the content of Clause 8.2.2 Lines 1232-1236 to Clause 8.2.3 and rephrase Lines 1246-1248 of Clause 8.2.3 as follows: "This review shall be conducted prior to . . . and	TN

					shall ensure that: a) product and service requirements . . . are clearly defined; b) it has the ability to meet . . . it offers; c) contract or order requirements differing . . . are resolved"	
2222	CQI 53	1246	8.2.3	This review shall be conducted prior to the organization's commitment to supply products and services... Apply consistent use of the active voice throughout the standard.	This review shall be conducted prior to the organization's commitment organization committing to supply products and services...	TAP
2223	GB	1246 – 8	8.2.3	Passive phrasing of the requirement – rephrase as an active requirement. Separate the two requirements into separate sentences.	Reword: The organization's shall conduct this review before committing to supply products and services to the customer. The organization shall ensure contract or order requirements differing from those previously defined are resolved.	EAP
2224	CQI 54	1249 - 1250	8.2.3	... the customer requirements shall be confirmed by the organization before acceptance. Apply consistent use of the active voice throughout the standard.	... the customer requirements shall be confirmed the organization shall confirm customer requirements before acceptance.	TAF
2225	IE	1249 -1250	8.2.3 Lines	The proposed text maintains an unhealthy ambiguity in the Standard as to whether customer requirements should always be documented.	Replace ". . . customer requirements shall be confirmed by the organization . . ." with ". . . customer requirements shall be documented and confirmed by the organization . . ."	TN
2226	ANS I	1249	8.2.3	A new term or phrase was introduced in this paragraph. What is a documented "statement?" Current wording: Where the customer does not provide a documented statement of their requirements, the customer requirements shall be confirmed by the organization before acceptance	Replace documented statement with documented information. Where the customer does not provide a documented statement of information of their requirements, the customer requirements shall be confirmed by the organization before acceptance.	TN
2227	DE	1249	8.2.3	It appears doubtful whether these requirements of the standard can be fulfilled by organizations of all sizes and in all situations. Example: A customer requests a hairdresser to cut a specific hair shape. This is regularly never done by writing. However it could be reasonable that the hairdresser repeats the customer's requirements to make sure that he correctly	Add „where appropriate“ at the end of line 1250	TAP

				understood them, as mentioned in para 3. But when reviewing the customer's requirements (and eventually modify them under mutual agreement) this will never end up in documented information in real life (para4).		
2228	NL	1249	8.2.3	'Demand' instead of 'requirements' to differentiate between general requirements and individual requirements 'Potential' customer because of consistency with 8.2.2. After acceptance it will be a customer.	Change (bold) Where de potential customer does not provide a documented statement of their demands , the customer demands shall be confirmed ...	TN
2229	ZA	1249	8.2.3	"a" ... "statement" is singular and could be misinterpreted as a statement of fact.	Rewrite "a documented statement" to "documented information"	TN
2230	CH	1249	8.2.3	It appears doubtful whether these requirements of the standard can be fulfilled by organizations of all sizes and in all situations. Example: A customer requests a hairdresser to cut a specific hair shape. This is regularly never done by writing. However it could be reasonable that the hairdresser repeats the customer's requirements to make sure that he correctly understood them, as mentioned in para 3. But when reviewing the customer's requirements (and eventually modify them under mutual agreement) this will never end up in documented information in real life (para4).	<i>Where existing</i> , documented information describing the results of the review, ..., shall be retained.	TAP
2231	MX	1249 & 1250	8.2.3	Where the customer does not provide a documented statement of their requirements, the customer requirements shall be confirmed by the organization before acceptance.	Where the customer does not provide a documented statement of their requirements, the customer requirements shall be confirmed, if it is possible , by the organization before acceptance. RATIONALE: There is not (reviser redacción) always possible to confirm customers requirements, this happens in many services where requirements are defined by the organization which is supplying the service. Hence, the customers' requirements confirmation should be asked only when it is possible to get them.	TAP
2232	ANS I	1251 -1252	8.2.3	This comment while editorial could be a technical comment when considering translation. Consistency in language is important for correct	The organization shall retain documented information describing the results of the review, including any new or changed requirements for	TAP

				translation.	the products and services, shall be retained.	
2233	GB	1251 – 52	8.2.3	Passive tense. Redundant 'the'	Reword: The organization shall retain documented information describing the results of the review, including any new or changed requirements for products and services.	EN
2234	TC2 10	1252	8.2.3	Consistency in reference to product and service by removing definite article	Change 'the products and services' to 'products and services'	EN
2235	NL	1253	8.2.3	Change is a different activity than reviewing. It happens on a different moment in the process. Similar to 8.3.6 and 8.5.6 'change' should be a different clause to draw enough attention to this subject.	Add 8.2.4 Change of requirements related to products and services	TAP
2236	ANS I	1254	8 Operation, 8.2 Determina- tion....	The use of "personnel" is inconsistent with the most common usage in the standard.	Change "individuals" to "persons" for consistency.	TAF
2237	DK	1254	8.2.3	Relevant customers shall also be made aware of changed requirements.	Change text into "Where requirements for products and services are changed, the organization shall ensure that relevant documented information is amended and that relevant personnel and relevant customers are made aware of the changed requirements."	TN
2238	JP 142	1254 1350 1415 1677	8.2.3 8.4.3 8.5.6 A.7	Consistency with Annex SL.	Change "personnel" to "persons."	TAF
2239	IT	1257 -1313	8.3	It is not clear the rationale behind the requirements of retaining documented information in clauses 8.3.5 and 8.3.6, whereas no such requirement is specified in the other clauses.	Modify the requirements related to documented information in clauses from 8.3.2 to 8.3.6.	TAP
2240	PH/ BPS	1257	8.3	The DIS specifically requires the inputs of customers/user groups into the design and development process. It also now explicitly requires substantiation of product claims and consideration of potential consequence of product failure.		C
2241	ANS I	1258	8.3.1	This paragraph is confusing and technically incorrect. Organizations can initiate Design & Development projects where there is no customer or where the project is exploratory or, ...or...or.... The organization needs a robust D & D process for any D & D project. The D & D phase of a	The organization shall establish, implement and maintain a design and development process.	TAP

				product life cycle has a profound impact on Cost of Quality		
2242	ZA	1258	8.3.1	Heading of subclause ("General") is meaningless unless related to main clause This is particularly frustrating when reference is made to this subclause to describe how these requirements are met in an organisation, e.g. in context of integrated management systems	Change heading of subclause to read: .."General information relating to design and development of products and services".. OR .."Introduction to design and development of products and services"	EN
2243	CZ	1259 -1262	8.3.1	The wording of this paragraph is rather confusing and the interpretation can be very difficult and cause the misunderstanding within an organization and/or between stakeholders. We recommend a new wording and adding Note 3	"If the context of the organization requires to create new products or services for its sustainable growth, the organization shall establish, implement and maintain a design and development process in order to ensure controlled conditions for production and service provision, including delivery and post-delivery activities. Note 3 The design and development process can be done by organization itself or it can be subcontracted."	TAP
2244	TC2 10	1259 - 1262	8.3.1	Clarify format and intent of text. It is not clear how 'detailed requirements' differs from 'requirements' used elsewhere in the document	Change to Where requirements of the organization's products and services are not either a) already established, or b) defined by the customer or by other interested parties, to the extent necessary for subsequent production or service provision, the organization shall establish, implement and maintain a design and development process.	EAP
2245	SE	1259 -1262	8.3.1	It is unlikely that "interested parties" would have "detailed requirements of the organization's products and services" having the importance that is suggested here, motivating the establishment of a design process.	Delete "or by other interested parties".	TAF
2246	AT	1259	8.3.1	It is not sufficient to specify the detailed requirements, it is necessary that the solution how to achieve these requirements is given. This is achieved by the design and development output.	Where the design and development output (see 8.3.5) for detailed requirements of the organization's products and services are not already established or not defined by the customer or by other interested parties	TN
2247	IN	1259	8.3.1	Delete 'already'	...product and services are not established...	TAP
2248	EOQ	1259	8.3.1	It is not sufficient to specify the detailed requirements, it is necessary that the solution	Where the detailed requirements and <u>characteristics</u> of the organization's products and	TN

				how to achieve these requirements is given.	services are not already established or not defined by the customer or by other interested parties	
2249	IAQG	1259 1260 1261 1262	8.3.1	This clause is misleading and is written in a negative sense "Where the detailed requirements of the organization's products and services are not already established or not defined by the customer or by other interested parties, such that they are adequate for subsequent production or service provision, the organization shall establish, implement and maintain a design and development process".	IAQG Priority Comment Reword - clarify Proposal: Simplify to read "The organization shall establish, implement and maintain a design and development process when required to enable subsequent production and service provision".	TAP
2250	CO	1259	8.3.1	This paragraph is not clear. What is the idea of this paragraph?	Clarify	C
2251	NL	1259	8.3.1	'detailed requirements' will confuse users. Before production can start, the organisation shall have available documented information that defines the characteristics of the products and service (8.5.1a) and documented information that defines the activities to be performed and the results to be achieved. It's obvious these documented information is the same as the 'detailed requirements'. But do the users understand this?	Change (bold) Where the characteristics of products and services and activities to be performed and the results to be achieved are not already established or not defined by the customer or ...	TN
2252	IE	1259	8.3.1	Change order of text to start the sentence with "The organisation ... ". Better clarity	The organisation shall establish, implement and maintain a design and development process where the detailed requirements of the organisation's products and services are not already established or not defined by the customer or by other interested parties such that they are adequate for subsequent production or service provision.	EAP
2253	CH	1259	8.3.1	'Products' do not have 'requirements. The wording "... requirements <u>of</u> the products ..." is incorrect.	<u>Change</u> to read: "... requirement <u>RELATED TO</u> the products ..."	EAP
2254	UY	1259	8.3.1	Propose a clearer requirement.	Delete "already".	EAP
2255	JP 121	1259	8.3.1	In design and development, means to realize the requirements should be determined as well.	Add "and the means to realize the requirements" after services in L1259.	TN
2256	GB	1259 – 1262	8.3	This wording is very difficult to interpret – it introduces terms like 'detailed' there is a list of sources of requirements duplicating those in 8.2.2 / 8.2.3	Reword: Where requirements are not adequately defined for production or service provision by either existing products and services or by customer or other interested parties the organization shall establish, implement and maintain a design and development process	EAP
2257	CH	1260	8.3.1	According to Annex A.3, only the relevant	<u>Change</u> to read:	TN

				requirements of <u>relevant</u> interested parties are to be addressed.	"... or by RELEVANT interested parties ..."	
2258	AR	1261 /1262	8.3.1	When requiring process or procedures, the words used are not always consistent throughout the document,	Change to: "... the organization shall establish, implement and maintain plan, implement and control a design and development process".	TAP
2259	CH	1262	8.3.1	The topic of risk needs to be addressed in relation to design and development.	Add to text to read: "...development process, <u>taking account of associated risks (see 6.1).</u> "	TAP
2260	PT	1263 -1266	8.3.1	Note 1: the expression "can also apply" contradicts what is stated in first paragraph of 8.3.1. On the other hand to state that 8.5 can be applied is too restrictive for a help as organizations may need to define requirements for contracting services or buying products (8.4), release of P&S (8.6) and control of NC P&S (8.7) On the other hand it is a repetition of second period of note 2 and the question of definition of 8.5 is applicable either to services or products or combination of both and that should be made more clear	Note 1: The organization can address in the design and development, definition of the requirements stated in 8.4, 8.5, 8.6 and 8.7 Note 2.: For services design and development planning can address the whole service delivery process.	TN
2261	IQNet	1263 -1266	8.3.1	This reference to requirements associated with processes is very relevant for a good understanding of this clause and its applicability and good use Note 1: the expression "can also apply" contradicts what is stated in first paragraph of 8.3.1., that clearly requires the need for detailed requirements needed for production and service provision On the other reference to 8.5 is too restrictive as there may be a need to define requirements related to other relevant issues of Operations, like for example, requirement associated with externally provided P&S and processes (8.4) release of P&S (8.6) and control of NC P&S (8.7) Note 2 with specific reference to services is too restrictive, as the design of requirements related to processes tend to be needed either for products and services .	Create only 1 note Note 1: Design and development planning can need to address the whole production process or product and service delivery process. Therefore organizations can choose to address, in the development process, the definition of requirements associated with sections 8.4, 8.5, 8.6 and 8.7.	TN
2262	SE	1263	8.3.1	NOTE 1 has no meaning in this context.	Delete NOTE 1.	TAF

		-1264				
2263	INLA C	1263	8.3.1 Note 1	The note should make reference to clause 8.3 (a equivalent note is included in current ISO 9001, clause 7.1, Note 2) and should indicate "design and development".	Revise Note 1: The organization can also apply the requirements given in 8.3 to the design and development of processes for production and services provision	TN
2264	IAQ G	1263 1264	8.3.1	NOTE 1 "The organization can also apply the requirements given in 8.5 to the development of processes for production and services provision" is not helpful.	Delete or clarify note Proposal: Delete the NOTE or clarify	TAF
2265	CO	1263	8.3.1	Note 1 is not clear. What is the idea of this note	Carify	TN
2266	AR	1263	8.3.1	The reference is not correct.	Change: 8.5 to 8.3	TN
2267	IE	1263	8.3.1	Suggest that the requirement for design records be made a general requirement rather than having in clauses 8.3.2, 8.3.3, 8.3.4 etc. Brevity	Add "The organisation shall maintain and retain documented information to confirm that design and development requirements have been met"	TN
2268	GB	1263	8.3 Note 1	Incorrect reference to clause 8.5	Replace 8.5 with 8.3	TN
2269	JP 122	1263	8.3.1	Typo	Change 8.5 to 8.3.	TN
2270	ANS I	1263 , 1265	8.3.1	Note 1 and Note 2 are confusing. It is very difficult to understand the intent of these notes. In addition, these requirements were previously in 7.1 Planning of Product Realization. Placing these notes in 8.3 does not provide clarification for clause 8.3.	Move note 1 and note 2 to Clause 8.1.	TN
2271	CZ	1264	8.3.1	A full stop is missing at the end of the sentence.	To be added.	EAP
2272	IAQ G	1265 1266	8.3.1	Note 2 "For services, design and development planning can address the whole service delivery process. The organization can therefore choose to consider the requirements of clauses 8.3 and 8.5 together" is not helpful.	Delete or clarify note Proposal: Delete the NOTE or clarify	TAF
2273	NL	1265	8.3.1	Design and development results in a (single) 'blueprint' of the product and service. In case (some) services this blueprint can be limited to a 'prove of concept', but 8.3 and 8.5 have different purposes and should not be combined. E.g. cleaning services; it would be not wise when an organization does not design a effective approach, including defining best cleaning products.	Remove Note 2: For service, design and development ca address the whole service delivery process. The organization can therefore choose to consider the requirements of 8.3 and 8.5 together.	TAF
2274	JP 123	1265	8.3.1	The expression "service provision" is used in 8.5.	Change "delivery" to "provision."	TN

2275	NL	1266	8.3.1	Understanding of the concept requirements is important to translate this element to the organization's management system.	Add Note x: Detailed requirements consist at least of a description of the characteristics of the product and services, the activities to be performed and the results to be achieved.	TN
2276	SE	1267 - 1278	8.3.2	The organization should also consider the effect on production, delivery, and post-delivery. Add a bullet after c) "d) the effect on production, delivery and post-delivery"	a) the nature, duration and complexity of the design and development activities; b) requirements that specify particular process states, including applicable design and development reviews; c) the required design and development verification and validation; d) <i>the effect on production, delivery and post-delivery</i> e) <i>the responsibilities and authorities involved in the design and development process;</i> f) <i>the need to control interfaces between individuals and parties involved in the design and development process;</i> g) <i>the need for involvement of customer and user groups in the design and development process;</i> h) <i>the necessary documented information to confirm that design and development requirements have been met</i>	TAP
2277	IQNet	1268 1333	8.3.2. and 8.4.2.	Is there any technical difference between the use of shall consider or shall take into consideration ?	If the meaning is the same, we propose to use the same expression.	EN
2278	CH	1268	8.3.2	In the context of this sentence, the meaning of the word 'determine' does not match the definition in 3.67.	<u>Change</u> to read: "In DECIDING ON the stages and controls ..."	TN
2279	IAQG	1270 1271	8.3.2.b	The start of bullet b) "requirements that specify" is misleading	Reword – clarify Proposal: Amend to read "requirements that specify <u>particular process stages, including applicable design and development reviews;</u> "	TAP
2280	NZ	1270	8.3.2	This requirement relates to specified requirements which could be externally or internally specified. It would be better to say 'stages and activities' to be more inclusive.	b) requirements that specify particular process stages <i>and activities</i> Include 'reviews' in the planning bullet c).	TN

				Design and development reviews cannot be restricted to this bullet since they are part of planning apart from specified requirements.		
2281	IAQ G	1272	8.3.2.c	The sentence in bullet c) "the required design and development verification and validation;" is incomplete.	Reword – improve Proposal: Amend to read "the required design and development verification and validation activities;"	TAF
2282	NZ	1272	8.3.2	'required ... verification and validation' could imply specified verification and validation only This requirement needs to cover planning of reviews, verification and validation activities. there is no need to say 'design and development reviews' - to simplify sentence just use 'reviews'.	c) the reviews, verification and validation needed to confirm that design and development requirements have been met	TN
2283	IE	1274 -1275	8.3.2e Lines	Interfaces should not be limited to people directly involved in the design and development process	Replace: "... parties involved in the design and development process." With: "... parties involved in or impacted by the design and development process."	TN
2284	IT	1274 -1275	8.3.2	Technical suggestion.	Modify bullet as follows: <i>e) the need to control interfaces between individuals and parties involved in the design and development process in order to ensure effective communication;</i>	TN
2285	ANS I	1274	8.3.2	Individuals and parties is not consistent with other language used in the standard. Consistency is important for user understanding and translation.	e) The need to control interfaces between <u>persons</u> individuals and parties involved in the design and development process.	TAF
2286	ANS I	1276	8.3.2	The terminology "user groups" is not used other places in the standard is not consistent.	Revise f) the need for involvement of customer and <u>other relevant interested parties</u> user-groups in the design and development process.	TN
2287	IE	1276	8.3.2f	Design and development planning needs to consider and address the extent of involvement of different parties	Replace: "The need for involvement of customer . . ." With: "The need for, and extent of , involvement of customer . . ."	TN
2288	ANS I	1277 -1278	8.3.2	Documented information is used without the clarifying maintain or retain. For clear understanding for users, consistent terminology should be used.	Revise g) the necessary documented information <u>to retain necessary</u> to confirm that design and development requirements have been met.	TAF
2289	NZ	1277	8.3.2	Reword: 'the necessary documentation' could suggest specified. As in 8.1 e) documented	The documentation <i>needed to demonstrate</i> that design and development requirements have been	TAF

				information is to demonstrate, not confirm	met	
2290	TT	1277	8.3.2	When determining the design and development for a product or service, risk impact should be considered, particularly for those products or services within a high risk environment, e.g. medical manufacturing, petroleum manufacturing, and safety issues.	Include new point, h) – <i>'the identification of risks in the design and development process as appropriate.'</i>	TN
2291	RO	1277 & 1278	8.3.2	Uniformity of using the term documented information	the necessary documented information to be retained in order to confirm that design and development requirements have been met	TAP
2292	MX	1278	8.3.2	The application of risk analysis in the design and development process is in order, looking forward the possibilities, probabilities and impact of failures in the process stages to detect critical stages or activities to require more care beyond normal.	Add h) the risk of failure in critical stages of the process.	TN
2293	TC69	1278	8.3.2	A hint on applicable and approved method should be given.	Add: Note: The application of special statistical Methods for planning experiments (Design of experiments – DoE) may be very useful for effectively and efficiently structuring of development activities.	TN
2294	BR	1279	8.3.2	The risks analysis used throughout this standard should occur in the project planning as well.	h) the risks that may affect project success;	TN
2295	CZ	1279	8.3.3	"Design and development I nputs"	"Design and development i nputs"	EAF
2296	IAQG	1280	8.3.3	Missing input statement (ref. ISO9001:2008 clause 7.3.2 c)	Add text - Improve Proposal: Add a new bullet to read "information derived from previous similar designs, where applicable". Approved	TAP
2297	AR	1280	8.3.3	Consider the experience of previous designs between D&D inputs	Add after paragraph "d", between lines 1285 y 1286 x) Results of functionality and performance of products and services from previous similar design and development, including complaints and customer perception.	TAP
2298	CN	1281 -1282	8.3.3.a)	Change the "being" into "to be" otherwise the requirement is for the product and service already being develop, it is wrong.	Change the "a) requirements essential for the specific type of products and services being designed and developed, including, as applicable, functional and performance requirements;" Into a) requirements essential for the specific type of	EAF

					products and services to be designed and developed, including, as applicable, functional and performance requirements;	
2299	IT	1281-1282	8.3.3	We suggest to expand the bullet.	Modify bullet as follows: <i>a) requirements essential for the specific type of products and services being designed and developed, including, as applicable, functional and performance requirements, customer-specified requirements, historical performance, any other information derived from previous similar designs and results from technical and risk assessments;</i>	TAP
2300	INLA C	1283	8.3.3	An important and still applicable requirement is missing. Add ISO 9001:2008, clause 7.3.2, bullet c) as a new bullet b) in clause 8.3.3	Add a new bullet: b) Where applicable, information derived from previous similar design	TAP
2301	ANS I	1284	8.3.3	"Standards or codes of practice" is vague. It is not clear what this entails.	Remove c) completely.	TN
2302	LC	1284	8.3.3 (c)	In 8.3.3 (c), "the organization shall determine standards and codes of practice <u>that the organization has committed to implement</u> "..... is this because these are voluntary? As opposed to regulatory and statutory requirements. It sounds optional or discretionary.	If these are relevant it should be dependent of whether the organization has committed to implement, or use the phrase "as appropriate".	TN
2303	ANS I	1285	8.3.3	This requirement seems to be more relevant to planning. d) internal and external resources needs for the design and development of products and services	Move d) to 8.3.2	TAF
2304	IAQ G	1285	8.3.3.d	Bullet d) "internal and external resource needs for the design and development of products and services;" is in the wrong clause.	Move text - clarify Proposal: Move to clause 8.3.2	TAF
2305	NZ	1285	8.3.3	This is a planning issue, not an input against which outputs will be verified. It duplicates 8.1 c).	Delete as duplication or move to 8.3.2 after bullet c)	TAF
2306	RO	1286	8.3.3	The sentence is not clear	the potential consequences of failure due to the nature of the products and services;	TN
2307	CO	1286	8.3.3	The risks of design and development of products and services should be analyzed. As a result of this, potential consequences are considered. (See IEC 60812)	e) The risks of design and development of products or services and the potential consequences. (For example, failure due to the nature of the products and services).	TN
2308	CA- 57	1286	8.3.3	The intended use and possible misuse of a product or service is an important factor in determining the potential consequences of failure and is an integral part of risk assessment.	Change to: "e) the potential consequences of failure due to the nature of the products and services taking into account their intended and other possible uses;"	TN

				Modify the current wording (copied below) to the wording shown in the column on the right – e) the potential consequences of failure due to the nature of the products and services;		
2309	IT	1286	8.3.3	We suggest to reintroduce some specifications which were in the CD.	We suggest to reintroduce them into the corresponding sub-clause in current DIS <i>e) the determined risks associated with threats and opportunities relevant to the design and development activities with respect to:</i> <i>1. the nature of the products and services to be designed and developed and potential consequences of failure,</i> <i>2. the level of control expected of the design and development process by customers and other relevant interested parties, and</i> <i>3. the potential impact of the organization's ability to consistently meet customer requirements and enhance customer satisfaction.</i>	TN
2310	JP 124	1286	8.3.3	Experienced failure is also important for prevention of recurrence.	Add "experienced failure" before item e).	TN
2311	GOS T R	1287	8.3 Design and development of products and services	Phrase "the level of control" shall be explained		C
2312	IE	1287	8.3.3	The phrasing is awkward leaving intent unclear. It is assumed that the organization needs to identify the necessary design and development controls in order to meet customer and other relevant interested parties needs	Rephrase to clarify Suggest - the necessary design and development controls in order to meet customer and other relevant interested parties needs.	TN
2313	NZ	1287	8.3.3	This will be determined under 8.2.3 a) and c) - review of requirements related to products and services - and therefore is already included in 8.3.3 a).	Delete as duplication (if retained should be in 8.3.2 not 8.3.3)	TAP
2314	RO	1287 & 1288	8.3.3	Clarification	the level of control expected for the design and development process by customers and other relevant interested parties	EAF
2315	BR	1288	8.3.2	Ensure that the identification of new risks introduced occur at a stage of development of products and services that make it possible to plan their controls	Include a new item: c) risks introduced with new products and services Change the numbering of bullets c) to g) accordingly	TN
2316	NL	1288	8.3.3	Delivery and after delivery activities might need	Add	TN

				specific tool or instructions. These should also be developed.	g) requirements for supporting supplies needed for preservation, delivery or post-delivery activities. Note: supporting supplies include, but is not limited to packing, installation tools, maintenance tools, user instructions or training equipment.	
2317	IE	1289-1290	8.3.3	The intention of these two lines would be more clearly expressed if the two sentences were combined.	Rephrase as follows: "Any conflicts amongst inputs shall be resolved to ensure that inputs are adequate for design and development purposes, complete and unambiguous."	EN
2318	SE	1289	8.3.3	An important input to design and development is the analysis of the business environment (trends, competitors, future customer requirements etc.). This is not mentioned in 8.3.2 or 8.3.3.	Add: " g) the business environment for new products and services, including trends, future customer demands and competition."	TN
2319	INLA C	1290	8.3.3	References to innovation are included in clauses 5.3 and 10.1. During design and development innovation may occur or needed. Add a note related to innovation.	Add a new Note: Opportunities for innovation can be considered when determining the design and development inputs	TAP
2320	ANS I	1290	8.3.3	There is no requirement to retain design and development inputs similar to ISO 9001:2008. This will be perceived as a reduction in requirements	Add Text The organization shall retain documented information related to design and development inputs	TAP
2321	IE	1290	8.3.3	Change to "Conflicts among design and development inputs shall be resolved".	Change to "Conflicts among design and development inputs shall be resolved".	EAP
2322	NG	1290	8.3.3 last paragraph	There is the need to add 'prior to implementation' at the end of the sentence for clarity and measurability	Conflicts resolved prior to implementation	TN
2323	ANS I	1292-1298	8.3.4	The record to retain documented information that is consistent with required records has not been included. There are many examples of information that should be retained as objective evidence.	The organization shall retain documented information of controls including any necessary actions.	TAP
2324	SE	1292	8.3.4	"The controls applied to the design and development process shall ensure that". This way of using an indirect way for expression of a requirement is different from the usual, clear way of expressing requirements in ISO 9001.	Replace with "The organization shall apply controls to the design and development process to ensure that".	TAF
2325	SE	1293	8.3.4	"The controls applied to the design and development process shall ensure that: a) the	Delete "clearly".	TAF

				results to be achieved by the design and development activities are clearly defined" Why use the word "clearly" here? This is the only place in the draft where something is required to be done "clearly". In every case when something is required to be documented, defined, etc. it should be done "clearly". What will become the difference when "clearly" be deleted? Who shall judge?		
2326	JP 125	1293	8.3.4	The expression "design and development <u>activities</u> " is inconsistent with the expression in L1292.	Change to "design and development <u>processes</u> ."	TAP
2327	ANS I	1294 -1298	8.3.4	The method in which b), c), and d) have been written does not provide the clarification that design reviews, verification, and validation can be conducted together or separately. Based on the philosophy to make the standard less prescriptive and easier to use, the note that has been previously used will help provide this clarification.	Add Note: NOTE Design and development reviews, verification, and validation have distinct purposes. They can be conducted and retained as documented information separately or in any combination, as suitable for the product and service and the organization.	TAF
2328	RO	1294	8.3.4	Consistency of approach with 8.3.4c and d	design and development reviews are conducted as planned in order to determine the suitability, adequacy or effectiveness of the results of design and development;	TN
2329	IE	1294	8.3.4b Line	The proposed text does not reflect the importance of 'follow-up' for the success of a review	Expand point b) as follows: " . . . as planned and actions arising from the review are adequately controlled. "	TAP
2330	IT	1294	8.3.4	The elimination of the reference to the participants in the design and development review (see ISO 9001:2008, 7.3.4) can result in diminishing the effectiveness of controls. A reference to the "design review" technique should be also considered.	Modify bullet b) as follows: <i>b) design and development reviews are conducted as planned, involving representatives of functions concerned with the design and development stage(s) and making use of relevant methods/techniques;</i> Consider to add a reference to the "design review" technique.	TN
2331	JP 126	1294	8.3.4	For clarification of the purpose and for continuity of 2008 version.	Change to: b) design and development review are conducted as planned <u>to evaluate the ability of the results of design and development to meet requirements and to identify any problems and propose necessary actions</u>	TAP

2332	NO	1295 -1296	8.3.4	ISO/TR 9002 should give guidance on verifications and the need for independency, also when the verification is carried out internally.		C
2333	SE	1295 -1296	8.3.4	The same requirement is stated twice: 8.3.4: The controls applied to the design and development process shall ensure that: ... c) verification is conducted to ensure that the design and development outputs have met the design and development input requirements. 8.3.5 The organization shall ensure that design and development outputs: a) meet the input requirements for design and development. This is once too much.	Change line 1295: Change from "outputs have met" to "are capable of meeting".	TAP
2334	IAQ G	1295 1297	8.3.4	Propose to use plural to avoid the requirement of a single report for each activity	Reword - improve Proposal: g) verification <u>activities are</u> is conducted to ensure that the design and development outputs have met the design and development input requirements; h) validation <u>activities are</u> is conducted to ensure that the resulting products and services are capable of meeting the requirements for the specified application or intended use (when known).	TAF
2335	JP 127	1295	8.3.4	"as planned" should be added as in 8.3.4 b).	Change to: c) verification is conducted <u>as planned</u> to ensure that the design and development outputs have met the design and development input requirements;	TN
2336	CO	1297	8.3.4	Align with 8.3.3 a) a) requirements essential for the specific type of products and services being designed and developed, including, as applicable , functional and performance requirements .	d) Validation is conducted to ensure that the resulting products and services are capable of meeting the requirements for the specified application or intended use when applicable .	TN
2337	CA- 58	1297 1298	8.3.4	The intended use of a product or service is a critical input to the design process. It is therefore highly unlikely that a product or service could be effectively designed without its intended uses being identified.	The words at the end of line 1298 "(when known)" should be deleted.	TAF
2338	JP 128	1297	8.3.4	"as planned" should be added as in 8.3.4b).	Change to:	TN

					d) validation is conducted <u>as planned</u> to ensure that the resulting products and services are capable of meeting the requirements for the specified application or intended use <u>(when known)</u> .	
2339	IAQ G	1298	8.3.4	8.3.4 Discusses controls for Design and Development processes. When viewed from a PDCA perspective 8.3.4.a contains 'Planning' attributes 8.3.4.b,c&d contains 'Do & Check' attributes No clear requirement on the 'Act' part of Design and Development (i.e. what to do if a deficient scenario is present)	IAQG Priority Comment Add text - Improve Proposal: Add e) wording at end of 8.3.4 to state a requirement organization to resolve insufficient outcomes of Review, Verification and Validation. Possible wording Where outcomes of the review, verification or validation processes do not meet applicable criteria, the organization shall take appropriate actions to ensure design and development requirements are met. <u>Met intent</u> If the 'Act' part of handling and insufficient outcome of the Review, Verification and Validation process is covered in a different part of the standard (possibly 8.7), then make a reference to it in section 8.3.4.	TN
2340	CN	1298	8.3.4 d)	Should delete the bracket, there are too many brackets in this standard	Change the "d) validation is conducted to ensure that the resulting products and services are capable of meeting the requirements for the specified application or intended use (when known)." Into d) validation is conducted to ensure that the resulting products and services are capable of meeting the requirements for the specified application or intended use when known.	EAP
2341	CO	1299	8.3.5	The outputs of the design and development process shall include not only information for the purchasing, but also information for production process and service provision. (This when an organization not only design but manufacture the products or provide the services), In this way, product can be repeated.	Include text from the current ISO 9001 as new bullet: Provide appropriate information for purchasing, production and service provision when applicable.	TN
2342	IE	1299	8.3.5	Change order of clauses: - Inputs - Outputs - Controls	Change order of clauses: - Inputs - Outputs - Controls	TN

				This will read better	Move this clause to before 8.3.4	
2343	SE	1300	8.3.5	Clarify it is the final outputs.	Add "final" to "outputs" i.e. "final outputs"	TN
2344	IE	1301	8.3.5 a)	Change "meet" to "satisfy"	a) satisfy the input requirements ...	TN
2345	RO	1302	8.3.5	Clarification	are adequate for the subsequent processes (e.g. purchasing, production and service provision) for the provision of products and services;	TN
2346	NL	1302	8.3.5	The documented information referred to in 8.5.1 a) and b) should be the output of D&D. To ensure users of the standard recognize this relationship, the description should be consistent.	Change into: b) define the characteristics of the products and services, the activities to be performed and the results to be achieved.	TN
2347	NL	1304	8.3.5	All products and service should have acceptance criteria otherwise it will be impossible to decide when a product can be released. And all requirements of the standard are to be considered applicable, unless determined not applicable by the organization. 'as applicable' is redundant.	Remove (bold) c) include or reference monitoring requirements, and acceptance criteria, as applicable	TAP
2348	NL	1305	8.3.5	Products should also be safe for installation, maintenance and de-installation. Users of the standard should be stimulated to consider these phases of the product life cycle.	d) ensure products to be produced, or services to be provided, are fit for intended purpose and their safe and proper installation , use, maintenance and de-installation .	TN
2349	NZ	1305	8.3.5	Design and development outputs cannot 'ensure' this. Use 9008 phrase 'specify the characteristics' and simplify the sentence.	d) specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper use.	TAP
2350	JP 129	1305	8.3.5	The verb "ensure" appears twice in the same sentence (L1300 and L1305), not a good writing.	Change to: d) <u>make</u> products to be produced, or services to be provided, <u>fit</u> for intended purpose and their safe and proper use	EAP
2351	FR	1305	8.3.5	Complete bullet d)	Bullet d) reads : Ensure products to be produced, or services ... are fit for intended purpose, when known, and ... In french Reprendre "l'usage prévu, lorsqu'il est connu"	TN
2352	GB	1305 – 6	8.3.5 d)	Technically this is not something that the 8.3.5 clause 'design outputs' can do – this is something only design controls can establish (8.3.4)	Amend to: d) specify the characteristics of the product or service that are essential for its safe and proper use or delivery."	TAP
2353	IN	1305 , 1306	8.3.5	rephrase	...are fit for intended purpose and <u>are</u> safe <u>for</u>	TN

					proper use...	
2354	SE	1307 -1308	8.3.5	"The organization shall retain the documented information resulting from the design and development process". The reason for formulating a requirement in this way is difficult to understand. It will be understood as "If there happens to be some documented information resulting from the design and development process it shall be retained". The requirement does not say that any documented information shall be prepared at all. It should be changed in order to consider that.	Replace with "The organization shall establish and retain documented information resulting from the design and development process as needed to meet requirements for the provision of products and services".	TN
2355	BR	1307	8.3.5	The phrase "The organization shall retain the documented information resulting from the design and development process" is incompatible with the clause title. It is more reasonable to require documented information about the controls instead of about the process. Change "process" to "controls" and move to clause 8.3.4	Change to read: "The organization shall retain the documented information resulting from the design and development process controls". Move this paragraph to clause 8.3.4, after line 1298	TN
2356	AT	1307	8.3.7	The sentence has the possible interpretation that all documented information produced in the design and development process needs to be retained. This is probably not the intent (this intent is e.g. expressed in the german translation).	The organization shall retain the documented information on the results of the design and development process.	TN
2357	EOQ	1307	8.3.7	"the documented information", indicates, that everything needs to be retained.	The organization shall retain appropriate documented information on the results of the design and development process.	TAP
2358	IAQ G	1307 1308 1313	8.3.5 8.3.6	The requirement to "retain documented information" is split in 2 clauses and can be combined. Moreover the requirements apply to the whole process (all clauses)	Move text - improve Proposal: - move the requirement to "retain documented information" " to retain in the "General" clause (8.3.1) - to include also the requirements relating to design and development changes "The organization shall retain the documented information resulting from the design and development process <u>including design and development changes</u>"	TN
2359	AR	1307	8.3.5	To be consistent with the Annex A.6, change in the last paragraph "Retain" by "maintain" (the result of the D&D is a "document" for the version	Change to: The organization shall retain maintain the documented information resulting from the design	TN

				2008)	and development process.	
2360	JP 130	1307	8.3.5	Documented information required by this paragraph is ambiguous due to wording "documented information resulting from the design and development process." Remember that this paragraph discusses on "design and development outputs."	Change to: The organization shall retain the documented information <u>of design and development outputs</u> .	TAP
2361	RO	1307 & 1308	8.3.5	From design and development process are resulting both documents and records	The organization shall maintain and retain the documented information resulting from the design and development process.	TN
2362	INLA C	1307 , 1308 & 1313	8.3.5 & 8.3.6	The requirements related to documented information in clauses 8.3.5 and 8.3.6 can be combined and included instead in clause 8.3.1 (line 1263). During D&D planning, the need of maintaining documented information must be considered.	Remove lines 1307, 1308 & 1313 and add new requirement in clause 8.3.1 (after line 1262) The organization shall maintain the documented information resulting from the design and development processes, including design and development changes.	TN
2363	BE	1308	8.3.5	In §8.3.3 Design and development inputs, no requirement exists to maintain documented information of those D&D inputs. In §8.3.5 Design and development outputs is requested to retain documented information "resulting of the design and development process" (why not "of D&D outputs"?). Documented information of D&D outputs only is insufficient because it can not be compared to D&D inputs because no requirement exists to retain documented information of D&D inputs. ISO 9001 is a standard for certification and in consequence certification auditors must be able to compare D&D outputs with D&D inputs.	Add requirement to retain documented information of D&D inputs and eventually reword the requirement in 8.3.5 to retain documented information of D&D outputs (similar to line 1313).	TAP
2364	IE	1309	8.3.6	Change is part of "Controls". Make 8,3,6 part of 8.3.4 and not have a separate clause	Make 8,3,6 part of 8.3.4 and not have a separate clause	TN
2365	QS	1309	8.3.6	Reorganize the clause to be in sequence.	Change as: The organization shall identify, review and control changes made to design inputs and design outputs 1311 during the design and development of products and services or subsequently	TAP
2366	NZ	1309	8.3.6	There are likely to be comments to remove this clause because of duplication with 8.5.6. However there are many circumstances (eg	Retain clause 8.3.6 and consider whether 8.5.6 is necessary.	C

				construction projects, some services) where control of design and development change is the one sub-clause of 8.3 that is applicable to the scope of a project or service.		
2367	IE	1310	8.3.6 Line	This line appears not to reflect the chronological sequence of change management activities	Rephrase: "... review, control and identify changes ..." As: "... identify, review and control changes .. "	EAF
2368	QS	1310	9.3.1	External providers issue and adequacy of resource required – these two points can be a separate main bullets and not part of main bullet c)	Shift c 5) and c 6) as main bullet g) and h)	TN
2369	CN	1310	8.3.6	Should change the sequence of the 3 verbs to meet logic.	Change the : "The organization shall review, control and identify changes made to....." Into: The organization shall identify, control and review changes made to.....	EAP
2370	NZ	1310	8.3.6	Reword to use 'design and development' without excessive repetition (currently uses 'design inputs and design outputs' which is not consistent with use of 'design and development').	The organization shall review, control and identify changes made during, or subsequent to, the design and development of products and services, to the extent that there is no adverse impact on conformity to requirements.	EAP
2371	JP 131	1310	8.3.6	Design is not accompanied by "and development."	Change to: The organization shall review, control and identify changes made to design <u>and development</u> inputs and design <u>and development</u> outputs...	TAP
2372	CQI 55	1311 - 1312	8.3.6	'...during the design and development of products and services or subsequently, to the extent that there is no adverse impact on conformity to requirements.' 'or subsequently' - This is after design and development and other clauses on changes then apply.	'...during the design and development of products and services or subsequently , to the extent that there is no adverse impact on conformity to requirements.'	TN
2373	IE	1311	8.3.6 Line	The phrase "... to the extent that ... " is confusing in this context.	Replace: "... to the extent that ... " With: "... to ensure that ... "	TN
2374	CA- 59	1313	8.3.6	Why in this clause, when the organization is required to "review, control and identify changes...", and then states: "Documented information on design and development changes shall be retained.", yet in a later clause (8.5.6) in Section 8, <i>Operations</i> , where the organization also has to review and control changes, the requirements on retention of documented	Change 2 nd paragraph to: "The organization shall retain documented information describing the results of the review of design and development changes, the personnel authorizing the change, and any necessary actions."	TAP

				information changes: "The organization shall retain documented information describing the results of the review of changes, the personnel authorizing the change, and any necessary actions. " The requirements for retention of documented information are equally important in both instances, and should, therefore, be consistent.		
2375	GB	1313	8.3.6	Passive tense	Reword: 'The organization shall retain documented information of design and development changes.'	TAP
2376	HU	1314 -1344	8.4	Examples at some points of this Clause would be useful for the understanding and coherent application of requirements by the quality practitioners and auditors, e.g. at 8.4.1 a) – c).		C
2377	BW	1314	8.4	Include "processes" on the title of clause 8.4	8.4 Control of externally provided processes, products and services	TAF
2378	NG	1314	8.4	Control of externally provided products and services	The title is not in harmony with the content of 8.4.1, needs to be change. To read <i>Control of externally provided processes, products and services</i>	TAF
2379	IT	1314	8.4	The title seems to be incomplete and inconsistent with the content of line 1316: <i>"The organization shall ensure that externally <u>processes</u>, products and services conform to specified requirements"</i> .	Modify title as follows: <i>8.4 Control of externally provided processes, products and services</i>	TAF
2380	SE	1314	8.4	Some superordinate aspects which are now stated in the 2 nd paragraph of 8.4.2 fit better as an introduction in the beginning of 8.4.	Add in the beginning of 8.4 the following, part of which should be moved from the 2 nd paragraph of 8.4.2: "The organization shall apply controls to ensure that externally provided processes, products and services do not adversely affect the organization's ability to consistently deliver conforming products and services to its customers".	TN
2381	JP 132	1314	8.4	The sub-clause 8.4 addresses processes, products and services. The "processes" should be added to the title.	Change to: Control of externally provided products and services <u>and outsourced processes</u>	TN
2382	ZA	1315	8.4.1	Heading of subclause ("General") is meaningless unless related to main clause This is particularly frustrating when reference is made to this subclause to describe how these	Change heading of subclause to read: .."General information relating to control of externally provided products and services".. OR .."Introduction to control of externally provided	TN

				requirements are met in an organisation, e.g. in context of integrated management systems	products and services"	
2383	TC2 10	1316 - 1317	8.4.1	Consistency in reference to products and service and clear separation between externally supplied processes and externally provided products and service. Consistency with line 1329.	Change to The organization shall ensure that externally provided processes or products and services conform to specified requirements.	EN
2384	BE	1316	8.4.1	“,” before “and”	Remove “,” after “products”	EAF
2385	JP 133	1316 1324 1327 1332 1334 1339	8.4	The expressions such as “externally provided processes” and “process is provided” are not appropriate. Better to review for consistency.	L1316: Change “externally provided processes, products, and services” to “ <u>outsourced process and</u> externally provided products and services.” L1324: Change “a process or part of a process is provided” to “a process or part of a process is <u>performed</u> .” L1327: Change “provide processes or provide products and services” to “ <u>perform</u> processes or provide products and services.” L1332: Change “external provision of processes, products and services” to “ <u>outsourced process and externally provided products and services</u> .” L1334: Change “externally provided processes, products and services” to “externally provided <u>products and services and outsourced processes</u> .” L1339: Change “externally provided processes, products and services” to “externally provided <u>products and services and outsourced processes</u> .”	TN
2386	IAQ G	1318 -1325	8.4.d	The requirement regarding the QMS of the external providers is to be added. It's a key point for ASD Industry who has implemented a certification scheme (ICOP) for the whole supply chain	IAQG Priority Comment Add text - Improve Proposal: Propose to add a bullet after bullet c) The organization shall communicate to external providers applicable requirements for the following: d) <u>their quality management system</u>	TAP
2387	JP 134	1318 -1325	8.4.1	The meaning of “the specified requirements” in L1318 is ambiguous. If it is the “specified requirements” in L1317, L1318 should be limited and be written as “for the controls to the external providers.” Or, if it is the requirements specified in 8.4 as a whole, it should be revised to include facilities used for product and service provision, not just	If the “specified requirements” in L1318 is the specified requirements in L1317, change to: The organization shall apply the specified requirements for the controls to <u>the external providers</u> when: a) products and service are provided by external providers for incorporation into the organization's own products and services;	TAP

				for built-in components, goods for direct shipment or outsourced goods.	b) products and services are provided directly ... c) a process or part of a process is ... If the “specified requirements” in L1318 is the requirements in 8.4, change to: The organization shall apply the specified requirements <u>in 8.4</u> for the control of externally provided processes, products and services when: a) products and service are provided by external providers for incorporation into the organization's own products and services; b) <u>products and service are used for the provision of the organization's own products and services;</u> c) products and services are provided directly ... d) a process or part of a process is ...	
2388	EOQ	1318 -1319	8.4.1	In the first paragraph of this clause processes, products and services are mentioned. In the second paragraph only products and services are mentioned. Processes should be added	The organization shall apply the specified requirements for the control of externally provided <u>processes</u> , products and services when	TAP
2389	INLA C	1318	8.4.1	For consistency between first and second paragraph, add “process” in line 1318	...of externally provided processes, products...	TAP
2390	PL	1318	8.4.1	The clause is saying about products, services and processes, so the title and the second paragraph should be added with the processes. Or the title of 4.1 could be just “Control of external provision “	The title: Control of external provision Second paragraph: “The organization shall apply the specified requirements for the control of externally provided processes, products and services when....”	TN TAF
2391	NZ	1318	8.4.1	Should this be ‘The organization shall <i>specify</i> the requirements for the control...’ rather than <i>apply the specified requirements</i> ’? Not all requirements for externally provided products and services are specified in design and development outputs (8.3.5) or product and service requirements (8.2).	Change to The organization shall <i>specify</i> the requirements for the control...	TAP
2392	TC2 10	1318	8.4.1	For consistency, use the general term requirements rather than ‘specified requirements’ to differentiate the requirements for the process or product and service and the requirements of	Delete ‘specified’.	TAF

				the International standard.		
2393	RO	1318 & 1319	8.4.1	Clarification	The organization shall apply the specified requirements for the adequate control of externally provided products and services when:	TAP
2394	ANS I	1324 -1325	8.4.1	Process is used inconsistently in the sentence by including function at the end.	Revise f) a process or part of a process is provided by an external provider as a result of a decision by the organization to outsource a process or function.	TAP
2395	ANS I	1324	8.4.1	The term "function" is used here, without proper context or understanding. To this point, the clause has been discussing outsourced processes; it is not clear, then, what an outsourced "function" may be.	Delete the word "function" and leave as "outsource a process."	TAP
2396	IN	1324	8.4.1	The use of term "function" is not clear. Up to this point, the clause has been discussing outsourced processes; it is not clear, then, what an outsourced "function" may be.	Delete the word "function" and leave as "outsource a process."	TAP
2397	IR	1324	8.4.1	In the item c) of this sub-clause the word "provided" needs to be replaced by the word "performed" since a process is performed while a product or a service is provided. See 3.14.	Replace the word "provided" by the word "performed" in the item c) of this sub-clause as follows: c) a process or part of a process is performed provided by an external provider as a result of a decision by the organization to outsource a process or function.	TN
2398	NL	1324	8.4.1	Not all outsourced processes have impact on conformity with requirements of products and services. Misunderstanding can arise between users and auditors when discussing which outsourced processes are related to this clause. Remark: in fact one can say that purchasing a product (bullet a) is the same as outsourcing a production process. So bullets a and b can be considered redundant.	Add (bold) c) a process or part of a process is provided by an external provider as a result of a decision by the organization to outsource an operational process or a part of this process.	TN
2399	ZA	1325	8.4.1 c)	Remove reference to "outsource"	End c) with "organization." Remove "to outsource"	TAF
2400	ZA	1325 1341	8.4.1 8.4.2	The word "functions" is introduced in the clauses 8.4.1 c) and 8.4.2 but there are no requirements relating thereto. Note that a function will consist of processes but has not been defined.	Delete "or function" in clause 8.4.1 c) and "or functions" in clause 8.4.2	TAF
2401	NL	1326	8.4.1	Confusion might arise about purchasing	Add	TN

				resources. Providing resources are part of the support processes. 8.4 should relate to purchasing material and not to equipment.	Note: Acquisition of resources are part of the provision process in clause 7.1. The requirements of this clause 8.4 can be applied to the purchasing of resources.	
2402	GB	1326	8.4.1	Redundant 'the'. Mixture of 'of' and 'and' – improve wording	Reword: The organization shall establish and apply criteria for evaluation, selection, performance monitoring and re-evaluation of external providers based on their ability to provide processes, products or services in accordance with specified requirements.	EAP
2403	DE	1327	8.4.1	The organization shall apply criteria for evaluation, ... of external providers based on their ability to provide ... This gives room for misinterpretations. What does it mean? Does it mean that a reliable provider needs less or a different control than an inexperienced? Maybe, subclause 8.4.2 would be a better place for para 3 and para 4.	Clarify and expand on that. Perhaps add a Note.	C
2404	CH	1327	8.4.1	The organization shall apply criteria for evaluation, ... of external providers based on their ability to provide ... This gives room for misinterpretations. What does it mean? Does it mean that a reliable provider needs less or a different control than an inexperienced? Maybe, subclause 8.4.2 would be a better place for para 3 and para 4.	Clarify and expand on that, perhaps in a note.	C
2405	NZ	1327	8.4.1	Including 're-evaluation' under this requirement could imply establishing a re-evaluation process and schedule for all external providers. Criteria for monitoring performance would identify when or if re-evaluation activity would be needed so the inclusion of 're-evaluation' is unnecessary.	Delete 're-evaluation': ... selection <i>and</i> monitoring of performance <i>and</i> re-evaluation of external providers. Also applies to line 1330.	TN
2406	AT	1328 1329	8.4.1	Combine the two paragraphs and streamline the last sentence.	... products and services in accordance with specified requirements. The organization shall retain documented information, see 8.1 e).	TN
2407	CQI 56	1329 - 1330	8.4.1	The organization shall retain appropriate documented information of the results of the evaluations, monitoring of the performance and re-evaluations of the external providers. Surely the selection of the external provider is required?	The organization shall retain appropriate documented information of the results of the selections , evaluations, monitoring of the performance and re-evaluations of the external providers.	TAF

2408	ANS I	1329 -1330	8.4.1	The word appropriate is not consistent with other parts of the standard. Typically appropriate is used with where appropriate or as appropriate. In other places of the standard "to the extent necessary" is used.	Revise The organization shall retain appropriate documented information <u>to the extent necessary</u> of the results of the evaluations, monitoring the performance and re-evaluations of the external providers.	TAP
2409	CL	1329 -1330	8.4.1	It says: "The organization shall retain appropriate documented information of the results of the evaluations, monitoring of the performance and re-evaluations of the external providers".	We suggest to add: "The organization shall retain appropriate documented information of the results of the evaluations, monitoring of the performance and re-evaluations of the external providers, <u>and of any necessary actions arising from these activities</u> " To be consistent with previous requirements.	TAP
2410	TH	1329 -1330	8.4	Information of the selection should be added.	The statement should read "The organization shall retain appropriate documented information of the results of the evaluations, <u>selection</u> , monitoring...".	TAP
2411	ANS I	1329 1330	8.4.1	This sentence does not include supplier selection retention of documented information	Add "selection" to lines 1329 and 1330 to read: "The organization shall retain....the results of the evaluations, selections, monitoring of the performance.....providers"	TAP
2412	EOQ	1329	8.4.1	The documentation requirement is inconsistent with the requirements on what shall be done. The critical point of the selection is mission.	The organization shall retain appropriate documented information of the results of the evaluations, selection , monitoring of the performance and re-evaluations of the external providers.	TAP
2413	CA- 60	1329	8.4.1	The statement is "The organization shall retain appropriate documented information of the results of the evaluations, monitoring of the performance and re-evaluations of the external providers" is inconsistent with the previous paragraph. The 3 rd paragraph states "The organization shall establish and apply criteria for the evaluation, selection , monitoring of performance and the re-evaluation of external providers...". Why is it important to retain information on the evaluation, monitoring and re-evaluation, but not on the selection? It may provide important information, during root cause analysis or process improvement activities.	Change to: "The organization shall retain appropriate documented information of the results of the evaluations, selection, monitoring of the performance and re-evaluations of the external providers"	TAP
2414	RO	1329 & 1330	8.4.1	Consistency with the previous paragraph	The organization shall retain appropriate documented information of the results of the evaluations, selection , monitoring of the	TAP

					performance and re-evaluations of the external providers.	
2415	NZ	1330	8.4.1	NZ comment on line 1327 recommends deleting 're-evaluation'.	If modification of line 1327 accepted, delete 're-evaluation'	TN
2416	IE	1331-1344	8.4.2	The paragraphs are in the wrong order and legibility would be improved if re-ordered	Put paragraph 2 and 3 in front of paragraph 1 and delete the words "a) and b) above" from paragraph 3. Change the word "accordingly" to "therefore" in paragraph 3.	TAF
2417	RO	1331	8.4.2	Consistency with the content of the chapter	Type and extent of control of for the external provision of processes, products, and services	TN
2418	TC2 10	1332-1333	8.4.2	Consistency in reference to products and service and clear separation between externally supplied processes and externally provided products and service. Consistency with line 1329.	Change to processes or products and services	TN
2419	CH	1332	8.4.2	In the context of this sentence, the meaning of the word 'determine' does not match the definition in 3.67.	<u>Change</u> to read: "In DECIDING ON the type and extent of controls ..."	TN
2420	SE	1333	8.4.2	Recognized practice in ISO standards.	Spell "organization" with "z".	EAF
2421	CQI 57	1337	8.4.2	b) the perceived effectiveness of the controls applied by the external provider. What use is an opinion in ensuring quality? We need some measure of the controls applied by the external provider. Or, if not, then delete bullet	b) the perceived effectiveness of the controls applied by the external provider. OR b) the perceived effectiveness of the controls applied by the external provider.	TAF
2422	IIOC	1337	8.4.2	The word perceived will lead to confusion and non-uniform application	Remove the word perceived	TAF
2423	INLA C	1337	8.4.2 b)	Change the word "perceived" to "expected" in bullet b). When determining controls, the expected results of the controls need to be determined. A perception is not objective.	b) the expected effectiveness of the...	TAP
2424	ANS I	1337	8.4.2 (b)	"Perceived" effectiveness is too subjective. Need some data or measurement criteria.	the perceived measured effectiveness of the controls applied by the external provider	TAP
2425	IAQ G	1337	8.4.2 (b)	"Perceived" effectiveness is too subjective. Need some data or measurement criteria.	IAQG Priority Comment Add text - Improve Proposal: the perceived <u>measured</u> effectiveness of the controls applied by the external provider	TAP
2426	ZA	1337	8.4.2	"Perceived" effectiveness is not to be used in relation to the definition of effectiveness. The sentence would read "perceived extent to which planned activities are realised...."	Delete "perceived"	TAF
2427	TC2 10	1337	8.4.2	The organization retains responsibility to	Remove, 'perceived' and Amend to: "b) the effectiveness of the controls applied by the	TAF

				determine these aspects, and the use of 'perceived' to modify effectiveness makes the text weak.	external provider."	
2428	JP 135	1337	8.4.2	The purpose of "controls applied by external providers" is ambiguous. Risk-based thinking is mentioned in A.8.5, but the requirement is not explicit.	Change to: b) <u>potential nonconformities</u> and the perceived effectiveness of the controls applied by external providers.	TN
2429	GB	1338 - 40	8.4.2	Huge overlap with requirements captured in line 1334 – 1336.	Eliminate the duplication by moving lines 1338 - 1340 to the beginning of clause 8.4.2. Delete bullet a) and combine bullet b) with lines 1332 - 1333	TAP
2430	NZ	1338	8.4.2	Add a reminder that retention of documented information is a key option for controlling external provision of products and services.	Change to read: "The organization shall establish and implement verification or other activities <i>including retention of documented information</i> necessary to ensure ..."	TN
2431	SE	1338	8.4.2	Unclear what "activities" are intended.	Exemplify intended activities in a note.	C
2432	RO	1338 & 1339	8.4.2	Addition for clarification	The controls to be applied to the external provision of processes, products and services shall include both the controls to be applied to the external provider and to the process output, product and service to be provided.	TAP
2433	RO	1338 , 1339 & 1340	8.4.2	Consistency with the content of the chapter	The organization shall establish and implement verification or other activities necessary to ensure the externally provided processes, products and services meet specified requirements . do not adversely affect the organisation's ability to consistently deliver conforming products and services to its customers.	TAP
2434	SE	1339 -1340	8.4.2	The 2 nd paragraph of 8.4.2 contains the phrase "do not adversely affect the organisation's ability to consistently deliver conforming products and services to its customers". Such superordinate aspects should most suitably be considered at the beginning of 8.4 and not primarily in conjunction with verification.	Replace with "meet specified requirements".	TAP
2435	ZA	1339	8.4.2	"...do not adversely affect the organisation's ability...." gives a negative connotation on externally provided processes, products and services. The verification should ensure that the externally provided processes, products and services meet the organisations ability to supply conforming products and services	Replace "do not adversely affect" with "meet".	TAP
2436	TC2	1339	8.4.2	Consistency in reference to products and service	Change to	TN

	10			and clear separation between externally supplied processes and externally provided products and service. Consistency with line 1329.	 processes or products and services	
2437	SE	1339	8.4.2	Recognized practice in ISO standards.	Spell "organization" with "z".	EAF
2438	ANS I	1341 -1344	8.4.2	This requirement is not written in clear language as required by the design specification. Furthermore, the beginning of the sentence is a statement and not written as a requirement. The reference to a) and b) above is confusing.	Revise The organization shall define the controls it intends to apply to the external provider and the controls it intends to apply to the resulting process output when a process or function of the organization has been outsourced to an external provider.	TAP
2439	TC2 10	1341 - 1344	8.4.2	This paragraph duplicated text elsewhere and above. The important aspect on defining control is lost in the duplicative text. The defined controls should precede the verification.	Amend text and relocate to penultimate paragraph The organization shall define both the controls it intends to apply to the external provider and those it intends to apply to the resulting process output.	TAP
2440	ANS I	1341	8.4.2	The term "functions" is used here, without proper context or understanding. To this point, the clause has been discussing outsourced processes; it is not clear, then, what an outsourced "function" may be.	Processes or functions of the organization which have been outsourced to an external provider remain within the scope of the organization's quality management system.	TAP
2441	IN	1341	8.4.2	The use of term "function" is not clear. Up to this point, the clause has been discussing outsourced processes; it is not clear, then, what an outsourced "function" may be.	Delete the word "functions" and leave as "processes of the organization."	TAF
2442	JP 136	1341	8.4.2	Clarification	Change to: Processes or functions of the organization which have been outsourced to an external provider <u>shall</u> remain within the scope of the organization's quality management system,	TAP
2443	RO	1343 & 1344	8.4.2	The content of the paragraph was placed in a new paragraph above.	accordingly, the organization shall consider a) and b) above and define both the controls it intends to apply to the external provider and those it intends to apply to the resulting process output.	TAP
2444	AR	1344 / 1368 / 1379 / 1380 / 1383 / 1397 / 1425 / 1426 / 1431 /	8.4.2	"process output" is used as a term, though it has not been defined in ISO/DIS 9000. Two different terms are defined as follows: "process" and "output". The use of the two words to make up a term is absolutely wrong, as it is clearly shown by the definition of "output" is: "result of a process".	Do not use "process output"	TAF

		1440				
2445	ZA	1344 / 1368 / 1379 / 1380 / 1383 / 1397 / 1425 / 1426 / 1431 / 1440	process output	"process output" is used as a term, though it has not been defined in ISO/DIS 9000. Two different terms are defined as follows: "process" and "output". The use of the two words to make up a term is absolutely wrong, as it is clearly shown by the definition of "output" is: "result of a process".	Do not use "process output" rather use "output from a process" because this is grammatically correct.	TAP
2446	BR	1344	process output	"process output" is used as a term, though it has not been defined in ISO/DIS 9000. Two different terms are defined as follows: "process" and "output". The use of the two words to make up a term is absolutely wrong, as it is clearly shown by the definition of "output" is: "result of a process". That happens in lines 1344, 1368, 1379, 1380, 1383, 1384, 1397, 1425, 1426, 1431, 1440, 1442.	Do not use "process output". Use "products and services" instead.	TAP
2447	IAQ G	1345 -1354	8.4.3	It is essential for all business processes related to management system including QMS within not only organization but also external provider(s) to be aware of importance of compliance/ethics. Therefore, it should be explicitly specified for awareness of personnel.	Add text - Improve Proposal: Add the following. <u>g) activities to be aware of importance of compliance/ethics and product/service safety relating to products and services.</u>	TN
2448	CO	1345	8.4.3	This literal is not clear. What is the idea of this paragraph? d) their interactions with the organization's quality management system;	Clarify	C
2449	BE	1345	8.4.3	§8.5.1 Control of production and service provision contains requirements about availability of matters required to create controlled conditions for production or service provision. Those requirements might also be integrated in §8.4.3 Information for external providers. E.g. §8.5.1: a) the availability of documented information that defines the characteristics of the products and services b) the use, and control of suitable infrastructure and process environment However, these requirements of §8.5.1 are not listed in §8.4.3.	Review §8.4.3 taking in account the requirements of §8.5.1 and eventually also other requirements of §8.5 like e.g. §8.5.2 Identification and traceability or §8.5.3 Property belonging to customers.	TN
2450	TR	1345	8.4.3	In the title "communication" should be used instead of "Information"	New title is as follows; Communication for external providers	TN

2451	DE	1346	8.4.3	Line 1346 and 1350 In reality, no customer will specify to his supplier how the supplier's personnel has to be qualified for standard operations, except from specific qualifications for e.g. welding.	Please change to read: c) where necessary, competence of personnel	TN
2452	PT	1346	8.4.3	As stated the sentence gives idea that a) to f) have all applicable requirements which might not be always the case	The organization shall communicate applicable requirements to external providers. The organization shall consider, where applicable, the need to communicate on the following (...)	TN
2453	IQNet	1346	8.4.3	As stated the sentence a) to f) will have all applicable requirements which might not be always the case. Further clarification needed	Change to The organization shall communicate applicable requirements to external providers. The organization shall consider, where applicable, the need to communicate on the following (...)	TN
2454	NL	1347	8.4.3	Inconsistent language, in relation to 8.3.5 and 8.5.1 a and b. To make the interaction more clear to the users of the standard it should be made clear that the output of D&D (e.g. product characteristics) are input to the 'purchasing' process.	Change (bold) a) the characteristics of the products and services to be provided or the processes to be performed on behalf of the organization and the activities to be performed and the results to be achieved.	TN
2455	RO	1349	8.4.3	Clarification of content. Methods, processes or equipment cannot be released.	approval of products and services, methods, processes or equipment and / or release of products and services;	TAP
2456	EOQ	1350	8.4.3	The inclusion of qualification is inconsistent: In section 7.2 there are only requirements on competence, so the term should be used consistently	competence of personnel, including necessary qualification	TN
2457	RO	1351	8.4.3	Clarification of content.	their the interactions they shall have with the organization's quality management system	EAP
2458	IAQG	1351	8.4.3.d	The interactions of the external providers are not limited to the QMS	Delete text - improve Proposal: d) their interactions with the organization' quality management system;	TN
2459	IE	1351	8.4.3	The wording here is too vague – need to be clear about QMS requirements that external providers must comply with	Reword to – the necessary QMS requirements to be complied with	C
2460	AU	1351		Insert processes	After "organization's" add 'the processes within' the QMS	TN
2461	SE	1352-1355	8.4.3	e) seems to include part of f). f) seems to include part of e).	Combine e) and f) in order to get rid of the duplication/overlapping. Suggestion: new e):	TN

					"the control and monitoring of the external provider's performance to be applied by the organization including verification activities that the organization, or its customer, intends to perform at the external provider's premises"	
2462	ZA	1354	8.4.3	The verification activities referred to here are different from the design and development verification in clause 8.3.2 c). The definitions of verification and objective evidence are more focussed on the design and development verification because in the notes refer to "other forms of determination" and "or other means" which could include audits, surveillances and hold points, The word audit is an important verification activity at external provider's premises and should have been included in the definition. Since it is not the case a note to this clause would serve a value adding clarification.	Add "NOTE Verification (3.54) activities could include audit, surveillance, hold points, release or other means."	TN
2463	CA-61	1354	8.4.3	"verification activities that the organization, or its customer, intends to perform at the external provider's premises." Verification is performed, to check that the output of a process conforms to the input requirements for that process. Certainly, the organization would be aware of the requirements they placed on the external provider, so the organization would be in a position to do verification, and they may be able to do validation. But, the customer only knows the requirements for their "specific intended use or application", so they would only be able to perform validation at the external provider's premises.	Change to: "verification and/or validation activities that the organization, or its customer, intends to perform at the external provider's premises."	TAP
2464	CQI 58	1356 - 1357	8.4.3	'The organization shall ensure the adequacy of specified requirements prior to their communication to the external provider.' Adequacy comes before communication.	Move 2 nd para before 1 st para (line 1346)	TAF
2465	INLA C	1358 - 1386, 1396 - 1400, 1425 - 1444	8.5, 8.7	In several clauses in section 8 the concept "process outputs" is introduced. In clause 8.5.2 a Note clarifies the meaning of this concept: Process outputs are the results of any activities which are ready for delivery to the organization's customer or to an internal customer (e.g. receiver of the inputs to the next process); they can include products, services, intermediate parts, components, etc. ISO/DIS 9000 defines "output" as: result of a	Consider these options: Change "process outputs" in all section 8 by only "output" (see clauses 8.5.1, 8.5.2, 8.5.4, 8.7) Move the Note in 8.5.2 to the end of clause 8.5.1 and make a clarification, with a Note to entry, in the definition of "output" in ISO/DIS 9000. Option 2 is the best way to proceed, in our opinion.	TAP

				process. Based on this definition there is no need to include the word “process”; “output” is enough. Also, clause 4.4, bullet a) (line 975) states: the inputs required and the outputs expected from these processes; In this bullet, the concept “process output” is not used.		
2466	IE	1358 -1362	8.5	The use of controlled conditions in this section is very much a manufacturing focus and not service friendly. In clause 7 the requirements relate to the environment necessary for the operation of processes. There should be consistency throughout the standard	Change to Establishing the environment for production The organization shall establish the environment for product and service provision including any necessary controls identified through the application of risk based thinking. Necessary controls can include:	TN
2467	LT	1358	add new in 8.5		Bottleneck management The organization shall ensure that bottlenecks are managed. Bottleneck management include: - identification of bottleneck – process; - identification of bottleneck-place in process; - bottleneck-place review; - determining (establishing) actions to improve situation; - performing improvement actions; - evaluation of results on bottleneck management for a particular periods of time.	TN
2468	LT	1358	add new in 8.5		Problem management The organization shall ensure that problems are managed. Problem management include: - identification of problem, problem holder and problem owner; - problem review; - problem solving (set of actions); - reports on problem solving actions (problem owner to problem holder); - evaluation of results on problem management for a particular periods of time.	TN

2469	JP 138	1360 -61	8.5.1	Make the sentence logical.	Change to: The organization shall implement <u>production and service provision under controlled conditions</u> .	TAF
2470	DE	1361	8.5.1	(post-)delivery seems to be the wrong expression for services	Please change to read: The organization shall implement controlled conditions for production and service provision, including delivery and post-delivery or post-provision activities.	TN
2471	NL	1361	8.5.1	Preservation is also an important stage in the product life cycle. See clause 8.5.4	Add (bold) The organization shall implement controlled conditions for production and service provision, including preservation , delivery, and post-delivery activities.	TN
2472	BR	1362	8.5.1	It is too much to require documented information referred in bullets 'a' and 'b', "as applicable". By the other hand it should be mandatory for bullets c) to g).	Delete "as applicable" from the caput and insert in bullet h) and insert "as necessary" in bullets a) and b), to read: "Controlled conditions shall include, as applicable : a) "the availability of documented information ... products and services, as necessary ;" b) "the availability of documented information ... activities... results to be achieved, as necessary ;" c) ... g) h) The implementation of products and services release...activities, <u>as applicable</u> ."	TN
2473	JP 141	1362 1372	8.5.1	There is a duplication of " applicalbe" in one sentence.	Delete the "where applicable" in L1372.	TAF
2474	IT	1363 -1375	8.5.1	We suggest to add a new specification.	Add a new bullet as follows: [...] f) the competence and, where applicable, required qualification of persons; g) the potential consequences of failure due to the nature of the products and services or processes; h) the validation, and periodic revalidation, of the ability to achieve planned results of any process for production and service provision where the resulting output cannot be verified by subsequent	TN

					monitoring or measurement; [...]	
2475	ISS/ RS	1363 - 1366	8.5.1	According to A.6 par.2 it is not clear if requirements under a) and b) shall be retained/or maintained as documented information	Add sentence: The organization shall maintain documented information to support activities under a) and retain documented information as evidence of activities under b).	TN
2476	NL	1363	8.5.1	A product (or services) contains more than just the 'product'. Supporting supplies (packing) also need to be realised.	Add (bold) a) the availability of documented information that defines the characteristics of the products and services, and supporting supplies.	TN
2477	GB	1363	8.5.1 a)	Redundant 'the' (three off)	Reword: a) availability of documented information that defines product and service characteristics;	EAF
2478	GB	1365	8.5.1 b)	Redundant 'the' (three off)	Reword: b) availability of documented information that defines activities to be performed and results to be achieved;	EAP
2479	TC6 9	1367 -1369	8.5.1	The sentence should end with a semicolon, like the other intermediate sentences, not a dot: "c) monitoring and measurement activities at appropriate stages to verify that criteria for control of processes and process outputs, and acceptance criteria for products and services, have been met."	"c) monitoring and measurement activities at appropriate stages to verify that criteria for control of processes and process outputs, and acceptance criteria for products and services, have been met."	EAF
2480	CA- 62	1367 - 1369	8.5.1	Modify the current wording (copied below) to the wording shown in the column on the right. "Controlled conditions shall include, as applicable: c) monitoring and measurement activities at appropriate stages to verify that criteria for control of processes and process outputs, and acceptance criteria for products and services, have been met."	Change to: "Controlled conditions shall include, as applicable: c) the identification and implementation of monitoring and measurement activities at appropriate stages, establishing criteria for the control of processes and process outputs, and verification that defined acceptance criteria for products and services have been met."	TAP
2481	GB	1367 - 9	8.5.1 c)	Extensive duplication with clause 9.1.1	Review overlap and state requirement once only – suggest under 9.1.1.	TN
2482	CZ	1369	8.5.1	Semicolon at the end of the bullet instead of a full stop.	To be corrected.	EAF
2483	INLA C	1370	8.5.1 d)	Revise bullet d) for consistency with clause 7.4: "Environment for the operation of processes".	Change; d) the use, and control of suitable infrastructure and environment for the operation of processes;	TAP
2484	FI	1370	8.5.1	Point d: does the word infrastructure also cover production equipment, if not, it should be mentioned separately.	d) the use and control of suitable equipment, infrastructure and process environment	TN

2485	TC2 10	1370	8.5.1	Correct punctuation	Delete comma after 'use'	EAF
2486	JP 139	1370	8.5.1	Control of process environment is required in 7.1.3 and 7.1.4. Duplication. In addition, the term "environment for the operation of processes" is used in 7.1.4.	Delete ", and control" and change "process environment" to "environment for the operation of processes" to be consistent with 7.1.4.	TAF
2487	SE	1371	8.5.1	"the availability and use of suitable monitoring and measuring resources". A requirement for "availability and use" is already covered by c) in the same paragraph. The new thing in e) is "suitable" and if it is necessary to point that out the requirement should be expressed in another way.	Replace with "use of monitoring and measuring resources that are suitable for the monitoring and measurement activities". Move the requirement to a place close to c), e.g. change places between d) and e).	TN TN
2488	ANS I	1372 -1375	8.5.1	Including f) and g) in the overall list of controls for production and service provision significantly increases the impact to all processes and just not those that cannot be verified by subsequent and monitoring. This could be eliminated by separating f) and g) as a standalone paragraph after h).	Where the resulting output of production and service provision cannot be verified by subsequent monitoring or measurement, the organization shall establish the validation, and periodic revalidation for the processes. This shall include the competence, and where applicable, require qualification of persons.	TN
2489	EOQ	1372	8.5.1	The inclusion of qualification is inconsistent: In section 7.2 there are only requirements on competence, so the term should be used consistently	the competence and, where applicable, required qualification of persons	TN
2490	IR	1372	8.5.1	As stated in Note 1 to 3.10 "competence"; "Demonstrated competence is sometimes referred to as qualification". Meanwhile, the term <u>qualification</u> is not specifically defined in ISO 9000 and ISO 9001 standards Therefore, the two terms competence and qualification cannot be used at the same level in the item f) of this sub-clause.	Read item f) as follows: f) the competence and, where applicable, required qualification of persons;	TN
2491	JP 140	1372	8.5.1	Item f) lists a condition to be controlled for production and service provision, with respect to persons. The item should list control to be implemented on the condition.	Corrected text reads: f) appointment of competent or qualified persons, as applicable;	TAP
2492	DE	1373	8.5.1 g)	"the validation and periodic revalidation.." Periodic could be every 5 years. This is more about intervals planned by the organization.	change to revalidation in planned intervals	TN
2493	CO	1373	8.5.1.	Provide more information regarding validation and revalidation.	Include the following note in g): Note: During validation or revalidation, the organization	TN

					should take into account, among others: • The defined criteria for the review and process approval • Equipment approval and qualification of the personnel. • The use of specific methods and procedures • Applicable requirements for documented information	
2494	AR	1374	8.5.1	Validation is required when the resulting input cannot be verified or it is not economically convenient to do so (see definition 3.12)	Change to: “... where the resulting output cannot be verified by subsequent monitoring or measurement” (see 3.12 note 4).	TN
2495	IAQ G	1376	8.5.1.i	It's expected for all organizations to prevent human errors caused by human factors as much as possible and to carry out production and service provision under controlled conditions.	Add text - Improve Proposal: Add the following. i) the prevention of human errors [e.g., utilizing <u>automation, processes considered mistake-proofing</u>].	TAP
2496	IE	1376	8.5.1h Line	The proposed phrasing describes an activity rather than a control	Rephrase: "h) the implementation of products release activities." As: "h) ensuring the effective implementation of products release activities."	TN
2497	NZ	1376	8.5.1	The sentence is clumsy; 'products and services' can be omitted because of context of clause.	h) the implementation of release, delivery and post-delivery activities	TAF
2498	JP 137	1376	8.5.1	Add an item on the prevention of human errors to prevent troubles due to human error as much as possible and ensure the provision of products and services under controlled conditions.	Add the following: i) the prevention of human errors [e.g., utilizing automation, mistake-proofing].	TAP
2499	JP 143	1376	8.5.1	This item makes no sense since the release of products and services, and delivery and post-delivery activities are part of the production and service provision that must be performed under controlled conditions, and they are by no means counted as controlled conditions.	Add “product and service release” after “including” in L1361 and delete item h).	TN
2500	NL	1377 - 1386	8.5.2	Identification and traceability is not a process stage like the other sub clauses.	Turn 8.5.2 into a sub clause of 8.5.1: 8.5.1 Control of production and service provision 8.5.1.1 General 8.5.1.2 Identification and traceability	TN
2501	SE	1377 -1386	8.5.2	The processes related to identification and provision of traceability are actually support	Move these requirements to a new sub-clause under 7.	TN

				processes and not production processes. Usually they are of importance even during, at least, customer communication, design and development and control of externally provided products and services.		
2502	IE	1377	8.5.2	This clause appears to apply to outputs only. Identification and traceability can apply to inputs and general areas.	Add sentence after heading "The organisation shall use identification as appropriate where product, service, intermediate product, customer and customer property requires unique reference.	TN
2503	SE	1377	8.5.2	"Identification" is an activity. "Traceability" is a characteristic. The two concepts should be systematically equal and the title more logical.	Change title to "Identification and provision of traceability".	TN
2504	NO	1378 - 1379	8.5.2	The organisation should determine traceability requirements on their materials, components and products based on the risk related to the product and services. This should be reflected in the requirements.	Modify lines 1378 -1379 as follows "When necessary to ensure conformity of products and services, <u>the organization shall determine traceability requirements.</u> "	TN
2505	SE	1378 -1379	8.5.2	"Where necessary to ensure conformity of products and services ...". This is not the most relevant criterion in this case. Identification is necessary in order not to mix up products and components during different processes and it typically starts when design documents are prepared.	Replace with "Where necessary to ensure control of processes ...".	TN
2506	ANS I	1380 -1381	8.5.2	The use of process outputs may make this clause easier to apply for service industries. However, it is at the detriment of longer term users. Language should be modified to be friendly to both.	The organization shall identify the status of <u>products and services, including process outputs</u> , with respect to monitoring and measurement requirements throughout production and service provision.	TN
2507	SE	1380 -1381	8.5.2	"The organization shall identify the status of process outputs with respect to monitoring and measurement requirements throughout production and service provision". This activity is planned in conjunction with planning of the monitoring and measurement activities and it is carried out by the same individuals who carry out the monitoring and measurement activities. The fact that the word "identify" happened to be used is not a relevant reason for putting it together with "Identification and traceability", which concerns things with which it has no relationship at all. In addition, "indicate" is a more suitable term than "identify" and it gives more hits on Google in this context than does "identify".	For logical as well as practical reasons, this requirement should be moved to the place where the requirements for verification (or monitoring and measurement) are stated. Combine with the 1 st paragraph of sub-clause 8.6. The text will read: "The organization shall implement the planned arrangements at appropriate stages to verify that product and service requirements have been met. Evidence of conformity with the acceptance criteria shall be retained. The organization shall indicate the status of process outputs with respect to monitoring and measurement requirements throughout production and service provision". This should be moved to a place directly after	TN

				See also related comment under 8.6.	8.5.1 and form a new sub-clause 8.5.x "Verification of conformity and indication of verification status".	
2508	ANS I	1382 -1383	8.5.2	The use of process outputs may make this clause easier to apply for service industries. However, it is at the detriment of longer term users. Language should be modified to be friendly to both.	Where traceability is a requirement, the organization shall control the unique identification of the <u>products and services</u> , including process outputs, and retain any documented information necessary to maintain traceability.	TN
2509	IT	1382 -1383	8.5.2	The sentence should be completed with other specifications.	Modify sentence as follows: <i>Where traceability is a requirement, the organization shall control the unique identification of the process outputs, and retain any documented information necessary to maintain traceability. The effectiveness of the implemented traceability shall be verified.</i>	TN
2510	CZ	1382 -1383	8.5.2	We recommend to mention also process inputs. In many processes, inputs are in terms of feedback and traceability very important. The output of the process can be a product or a service, where different input materials could be used as inputs (e.g. different batches of processed raw materials or raw materials from different suppliers).	To be corrected for example as follows: "The organization shall identify the status of process <u>inputs</u> and outputs with respect to monitoring and measurement."	TN
2511	TC4 6/SC 11 Liais on (FR)	1383	8.5.2 Identification and traceability	Add refs to ISO15489 and ISO30300's	"Where traceability is a requirement, the organization shall control the unique identification of the process outputs, and retain any documented information necessary to maintain traceability. ISO15489 and ISO300 series provide guidance on the proper way to manage records"	TN
2512	ES	1384 -1386	8.5.2	For consistency with the definition of "customer" the use of the term "internal customer" in this sentence should be avoided. A customer can be internal or external to the organization	Delete references to internal customer: NOTE Process outputs are the results of any activities which are ready for delivery to the organization's customer or to be an input for the next process; they can include products, services, intermediate parts, components, etc.	TN
2513	BR	1384	NOTE	There is a "hidden" definition of process outputs, what is incorrect because definitions are forbidden in the text of the standards. Besides, notes in the text are informative and not normative, thus, the aforementioned definition does not clarify the concept in question. See also lines 740 and 760.	Delete the note	TAF
2514	ANS I	1384	8.5.2	The use of the term process outputs is not clear. This is the first time the note is added but the term is used elsewhere. It is understood that this	Delete NOTE. If clarification is required, this could be addressed	TAF

				might be easier for the service industry to apply, but this note does not provide clarity.	in Annex A.2 which deals with products and services.	
2515	DK	1384	8.5.2	The note is not needed.	Delete note.	TAF
2516	CO	1384	8.5.2	Move the note to definition 3.46. This note is general for all requirements. NOTE Process outputs are the results of any activities which are ready for delivery to the organization's customer or to an internal customer (e.g. receiver of the inputs to the next process); they can include products, services, intermediate parts, components, etc.	Move the note to process definition. (3.46)	TN
2517	AR	1384	8.5.2	There is a "hidden" definition, what is incorrect because definitions are forbidden in the text of the standards. Besides, notes in the text are informative and not normative, thus, the aforementioned definition does not clarify the concept in question.	Delete the note.	TAF
2518	CO	1386	8.5.2	Include text of current ISO 9001 as note 2. Make some reference to configuration management.	Include text of current ISO 9001 as note 2: Note 2 In some industry sectors, configuration management is a means by which identification and traceability are maintained.	TN
2519	IE	1387 , 1394- 1395	8.5.3 Lines	It is not obvious how "property belonging to . . .external providers" would arise.	Expand the NOTE to describe how "property belonging to . . .external providers" might arise.	C
2520	NL	1387 - 1395	8.5.3	Property belonging to customers or external providers is not a process stage like the other sub clauses.	Turn 8.5.3 into a subclause of 8.5.1: 8.5.1 Control of production and service provision 8.5.1.1 General 8.5.1.2 Identification and traceability 8.5.1.3 Property belonging to customers ...	TN
2521	BR	1387	8.5.2	Property belonging to any interested part can be, potentially under organization's control, especially intellectual property and personal data.	For consistence, to change all references to "external providers" for "interested parties", in clause 8.5.3. That means lines: 1387, 1388, 1390, 1392.	TN
2522	IR	1387	8.5.3	The issue of customer property that has been placed under control of an external provider and is in use by such a provider is also to be addressed in this sub-clause.	Add a sentence at the end of the first paragraph as follows: The requirements of this sub-clause are also equally apply to the customer property that has been placed under control of an external provider and is in use by such a provider.	TN

2523	HU	1388	8.5.3	The 'customer' is used as a singular noun, but the 'providers' as plural one.	Suggestion: 'customers'	EAF
2524	CA-63	1388	8.5.3	There are two distinct requirements in this text. In order to offer clarity it would be better to separate the paragraph in two.	Change to: "The organization shall exercise care....or being used by the organization." "The organization shall identify, verify, protectthe products and services."	EAF
2525	ANS I	1392 -1393	8.5.3	This requirement has been expanded beyond lost, damaged, or otherwise found to be unsuitable for use. The words "incorrectly used" means an organization would have to report when an employee has a tool or fixture and incorrectly uses it because he wasn't trained properly. The emphasis should be used in an unauthorized manner	Revise When property of the customer or external provider is incorrectly used , lost, damaged, <u>used in an unauthorized manner</u> or otherwise found to be unsuitable for use, the organization shall report this to the customer or external provider.	TN
2526	ANS I	1392 -1393	8.5.3	The clause requires that issues with property are reported to the customer, but no longer requires any type of objective evidence as was required in ISO 9001:2008. This can be perceived as a reduction in requirements.	Revise Shall report this to the customer or external provider <u>and retain as documented information</u> .	TAP
2527	IAQ G	1392	8.5.3	The words "incorrectly used" were added regarding the use of customer owned property. What is the definition of "incorrectly used"?	IAQG Priority Comment Add definition - clarify Proposal: removing the wording or adding a definition of <u>incorrect use</u> , such as defined by contract or purchase order?	TAP
2528	CQI 59	1394 - 1395	8.5.3	Documented information is missing.	Customer property can include material, components, tools and equipment, customer premises, <u>documented information</u> , intellectual property and personal data	TN
2529	IT	1394 -1395	8.5.3	Technical suggestion.	Modify note as follows: <i>NOTE Customer and external provider property can include material, components, tools and equipment, customer premises, intellectual property and personal data.</i>	TAF
2530	JP 144	1394 -1395	8.5.3	Add external provider's property.	Change to: Customer's or <u>external provider's property</u> can include material,...	TAF
2531	BR	1394	8.5.3	Note refers to "customer property" while the 8.5.3 refers to "customer or external providers properties".	For consistence, to change "Customer property" for "Customer or external provider property"	TAF

2532	ES	1394	8.5.3	To be consistent with all 8.5.3, indicate in the note the property of external providers	Add to note the following: Note: Property belonging to customers or external providers can include identification, handling, ...	TAF
2533	AT	1394	8.5.3	Property here addresses not only customer property but also that from external providers. Either add the external providers or drop customer.	Customer property can include material, components, tools and equipment, customer premises, intellectual property and personal data	TAF
2534	BW	1394	8.5.3	Rephrase the NOTE text	NOTE Property of customer or external provider, can include material, components, tools and equipment, customer premises, intellectual property and personal data.	TAF
2535	EOQ	1394	8.5.3	Property from external providers is not included – reformulate!.	Customer property can include material, components, tools and equipment, customer premises, intellectual property and personal data	TAP
2536	IR	1394	8.5.3	Taking into account the title of this sub-clause the word property addressed in the sub-clause relates both to customers and external providers. Hence, this should be reflected in the NOTE to the sub-clause.	Read the NOTE to this sub-clause as follows" NOTE Customers or external providers property can include material, components, tools and equipment, customer premises, intellectual property and personal data.	TAF
2537	TH	1394	8.5.3	"material" should read "materials".		TN
2538	IN	1394 & 95	8.5.3	The clause addresses Property belonging to Customer and External providers, however the note at the end of clause does not address External providers.	The note need to be amended to include property belonging to external provider.	TAF
2539	IR	1396	8.5.4	The issue of preservation is also to include the transportation of products under responsibility of the organization for delivery of products to the customer in its premises.	Add a sentence at the end of the first paragraph as follows: The requirements of this sub-clause are also apply to the transportation of products under responsibility of the organization for delivery of products to the customer in its premises.	TN
2540	IE	1396	8.5.4	"Preservation" is not universally understood. There is much confusion from the introduction of this title in the 2000 version.	Change "Preservation" to "Handling, Storage, Packaging and Delivery" as 1994 version of standard.	TN
2541	IE	1396	8.5.4	Preservation is an action taken to address risk. The addition of this clause is not service friendly. Delete and add possible actions that can be taken to next section 8.5.5	Delete section	TN
2542	ANS I	1397 -1398	8.5.	The use of process outputs may make this clause easier to apply for service industries. However, it is at the detriment of longer term users.	The organization shall ensure preservation of <u>products and services, including</u> process outputs, during production and service provision to the	TN

				Language should be modified to be friendly to both.	extent necessary to maintain conformity to requirements.	
2543	IT	1397-1398	8.5.4	Technical suggestion.	Modify sentence as follows: <i>The organization shall ensure preservation of process outputs during production and service provision, including delivery to the intended destination, to the extent necessary to maintain conformity to requirements.</i>	TN
2544	GB	1397-8	8.5.4	Logical rewording	Reword: During production and service provision the organization shall ensure preservation of process outputs to the extent necessary to maintain conformity to requirements.	EN
2545	INLA C	1397 & 1398	8.5.4	Preservation activities must be considered during all stages of production and service provision.	Add: During production and service provision, the organization shall ensure preservation of process outputs throughout internal processing and delivery to the intended destination, to the extent necessary to maintain conformity to requirements.	TN
2546	ANS I	1399-1400	8.5.4	The clause continues the legacy of MIL-Q-9858 and does not address contamination of product, which can affect both tangible products (foreign objects) intangible products (software virus injections) and services. Merely indicating "protection" is insufficient.	"Preservation can include identification, handling, packaging, storage, transmission or transportation, contamination control and protection."	TAP
2547	ANS I	1399-1400	8.5.4	The "downgrade" of this requirement to a note which was previously a requirement in ISO 9001:2008 will confuse users and give the impression of a reduction of requirements.	Move the text in the note to the text of the requirement with modification to include contamination. Preservation can include identification, handling, packaging, storage, transmission or transportation, contamination control and protection	TN TAP
2548	KE	1399	8.5.4	Preservation is for process outputs '.	Add" process outputs '	TN
2549	PT	1401-1410	8.5.5	We understand and fully accept the need to make post delivery activities more explicit in the standard, but as requirements are defined in the section they need to be considered at earlier stages of Operational planning, either at 8.1, 8.2 and 8.3	Consider to include and make more explicit consideration of requirements related to post delivery in 8.1, 8.2 and 8.3	C
2550	ANS I	1401	8.5.5	In the listing of requirements for post-delivery activities that shall be considered customer requirements is not listed	Add an item to the list of activities that the organization shall consider as follows: e) customer requirements	TAF
2551	NL	1401	8.5.5	If delivery is an activity for which requirements are to be determined and reviewed, the standard	Add	TN

				should contain requirements on this activities	8.5.5 Delivery The organization shall meet requirements for delivery activities associated with the products and services. In determining the extent of delivery activities that are required the organisation shall consider: a) the risks associated with the products and services; b) the assumed qualifications of users of the products and services c) statutory and regulatory requirements. Note: delivery activities can include transportation, installation, instruction to training to customer personnel. And 8.5.6 Post-delivery activities 8.5.7 Control of changes	
2552	GB	1402 – 1408	8.5.5	Introductory paragraph is in the wrong place logically.	Move lines 1402 – 3to after requirements a) – d). Reword clause as follows: In determining the extent of required post-delivery activities the organisation shall consider: a) statutory and regulatory requirements. b) the risks associated with products and services; c) the nature, use and intended lifetime of products and services; d) customer feedback; The organization shall meet requirements for post-delivery activities associated with products and services.	TAP
2553	SE	1404	8.5.5	Recognized practice in ISO standards.	Spell "organization" with "z".	EAF
2554	ANS I	1405	8.5 Production and..., 8.5.5 Post-delivery	It is unclear how products and services themselves pose risks to the customer. It is more likely that the use of products and services could pose such threats. This clarification would improve the intent and understanding.	Insert "use of its" before "products and services."	TN
2555	AT	1405	8.5.5	Here only risks are addressed. Post-delivery services offer also many opportunities to satisfy customer needs and expectations.	the risks and opportunities associated with the products and services	TN

2556	DE	1405	8.5.5	use always the term risk an opportunities together	a) the risks and opportunities associated with the products and services;	TN
2557	EOQ	1405	8.5.5	Here only risks are adressed – this is inconsistent wording to the rest of the standard	the risks and opportunities associated with the products and services	TN
2558	JP 145	1405	8.5.5	The term “risk” should not be used explicitly in Clause 8. The clause 8 activity is based on clause 6 and risk based thinking.	Change “risk” to “potential undesired consequence.”	TAF
2559	ANS I	1406	8.5 Production and..., 8.5.5 Post-delivery	Relating the products and services to the organization improves the clarity and intent.	Replace “the” with “its” before “products and services.”	EAF
2560	NG	1406	8.5.5	Post-delivery activities	To ensure process flow, post-delivery activities should come after subclause 8.6; release of product and services.	TN
2561	IE	1411 -1415	8.5.6	The addition of this general section is very confusing as changes are dealt in a general way in clause 6.3 also. If this is to remain need to make it more production focused. Also wording is contradictory i.e. control unplanned changes	Change to Production process changes The organization shall identify and implement productions process changes necessary for improvements- see 10. Changes shall be evaluated to assess the potential impact on conformity to customer requirements. Actions necessary to maintain conformity to customer requirements shall be implemented. Documented information on production process changes and the necessary actions shall be maintained.	TAP
2562	IT	1411 -1415	8.5.6	It would be better to specify the relation between control of changes in production and service provision and the more general concept of planning of changes, as specified in clause 6.3.	Add an explanatory note accordingly.	C
2563	SE	1411 -1415	8.5.6	This paragraph is confusing, and lacks connection with 6.3. Unplanned changes cannot be controlled, but the effects of unplanned changes can be controlled. Authorizing unplanned changes makes no sense! What about planned changes, do they not need to be reviewed and controlled?	Rewrite! “The organization shall review and control the effects of unplanned changes.”	TN
2564	BR	1411	8.5.6	Delete the whole clause. It’s already covered by clause 8.1, 3 rd paragraph (lines 1218-1219) which is high level text (Annex SL) and by clause 6.3, especially in line 1083.	Delete clause 8.5.6	TN

2565	AU	1411	Title	Change title to include unplanned changes	Change to 'Control of unplanned changes'	TN
2566	NZ	1411	8.5.6	The concept of 'unplanned changes' is unclear, especially since 8.1 Annex SL text refers to 'unintended changes' ('<u>control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary</u>'). It is not clear what changes are covered by this clause that are not already covered by either: 8.1 as above, or 8.3.6 – changes made during, or subsequent to, the design and development of products and services. The requirement to retain documented information under this clause could be extremely onerous eg in low risk situations controlled by competent people. It could be misused in 2nd or 3rd party audits. This is 'Interpretation request' territory!	Delete whole clause: - delete P1 as duplication. - delete P2 as potentially onerous and subject to variable application and interpretation .	TAP
2567	TH	1411	8.5.6	Clarification and example for unplanned change should be added as a NOTE.		TN
2568	SE	1411	8.5.6	The title doesn't mirror the text.	Change the title to "Control of unplanned changes"	TN
2569	CQI 60	1412	8.5.6	The organization shall review and control unplanned changes essential for production or service... The restriction to unplanned changes is unnecessary. All changes should be reviewed and controlled. Delete unplanned.	The organisation shall review and control unplanned changes essential for production or service...	TAF
2570	BR	1412	8.5.6	Any change, not just unplanned ones, shall be reviewed and controlled. Besides, this change is compatible with the text of Annex SL in line 1218	Change text to: "The organization shall review and control <u>planned and unintended</u> changes essential for production or service provision to the extent necessary to ensure continuing conformity with specified requirements."	TAP
2571	ANS I	1412	8.5.6	The word unplanned changes is misleading of the requirement. There are three types of changes: 6.3 is changes to the quality management system, 8.3 addresses design changes, and 8.5.6 should address all other changes, planned or unplanned.	The organization shall review and control unplanned changes essential for production or service...	TAF
2572	ANS I	1412	8.5.6	The different types of changes are not clear. Clarification between these changes could eliminate potential confusion of users.	Create an annex that describes the different types of changes.	TN

2573	DK	1412	8.5.6	Planned changes shall also be controlled.	Change text into: "The organization shall review and control unplanned changes essential for production or service provision to the extent necessary to ensure continuing conformity with specified requirements."	TAF
2574	IAQG	1412	8.5.6	8.5.6 is titled 'Control of Changes'. Changes come from a variety of sources, mostly planned. However, the first sentence uses the word 'unplanned changes' which seems to limit the requirements of this section to only a small sector of change sources, leaving this clause not applicable to these many other sources of change types.	IAQG Priority Comment Reword - improve Proposal: Revise wording - 'review and control changes'.	TAF
2575	CA-64	1412	8.5.6	I disagree with the term of unplanned changes. I would expect and planning should be made to control all type of changes that may affect the delivery of Products and Services. By stating unplanned changes we may restrict and forget changes that could potentially be implemented but not controlled, therefore introducing a certain degree of risk that is not controlled.	The organization shall review and controls changes essential for productions or service provision....	TAF
2576	JP 146	1412	8.5.6	The changes that an organization should review and control are not only limited to unplanned changes. Process change including planned changes should be appropriately controlled.	The organization shall review and control unplanned changes essential for production or service provision to the extent necessary to ensure continuing conformity with specified requirements.	TAF
2577	RO	1412, 1413, 1414 & 1415	8.5.6	Delete. The chapter is not clear and is not adding any value.	8.5.6 Control of changes The organization shall review and control unplanned changes essential for production or service provision to the extent necessary to ensure continuing conformity with specified requirements. The organization shall retain documented information describing the results of the review of changes, the personnel authorizing the change, and any necessary actions.	TN
2578	NL	1413	8.5.6	Clarify the origin of these changes	Add Note: These changes may be the result of progressive (technical) understanding of the organization or due to unforeseen (technical) obstacles during the production process which is deviated from the original requirements. Unforeseen changes due to changing needs and expectations of the customer should be reviewed, as described in 8.2.3	TN

2579	BR	1414	8.5.6	It is too bureaucratic and do not add value to require documented information referred to review of changes where items impacted by the changes were not originally documented.	Change the 2nd paragraph to read: "The organization shall assure that all documented information impacted by the carried out changes be amended and reapproved by the authorized personnel, as appropriate".	TAP
2580	ANS I	1417 -1419	8.6	The language "Evidence of conformity with the acceptance criteria shall be retained" is not linked to the other requirement in this requirement for retaining documented information. It is not clear what this should be retained as.	Revise Evidence of conformity with the acceptance criteria shall be retained <u>as documented information</u> .	TAP
2581	IE	1417	8.6	Delete "the"	The organisation shall implement planned arrangements	EAF
2582	QS	1417	8.6	Evidence for verification of product and service provision at appropriate stages shall be through documented information.	Change as : Evidence of conformity with the acceptance criteria shall be retained as documented information.	TAP
2583	RO	1418 & 1419	8.6	Rephrase for more clarity.	Documented information shall be retained to provide: a) evidence of conformity with the acceptance criteria; b) traceability to the person(s) authorizing release of products and services for delivery to the customer.	TAP
2584	ANS I	1420 -1424	8.6	Documented information is used without maintain / retain. It is important to be consistent for ease of understanding and translation.	Revise <u>The organization shall retain</u> Documented information shall to provide traceability to the person(s) authorizing release of products and services for delivery to the customer.	TAP
2585	IE	1420	8.6	Replace "the" with "all"	" ...Not proceed until all planned arrangements "	TN
2586	ANS I	1421	8.6	The word verification is used with a different meaning than its formal QA definition which may be confusing to unsophisticated users (e. g. SMEs). ISO 9001:2008 linked to 7.1 planning of product realization so that the planned arrangements was clear. Not including this can cause confusion.	Reword the sentence as follows: "The release of products and services to the customer shall not proceed until the planned arrangements (<u>see 8.1</u>) for verification of conformity have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer.	TAP
2587	JP 147	1422 -1424	8.6	The term "retain" should be consistently used when record is required. To be consistent with the explanation in A.6.	Change to: The documented information shall <u>be retained to</u> provide traceability to	TAP

2588	BR	1422	8.6	The paragraph refers to documented information, but do not require it to be retained.	To change "Documented information shall provide traceability ..." for "The organization shall retain documented information that provides traceability ..."	TAP
2589	IR	1422	8.6	As per the current formulation of the second paragraph of the organization's own personnel may approve products for release and delivery to customers without satisfactory completion of planned arrangements for verification of product conformity and without obtaining prior consent of the customer and relevant regulatory authority enforcing the mandatory implementation of standards. This will certainly enhance the risk of delivery of non-conforming products to customers.	Read the second paragraph as follows: The release of products and services to the customer shall not proceed until the planned arrangements for verification of conformity have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer. The organization's personnel themselves cannot approve release of non-conforming products and services to the customer without obtaining prior consent of the customer and relevant regulatory authority. Documented information shall indicate the person(s) authorizing release of products for delivery to the customer.	TN
2590	TT	1423	8.6	With the use of automated systems, person(s) are not always involved in the release of products or services for delivery. This comment is intended to address situations where there is no direct involvement of human beings in release.	Replace "Documented information shall provide traceability to the person(s) authorizing release of products and services for delivery to the customer" with "...traceability to the person or authority responsible for release of..."	TN
2591	RO	1423 & 1424	8.6	Delete and include in the first paragraph	Documented information shall provide traceability to the person(s) authorizing release of products and services for delivery to the customer.	TAP
2592	SE	1425 -1444	8.7	The expression "process outputs, products and services" is confusing as "products and services" are actually covered by the concept "process outputs".	Delete "products and services" in title: Change the title to read "Control of nonconforming process outputs". On line 1426, delete "products and services".	TAP
2593	GB	1425 - 44	8.7	Some redundant terms. Logical order does not reflect current practice.	Reword: The organization shall ensure process outputs, products and services that do not conform to requirements are identified and controlled to prevent their unintended use or delivery. This applies also to nonconforming products and services detected after product delivery or during service provision. The organization shall take appropriate action based on the nature of the nonconformity and its impact on conformity of products and services in one or more of the following ways: a) segregation, containment, return or suspension of provision of products and services;	TAP

					b) correction; c) informing the customer; d) obtaining authorization for • use without correction • release, continuation or re-provision of the products and services • acceptance under concession Where nonconforming process outputs, products and services are corrected, conformity to requirements shall be verified. The organization shall retain documented information of actions taken on nonconforming process outputs, products and services including on any concessions obtained and on the person or authority that made the decision regarding dealing with the nonconformity.	
2594	DE	1425	8.7	Use singular or plural	Change „products“ to „product“	EAP
2595	DE	1425 1426/27	8.7	Either refer to outputs or products and services only, but not to both The requirements should be addressing the organization directly	The organization shall identify and control nonconforming products and services to prevent their unintended use or delivery. Please change title accordingly: Control of nonconforming products and services	TAP
2596	TBS	1425 ,1426 &1431	Sub clause 8.7	Process outputs includes products, services, intermediate parts, components etc. Following this fact when text appear as “ process output , products and services” it means three different elements while not	The text “ process outputs , products and services” should be replaced by text “Process outputs “ And add NOTE after paragraph 3 “NOTE Process outputs they can include products, services, intermediate parts, components, etc.”	TN
2597	INLA C	1426	8.7	The requirements in this clause are to be applicable only for the production and service provision processes.	Add: During production and service provision, the organization shall ensure...	TN
2598	ANS I	1428 -1430	8.7	The requirement refers to corrective action. This implies corrective action as required by clause 10. In some instances, action or correction is all that is necessary. The bullet list a) through d) illustrates this point as well as lines 1442-1444.	Revise The organization shall take appropriate corrective action based on the nature of the nonconformity and its impact on the conformity of products and services.	TAF
2599	INLA C	1428	8.7	Add “correction”. A corrective action not always be possible to deal with non conforming process outputs, products and services.	The organization shall take appropriate correction and corrective action based on...	TN

2600	ANS I	1428	8.7	Add the words "correction and" to be consistent with line 1433. Rationale: in some cases, correction (simply eliminating the non-conformance) is sufficient.	The organization shall take appropriate <u>correction and</u> corrective action based on the nature of the nonconformity	TN
2601	ANS I	1428	8.7	The first sentence is technically not correct in stating that "The organization shall take appropriate corrective action ...". The standard cannot and should not require corrective action. That is the prerogative of the organization to decide how to handle nonconformity (which is correctly indicated in the 2 nd paragraph of this clause.	Change the wording of the 1 st sentence of the 2 nd paragraph as follows: "... The organization shall take appropriate action based on the nature of the nonconformity and its impact on the conformity of products and services. ..."	TAF
2602	ANS I	1428	8.7	There should not be a requirement to take corrective action on every product/service nonconformity. Plus, the clause corrective action and then lists correction and other remedial actions.	Delete 'corrective' The organization shall take appropriate corrective action based on the nature of the nonconformity and its impact on the conformity of products and services.	TAF
2603	BW	1428	8.7	Include reference to 10.2	The organization shall take appropriate corrective action (see 10.2) based on the nature of the nonconformity and its impact on the conformity of products and services. This applies also to nonconforming products and services detected after delivery of the products or during the provision of the service.	TN
2604	DE	1428	8.7	... action based on the nature of the nonconformity and its impact on the conformity of products and services. Sounds odd. The impact of a nonconformity on the conformity is that the product or service is not conform anymore.	... action based on the nature of the nonconformity and its impact or potential impact on the conformity of products and services.	TN
2605	CO	1428	8.7	Corrective actions are not always taken. The following literals state how to deal with nonconforming outputs, products and services.	The organization shall take appropriate corrective action when applicable , based on the nature of the nonconformity and its impact on the conformity of products and services	TN
2606	LU	1428	8.7	The term corrective action is confusing; in this case we speak about repair action.	The organization shall take appropriate <u>repair</u> corrective action based on the nature of the nonconformity	TN
2607	AR	1428	8.7	Actions to deal/control the NCP&S are confused with corrective actions. The second paragraph should be applied to the treatment of the NCP&S descripts in the third paragraph and it is not clear.	1- Change 2 nd paragraph to: The organization shall deal with nonconforming products and services taking appropriate action based on the nature of the nonconformity and its impact on the conformity of products and services.	TN

				If we agree to include corrective action in this clause should be referenced to clause 10.2.	This applies also to nonconforming products and services detected after delivery of the products or during the provision of the service. 2- Change line 1431/1432 to: Appropriate action can include: 3- Add (at the end of sub clause) The organization shall consider the need of corrective actions (see 10.2)	
2608	NL	1428	8.7	One of the actions to reduce undesired effect (of risks) is to plan actions to repress or correct the damage. When the undesired effect occurs the organization should carry out planned action(s).	Change/add The organization shall carry out repressive or corrective action(s) as planned (see 6.1). When no appropriate action(s) have been planned, the organization shall action based on the investigation of the nature of the nonconformity and its impact ...	TN
2609	CH	1428	8.7	... action based on the nature of the nonconformity and its impact on the conformity of products and services. Sounds odd. The impact of a nonconformity on the conformity is that the product or service is not conform anymore.	... action based on the nature of the nonconformity and its impact <i>or potential impact on the conformity of products and services.</i>	TN
2610	UY	1428	8.7	We suggest include a reference to paragraph 10.2 after "corrective action". If we refer to section 10.2 we suggest that organization take corrective actions and managed as such. The rest of the chapter is not clear to propose that organizations take corrective actions as such.	Include a reference to paragraph 10.2 after "corrective action".	TN
2611	TC2 10	1428	8.7	The requirement of Corrective action is defined in 10.2 and the 1 st sentence of 2 nd paragraph is not in the correct place.	Move 1 st sentence of 2 nd paragraph to clause 10.2.	TN
2612	RO	1428 & 1429	8.7	Clarification	The organization shall take appropriate corrections and corrective action based on the nature of the nonconformity and its impact on the conformity of products and services.	TN
2613	JP 148	1429	8.7	This sentence should be a sentence with "shall."	Change to: "This <u>shall also</u> apply to..."	EAF
2614	UA	1430	8.7	The service-specific nonconformity can be detected not only during the provision of the service, but also after this service have been provided, for example, suffering from food poisoning after a meal in a catering establishment.	To replace 'detected after delivery of the products or during the provision of the service' with 'detected after delivery of the products or during or after the provision of the service'.	TAF

2615	JP 149	1430	8.7	The “during or after” is also applied to services. This sentence does not have the term “shall” though it is a requirement.	Change to: This <u>shall</u> apply also to nonconforming products and services detected after <u>or during</u> delivery of the products <u>and</u> services.	TAP
2616	NL	1431 -1439	8.7	A relation (link) to 6.1 is missing. 1433-1439 should also require a review of the risks addressed in 6.1.1.	Add e) review and, where necessary, revise the addressed risks and actions in 6.1.1 and 6.1.2	TN
2617	ANS I	1431 -1432	8.7	The use of process outputs may make this clause easier to apply for service industries. However, it is at the detriment of longer term users. Language should be modified to be friendly to both. In this situation, products and services should be used.	As applicable, the organization shall deal with nonconforming process outputs , products and services in one or more of the following ways.	TN
2618	IAQ G	1431	8.7	8.7 Control of nonconforming clause includes the statement “As applicable” yet it does not provide value nor clarification.	Delete text - improve Proposal: Remove: “As applicable”	TAF
2619	NL	1431	8.7	The organization can choose by itself which way it wants to react to a nonconforming product. That leaves enough room for a customised approach.	Remove (bold) As applicable , the organization ..	TAF
2620	SE	1431	8.7	Why only as applicable? The organization shall always deal with nonconforming process outputs, products and services.	Remove: as applicable	TAF
2621	IE	1433 -1439	8.7 Lines	The points a) to d) do not include the common disposition method of “disposal”.	Add an additional point: e) disposal	TN
2622	IAQ G	1433	8.7	To avoid the confusion between “correction” and “corrective action”	Reword - improve Proposal: bullet a) : “taking action to eliminate the detected nonconformity” (as it is in the current version)	TN
2623	ANS I	1434	8.7	Identification has not been identified as one of the controls. This is a key control since nonconformity product cannot always be segregated.	a) <u>Identification</u> , segregation, contain, return or suspension of provision of products and services	TN
2624	NZ	1435	8.7	ISO 9001:2008 clause 8.3 bullet d) has been removed (<i>by taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started</i>). Consider an example: a surgeon has operated on the wrong side and removed the normal, rather than the diseased, kidney. Informing the customer is only a small part of the actions needed since not only	Delete c) Add new last bullet d) taking action appropriate to the effects, or potential effects, of the nonconformity where nonconforming products and services are detected during or after delivery or provision. or add as e) if c) is retained.	TN

				must the operation be repeated but the patient will need extensive additional care and compensation. In the 2008 revision bullet d) was moved from general text into the list of options. This was an essential change to this clause for many services. The bullet is also needed to cover initiation of product recalls etc. Needs to be reinstated but suggest modify to 'during or after delivery or provision'.	The 2 nd sentence in P2 Line 1429 can then be deleted.	
2625	ES	1436 -1439	8.7 d)	As presented is structured now in three separated dashes, but differences are not clear on "use as-is" and "release". Terms "continuation" and "re-provision" are new and not explained, therefore difficult to understand and translate. Previous version was more clear.	Keep it as in ISO 9001:2008 8.3.b) without sub structuring to 3 levels	TAP
2626	TC2 10	1436 -1439	8.7	The difference between the situations in the three sub-bullets is unclear. These appear to be subsets of the same situation addressing concessions.	Amend to d) obtaining authorization for acceptance under concession.	TAF
2627	PL	1436 -1437	8.7	Meaning of "obtaining authorization for use "as-is" is not clear.	Clarify wording.	TAP
2628	FR	1436	8.7	Add a note	Add a note to indicate that for products several options exist such as waste, modification, repair and recycle ajouter une note pour les produits la notion de rebut, retouche,	TN
2629	CQI 61	1437 - 1439	8.7	- use "as-is"; - release, continuation or re-provision of the products and services; - acceptance under concession. The three bullets under d) are unordered; to be consistent with all other lists in the standard and to ensure sufficient unique identification of requirements the bullets should be ordered.	1) use "as-is"; 2) release, continuation or re-provision of the products and services; 3) acceptance under concession.	TAP
2630	IE	1438	8.7 d)	This sentence is unintelligible	Change to " release of the products and services"	TAP
2631	INLA C	1439	8.7	A NC output, product or service that was dealt must be identified by suitable means. Add a new Note after line 1439).	Add a new Note: Note: After correction, segregation, containment, return, suspension of provision or granting authorization an identification may be required.	TN

2632	AR	1442	8.7	Is important to maintain a record of the nature of the conformities.	Add bullet in red colour. The organization shall retain documented information of: - the nature of the nonconformities - actions taken on nonconforming products and services, - any concessions obtained and on the person or authority that made the decision regarding dealing with the nonconformity and	TAP
2633	NL	1442	8.7	As one of the input for evaluating the effectiveness of actions to risks, the organization should record incidents due to failing preventive actions.	Add (bold) The organization shall retain documented information of actions taken on nonconforming process outputs, products and services, including results of investigations and on any concessions obtained and ...	TN
2634	NG	1443	8.7	Delete the second 'on'	'..... obtained and the person.....'	EAP
2635	ZA	1444	8.7	Poor English – "decision regarding dealing with"	Change to "decision on how to deal with the nonconformity."	EAP
2636	ANS I	1445	9 Performance Evaluation	The words performance evaluation are frequently associated with employee performance reviews. The title should be changed to avoid this.	Performance <u>and</u> Evaluation	TN
2637	IE	1445	9	Clause 9 needs to reflect and emphasise the logical relationship between each of the main areas that need to be "monitored, measured, analysed and improved". These areas are customer satisfaction, products and services, processes and the quality management system. This logical relationship can be summarized as follows: Organizations create customer satisfaction by providing quality products and services produced by reliable processes maintained and improved by an effective management system. The reverse also applies and can be expressed as follows: Without an effective management system an organization ends up with unreliable processes that produce inconsistent products and services and lead to customer dissatisfaction. The existing Clause 9 lacks a coherent structure and weakens the perception of the logical relationship between these 4 key elements of an	Restructure Clause 9 to "monitor, measure, analyse and evaluate" how well these four elements (customer satisfaction, products and services, processes and the quality management system), separately and together, contribute to the purpose of the quality management system. Rewrite Clause 9.1 to list these 4 key areas and address "measurement and monitoring" of each one in more detail in subsequent sub-clauses, 9.1.1 Customer satisfaction - the existing clause 9.1.2 9.1.2 Products and services - focus on the need for monitoring and measurement to identify trends. Also, refer to Clause 8.5.1c 9.1.3 Processes - focus on the need for monitoring and measurement to demonstrate the ability of the processes to produce consistent outputs 9-1-4 Quality Management System - focus on	TN

				effective system .	internal audits as a tool to evaluate the ability of the management system to maintain reliable processes that produce consistent quality in the products and services that lead to customer satisfaction - see separate comment on Clause 9.2. This can be followed by a new Clause 9.2 based on the existing clause 9.1.3 "Analysis and evaluation" (modified for better alignment with the logical sequence of the four key areas as described above) - see separate comment on Clause 9.1.3. This can be followed by the existing Clause 9.3 "Management review" (again, with the sequence of points in the existing Clause 9.3.1 aligned with the logical sequence of the four key areas as described above) - see separate comment on Clause 9.3.1.	
2638	ES	1447-1458	9.1.1.	This subclause should start with the requirement for the organization to evaluate the quality performance and the effectiveness of the QMS. Followed by what the organization shall determine for doing that. Move paragraphs 1st, 2nd and 3rd just to the opposite: 3rd, 2nd and 1st: 1st: 1457-1458 2nd: 1454-1456 3rd: 1447-1453	Reorder paragraphs: 1457-1458 The organization shall evaluate the quality performance and the effectiveness of the quality management system. 1454-1456 The organization shall ensure that monitoring and measurement activities are implemented in accordance with the determined requirements and shall retain appropriate documented information as evidence of the results. 1448-1453 The organization shall determine: a) what needs to be monitored and measured; b) the methods for monitoring, measurement, analysis and evaluation, as applicable, to ensure valid results; c) when the monitoring and measuring shall be performed; d) when the results from monitoring and measurement shall be analysed and evaluated.	EN
2639	IAQ G	1447	9.1.1	As requirement relating to monitoring and measurement of products and services is moved to 8.6 : "Release of products and services", the title of the clause is not consistent	Reword - clarify Proposal: replace the title "9.1.1 General" by 9.1.1 Monitoring and measurement of processes.	TN
2640	IQNet	1447	9.1.1	HLS text refers the need to determine the methods for monitoring, measurement, analysis and evaluation, as applicable, to	Add Note to 9.1.1 Note: To ensure valid results the organization can consider search on knowledge related to measurement methods in the specific context	TN

				ensure valid results; 9001:2015 added text does not build on this concept nor provides additional clarification on a theme core to quality. This is only done in 7.1.5 regarding M&M resources which is clearly short for addressing needs of validity of results in different sectors and application of 9001. It is the case to sampling, often used to evaluate conformity of product and service and to define acceptance criteria, use of statistical techniques as required for legal requirements (ex: statistical control for bottles as required CE MID Directive, etc., etc.), use of experimental design and broad use of statistics in social and natural sciences. Statistic and sampling is used either related to conformity of product and service, monitoring or to the provision of product or service itself as is the case of research, provision of market surveys and other surveys, etc. etc. Absence of reference to sampling and statistics is the standard, with the sole reference in 7.1.5 is way too short to reflect needs and use of statistics and sampling in quality management systems and the need to address these issues by organization. On the other hand it may create unnecessary pressure on 7.1.5 to include "calibration" of the absurd. We consider it would be relevant to add a clarifying note in this section	of what is being measured or the selection and use of relevant sampling or statistical methods	
2641	ZA	1447	9.1.1	Heading of subclause ("General") is meaningless unless related to main clause This is particularly frustrating when reference is made to this subclause to describe how these requirements are met in an organisation, e.g. in context of integrated management systems	Change heading of subclause to read: .."General information relating to monitoring, measurement, analysis and evaluation".. OR .."Introduction to monitoring, measurement, analysis and evaluation"	TN
2642	IQN et	1448 -1453	9.1.1	The section fails to identify the need to determine customer and legal requirements, besides those that are already considered only for M&M resources to ensure P&S conformity in 7.1.5	Add When determining the validity of results needed and the associated methods, the organization shall consider, in the extension necessary :	TN

					a) any applicable customer and legal requirements b) resources needed c) quality of information required in terms of any risks associated with decisions made	
2643	IE	1448 , 1457- 1458	9.1.1 Line	Clause 9.1.1 lacks a powerful opening sentence and provides a poor framework for the rest of Clause 9.	Move lines 1457 and 1458 to between 1447 and 1448. Expand point 9.1.1 a) as follows: a) what needs to be monitored and measured to demonstrate a coherent relationship between: - customer satisfaction - the quality of the goods and services provided by the organization - the reliability of the organization's processes - the effectiveness of the quality management system in ensuring reliable processes.	TN
2644	IAQ G	1448 1457 1458	9.1.1	The last sentence of the clause should be at the beginning in order to introduce the requirements	Move text - improve Proposal: move the following sentence in 1448 to the top of the clause The organization shall evaluate the quality performance and the effectiveness of the quality management system.	EN
2645	CA- 65	1448 - 1458	9.1.1	Lines 1448 – 1458; this section should be changed, the requirement identified on line 1457 does not seem to fit and looks like it has been added just for the opportunity to add it. I would rewrite this paragraph and start with the idea that quality performance and effectiveness is the intent of the section and specific activities are needed to achieve this.	9.1.1 General The organization shall evaluate the quality performance and the effectiveness of the quality management system through determination of; a) what needs to be monitored; b)	EN
2646	CH	1448 , 1455	9.1.1	In the context of these 2 requirements, the meaning of the word 'determine' does not match the definition in 3.67.	<u>Change</u> to read: (L1448) "The organization shall DECIDE ON ..." (L1455) "... accordance with the DECIDED requirements ..."	EN
2647	ANS I	1450 -1451	9.1.1	It is not clear if the "as applicable" in this requirements applies to all of the methods (monitoring, measurement, analysis and evaluation) or just analysis and evaluation.	Revise <u>As applicable</u>, the methods for monitoring, measurement, analysis and evaluation, as	TAP

					applicable to ensure valid results;	
2648	PT	1452	9.1.1	Consider referring the use of statistical techniques and sampling, as there is an increase for requirements related to statistics and use of statistical techniques not only quality related but used in many sectors for monitoring and measurement. The non explicit consideration on the importance of usage of sampling and statistical techniques in the standard is not consistent with quality management systems nor with the intent of this review	a) determine the methods for monitoring, measurement, analysis and evaluation, as applicable, <u>including where applicable, sampling and statistical techniques</u> , to ensure valid results.	TN
2649	IIOC	1453	9.1.1	The current text does not specify the requirement for persons undertaking monitoring and measurements activities to be suitably competent,	Consider an additional requirement (e) to specify the requirement for competence of personnel performing monitoring and measurement tasks.	TN
2650	ANS I	1454 -1456	9.1.1	The word appropriate is not consistent with other parts of the standard. Typically appropriate is used with where appropriate or as appropriate. Would an organization retain inappropriate documented information. In other places of the standard "to the extent necessary" is used. In this case, it appears that the documented information being discussed is to retain the identified documented information for other clauses.	The organization shall ensure that monitoring and measurement activities are implemented in accordance with the determined requirements and shall retain appropriate documented information as evidence of the results.	TN
2651	NL	1454 -1456	9.1.1	Risk based thinking has not sufficiently been incorporated in the PDCA cycle	Change into: The organisation shall ensure that monitoring and measurement activities are consistent with the determined risks and are implemented in accordance with the determined requirements and. The organisation shall retain appropriate documented information as evidence of the results.	TN
2652	EOQ	1454	9.1.1	Currently the organisation is completely free what it measure. There needs to be a link to section 9.1.3. to guarantee that the data necessary to evaluate the topics listed there, are gathered.	The organisation shall gather appropriate data for analysis and evaluation.	TN
2653	ISS/RS	1454 1455 1456	9.1.1	it is not clear that the obligation to retain the documented information applies both to 9.1.2 and 9.1.3	<u>The organization</u> shall ensure that monitoring and measurement activities are implemented in accordance with the determined requirements and shall retain appropriate documented information as evidence of the results.	EN

2654	RO	1454 , 1455 & 1456	9.1.1	Consistency	The organization shall ensure that monitoring, measurement, analysis and evaluation activities are implemented in accordance with the determined requirements and shall retain appropriate documented information as evidence of the results.	TN
2655	IAQ G	1455 -1456	9.1.1	Regarding "The organization shall evaluate the quality performance and the effectiveness of the quality management system.", the organization should evaluate the effectiveness of not only the QMS but also its processes, on the basis of the requirements of process approach in clause 4.4.	Add text - Improve Proposal: Change as follows. "The organization shall evaluate the quality performance and the effectiveness of the quality management system <u>and its processes.</u> "	TN
2656	SE	1455	9.1.1	The meaning of "the determined requirements" is not obvious as "requirements" have not been mentioned before in this context.	Replace "the determined requirements" with "the planned arrangements" which is an expression that has been used before.	TN
2657	ANS I	1457 -1458	9.1.1	Appears to be confusion between the terms "quality performance" and "performance of the quality management system" which implies that these are two distinctly different things. In some cases, both terms have been used together such as at line #1457 at 9.1.1 "The organization shall evaluate the quality performance and the effectiveness of the quality management system while in other places within ISO 9001:2015, only 1 term has been used. In ISO 9001:2008 instead of quality performance, the term consistently used was "performance of the quality management system". The fact that quality performance is not defined will further confuse users.	The organization shall evaluate the quality performance and the effectiveness of the quality management system.	TAF
2658	ZA	1457 - 1458	9.1.1	On what should the evaluation be based?	Consider: "...evaluate the quality performance of the quality management system based on the identified criteria such as quality objectives (clause 6.2), and operational planning. "	TN
2659	CO	1457	9.1		Include guidance regarding what and how evaluate quality performance. (for example, nonconformities)	TN
2660	NL	1457	9.1.1	Since process approach is one of the QMP's this is to be considered one of the pillars of the success of the organisation. To improve (operational) processes the organization should know more about the actual performance of these	Add The organization shall evaluate the quality performance of its processes and the effectiveness of the quality management system.	TN

				processes. (The other processes should be considered part of the 'system' processes).		
2661	CH	1457	9.1.1	The term 'quality performance' is unclear, and the performance relates to the effectiveness of the QM system. (See also line 1506)	Delete the word 'quality' to read ".. evaluate the performance and the effectiveness of the quality management system."	TAF
2662	NG	1457	9.1.1	The introduction of '.....the quality performance and....' Is quite ambiguous. No text has explain this before now	Replace or rephrase or put in the definition of terms	TAP
2663	MX	1457 & 1458	9.1.1	The organization shall evaluate the quality performance and the effectiveness of the quality management system.	The organization shall evaluate the quality of products and services; performance of processes and the effectiveness of the quality management system RATIONALE: The wording of the sentence is ambiguous. It is important that the standard specifies what needs to be measured.	TN
2664	IT	1458	9.1.1	It would be appropriate to envisage that the evaluation of the quality performance and effectiveness of the QMS are planned and carried out in consistency with the monitoring system of the global performance of the organization.	Add a note: <i>NOTE The evaluation of the quality performance and effectiveness of the QMS should be planned and carried out in consistency with the monitoring system of the global performance of the organization.</i>	TN
2665	ANS I	1460 -1461	9.1.2	"Of the degree" is not appear to be clear language	Revise to read The organization shall monitor customer perceptions relating to whether customer requirements have been met.	TN
2666	TR	1460 -1461	9.1.2	This statement can be restricted with customer requirements. Because companies can derive its own internal requirements and monitoring customer perception of the degree cannot be possible.	The organization shall monitor customer perceptions of the degree to which customer requirements have been met.	TAP
2667	DE	1460	9.1.2	use wording of ISO 9000	...of the degree to which expectations have been met.	TAF
2668	PE	1460	9.1.2	This requirement, as it is presented, does not request any evidence; which is contrary to all other <u>monitoring</u> requirements included in this DIS where the request " <i>retain documented information</i> " is always mentioned.	It should say: " <i>The organization shall monitor customer perceptions of the degree to which requirements have been met and retain documented information.</i> "	TN
2669	ISS/RS	1460 1461	9.1.2	The organization shall monitor customer perceptions of the degree to which requirements have been met.	The organization shall monitor customer perceptions of the degree to which requirements have been met and shall retain appropriate documented information as evidence of the results.	TN

2670	CA-66	1460	9.1.2	This clause on 'customer satisfaction' is now inconsistent with the definition of that term, as proposed in ISO/DIS 9000 (3.9.3) and in this document (3.57). In this clause, it states: "The organization shall monitor customer perceptions of the degree to which requirements have been met." However, in the definition (3.57), it states: "customer's perception of the degree to which the customer's expectations have been fulfilled."	Change this clause (9.1.2) to: "The organization shall monitor customer perceptions of the degree to which expectations have been fulfilled." [changed "met" to "fulfilled" for consistency]	TAF
2671	NZ	1460	9.1.2	P1 seems to state the same requirement as P2 using different words for perceptions. Given the Note relates to the wording used in P2, suggest deleting P1 and modifying P2 to include monitoring.	Delete P1 and modify P2 to include monitoring: The organization shall obtain <i>and monitor</i> information relating to customer views and opinions...	TAP
2672	ANS I	1462-1463	9.1.2	The use of information, not related to documented information, could potentially confuse users.	The organization shall obtain <u>information data</u> relating to customer views and opinions of the organization.	EN
2673	CN	1462	9.1.2	It should be organization not organisation	Change the organisation into organization	EAF
2674	CA-67	1462	9.1.2	The statements in the rest of this clause constitutes an incomplete account of the organization's role in monitoring customer satisfaction, or acting on the information obtained.	Replace paragraphs 2 and 3 with the following: The organization shall determine the customer's satisfaction with the delivered product/service, and with other aspects of the organization or its processes. The methods and means for obtaining this information shall be determined. The organization shall review the information obtained regarding the customer's view of the organization and its delivered product/service, and determine the actions to be taken which will serve the interests of the customer and the organization. The organization shall review the effectiveness of actions taken in response to information obtained regarding customer satisfaction.	TAP
2675	SE	1462	9.1.2	Recognized practice in ISO standards.	Spell "organization" with "z".	EAF
2676	RO	1462 & 1463	9.1.2	Correction	The organization shall obtain information relating to customer views and opinions of about the organization and its products and services.	EN
2677	DE	1464	9.1.2	Sentence in line 1464 is superfluous, as already covered in 9.1.1 b)	Delete line 1464	EN
2678	ANS I	1464	9.1.2	The use of information, not related to documented information, could potentially confuse users.	The methods for obtaining and using this <u>information data</u> shall be determined.	EN

2679	KE	1464	9.1.2	"customer information is need to be used to meet customer satisfaction	The methods used for obtaining and using this information "for customer satisfaction" shall be determined	TAP
2680	NL	1464	9.1.2	It is hard to use information about customer satisfaction when it is not recorded somehow. The method of using is described in 9.1.3	Add (bold) The methods for obtaining and documenting this information shall be determined.	TN
2681	AU	1464	9.1.2	"The methods for obtaining and using this information shall be determined" does not make sense.	"The processes for obtaining and using this information shall be documented "	TN
2682	CA-68	1464	9.1.2	This requirement should be done through Documented Information. It would be essential that this process be documented and evidence of the completion of this activity be maintained. Furthermore since this is a critical part of the business operation actions arising from poor Satisfaction shall be determined and maintained.	The methods for obtaining and using this information shall be determined and the results of this activity shall be maintained as documented information. Adding as a new line : The organization shall maintain as documented information a process for addressing situation where customer satisfaction is not achieved	TN
2683	CH	1464	9.1.2	In the context of this requirement, the meaning of the word 'determine' does not match the definition in 3.67.	<u>Change</u> to read: "The methods ... shall be DECIDED ON."	TN
2684	IT	1465-1467	9.1.2	Technical suggestion.	Modify note as follows: <i>NOTE Information related to customer views can include customer satisfaction or opinion surveys, customer data on delivered products or services quality, internal and external focus-groups, market-share analysis, compliments, warranty claims and dealer reports.</i>	TAP
2685	ANS I	1465	9.1.2	The use of information, not related to documented information, could potentially confuse users.	Note <u>Data</u> Information related to customer views can include....	EN
2686	NL	1465	9.1.2	Customer satisfaction or opinion surveys (most of the time by an 'independent' consultancy firm) are not the most effective approach for most users. Putting this as the first example, will draw to much attention to this approach. More 'daily' approaches should be shown as example	Change/add Note: information related to customer views can include customer satisfaction or opinion surveys, after sales meeting, project evaluations, site acceptance tests, internet forum about product or services of organisation, delivery note, customer data on delivered products or services, market-share analysis, compliments, warranty claims and dealer reports.	TN
2687	CA-69	1465	9.1.2	One of the QMPs is on 'Customer focus', of which 'customer satisfaction' is a key element, yet this clause is rather sparse. As a minimum, this	Add reference at the end of the NOTE: "Further guidance on "Customer Satisfaction	TN

				clause should at least reference ISO 10004, since the only topic this clause deals with, is obtaining "information relating to customer views and opinions" and ISO 10004 provides guidance on monitoring and measuring customer satisfaction	Measurement' will be found in ISO10004	
2688	MX	1465 & 1466	9.1.2	Information related to customer views can include customer satisfaction or opinion surveys, customer data on delivered products or services quality, market-share analysis, compliments, warranty claims and dealer reports.	Information related to customer views can include customer satisfaction or opinion surveys, customer focus groups , customer interviews , customer data on delivered products or services quality, market-share analysis, compliments, warranty claims and dealer reports. RATIONALE: Focus groups and interviews are methods which permit assess customer satisfaction as well.	TAP
2689	IR	1466	9.1.2	Customer complaints are important feedback received from customers about the status of actual product delivered to the customer. As stated in Note 2 to the sub-clause 3.57: <i>Complaints</i> are a common indicator of low customer satisfaction, although their absence does not necessarily imply high customer satisfaction. Hence, customer complaints need to be explicitly addressed in this sub-clause.	Read Note to the sub-clause 9.1.2 as follows: NOTE Information related to customer views can include customer satisfaction or opinion surveys, customer complaints , customer data on delivered products or services quality, market-share analysis, compliments, warranty claims and dealer reports.	TN
2690	JP 150	1466	9.1.2	The expression "products and services" should be consistently used throughout the text.	Change "products <u>or</u> services" to "products <u>and</u> services".	TN
2691	IE	1467	9.1.2	Add requirements regarding documents to be retained.	Add "shall be determined and related documented information shall be retained"	TN
2692	UY	1468	9.1.3	We think that is important to include explicitly the applicable statutory and regulatory requirements as an output of analysis and evaluation.	Include as an output of analysis and evaluation the applicable statutory and regulatory requirements.	TN
2693	ANS I	1469 -1470	9.1.3	The use of information along with data, not related to documented information could confuse some users. Data was used in this section previously. Additionally, what would the other sources. This broadens the standard and is vague.	The organization shall analyse and evaluate appropriate data and information arising from monitoring, <u>and</u> measurement and other sources .	TAP
2694	ISS/ RS	1469 1470	9.1.3	The organization shall analyse and evaluate appropriate data and information arising from monitoring, measurement and other sources.	The organization shall analyze and evaluate appropriate data and information arising from monitoring, measurement and other sources. and shall retain appropriate documented information as evidence of the results.	TN

2695	NL	1469	9.1.3	The retained documented information from the operational processes contain valuable information about the performance of the processes. Therefore the retained documented information should be input of the evaluation processes. Data is mentioned for the first time, so it is not clear where this originates from.	Change (bold) The organization shall periodically collect retained documented information arising from operational processes, monitoring and measuring and other sources.	TN
2696	TC69	1470	9.1.3	It should be explicitly demanded that the methods used for analysis and evaluation should be defined (or determined – if that was the better English word).	After measurement and other sources add: The methods for analysis and evaluation shall be defined.	TN
2697	NL	1470	9.1.3	According to QMP Evidence-based decision making (ISO/DIS 9000, line 308) data should be accurate, reliable and secure. Organizations should before using data determine reliability of data, to prevent they base actions on false data.	Add (bold) ... and other sources. Before analysing and evaluating data the organization shall confirm reliability of available data and information.	TN
2698	NL	1470	9.1.3	The process of analysis and evaluation is one of the toughest and most misunderstood. Good explanation of expectations is lacking. Analysis is translating 'raw data' into meaningful information, e.g. by preparing graphs or tables. Evaluation is comparing the information with predefined standards, like performance indicators and quality objectives. During the management review the organization will 'judge' whether deviation of the indicators or objectives is a call-to-action.	Add as par 2: The organization shall periodically consolidate and put the relevant documented information into a format suitable to compare results with predefined standards. - Results from processes are compared with performance indicators (see 4.4 c) - Results from the quality management system are compared with quality objectives (see 6.2) Note: analysis and evaluation of process performance and effectiveness of the quality management system do not need to be executed at the same frequency.	TN
2699	LU	1471	9.1.3	Include the risks based approach	output of analysis and evaluation shall be used to: h) <u>determine the risk and opportunities to control.</u>	TAP
2700	NL	1471	9.1.3	The output from evaluation should be used to improve (operational) processes, but also to improve the quality management system. Therefore we need to differentiate between two outputs.	Change / add The output of analysis and from the process evaluation shall contain, at least: a) (possible) sources of nonconforming products and complaints (including performance of external providers);	TN

					b) compliance with statutory and regulatory requirements; c) applied resources; d) adequacy of planned actions on determined risks, and e) overall score on performance indicators. The output from quality management system evaluation shall contain, at least: a) customer satisfaction in relation to process performance; b) overall score on conformity of products and services with requirements c) status of corrective actions d) a summary of process evaluation output.	
2701	IE	1472-1478	9.1.3 Lines	The order of points a) to g) should be aligned with the logical sequence that links customer satisfaction to the quality of the products and services which depend on reliable processes maintained by an effective quality management system	Re-order points a) to g) as follows: b), a), d), e), f), c), g)	EN
2702	ANS I	1472	9.1.3	Language is not consistent with analysis and evaluation.	Demonstrate <u>assess</u> conformity and products and services to requirements.	TAP
2703	NZ	1473	9.1.3	The output of analysis and evaluation cannot be used to enhance customer satisfaction. It can be used to monitor, but if changed to 'assess and monitor' in b) would need to also use in bullets e) and f). Outputs can be used as an input to improvement of processes, products and services, which could enhance customer satisfaction but this can be dealt with in P2.	b) assess customer satisfaction or b) <i>monitor and</i> assess customer satisfaction and modify bullets e) and f) similarly.	TN
2704	ANS I	1474	9.1.3	Language is not consistent with analysis and evaluation. Usually ISO use "suitability, adequacy and effectiveness" for Quality Management System.	Ensure <u>Assess</u> conformity, <u>suitability</u> , and effectiveness of the quality management system	TAP
2705	CA-70	1474	9.1.3	This line for me is a duplication , see line 1457.	Remove 9.1.3 c)	TN

				We are saying the exact same thing. I would recommend removing the line		
2706	INLA C	1475	9.1.3 d)	In conjunction with planning has been successfully implemented is important to evaluate the risk planning	Add: d) Demonstrate that planning, including actions to address risks and opportunities , have been successfully implemented	TAP
2707	BR	1475	9.1.3	To improve clear understanding and improved wording.	Change text to: "d) demonstrate that planned actions have been successfully implemented;	TAP
2708	ANS I	1475	9.1.3	Item c) ensure conformity and effectiveness of the quality management system would include any requirement of the standard. Clause d) is not needed.	Delete d) d) demonstrate that planning has been successfully implemented.	TN
2709	CO	1475	9.1.3	Be consistent with the terms used throughout this document. (See 3.06)	d) demonstrate that planning has been effectively implemented;	TAP
2710	HU	1475	9.1.3.	It is not clear what is the meaning of this sentence, what is the real requirement? One meaning: the requirement is that a plan shall be created/developed (independently from the quality of the plan); the other meaning: a plan shall be successfully completed/used (in this case the success of planning means that an appropriate plan has been developed)	Alternative wording depending on what this point wants to emphasize 'demonstrate that planning has been successfully completed' or 'demonstrate that plan appropriate to the organisation (or operation) has been successfully developed/created and implemented'	TAP
2711	TT	1475	9.1.3d	It is not clear whether the planning to be analyzed relates to a specific clause of the standard, or a number of clauses	Clarify whether the planning to be analyzed comes out of clause 6.1, 6.2, 8.1 or somewhere else	TN
2712	CZ	1475	9.1.3	d) demonstrate that planning has been successfully implemented;	"planning" in this context is ambiguous; could it be interpreted as quality policy or objectives? d) demonstrate that quality objectives has been successfully implemented;	TAP
2713	SE	1475	9.1.3	"demonstrate that planning has been successfully implemented;" It is not clear what "planning" refers to; "demonstrate that a planning function has been successfully implemented;" or "demonstrate that the implementation of plans has been successful;"	Replace by: "demonstrate that the implementation of plans has been successful;"	EN
2714	JP 151	1476 -1477	9.1.3	Improvement of the performance is missing from the intended purposes of using outputs of analysis and evaluation.	Change to: e) assess <u>and improve</u> the performance of	TN

					processes; f) assess <u>and improve</u> the performance of external provider(s)	
2715	ANS I	1476	9.1.3	This language is not consistent with clause 4.4 which talks about performance indicators.	Revise 9.1.3 e) assess the performance of the processes <u>for the quality management system</u>	TN
2716	ANS I	1478	9.1.3	The word determine seems out of place with the other words used in the list.	Determine <u>assess</u> the need <u>for</u> or opportunities for improvements within the quality management system.	TAP
2717	ANS I	1478	9.1.3	Determine the need or opportunities for improvements is not clear.	g) determine the need <u>for</u> or opportunities for improvements.	TAP
2718	NL	1478	9.1.3	Analysis and evaluation of risks are not required.	Add h) demonstrate that undesired effects have been prevented or reduced (6.1.1.)	TN
2719	IAQ G	1479 -1480	9.2.1	Regarding "The organization shall conduct internal audits ... whether the quality management system;" the organizations should conduct the internal audit effectively not only the QMS but also its processes, on the basis of the requirements of process approach in clause 4.4.	Add text - Improve Proposal: Change as follows. "The organization shall conduct internal audits ... whether the quality management system <u>and its processes</u> ;"	TN
2720	DE	1479	9.1.3	reference to statistical methods is missing add Note s	Note 1: Analysis of such data is typically done by using established statistical methods, which can differ from organization to organization or from sector to sector. Note 2: Important methods are documented in related national and international standards.	TAP
2721	TC6 9	below 1479	9.1.3	Use of statistical methods should be explicitly mentioned for those who are concerned.	Add: Note 1: Analysis of such data is typically done by using established statistical methods, which may differ from organization to organization or from sector to sector. Note 2: A lot of important methods are documented in related national and international standards.	TAP
2722	NZ	1479	9.1.3	At present 9.1.3 does not link well into the PDCA cycle. The outputs (rather than 'results') become inputs not only into management review but also improvement.	The <u>results outputs</u> of analysis and evaluation shall <u>also</u> be used to provide inputs to management review <u>and improvement of processes, products and services</u> .	TN
2723	IE	1480	9.2	The title of this clause refers to an activity (Internal auditing) - not to the target of the	Change the title from "Internal audit" to " Quality	TN

				"monitoring, measurement, analysis and evaluation" (in this case the quality management system). Need to clarify how the internal audit emphasis on "conformance" and "effectiveness" relate to the purpose of the QMS. This can provide an inspiring context for what can otherwise be a random and apparently aimless "audit for its own sake".	management system". Expand the first line of Clause 9.2.1 as follows: " at planned intervals to evaluate the ability of the quality management system to maintain reliable processes that ensure consistent quality in the products and services that lead to customer satisfaction. Internal audits shall provide information"	
2724	TC69	1481-1482	9.2.1	The sentence should end with a colon, not a semicolon: "The organization shall conduct internal audits at planned intervals to provide information on whether the quality management system;"	"The organization shall conduct internal audits at planned intervals to provide information on whether the quality management system:"	EAF
2725	NL	1481	9.2.1	A lot of users of the standard do not understand that internal audits also can be conducted when a specific situation occurs. Clarification that internal audits can be conducted more flexible than just according a strict program is needed.	Add (bold) The organization shall conduct internal audits at planned intervals, or when a specific situation or event oblige the organization, to provide information on whether the quality management system:	TN
2726	CA-71	1481	9.2.1	9.2.1 The organization shall conduct internal audits There is no title for paragraph	Add sub-title Performing internal audits	EN
2727	IT	1481 1487	9.2.1 9.2.2	Editorial suggestion.	It would be appropriate to indicate a title for sub-clauses 9.2.1 and 9.2.2, for editorial consistency within the text.	EN
2728	CZ	1482	9.2.1	Semicolon at the end of the introductory sentence is not correct.	Colon should be used instead of a semicolon.	EAF
2729	BR	1483	9.2.1	Add one more item in letter a), because the internal audits also verify compliance with requirements of customer, statutory and regulatory	3) Customers, statutory and regulatory requirements.	TN
2730	IAQG	1484	9.2.1 b)	Regarding "The organization shall conduct internal audits ... whether the quality management system;" should be the requirements that conduct the audit based on not only QMS but also performance indicators, on the basis of the requirements of process approach in clause 4.4.	IAQG Priority Comment Add text - Improve Proposal: Change as follows. Add bullet c) <u>considers related performance indicators for the processes of the quality management system."</u>	TN
2731	CO	1487	9.2.2	Auditors should be competent to carry out audits.	Include in 9.2.2 a new literal: x) ensure that auditors are competent on the basis of appropriate education, training, or experience	TN

2732	CA-72	1487	9.2.2	9.2.2 <u>The organization shall: ...</u> There is no title for paragraph	Add sub-title Preparing internal audits	EN
2733	ANS I	1488-1491	9.2.2	The inclusion of customer feedback and quality objectives may provide too strong of focus on those items.	Revise and develop note, if necessary to address quality objectives, customer feedback. a) plan, establish, implement and maintain an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the quality objectives , the importance of the processes concerned, customer feedback , changes impacting on the organization, and the results of previous audits;	TAF
2734	ANS I	1488-1491	9.2.2	The US TAGs to 176 and 207 Liaison Group recommends alignment between the two standards with respect to the following: e) ...take into consideration... risk associated with threats and opportunities <u>changes impacting on the organization...</u> Rational: 'risk associated with threats and opportunities' is redundant with the other considerations already listed. It is more appropriate to take into consideration changes when developing the audit programme. Propose editorial comment for alignment.	For 9001: no change For 14001: a) plan, establish, implement and maintain an audit programme(s), including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the <u>environmental</u> importance of the processes concerned, risk associated with threats and opportunities <u>changes impacting on the organization</u> and the results of previous audits	C
2735	NO	1488-1491	9.2.2	It is important that the organization also takes into consideration criticality and complexity of products and processes when audit programs are planned. Changes in processes must also be reviewed.	a) plan, establish, implement and maintain an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the quality objectives, the importance of the processes concerned, <u>the criticality and complexity of products and processes</u> , customer feedback, changes <u>in processes</u> or impacting on the organisation, and the results of previous audits;	TN
2736	FR	1488	9.2.2	The risks are not taken into account define the audit programme	a) plan, establish, implement and maintain an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the quality objectives, the importance of the	TN

					processes concerned, the associated risks and opportunities, customer feedback, changes impacting on the organisation, and the results of previous audits;	
2737	MX	1488, 1489, 1490 and 1491	9.2.2	a) plan, establish, implement and maintain an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the quality objectives, the importance of the processes concerned, customer feedback, changes	a) plan, establish, implement and maintain an audit programme(s) which include(s) the frequency of auditing; the methods for conducting the audit; the responsibilities of whom are in charge of executing the different stages of the audit process; the planned requirements for the audit and how they are going to be reported, these requirements shall take into consideration the quality objectives, the importance of the processes concerned, customer feedback, changes RATIONALE: The current wording of the sentence is confusing, clear clarifications about what needs to be done is need it	TN
2738	DE	1488 to 1491	9.2.2	Please improve usability and practically and separate bullet "a)". That will ease the handling because references will be possible. For such a multitude of information as given in a) it will be better to split.	Proposal: a) plan, establish, implement and maintain an audit programme(s) including 1) frequency, 2) methods, 3) responsibilities, 4) planning requirements, and 5) reporting, which shall take into consideration the 6) quality objectives, 7) the importance of the processes concerned, 8) customer feedback, 9) changes impacting on the organisation, and 10) the results of previous audits; b) ...	TN
2739	INLA C	1490	9.2.2 a)	For consistency with clause 6.1 and ISO/DIS 14001, add "risks associated"	Add in line 1490: ...the importance of the processes concerned,	TN

					risks associated, customer feedback,...	
2740	ANS I	1490	9.2.2	Why should customer feedback be a required part of an internal audit? Are customers internal, external, or both in this clause?	Eliminate customer feedback.	TAF
2741	NL	1490	9.2.2	To improve the risk based thinking throughout the clauses and to harmonize with ISO 14001 As well as a relation to 6.1.	...shall take into consideration quality objectives, the importance of the processes concerned, customer feedback, changes impacting on the organisation, the risks addressed in 6.1 and the results of previous audits;	TN
2742	MX	1491	9.2.2	impacting on the organisation, and the results of previous audits;	impacting on the organization, and the results of previous audits; RATIONALE: British English spelling is used	EAF
2743	CN	1491	9.2	It should be organization not organisation	Change the organisation into organization	EAF
2744	SE	1491	9.2.2	Recognized practice in ISO standards.	Spell "organization" with "z".	EAF
2745	BW	1491 , 1674	9.2.2 A.7	Spelling of organization used is "organisation"	Use "organization" for consistency	EAF
2746	MX	1493	9.2.2	select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;	select auditors and conduct audits in a way that ensure objectivity and the impartiality of the audit process; RATIONALE: the current wording of the sentence is confusing	TN
2747	MX	1493	9.2.2	We suggest that is necessary to be specific about impartiality. We think that it isn't enough to sayc)select auditors and conduct audits to ensure objectivity and impartiality of the audit process	c) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process. Auditors shall not audit their own work.	TN
2748	DE	1494	9.2.2	...to relevant management; "management" is defined differently and has to be qualified in some way	Please use "to relevant top management" instead of "to relevant management" or use other qualifier	TN
2749	TT	1494	9.2.2	Results of an audit must be communicated to Top Management apart from 'relevant management' as the risk of manipulating information and operations is real.	Add at the end of the sentence:relevant management, <i>'including Top Management without undue delay.'</i>	TN
2750	IN	1494 to 1497	9.2.2	Verification of Corrective Actions on reported NC is essential for effective QMS'	To insert a new bullet f) follow up activities shall include the verification of the actions taken and the reporting of verification results.	TN
2751	CQI 62	1495	9.2.2	e) take necessary correction and corrective actions without undue delay; the phrase 'without undue delay' is negative and could cause confusion; replace with the positive, clearer phrase in a timely manner.	e) take necessary correction and corrective actions without undue delay in a timely manner.	TN
2752	BR	1495	9.2.2 e)	In some cases correction of nonconforming product or service can be included in the corrective actions to be taken. Besides,	e) take necessary correction and corrective actions, as appropriate , without undue delay;	TAP

				sometimes just correction suffices and sometimes it is up to the organization to evaluate the risk of doing nothing.		
2753	RO	1495	9.2.2	Reformulation	ensure that take necessary correction and corrective actions are taken by the management responsible for the area being audited without undue delay;	TN
2754	BE	1495	9.2.2.e	"Containment actions" to avoid occurrence of similar non-conformities should be in place as long as the corrective actions have not been implemented satisfactory. This concepts of "containment actions" is missing.	Change to "take necessary correction and corrective actions without undue delay" Or add requirement for "containment actions" as long as corrective actions are not satisfactory implemented.	TN
2755	BG	1496 -1497	9.2.2	Change this requirement in: f) retain documented information as evidence of the implementation of the audit program and the audit results	To become: f) The organization shall maintain documented information to the extent necessary to support the operation of processes and retain documented information as evidence of the implementation of the audit programme	TN
2756	NZ	1499	9.3	Title is Annex SL but not blue font.	If to be used in FDIS, change title to blue font.	EAF
2757	TR	1499	9.3	Output of the Clause 5.3 Para (c) should be considered as an input for management review.	In Clause 9.3 following sub-clause should be added : <i>"reporting on the performance of the quality management system" (See Clause 5.3 (c))</i>	TAP
2758	NL	1500 -1520	9.3.1	A management review should take place at least at two levels in an organisation: at process level (as part of process management) and at the system level (as part of system management). The system level is focused on the effectiveness of the control of the processes. At the process level is assessed whether sufficient performance activities. On these two levels and different information criteria.	Change 9.3.1 System review Top management ... effectiveness. The management review shall be planned and carried out taking into consideration: a) the status of actions from previous management reviews; b) changes .. strategic direction; c) information on the quality performance, including trends and indicator for: 1) nonconformities and corrective actions 2) monitoring and measuring results 3) audit results 4) customer satisfaction 5) issues concerning external providers and other relevant interested parties 6) adequacy of resources required for maintaining an effective qms 7. process performance and conformity of products and services 4) adequacy of resources required for maintaining an effective management system; d) output from quality management system evaluation. e) new potential opportunities for continual	TN

				improvement; Based on these inputs top management shall determine whether the quality management system achieves its intended results. The outputs of the quality management system review shall include decisions and actions related to: a) continual improvement opportunities related to the products and services in relation to the customer requirements ; b) any need for changes to the quality management system and its processes; and c) the need of resources; 9.3.2 Process review Management shall review the operational processes under its control at planned intervals to ensure its effectiveness. The management review shall be planned and carried out taking into consideration: a) status of actions from previous process reviews b) changes in external and internal issues that are relevant to the process, including the quality policy c) information on the quality performance, including trends: 1) nonconformities and corrective actions 2) monitoring and measuring results 3) audit results 4) issues concerning external providers and other relevant parties; 5) adequacy of resources required for controlled operation of processes, taking into account competence, awareness, communication and documented information; d) new potential opportunities for continual improvement The outputs of the process review shall include decisions and actions related to: a) any need for changes within the control of the process; b) the need to adapt resources, competence, awareness, communication or documented information.	
2759	CQI 63	1500 - 1501	9.3.1	Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, and effectiveness. Add new (after line 1515) NOTE This review may be undertaken with other management system standards as a combined	TN

				Acknowledging that many organisations use more than one ISO management system standard, add a note that allows for combined reviews.	review.	
2760	ANS I	1500	9.3.1	9.3.1 is what we indicated was management review inputs in previous versions of the standard. 9.3.2 still uses output.	Label 9.3.1 as Management Review Input	TAF
2761	CO	1500	9.3.1		Improve the numbering for better understanding.	TAP
2762	CA-73	1500	9.3.1	9.3.1 <i>Top management shall review the</i> There is no title for paragraph	Add sub-title Management review inputs	TAF
2763	IT	1500 1532	9.3.1 9.3.2	Editorial suggestion.	It would be appropriate to indicate a title for sub-clauses 9.3.1 and 9.3.2, for editorial consistency within the text.	TAF
2764	INLA C	1501	9.3.1	It is important to define a minimum of "planned intervals"	Include a note: "The revision of quality management system has to be done at least one time per year"	TN
2765	BE	1501	9.3.1	"," before "and"	Remove "," after "adequacy"	EAP
2766	IT	1501 1504- 1505	9.3.1	The management review shall be planned and carried out in alignment with the strategic direction of the organization and taking into account the changing business environment (note that this aspect addressed in the CD). Furthermore, it would be appropriate to enhance the connection with the strategy and global objectives of the organization.	Add the following new paragraph: Management review shall be planned and carried out in alignment with the strategic direction and the global objectives of the organization. Modify bullet b) as follows: <i>b) changes in external and internal issues that are relevant to the quality management system, including its strategic direction and business environment;</i>	TAP
2767	JP 152	1502	9.3.1	It is not necessary to change the text of Annex SL. Duplication with L1501.	Change to: The management review shall <u>include</u> consideration of:	TN
2768	IAQ G	1502 , 1479	9.3.1, 9.1.3	There is a connection between inputs to management review in 9.1.3 and the management review requirements in 9.3.1, but no reference or alignment of language the two sections.	Add text - Improve Proposal: Align language in management review 9.1.3 and the management review requirements in 9.3.1. Suggest reference from one section to the other for better alignment.	TN TN
2769	NO	1504 -1505	9.3.1	The standard will be more user friendly if the text give reference to the requirement.	b) changes in external and internal issues (4.1), that are relevant to the quality management system including its strategic direction;	EN
2770	IT	1504 -1505 1512	9.3.1	It is important to make reference to clauses 4.1 and 4.2 for a more in-depth understanding of the importance of the "internal and external issues" and "relevant interested parties".	Modify bullets as follows: [...] <i>b) changes in external and internal issues that are relevant to the quality management system including its strategic direction (see 4.1);</i> [...] <i>5) issues concerning external providers and other</i>	EN

					<i>relevant interested parties (see 4.2); [...]</i>	
2771	ANS I	1506	9.3.1	The word indicators is not used anywhere else in the standard and is not consistent language. What do we now mean by “quality performance” – how is that defined? The performance of the QMS, however, is relevant. The inclusion of trends and indicators does not fit well for items 5 and 6.	Revise e) Information on the <u>quality performance of the quality management system</u>, including trends and indicators for <u>related to</u>	TAP
2772	AT	1506	9.3	The draft introduces the term “quality performance” in addition to the term “performance of the quality management system”. If all of the listed items are part of quality performance, what is then the performance of the quality management system? Proposed change puts more focus on quality performance We also want to highlight that in 5.3 the term “performance of the quality management system” is used. The use of “quality performance” and “performance of the quality management system” is confusing.	c) information on the quality performance, including trends and indicators for: 1) nonconformities to customer requirements and corrective actions; 2) customer satisfaction; d) information on the performance of the quality management system, including trends and indicators for: 1) monitoring and measurement results; 2) audit results; 3) issues concerning external providers and other relevant interested parties; 4) adequacy of resources required for maintaining an effective quality management system; 5) process performance and conformity of products and services;	TAP
2773	EOQ	1506	9.3	These are mainly indicators for the “Performance of the quality management system”.	information on the quality performance and the performance of the quality management system, including trends and indicators for	TAP
2774	PT	1506 989 1147 1152	9.3.1 Managament review 5. Leadership 7.2 Competence 7.3 Awareness	The standard has now a stronger focus on leadership and people engagement. Regarding people, the standard now requires leaders to assure their engagement, more clear definition of their roles and responsibilities in section 5. In section 7 states people shall be aware and in 7.3.2 addresses competence. The PDCA Cycle on these issues is not closed as verification and improvement is missing. After careful analyses by PT committee, we consider that verification and demonstration of	In 9.3.1 after 6) adequacy of resources required for maintaining an effective quality management system; and Insert a new bullet: 7) effectiveness of people awareness and competence	TN

				the effectiveness of these issues related to engagement and awareness can be monitored or verified in different ways in the standard, namely in 9.1.or 9.2, but on the limit it shall be considered in management review and should be explicit		
2775	PT	1506	9.3.1 Managamen t review	Indicators too restrictive or is not clear what is the intended use	1. Clarify what is pretended with the use of indicators and which.	TAP
2776	IQN ET	1506 989 1147 1152	9.3.1 Managamen t review 5.Leadershi p 7.2 Competenc e 7.3 Awareness	The standard has more requirements on leadership and on leaders promoting people engagement in section 5.1. In section 5.3 roles, responsibilities and authorities engagement is reinforced through a more thorough definition of responsibilities for relevant roles as well as a reinforcement on understanding of roles, responsibilities and authorities within the organization. Section 7.3 requires people to be aware and 7.2 to be competent. In section 7.2 effectiveness of competence is addressed but it is no longer an input to verification or improvement. The PDCA Cycle is not closed in a way that can provide confidence and ways to demonstration the organization that people engaged, aware and, and therefore weakens the reinforcement of leadership and engagement. On an auditability perspective it will be extremely difficult to assess that the organization addresses these issues in an effective manner if they are not required to asses it. We consider a more explicit reference to verification of engagement and awareness should be done in section 9, and clarification on these reinforced requirements could be provided in annex A	In section 7.3 add: Where applicable, the organization shall take actions to ensure people awareness and evaluate the effectiveness of the actions taken. In 9.3.1 Management review add after 6 6) adequacy of resources required for maintaining an effective quality management system; and 8) Adequacy of engagement and competence of people, roles definition and effectiveness of any actions taken	TN
2777				Secretariat Note: comment no. 2777 repeated the preceeding comment 2776, so has been deleted		

2778	AU	1506	9.3.1 c)	Customer complaints fall into the category of 'information on the quality performance' and should be considered during Management Review. However, customer complaints are not clearly included in this clause. <i>Customer satisfaction</i> (9.1.3) does not include customer complaints. Note that previously (currently) ISO 9001 used the term 'customer feedback' – this includes both positive and negative feedback.	Change 1510 to 'Customer satisfaction and customer complaints'	TN
2779	CH	1506	9.3.1	The term 'quality performance' is unclear, and the performance relates to the effectiveness of the QM system (See also line 1457)	<u>Change</u> to read: "c) information on the PERFORMANCE OF THE QUALITY MANAGEMENT SYSTEM, including ..."	TAP
2780	NZ	1506	9.3.1	Order of subsections: Review should be starting with what is going well not just focussing on the negative. A reordering of clauses may be useful to get users of the standard thinking positively. Final order is a matter of opinion.	Change order of clauses to read: 1) Customer satisfaction; 2) Monitoring and measurement results; 3) Process performance and conformity of products and services; 4) Issues concerning external providers and other relevant interested parties; 5) Audit results; 6) Nonconformities and corrective actions; 7) Adequacy of resources required for maintaining an effective quality management system.	TAP
2781	NG	1506	9.3.1	Define 'quality performance' see 1457	Define "quality performance"	TN
2782	IT	1506	9.3.1	The preposition "for" instead of "in" (as in HLS) changes the meaning of the sentence. Trends can include the use of appropriate indicators.	Modify bullet as follows: <i>c) information on the quality performance, including trends (and related indicators) and indicators for in:</i>	TAP
2783	UY	1506	9.3	We think it is important to include as management review input the analysis of compliance with 7.1.6 clause about organizational knowledge.	Include organizational knowledge result in the list of information on the quality performance.	TN
2784	JP 153	1506	9.3.1	"indicators" are included in the items 1) thru 7).	Delete "and indicators for" to simplify.	TAF
2785	IE	1507 -1513	9.3.1 Lines	The order of points 1) to 7) should be aligned with the logical sequence that links customer satisfaction to the quality of the products and services which depend on reliable processes maintained by an effective quality management system . Point 7) should be broken into two points to better	Break Point 7) into two: 7) Conformity of products and services 8) Process performance	TN

				align with the above. 7) Conformity of products and services 8) Process performance	Re-order points 1) to 8) as follows: 4), 7), 8), 3), 6), 2), 5), 1)	
2786	CA-74	1507	9.3.1	Big improvement. We now have the agenda almost in the right order. For bullet c) 7) "process performance and conformity of products and services". Why is management review only looking at process performance? A Note to entry, in the definition for "performance" states: "Performance can relate to the management of activities, processes, products and services, systems of organizations." This Standard is about quality management systems , so system performance should also be considered. Further, in §4.1, Note 2, it mentions "performance of the organization" as a consideration in understanding the internal context of the organization so, one would think that management review should evaluate that organizational performance data.	A business will address its 'issues/factors' in this order: 1) customer satisfaction and customer complaints; 2) monitoring and measurement results; 3) organizational, system and process performance, as well as conformity of products and services to requirements.; 4) issues concerning external providers and other relevant interested parties; 5) audit results; 6) nonconformities and corrective actions 7) adequacy of resources required for maintaining an effective quality management system	TAP
2787	IT	1508 -1513	9.3.1	Monitoring and measurement results should include bullets 4, 5, 6 and 7 for consistency with the contents of clause 9.1.	Move bullets 4),5),6),-7) under bullet 2).	TN
2788	ES	1510	9.3	Should not be limited to customer satisfaction (basically complaints) but also many other aspects of customer feedback	Delete "satisfaction" and complete: c) information on the quality performance, including trends and indicators for: [...] 4) customer satisfaction <u>views and opinions of the organization and its products and services</u>	TN
2789	PE	1510	9.3.1	It should include the complaints in the management review	It should say: <i>"customer satisfaction, <u>including complaints</u>".</i>	TN
2790	ES	1511	9.3.c) 5	The references to "interested parties" create significant conflicts. The proposed deletion mets the Annex SL structure and is consistent with the new redaction of 4.2.	Delete interested parties: 9.3 Management review c) information on the quality performance, including trends and indicators for: 1) nonconformities and corrective actions; 2) monitoring and measurement results; 3) audit results; 4) customer satisfaction; 5) issues concerning external providers and other relevant interested parties; 6).....	TAP

2791	ES	1511	A.3	References to interested parties could generate more confusion than it tries to clarify. For example: unions always could have impact on the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements or the organization's aim to enhance customer satisfaction.	Delete text as follows: A.3 Context of the organization Context", There is no requirement in this International Standard for the organization to consider interested parties which have been determined by the organization not to be relevant to its quality management system. Similarly, there is no requirement to address a particular requirement of a relevant interested party if the organization considers that the requirement is not relevant. Determining what is relevant or not relevant is dependent on whether or not it has an impact on the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements or the organization's aim to enhance customer satisfaction. The organization can decide to determine additional needs and expectations that will assist it to meet its quality objectives. However, it is at the organization's discretion whether or not to accept additional requirements to satisfy interested parties beyond what is required by this International Standard.	TAF
2792	ANS I	1511	9.3.1	This requirements is focused on what used to be suppliers. Including other relevant interested parties in this sub-clause is mixing two different topics. Other relevant interested parties would be more relevant to customer satisfaction.	4) Feedback, including customer complaints, from customers and other relevant interested parties. 5) issues concerning external providers	TAP
2793	RO	1511	9.3.1	Reformulation	issues concerning performance of external providers and other relevant interested parties;	TAP
2794	GB	1511	9.3.1 c) 5)	Term issue remains problematic (see comment on 4.1)	Define term. Suggest reword: 'external provider performance and issues concerning other relevant interested parties;	TN EAP
2795	ANS I	1512	9.3.1	Adequacy of resources required for maintaining an effective quality management system does not fit with the lead-in phrase wher the organization is considering trends.	Label 6) as a separate alpha letter in the list and not as a sub-set of c)	TAF
2796	RO	1512	9.3.1	Reformulation	adequacy of resources allocated required for maintaining an effective quality management system;	TN
2797	ANS I	1513	9 Performing	Both "process performance" and "conformity of products and services" should be related to	Insert "to requirements" after "services."	TN

			evaluation, 9.3 Management Review	specified requirements.		
2798	NL	1513	9.3.1	In different clauses (eg. 5.1.2) Conformity of products and services is related to products and services that meet customer requirements and applicable statutory and regulatory requirements. It is strange that in line with required information on quality performance in the management review there is no reference to statutory and regulatory requirements	Add bullet point 8) conformity on statutory and regulatory requirements	TN
2799	CQI 64	1514	9.3.1	d) the effectiveness of actions taken to address risks and opportunities Change all instances of 'risks and opportunities' to 'opportunities and risks' to emphasize the positive nature of a Quality Management System. See CQI General comment.	d) the effectiveness of actions taken to address risks and opportunities and risks	EN
2800	ANS I	1514	9.3.1	The use of the word risk has caused a large amount of comment from those who are experienced with the application of risk as well as those who are involved in ISO 31000. The term "opportunities" is not defined. Since the definition of "risk" is included, and contradicts those of other ISO standards which treat risk and opportunity as identical ("positive risk"), this must be corrected. Using this terminology as it is written in Annex SL is technically incorrect and has resulted in much feedback has the potential for lack of understanding and misinterpretation in the marketplace. Risks and its opportunities should be replaced by risks and its effects with some clarification added in the requirements related to terminology.	d) the effectiveness of actions taken to address risks and <u>its effects</u> opportunities (see clause 6.1)	TN
2801	CZ	1514	9.3.1 d)	„... (see <u>clause</u> 6.1);“	„... (see 6.1);“	EAF
2802	CQI 65	1515	9.3.1	In reviewing the QMS it is important that top management have evidence on the level of quality awareness	Add f) the level of quality awareness and commitment of management and person(s) doing and supervising work under its control	TN
2803	BR	1515	9.3.1	Exclude the word continual to be consistent with the new QMP's and with the clause 10.	e) new potential opportunities for continual improvement.	TAF
2804	ANS I	1515	9.3.1	There is no consideration of organizational knowledge. Without some link to the actual requirement, the potential for misinterpretation of	f) Review of organizational knowledge	TN

				clause 7.1.6 is large. This change is not needed if the decision is to delete 7.1.6.		
2805	ANS I	1515	9.3	The US TAGs to 176 and 207 Liaison Group recommends alignment between the two standards with respect to the following: -Opportunities for continual improvement Rational: Opportunities for continual improvement are an output of the management review, and flow from the evaluation and analysis of XXX performance and the other considerations listed in para 2.	For 9001: e) new potential Opportunities for continual improvement For 14001: no change	TN
2806	ANS I	1515	9.3.1	I think Management Review should review the whether the system has been effective in achieving Quality Objectives	Add a statement for the review relevancy of policy and objectives and the achievement of objectives.	TAP
2807	DK	1515	9.3.1	"new potential opportunities" can be made simpler by writing "oportunities"	Change "new potential opportunities" to "opportunities"	TAF
2808	IT	1515	9.3.1	The sentence should be completed with other specifications.	Modify bullet as follows: e) <i>new potential opportunities for continual improvement and innovation.</i>	TN
2809	IT	1515	9.3.1	It is important to clarify that the management review shall be planned and carried out taking into consideration the quality objectives and the quality policy.	Add a new bullet as follows: f) the progress in the achievement of quality objectives and implementation of quality policy.	TN
2810	GB	1515	9.3.1 e)	Potential and opportunity is tautological, 'new' adds nothing	Reword as: 'opportunities for continual improvement'	TAP
2811	JP 154	1515	9.3.1	"New potential opportunities" is too wide.	Delete "new potential" as "e) opportunities for continual improvement."	TAP
2812	JP 155	1515	9.3.1	One of key issues to be covered by management review is assessment of degree to which quality objectives have been achieved. Introduce a new Item f) after Item e) to cover this.	A new Item f) reads: f) degree to which quality objectives are achieved.	TN
2813	CA-75	1516	9.3.2	9.3.2 <i>The outputs of the management review ...</i> - There is no title for paragraph	Add sub-title Management review outputs	TAF
2814	CQI 66	1517	9.3.2	continual improvement opportunities; This limits the output of management review to continual improvement opportunities. As stated, it contradicts clause 10.1. It should be simply 'improvement opportunities' (which includes continual improvement).	continual improvement opportunities;	TAF

2815	BR	1517	9.3.2	Exclude the word continual to be consistent with the new QMP's and with the clause 10.	a) continual improvement opportunities;	TAF
2816	DE	1517	9.3.2.a	maybe it's good to extend paragraph	add ... , including those related to the effectiveness of the quality management system	TN
2817	IT	1517	9.3.2	It would be appropriate to include the innovation opportunities.	Modify bullet as follow: a) <i>continual improvement and innovation opportunities</i>	TN
2818	JP 156	1517	9.3.2	Correct the phrase "continual improvement opportunities" to "opportunities for continual improvement" for consistent wording. *This is a comment to Annex SL text.	Corrected text reads: a) opportunities for continual improvement:	TN
2819	IT	1518	9.3.2	It would be better to clarify that the outputs of the management review should include decisions and actions related to any need for changes to the QMS, including the quality objectives, the quality policy and resource needs.	Modify bullet as follow: b) <i>any need for changes to the QMS, including the quality objectives, the quality policy and resource needs.</i>	TN
2820	GB	1518	9.3.2	Additional text 'including resource needs' duplicates requirement in 7.1.1	Delete wording	TN
2821	IE	1519	9.3.2	Following management review there should be a clear statement on the overall performance of the QMS with actions identified to improve the sytem	Add sentence The results of the management shall determine the overall performance of the QMS i.e. were quality objectives achieved and identify any necessary actions needed to improve the QMS.	TN
2822	IT	1520	9.3.2	It would be appropriate to enhance the connection with the strategic management and the global performance of the organization.	Add a note: NOTE The management review should take into account relevant issues of top management (e.g. strategic plan, business plan, annual report, key performance indicators, risk assessment report, etc), as appropriate, according to the size, complexity and structure of the organization.	TN
2823	AR	1522	10.1	The note is confuse because the first and second example have requirements in 10.2 and 10.3 but there are not any information about others.	We suggest delete note in 10.1 and add a the following note in 10.3 NOTE: In the quality field it is usual the use of "continual improvement" as a synonymous of "incremental improvement". However, in this International Standard "continual improvement" has a broader meaning, including incremental improvement, by step change (e.g.: breakthrough), creative improvement (e.g.: innovation) or by re-organization (e.g.: transformation).	TN

2824	ZA	1522	10.1	Heading of subclause ("General") is meaningless unless related to main clause This is particularly frustrating when reference is made to this subclause to describe how these requirements are met in an organisation, e.g. in context of integrated management systems	Change heading of subclause to read: .."General information relating to improvement".. OR .."Introduction to improvement"	EN
2825	PL	1523 -1531	10.1	It is not clear if actions taken for improvement should be documented. From A4 it results that they needn't.		C
2826	NL	1523 -1524	10.1	Risk based thinking has not sufficiently been incorporated in the PDCA cycle	Add the following sentence: "The organisation shall prioritize these opportunities for improvement and actions based on the determined risks"	TN
2827	JP 157	1523	10.1	It is required to determine and select opportunities for improvement in clause 10, but the relation with performance evaluation in clause 9 is not clear. It does not necessarily require conducting clauses 9 and 10 in coordination.	Add "by analysing the results of performance evaluation comprehensively" after " for improvement" to read: The organization shall determine and select opportunities for improvement <u>by analysing the results of performance evaluation comprehensively</u> and implement necessary actions...	TN
2828	CH	1523 , 1525	10.1	Line 1523 refers to 'opportunities' (plural). Line 1525 refers to singular.	<u>Change</u> line 1525 to read: "THESE shall include ..."	EAF
2829	IE	1526 -1528	10 .1 Lines	The order of points a) to c) should be aligned with the logical sequence that links customer satisfaction to the quality of the products and services which depend on reliable processes maintained by an effective quality management system .	Reorder points a) to c) as follows: b), a), c)	EAF
2830	AT	1526	10.1	The improvement of processes should also contribute to improvement and not only to prevent non-conformities	improving processes to prevent nonconformities	TN
2831	EOQ	1526	10.1	The improvement of processes has a broader aim. Limiting it to prevent non-conformities is not useful.	improving processes to prevent nonconformities	TAP
2832	ANS I	1527	10.1	The word predicted requirements is not used anywhere else in the standard. This terminology has the potential to confuse users. Determined is more consistent with determining requirements in clause 8.2.	b) Improving products and services to meet known and predicted determined requirements <u>as well as those developed to meet potential future needs</u> .	TAP

2833	IAQ G	1527	10.1(b)	The term “predicted requirement” is not defined. Is it related to the use of “meeting defined requirements” or “claims” mentioned in 8.2.2(b)?	Add definition - clarify Proposal: Add definition for “ <u>predicted requirements</u> ”.	TAP
2834	ZA	1527	10.1	The improvement to enhance customer satisfaction should focus on meeting customer requirements and expectations (0.3 lines 265-268). Requirements not stated by the customer (8.2.3 b) and expectations could enhance customer satisfaction. The distinction between known requirements and “predicted requirements” not defined nor is it clear.	Change to “b) improving products and services to meet known requirements and customer expectations.”	TAP
2835	IE	1528	10.1	The statements here are all about maintain what we do – what about new product offerings	Add new point Offering new products and service	TAP
2836	ZA	1528	10	The purpose of improvement is not the system it's the organization's business performance. This is still and has been a weakness of ISO 9000.	Improving quality management system and business performance results	TN
2837	CN	1528	10.1 c)	Replace the “results” with “performance”	Change the “c) improving quality management system results.” Into c) improving quality management system performance.	EAP
2838	NZ	1528	10.1	c) current wording might not be readily understood. Change to effectiveness.	Change c) to: c) improving <i>the effectiveness of the</i> quality management system.	TAP
2839	IT	1528	10.1	It would be appropriate to include innovation as key element for improvement.	Add the following bullet: <i>d) introduction of innovation in processes and/or products and services provided.</i>	TN
2840	SE	1528	10.1	“Quality management system results” is not a known concept and it could cause confusion. It is better to use the same expression as is used in 5.1.1 a), 9.1.3 c) and 10.3.	Replace with “effectiveness of the quality management system”.	EAP
2841	JP 158	1528	10.1	The “quality management system results” are considered to be “products and services” and defined in b).	Change to: Improving quality management system <u>to enhance its quality performance</u>	TAP
2842	ANS I	1529 -1531	10.1	The note has the potential for causing more debate than clarification since there are many interpretations on whether all of the examples listed are truly examples of improvement.	Delete Note.	TAP
2843	TT	1529 - 1531	10.1	“Innovation” is a term used to encompass the	Change “creatively (e.g. innovation)” to “creatively	TAP

				range from incremental to radical / breakthrough change (evolutionary vs. revolutionary), yet the note does not clearly describe what innovation actually is, but uses it in the context of creativity only. Innovation (from J. Schumpeter) is classified into 5 types: new products, new methods of production, new sources of supply, the exploitation of new markets and new ways to organise business. P. Drucker identified 7 opportunities for innovation: Four such areas of opportunity exist within a company or industry: unexpected occurrences, incongruities, process needs, and industry and market changes. Three additional sources of opportunity exist outside a company in its social and intellectual environment: demographic changes, changes in perception, and new knowledge. Whichever model is used, "innovation" can happen incrementally or by "step change".	(e.g. brainstorming, experimentation)"	
2844	JP 159	1529 -1531	10.1	Useless and confusing.	Delete Note.	TN
2845	UY	1529	10.1	We think it is no clear the example that corrective action is an action for improvement, because strictly, a corrective action it is not an improvement action.	Delete of the note the corrective action as example of improvement.	TN
2846	JP 160	1529	10.1	To make the expression "Improvement can be effected reactively..." easy to understand.	Change "effected" to "done" or "achieved", for example.	EAF
2847	CN	1530	10.1 Note	It should be re-organization not re-organisation	Change the re-organisation into re-organization	EAF
2848	TH	1530	10.1	"step change" should read "radical change".		TN
2849	SE	1530	10.1	Recognized practice in ISO standards.	Spell "organization" with "z".	EAF
2850	NO	1531	10.1	Experiences in previous projects are important inputs when designing new projects. Add a new Note 2 on "lessons learned"	Add a Note: Note 2 Basis for improvement could be to actively seek and record lessons learned as basis for improvements.	TN
2851	SE	1532 -1550	10.2	It is motivated to include a remark in 10.2 stating that requirements in respect of nonconforming	Add a NOTE: "Requirements in respect of nonconforming process outputs are outlined in	TN

				process outputs are laid down in 8.7.	8.7"	
2852	ANS I	1532	10.2	Corrective action is not "improvement". Action taken to return a non-conformance to conformance is by definition "corrective action." It should not be allowed for organizations to demonstrate improvement by only corrective action.	Move entire section to after section 8.7	TN
2853	PH/ BPS	1532	10.2	It is clear in expressing the requirement that nonconformity be addressed with both corrections and corrective actions.		C
2854	NG	1532	10.2	There is the need to link 10.2.1 to 8.7, harmonise the texts in the two sections and if possible explain justification for the inclusion of both in two separate areas. There is contradiction at the moment when interpreting and applying the two	There is the need to rework the two sections for the purpose of harmonizing them. The title with nonconformity appearing under subclause 10.2, 1532 is definitely referring to process/system nonconformity is also dealt with under subclause 8.7 partly and product related issues as the second part. One good option is to amend subclause 10.2 to read "handling of customer complaints' only while 8.7 will exclusively deal with internal process issues, (NC from process inputs and outputs), products and services	TN
2855	CQI 67	1532 and 1533	10.2	Nonconformity and corrective action There is no provision for planned corrective actions i.e. action prior to a nonconformity. For example, since the Standard is proposed as a single management system, equipment, can have cycles of planned shutdowns or through 'monitoring' to avoid non-conformance	10.2.1 When a nonconformity occurs, or could potentially occur , including those arising from complaints, the organization shall:	TN
2856	INLA C	1533	10.2.1	Is important to maintain the current intent of ISO 9001:2008 in clause 8.5.2 a). Any customer complaint shall be an input for the corrective action process.	Change: When a nonconformity occurs, including any customer complaint , the organization...	TN
2857	CA- 76	1533	10.2.1	10.2.1 When a nonconformity occurs , including ... - There is no title for paragraph	Add sub-title Addressing non-conformities and corrective action	TN
2858	CH	1533	10.2.1	Nonconformities do not 'arise from' complaints, but can be the origin of complaints.	<u>Change</u> to read: "... including those which THOSE WHICH ARE THE SUBJECT OF complaints ..."	TN
2859	IT	1534 -1535	10.2	Add a cross-reference to clause 8.7.	Modify bullet list as follows: [...] <i>a) react to the nonconformity, and as applicable:</i> <i>1) take action to control and correct it (see 8.7);</i> [...]	TN
2860	IAQ	1534	8.7	The clause 8.7 covers partly this clause	Add text - Improve	TN

	G				Proposal: bullet a) to add the link to the clause 8.7 : a) react to the nonconformity, and as applicable (see clause 8.7)	
2861	LU	1534	10.2.1	The sentence is not clear with the term “ as applicable”	react to the nonconformity, and as applicable	TN
2862	LC	1534	10.2.1 (a)	Possibly use “ respond to the nonconformity.....” and not “ react to.....”, as the response to the nonconformity, signals some level of preparedness, if the risk-management approach is being adopted.	Change the word ‘react’ to ‘respond’	TN
2863	ANS I	1536	10.2.1	The words “deal with the consequences” are very slangy. Suggest “manage any consequences” instead.	“manage any consequences”	TN
2864	ANS I	1536	102.1	The US TAGs to 176 and 207 Liaison Group recommends alignment between the two standards with respect to the following: -Implement action needed Rational: Clarify that first one must determine the action needed, then implement it. Further, consistent with the title of this clause, clarify that it is ‘corrective action’ that is intended.	For 9001: c) <u>determine and</u> implement any action needed; For 14001: no change	TN
2865	IAQ G	1536	10.2.1(A)2	What does “deal with the consequences” mean? Is this consequences of the actual nonconformity or the corrective action? Litigation? Enforcement? This is very vague? What action, behaviour or attribute do we want here?	Add definition - clarify Proposal: Need further clarification or definition of “ <u>deal with the consequences</u> ”.	TN
2866	AU	1536	10.2.1 a) 2)	This is colloquial English and should be avoided. Will confuse non-native English speakers	Replace with, ‘address the consequences of the nonconformity.’	TN
2867	CA-77	1536	10.2.1	“Deal with the consequences” – “deal” is a colloquial term	Change to “address the consequences”	TN
2868	IAQ G	1537	10.2.1	The requirement states: “review the effectiveness of any corrective action taken;” This could be interpreted as a requirement to review the effectiveness of all corrective actions taken within and organization. This could almost be a logistical impossibility depending on the size and number of corrective actions taken within a given organization.	Reword – clarify Proposal: d)monitor the effectiveness of corrective actions taken within the organization;	TN
2869	FR	1537	10.2.1	Add a bullet after bullet b) to define the verification criteria for the effectiveness of the corrective action.	Add a bullet after bullet b) to define the verification criteria for the effectiveness of the corrective action.	TN
2870	CO	1539	10.2	Delete numerals 1), 2) and 3), the text in b is	Delete:	TAP

				enough. Some of them can create confusion like reviewing the nonconformity.	1) reviewing the nonconformity; 2) determining the causes of the nonconformity 3) determining if similar nonconformities exist, or could potentially occur	
2871	NL	1539	10.2.1	A non- conformity means a difference between reality and a planned situations (requirement, objective). It is important the organisation reaches consensus about the real problem to determine the right action to eliminate the cause.	Add Ensure a clear description of the nonconformity is available, consisting of at least: 1) a statement of the problem 2) the requirement from which the situation deviates 3) objective evidence of the deviation	TN
2872	CQI 68	1540	10.2.1	2) determining the causes of the nonconformity Consideration should be given, not just to nonconformity, but also to relevant trends.	2) determining the causes of the nonconformity and analysing any relevant trends	TN
2873	ANS I	1542		"Implement any action needed" does not include the concept of proportion.	"implement actions appropriate to the effects of the nonconformities encountered."	TN
2874	IAQ G	1542	10.2.1 e)	Regarding "make changes to the quality management system, if necessary.", since corrective action may be affected by not only QMS change but also its processes change on the basis of the requirements of process approach in clause 4.4, it should be clarified.	Add text - Improve Proposal: Change as follows. "e) make changes to the quality management system <u>and its processes</u> , if necessary."	TN
2875	AU	1543	10.2.1 d)	There needs to be a time element. Many organizations do not leave enough time for the CA to bed in and prematurely close the nonconformity.	Insert 'following a planned period of implementation' before 'review the effectiveness of any corrective action taken.'	TN
2876	NL	1544	10.2.1	A relation (link) to 6.1 is missing. 1537-1544 should also require a review of the risks addressed in 6.1.1.	Add f) review and, where necessary, revise the addressed risks and actions in 6.1.1 and 6.1.2	TAP
2877	DK	1546	10.2.1	The note is not needed.	Delete the note: "NOTE 1 In some instances, it can be impossible to eliminate the cause of a nonconformity"	TAF
2878	IAQ G	1546	10.2.1	The NOTE 1 is confusing	Add text - clarify Proposal: To add a sentence as follows : NOTE 1 In some instances, it can be impossible to eliminate the cause of a nonconformity. <u>In that case the risk of continuing provision of products or service should be evaluated and appropriate action taken.</u>	TAP

2879	ZA	1546	10.2.1 Note 1	"can be impossible" means that an organization is not able to. May be the organization is able to but it is not possible at that point in time for technology or economic reasons. If so then permission should be requested from the customer.	Change "can be impossible" to "may not be possible"	TAP
2880	UY	1546	10.2.1	We think that is better say that the cause of a nonconformity couldn't be under the organization control, than in some instances it can be impossible to eliminate a cause of nonconformity. In this way it is inducing the organization to take action to mitigate the effect of the cause that <u>they</u> can't eliminate. If we say that there are causes that can not be eliminate, we are inducing the organization does not take an action on them.	Replace "...it can be impossible to eliminate the cause of a nonconformity" by "it can be out of the organizational control to eliminate a cause of a nonconformity".	TAP
2881	JP 161	1546	10.2.1	Useless and confusing.	Delete Note 1.	TAF
2882	NL	1547	10.2.1	Some users of the standard do not understand that one nonconforming product or service directly mean that there is a process nonconformity. Clarification is needed because users might start (process) corrective actions in situations where this in not necessary.	Add Note 3: One incidental nonconforming product does not necessarily mean a process nonconformity.	TN
2883	SE	1547	10.2.1	NOTE 2 Corrective action can reduce the likelihood of recurrence to an acceptable level. The use of "can" is too passive.	Delete NOTE 1 and 2 and change to: New "NOTE 1 The aim of corrective action is to eliminate root cause of the nonconformity or if that is not possible reduce the likelihood of recurrence to an acceptable level."	TN
2884	JP 162	1547	10.2.1	Useless and confusing.	Delete Note 2.	TAF
2885	BG	1548	10.2.2	Change this requirement: "The organization shall retain documented information as evidence of."	To become: 'The organization shall maintain documented information to the extent necessary to support the operation of processes and retain documented information as evidence of:	TN
2886	CA- 78	1548	10.2.2	10.2.2 The organization shall retain documented ... - There is no title for paragraph	Add sub-title Documenting non-conformities and corrective action	TN
2887	IE	1549	10.2.2	Make three bullet points	A) The nature of the nonconformities B) Any subsequent actions taken C) The results of any corrective action	TN

2888	AU	1552 -3	10.3	One needs to review the suitability of the system to decide whether to improve it	Change to: 'The organisation shall review the suitability, adequacy and effectiveness of the quality management system to determine whether there is need for improvement'	TN
2889	PH/ BPS	1551	10.3	It helps QMS users to identify areas of underperformance and helps top management identify where they need to plan more improvements to their QMS.		C
2890	IQN et	1551	10.3	Scope of the standard explicitly refers to consistently provide P&S according to requirements, but nowhere in improvement section the need to improve consistency of results is addressed being this one of the core areas of quality management .	add Note: Continual improvement can include actions to increase consistency of process outputs, products and services, as for example actions to increase level of conforming outputs and reduce process variance.	TN
2891	IIOC	1552 /1553	10.3	If the required improvement shall be in these dimensions like suitability, adequacy and effectiveness, auditor may be confused about what kind of evidence shall be collected. Based on QS9000 experience before, auditee may have to demonstrate the improvement on the three dimensions.	Change to "the organisation shall continually improve its quality management system".	TN
2892	FR	1552	10.3	Complete the first paragraph	The organization ... of the quality management system and its processes	TN
2893	ANS I	1554	10.3	The term underperformance has the potential for being misinterpreted and is not used anywhere else. Underperformance could be one month or six months, but this requirement does not provide enough flexibility. Additionally, this data is looked at in management review and opportunities for improvement is an output from management review so this requirement could actually be deleted.	Revise with consistent language in 9.1.3 The organization shall consider the outputs of analysis and evaluation, and the outputs from management review, to confirm if there are areas of underperformance <u>is a need for</u> or opportunities for continual improvement. Option 2 The organization shall consider the outputs of analysis and evaluation, and the outputs from management review, to confirm if there are areas of underperformance or opportunities for continual improvement. Option 3 - Delete requirement.	TAP
2894	MX	1554	10.3	The organization shall consider the outputs of analysis and evaluation	The organization shall consider the outputs of analysis and evaluation (see 9.1.3)	TN
2895	CO	1554	10.3	Improvement is not going from underperformance to better performance, it is enhance performance.	Change underperformance by where the performance could be improve.	TN

				.	The organization shall consider the outputs of analysis and evaluation, and the outputs from management review, to confirm if there are aspects where the performance could be improve or opportunities that shall be addressed as part of continual improvement	
2896	BR	1555	10.3	The standard is process oriented, "areas" is an alien term.	Management review, to confirm if there are areas processes of underperformance or opportunities that shall be.	TAP
2897	MX	1555	10.3	management review, to confirm if there are areas of underperformance or opportunities that shall be	management reviews and audits , to confirm if there are areas of underperformance or opportunities that shall be RATIONALE: Audits may be also a source to identify potential improvements	TN
2898	DE	1555	10.3	Please check the given wording. The used term "underperformance" is not clear should be avoided. Where does underperformance start? The organization shall consider the outputs ... from management review, to confirm if there are areas of underperformance ... The use of the "confirm" in this context appears to be wrong. Check wording!	Please reword line 1555: ...to identify opportunities or areas where the performance needs to be improved that... And line 1557/8 Where applicable, the organization shall select and utilize appropriate tools and methods for supporting continual improvement.	TAP
2899	CH	1555	10.3	The organization shall consider the outputs ... from management review, to confirm if there are areas of underperformance ... The use of the "confirm" in this context appears to be wrong. Check wording!	The organization shall consider the outputs ... from management review, <i>in order to find out</i> if there are areas of underperformance ...	TAP
2900	JP 163	1555	10.3	The expression "underperformance" is ambiguous.	Change to: "under-expectation quality performance"	TAP
2901	PL	1555 and 1558	10.3	The word "underperformance" is not clear, nor precise. From definition it is "measurable result" so some qualifier is needed like under planned performance or expected performance	"...if there are areas of underperformance <u>out of intended/ assumed / expected performance</u> or opportunities that shall be addressed as part of continual improvement..."	TAP
2902	ANS I	1557 -1558	10.3	The term underperformance has the potential for being misinterpreted and is not used anywhere else. Underperformance could be one month or six months, but this requirement does not provide enough flexibility. In addition, the phrase "investigation of the	Where applicable, the organization shall select and utilize applicable tools and methodologies for investigation of the causes of underperformance and for supporting continual improvement.	TN

				causes implies causal analysis as it related to nonconformity and corrective action.		
2903	IE	1557 - 1558	10.3 Lines	Clause 10.3 lacks a focus on the need to ensure that all actions taken for continual improvement need to be effectively controlled.	Expand lines 1557-1558 as follows: The organization shall select and utilise appropriate tools and methodologies to ensure that actions, whether reactive or proactive, that could otherwise compromise the integrity of the quality management system are adequately controlled.	TN
2904	IIOC	1557 1558	10.3	"Where applicable" will lead to confusion and non-uniform application. Where applicable, utilise applicable - in same sentence ? does not read correctly. Continual improvement – where applicable?	Remove the words "where applicable" and "continuous" for clarity and ease of interpretation.	TN
2905	SE	1557	10.3	Same practice as for "organization".	Spell "utilize" with "z".	EN
2906	JP 164	1557	10.3	The term "methodology" is not used in the requirements. For consistency.	Change "methodology" to "method."	TN
2907	FR	1557	10.3		Delete the 3rd §	TAF
2908	PH/ BPS	1560 -1692	Annex A	Section "A" items are helpful guide to QMS users, consultants and external auditors to prevent exaggeration of actions or expectations what to include within the QMS.		C
2909	ANS I	1561	Annex	The annex is listed as informative. During discussion in Versailles, it was determined that the annex would be normative so that it could be used as clarification for users.	Revise informative to normative.	TN
2910	CZ	1564 -1580	A.1	For better understanding of the standard text we recommend to add an analogous text as in ISO/DIS 14001.	See ISO/DIS 14001:2014, Annex A.3, lines 674-718.	TN SC1 maintains a Glossary as well as defined terms. Issues raised by TGs included in Annex A.
2911	JP 165	1568 - 1569	A.1	For better clarification of the intent of the standard.	Change to: ...structure and terminology do not <u>require</u> to be reflected...	TAP

2912	AU	1574	A.1	Add an extra sentence to suggest that it is preferable to design the management system around the organisation's processes	Add: It is preferable that the organisation's quality management system is designed around the processes used to design and produce the products and services that it delivers.'	TAP
2913	TN	1576	Annexe A	According to paragraph 4, we do not require agencies to use in their systems, the terms defined in this standard ... That would mean they are not in themselves a requirement. Is it really the case for such a standard?	Delete this paragraph	TN.
2914	TC69	1579-1580	A.1	The line should not consist of only a bracket and a dot, but a word, a bracket and a dot: "rather than "documented information"; or 'supplier', 'partner', vendor etc. rather than 'external provider')."	""rather than "documented information"; or 'supplier', 'partner', vendor etc. rather than 'external provider')."	EAF
2915	MX	1579	Annex A	Missing a comma	... or 'supplier', 'partner', vendor, etc. ...	EAF
2916	CZ	1579	A.1	Inconsistent and missing quotes.	To be corrected and added.	EAF
2917	PT	1580	10.3	Continual improvement as stated in 10.3 creates confusion with note in 10.1 that puts continual improvement as solely incremental. Paragraph 2 and 3 of 10.3 do not address the concept of continual. Therefore combination of 10.1 and 10.3 is confusing and a repetition. The title does not address the revision of QMP but we acknowledge the need to keep HLS	In 10.3 move paragraph 2 and 3 to 10.1 In 10.3 change to: The organization shall continually improve the suitability, adequacy, and effectiveness of the quality management system, as outlined in 10.1.	TN
2918	PT	1580	10.3	Scope of the standard explicitly refers to consistently provide P&S according to requirements, but nowhere in improvement section the need to improve consistency of results is addressed being this one of the core areas of quality management . We consider relevant to address this specific issue in the context of continual improvement	After "Where applicable, the organization shall select and utilise applicable tools and methodologies for investigation of the causes of underperformance and for supporting continual improvement" add Note: Continual improvement can include actions to increase consistency of process outputs, products and services, as for example actions to increase level of conforming outputs. (see our previous comment to change part of 10.3 to 10.1).	TN 9002
2919	IIOC	1582		Table B.1 Exclusions Not Used (See Annex A.4 for clarification of applicability)	Table B.1 Exclusions Not Used (See Annex A.5 for clarification of applicability)	EAF
2920	INLAC	1582	Annex A	Revise the references in the table.	Change to Table A.1 (B.1 is incorrect) and it must be Annex A.5 in exclusions row.	EAF

2921	BR	1582	A.1	The references are mistaken	Replace: 1) Title "table B. 1" by "table A. 1"; 2) The mention of "A.4" by "A.5".	EAF
2922	ANS I	1582	A.1	There are some differences in terminology that should be added.	Management Representative – Requirements are not specific to one individual but all of management Quality Manual – Documented Information	TAF
2923	IN	1582	Annex-A	Justification- Correct reference	We may refer to A.5 for exclusions, in place of A.4 .	EAF
2924	ID	1582	Annex A	inappropriate reference of A.4 Clarification of applicability	change A.4 to A.5 Clarification of applicability	EAF
2925	IAQ G	1582	A.1	Table B.1 label is incorrect.	Reword - editorial Proposal: Table label should be A.1	EAF
2926	IAQ G	1582	A.1	Annex reference A.4 in table is incorrect.	Reword - editorial Proposal: Annex reference should be A.5	EAF
2927	PE	1582	A.1	The identification of the table (B.1) does not correspond to the section (A)	It should say: <i>Table A.1</i>	EAF
2928	TN	1582		Replace "(see Appendix A.4 for a clarification of the applicability)" with "(see Appendix A.5 for a clarification of the applicability)"		EAF
2929	PT	1582		See Annex A.4 for clarification of applicability	See Annex A.5 for clarification of applicability	EAF
2930	PT	1582		See Annex A.4 for clarification of applicability	See Annex A.5 for clarification of applicability	EAF
2931	IQN et	1582	Annex A	wrong letter in the title	Table A.1	EAF
2932	IQN et	1582	Annex A	wrong reference	See Annex A.5 for clarification..	EAF
2933	AR	1582	Annex A	Table B.1, B.1 is wrong.	Should be Table A.1	EAF
2934	AR	1582	Annex A	Not used (See Annex A.4 for clarification of applicability), A.4 is wrong.	Not used (See Annex A.5 for clarification of applicability)	EAF
2935	IR	1582	Annex A	The reference made to the Annex A.4 in Table B.1 is not correct and instead reference is to be made to the sub-clause A.5 of the Annex A.	Read the text in the second row and second column as follows: "Not used (See A.5 of the Annex A for clarification of applicability)".	EAF
2936	HU	1582	A.1	The identification of the Table is incorrect (Table B.1).	Correct identification: Table A.1	EAF
2937	HU	1582	A.1	The reference to the identification of Clause of Applicability is incorrect (Annex A.4).	Correct identification: Annex A.5	EAF
2938	AU	1582			Change table designation to Table A1	EAF
2939	ZA	1582	Table B1,	Incorrect numbering of Annex	Change "A.4" to "A.5"	EAF

			Row 3						
2940	CA-79	1582	Annex A.1	Table is identified as “B.1”, but it is in Annex A. It should be Table A.1 The entry for “Exclusions” indicates: “(See Annex A.4 for clarification of applicability)”. Reference should be to Annex A.5	Change to “Table A.1” Change to: “(See Annex A.5 for clarification of applicability)”	EAF			
2941	CH	1582	A.1	Table B.1 is wrong	Change to table A.1	EAF			
2942	CH	1582	A.1	Exclusion: link to A.4 is wrong	Change link to A.5	EAF			
2943	NZ	1582	Annex A	Table wrongly labelled	Change B.1 to A.1	EAF			
2944	IT	1582	A.1	Editorial mistakes.	“Table B.1” should be “Table A.1”. Replace reference to A.4 with A.5.	EAF			
2945	CZ	1582		Table indicated incorrectly.	A.1 should be used.	EAF			
2946	CZ	1582	A.1	Incorrect reference for exclusions (2 nd line) in the column for ISO 9001:2015	A.5 should be used.	EAF			
2947	JP 166	1582	A.1 table	Numbering is incorrect.	Change “Table B.1” to “Table A.1.”	EAF			
2948	JP 167	1582	A.1 table	Numbering is incorrect.	Change A.4 to A.5.	EAF			
2949	FR	1582	Annexe A	Error in reference table A1 not table B1 Erreur de N de §	Remplace Annexe 4 by Annexe 5 Replace reference of chapter 7.1.5 by 7.1.6	EAF			
2950	AU	1583		Add an extra row to the table to include measuring equipment	Add <table border="1"><tr><td>Measuring & monitoring equipment</td><td>Measuring & monitoring resources</td></tr></table>	Measuring & monitoring equipment	Measuring & monitoring resources	TAF	
Measuring & monitoring equipment	Measuring & monitoring resources								
2951	JP 168	1583	A.1	To be consistent with the explanation in L1668.	Change “Documentation” to “Documented procedure.”	TAP			
2952	CQI 69	1584	Annex A.1	Adopt the ISO DIS 14001 Annex A.3 for clarity and consistency.	A.3 Terms and definitions The terms that are defined in Clause 3 have a specialized technical meaning and are normative for use in this International Standard. This clause provides further explanation of some of the words that are commonly used in management system standards, to help the user understand their implications and to help in translations. - ‘Programme’: planned series of steps, projects or activities to be carried out. - ‘Design’: working out the form, fit or function of something. - ‘Purpose’: anticipated (intended or expected) outcome that guides planned actions. - ‘Determine’: establish or find out.	TN			

				- 'Define': state or describe exactly the nature, scope or meaning of that which is under consideration. - 'Identify': establish the identity of something. To avoid misunderstanding, clarifications of selected concepts are provided below. - 'NOTES' included in the various clauses of this International Standard are informative. - 'Continual' indicates duration that occurs over a period of time, but with intervals of interruption (unlike 'continuous' which indicates duration without interruption). 'Continual' is therefore the appropriate word to use in the context of improvement. - The word 'consider' means it is necessary to think about but can be rejected; and 'take into account' means it is necessary to think about but cannot be rejected. - The words 'appropriate' and 'applicable' are not interchangeable. 'Appropriate' means suitable (for, to) and implies some degree of freedom, while 'applicable' means relevant or possible to apply and implies that if it can be done, it should be done. - This International Standard uses the term 'interested party', the term 'stakeholder' is a synonym as it represents the same concept. - The word 'ensure' means the responsibility can be delegated, but not the accountability to make sure that it is performed. This International Standard uses some new terminology. A brief explanation is given below to aid both new users and those who have used prior editions of this International Standard. - 'Documented information' replaces the nouns 'documentation' and 'record' used in prior editions of this International Standard. To distinguish the intent of the generic term 'documented information', this International Standard now uses the phrase 'retain documented information as evidence of....' to mean records, and 'maintain documented information' to mean documentation other than records. The phrase "as evidence of...." is not a requirement to meet legal evidentiary requirements; its intent is only to indicate	
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					- objective evidence needs to be retained. The change from 'identify' to 'determine' is intended to harmonize with the standardized management system terminology, not to change the intent of the previous edition of this International Standard. The term 'determine' implies a discovery process that results in knowledge. - The term 'intended outcome' means what the organization intends to achieve by implementing its environmental management system, which includes enhancement of environmental performance, conformance to compliance obligations and fulfilment of environmental objectives. These are the minimal, core outcomes, and organizations can set additional intended outcomes for their environmental management system. - The use of the word 'any' implies selection and choice.	
2953	JP 169	1587	A.2	Single quotation mark is used.	Change "product" to "product".	EAF
2954	TT	1589	Annex A.2	An output category is information/data which should be included.	Add:(hardware, services, software 'information/data' and processed materials).	TN
2955	BG	1592 -1593	A2.	To explain the characteristic of Services and the requirements for the design and development of services add the provided additional text.	Additional text: "The non-applicability of design and development process to services cannot be justified."	TN
2956	CA-80	1597	Annex A.2	"...where, for example, a tangible product ...an intangible service has some associated tangible product." Although this is an example, it can be misleading, especially in the implied restriction that 'intangible services' would only have associated 'tangible products'. In this age, especially in the ever-increasing delivery of products (especially, software) via the internet, are more prevalent. Very frequently, a "service" is provided by such "intangible products", and will become even more frequent in the future.	Change to: "The organization needs to take into account where, for example, a tangible or intangible product has some associated intangible service or an intangible service has some associated tangible or intangible product."	TAP
2957	BR	1599	10	Innovation is mentioned several times along the text and defined, but not detailed anywhere. Furthermore, DESIGN SPEC. ANNEX A - ISO 9000 User Survey Report (SC2/N1017), fig. 113.3 - How important is it to incorporate the following concepts into ISO 9001? results were INNOVATION: 65% Positive and 24% Negative	Add clause 10.4 - Innovation The organization shall have innovation as a strategic policy, fostering it both internally through its people, and when relevant interacting with other interested parties such as customers and suppliers to innovate goods, services, processes and management practices in order to consider: a) changes in customer needs and expectations	TN

					b) changes in internal and external organizational context c) other relevant changes	
2958	ANS I	1600	A.3	The title is listed as the context of the organization, but the explanation is more related to clause 4.2 Understanding the needs and expectations of interested parties.	Option 1 Add content related to context of the organization. The organization is responsible for determining external and internal issues that are relevant to the organization. They will vary from organization to organization based on the product or service being provided. This is frequently the business environment of the organization. ISO 9001 requires that these issues be determined based on the strategic direction of the organization. While strategic planning is not a requirement of the standard, if your organization has a strategic planning method in place, it can be used to determine the external and internal issues of the organization. Option 2 The title should be relabelled as Interested parties if no change to content is made.	TAP
2959	GB	1605	A.3	Potential confusion over use of the word “issue” concerning context of the organization.	Suggest adding the following sentence to the end of this first paragraph of A.3 to clarify: “Issues can be seen as many events that can have a positive and negative effect on the QMS. An issue can be seen as a subject that people discuss or argue about, especially relating to political, economic, societal and technological effects on the organization, or a problem or threat that needs to be considered.	TN
2960	JP 170	1611	A.3	Is “in part” necessary?	Delete “in part.”	TAP
2961	JP 171	1612	A.3	“products and services” To be consistent with the description of Scope.	Change to “products <u>or</u> services.”	TN
2962	ANS I	1617	A.3	This explanation seeks to reduce the scope of the requirement in section 4.2 with respect to interested parties. However, the implication is that the organization has to actively deem a third party to be irrelevant before that interested party's requirements can be dismissed.	Change the wording to: “There is no requirement in this International Standard for the organization to consider interested parties which have <u>not</u> been determined by the organization to be relevant to its quality management system.”	TN
2963	CH	1618 , 1620	A.3	Whether ‘relevant’ (or not) is a <u>decision</u> . In the context of this paragraph, the meaning of	<u>Change</u> to read: “... which have been DECIDED ON by the”	TAP

				the words 'determined' (L1618) and 'Determining' (L1620) does not match the definition in 3.67.	"DECIDING what is relevant ..." "The organization can DECIDE ON additional needs ..."	
2964	CQI 70	1623	Annex A.3	Determining what is relevant or not relevant is dependent on whether or not it has an impact on the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements or the organization's aim to enhance customer satisfaction. It should be explicit that it is the organization that decides what is relevant.	Add after line 1623 It is the organization that decides what is and is not relevant.	TAP.
2965	IQNet	1627	A.3	needs is missing	..to satisfy interested parties' needs beyond what is required by this International Standard.	TAP
2966	ANSI	1629	A.4	Risk-based approach is the incorrect terminology.	Risk-based approach <u>thinking</u>	TAF
2967	PL	1629	A4.3	Informative Annex We suggest to add, that "organizational context" is included in 3 clauses, also in 4.3 Determining the scope of quality management system		TN
2968	JP 172	1629	A.4	"Risk-based approach" To be consistent with the description in 0.5.	Change to "Risk-based thinking."	TAF
2969	FR	1629	A.4	Add some examples of the main requirements that have been deleted, in reference to paragraph 3 of A.4	Add some examples of the main requirements that have been deleted, in reference to paragraph 3 of A.4	TAF
2970	ANSI	1631-1632	A.4	The current text is technically incorrect and will potentially lead to misunderstanding or misinterpretation by users.	This International Standard requires the organization to establish its context (see clause 4.1) and explicitly address uncertainties which can result in positive or negative consequences to the organization's objectives (see clause 6.1).	TN
2971	CQI 71	1632	Annex A.4	...determine the risks and opportunities... Change all instances of 'risks and opportunities' to 'opportunities and risks' to emphasize the positive nature of a Quality Management System. See CQI General comment.	...determine the the risks and opportunities and risks...	EN
2972	ANSI	1634-1637	A.4	The current text is technically incorrect and will potentially lead to misunderstanding or misinterpretation by users.	One of the key purposes of a quality management system is to act as a preventive tool. Consequently, this International Standard does not have a separate clause or sub-clause titled 'Preventive action'. The concept of actions to address potential nonconformities is expressed	TAP

					through the integration of risk-based thinking into quality management system requirements.	
2973	JP 173	1636	A.4	"Risk-based approach" To be consistent with the description in 0.5.	Change to "Risk-based thinking."	TAF
2974	ANS I	1639 -1640	A.4	The current text is technically incorrect and will potentially lead to misunderstanding or misinterpretation by users.	The risk-based thinking required in this International Standard has provided a method to reduce some prescriptive requirements and replace them performance-based requirements.	TAP
2975	JP 174	1639	A.4	"Risk-based approach" To be consistent with the description in 0.5.	Change to "Risk-based thinking."	TAF
2976	JP 175	1639	A.4	"The risk-based approach <u>to drafting this International Standard</u> " Is "to drafting this International Standard" necessary? The sentence is understandable without it.	Delete "to drafting this International Standard" to read: <u>Application of the risk-based thinking to this international Standard has facilitated...</u>	TAP
2977	ANS I	1642 -1643	A.4	The current text is technically incorrect and will potentially lead to misunderstanding or misinterpretation by users.	Although uncertainties and their effect(s) have to be determined and addressed, there is no requirement for formal risk management or a documented risk management process.	TN
2978	CZ	1642 -1643	A.4	This paragraph is quite confusing. It could be interpreted by clients that it is not necessary to implement this approach It would be more appropriate to guide the standard users towards optimal application of the approach which is consistent communicating significant risks, sharing awareness about the risks and the allocation of responsibilities for their treatment.	To be amended as follows: "formal risk management method..." or "Although risks and opportunities have to be determined and addressed, there is no requirement for using formal methods for risk management or a documented risk management process."	TAP
2979	CA- 81	1642	A.4	Lines 1642 – 1643; this does not agree with the presentation provided. Where is risk addressed in ISO 9001:2015 i.e. Clauses 4, 5, 6, 8, 9 and 10. See also 0.3	Delete these 2 lines	TN
2980	ANS I	1647 -1658	Annex A.5	This section, which clarifies applicability, and specifically mentions that exclusions are no longer required is not specific enough in providing the information where the requirements in this annex section are addressed.	At the end of P1 add a sentence These requirements are addressed in clause 4.3 Determining the scope of the quality management system	TAP
2981	GB	1647	A.5	"no longer makes reference" is illogical	Change to: "This International Standard does not make reference to "exclusions" (as per ISO	TAP

					9001:2008, clause 1.2) when ..."	
2982	CH	1647 , 1654, 1655	A.5	Whether 'applicable' (or not) is a <u>decision</u> (refer to line 1654). In the context of this paragraph, the meaning of the words 'determining' (L1647) and 'determine' (L1655) does not match the definition in 3.67.	<u>Change</u> to read: (L1647) "...when DECIDING ON the applicability.." (L1655) "... the organization can DECIDE that."	TAP
2983	CQI 72	1651	Annex A.5	...the nature of the risks and opportunities it encounters. Change all instances of 'risks and opportunities' to 'opportunities and risks' to emphasize the positive nature of a Quality Management System. See CQI General comment.	...the nature of the risks and opportunities and risks in it encounters.	EN
2984	CH	1653 -1658	A.5	Lines 1653-1658 repeat in other words what is already in 4.3.	<u>Reword</u> lines 1653-1658 to avoid repeating 4.3, but, if needed, to provide guidance on 4.3.	TAF
2985	ANS I	1654	A.5	The previous wording around "exclusions" which has been removed was better than what currently exists in this paragraph. This is very ambiguous. If this was intended to "loosen" the opportunity for exclusions	Change the wording to: "Where a requirement cannot be applied (for example where the relevant process is not carried out <u>within the scope of the organization</u>) the organization can determine that the requirement is not applicable."	TAP
2986	TC6 9	1654 , 1655	A.5	The clause beginning with "where" should be separated by a comma from the main clause: "Where a requirement cannot be applied (for example where the relevant process is not carried out) the organization can determine that the"	"Where a requirement cannot be applied (for example, where the relevant process is not carried out), the organization can determine that the"	EN
2987	ANS I	1660 -1672	A.6	This section only discussed documented information. However, information is also used.	If information is to be retained, update this annex section to describe information versus documented information.	TAF
2988	ANS I	1660	Annex A.6	This annex, which is normally not auditable and often not read, refers to maintain as needing a procedure and retain as a record. But since it is not normally auditable should these be placed in the definitions to provide a better understanding and something that could be auditable?	Revise 3.11 to include procedures is now expressed as a requirement to maintain documented information while records is now expressed as a requirement to retain documented information.	TN
2989	TC6 9	1662 , 1663	A.6	The clause beginning with "As part of the alignment.." should be separated by a comma from the main clause: "As part of the alignment with other management system standards a common clause on 'Documented Information' has been adopted..."	"As part of the alignment with other management system standards, a common clause on 'Documented Information' has been adopted..."	EAF
2990	ANS I	1664 -1666 1668	A.6	The explanation uses documented procedure which can be misleading, since the revised standard will not require procedures beyond want	Where ISO 9001:2008 would have referred to <u>specific terminology such as documents, quality manual,</u> or documented procedures (e.g.	TAP

		-1669		an organization deems necessary.	to define, control or support a process) that is now expressed as a requirement to maintain documented information.	
2991	BY	1665	Annex A.6	In the text uses the term «documented procedure», but in ISO / DIS 9000 used «procedure document».	We offer to bring these word combinations to one variant. But if there are differences in these phrases, explain them.	TN
2992	TC6 9	1668 , 1669	A.6	The clause beginning with “where” should be separated by a comma from the main clause: “Where ISO 9001:2008 would have referred to documented procedures (e.g. to define, control or support a process) this is now expressed as...”	“Where ISO 9001:2008 would have referred to documented procedures (e.g. to define, control or support a process), this is now expressed as...”	EAF
2993	AU	1668 to 1672		Delete these 2 paragraphs because they create translation problems		TN
2994	CA- 82	1669	Annex A	“Where ISO 9001:2008 would have referred to documented procedures (e.g. to define, control or support a process) this is now expressed as a requirement to maintain documented information.” So, the organization only has to maintain documented information; there is no requirement to implement documented information. This is supported by the definition of “documented information”, which states: “ <i>information</i> (3.50) <i>required to be controlled and maintained by an organization</i> (3.01) <i>and the medium on which it is contained</i> ”, which only requires the information to be controlled and maintained (which is adequate for the ‘records’ part of ‘documented information’), but does not explicitly require it to be implemented (in the case of processes related to the QMS).	Change to: “...this is now expressed as a requirement to maintain and implement documented information.”	TN
2995	PH/ BPS	1671 -1672	A.6	Why the term “records” now be referred to as “retained documented information”?	The term “records” can help users distinguish these from what are deemed documents (e.g. manuals, guidelines), especially in the application of required controls over them, such as retention period (for records), revision/edition, review and approval (for documents).	C.
2996	TC6 9	1671	A.6	The clause beginning with “where” should be separated by a comma from the main clause: “Where ISO 9001:2008 would have referred to records this is now expressed as...”	“Where ISO 9001:2008 would have referred to records, this is now expressed as ...”	EAF
2997	GB	1673	A.6	Annex A.6 does not address the removal of the requirement of ISO 9001:2008 to establish and maintain a quality manual Nor does it address the	Add: “There is no requirement in this international standard to establish and maintain something called a “Quality Manual”. The organisation is free	TN

				fact that it's removal gives far greater flexibility on how documented information is to be included in the QMS is to be formatted and communicated. Although this flexibility will be useful to all types of organisation it may be critical for small and micro organisation where the absence of hierarchical structures and the likelihood of individuals having multiple role responsibilities results in shorter and fewer lines of communications. Reflecting this aspect in the simplicity of formatting and presentation of the documented information is paramount to ensure there are cost benefits to small/micro businesses from implementation of the system.	to determine how required documented information will be presented and where it shall be located. Some organisations may opt to maintain their quality manual as a stand-alone document. Others may prefer to integrate it with other parts of the overall management system, eg in an operations manual or within their ICT system. Others, such as small/micro organisations, may use the flexibility to achieve the simplest possible format appropriate to the size and complexity of their organisation."	
2998	GB	1674	A.7	Correct clause numbering	Clause 7.1.6 Organisational knowledge addresses the need to determine and maintain ...	EAF
2999	ID	1674 , 1676	Annex A	inconsistency in using word "organisation" and "organization", "organisational" and "organizational"	change to "organization" and "organizational"	EAF
3000	BR	1676	A.7	Suggested to correct the sub clause number 7.1.5 Organisational knowledge.	7.1.6 Organisational knowledge	EAF
3001	ANS I	1676	A.7	The wrong clause number is referenced	Change 7.1.5 to 7.1.6	EAF
3002	IN	1676	Annex A (A.7)	Justification- Correct reference.	Clause no 7.1.5 to be corrected as 7.1.6	EAF
3003	16.	1676	A.7	A Syntactical correction is required	Please replace: "Clause 7.1.5 Organisational knowledge ...", with: "Clause 7.1.6 Organisational knowledge ..."	EAF
3004	CH	1676	A.7	a) 'Organizational knowledge' is not referred to in clause 7.1.5, but in 7.1.6. b) 'Organizational knowledge' is a new theme within ISO 9001 and awareness among users is sparse. The guidance presently given on what in fact constitutes 'organizational knowledge' <u>within the scope of ISO 9001</u> is presently insufficient and needs expanding.	a) <u>Correct</u> to read: "Clause 7.1.6" b) <u>Provide more guidance</u> on what in fact constitutes 'organizational knowledge' <u>within the scope of ISO 9001</u> . It could be useful to cite from or refer to ISO 9004, clause 6.7.	a) EAF b) TN
3005	TT	1676 1676 1677	A.7 A.7 A.7	Typo – Organisational knowledge is Clause 7.1.6 and not 7.1.5 Organisational Knowledge needs to be properly managed to achieve its goal. Management of OK would include maintenance as part of the process.	Change 7.1.5 to 7.1.6 Change the word 'maintain' to:the need to determine and ' <i>manage</i> ' the knowledge	EAF TAF

				Poor syntax -to ensure that 'it' can achieve conformity..... - 'it' here is misleading as it can refer to either organisational knowledge or the organization.	Change:to ensure that ' <i>the organisation</i> ' can achieve.....	EN
3006	JP 176	1676	A.7	Typo	Change "Clause 7.1.5" to "Clause 7.1.6."	EAF
3007	FR	1676	A.7	Error in reference. Knowledge management is in chapter 7.1.6	Error in reference. Knowledge management is in chapter 7.1.6	EAF
3008	CQI 73	1680	Annex A.7	...the risks and opportunities it needs to address,... Change all instances of 'risks and opportunities' to 'opportunities and risks' to emphasize the positive nature of a Quality Management System. See CQI General comment.	...the risks and opportunities and risks it needs to address,...	EN
3009	NL	1682 - 1686	A.6	Explanation of the change from documented procedure and records to documented information is not clear for the users by use of terms maintain and retain. This would cause many interpretation questions.	Better explanation needed.	TAP
3010	ANS I	1682	A.1	The wrong reference is used for the reference to applicability	Change A.4 to A.5	EAF
3011	IN	1688	A.8	The use of term "function" is not clear.	Delete the word "function" and leave as "outsource a process."	TN
3012	CH	1688	A.8	The wording "... processes <u>and</u> functions ..." is not consistent with 8.4.c).	<u>Change</u> to read: "... processes <u>and/OR</u> functions ..."	TN
3013	ANS I	1691 -1692	Annex A, A.8 Control of externally...	The intent of the current text "risk-based approach" being required is incorrect ISO 9001:2015 uses risk based thinking in its application of requirements.	The organization is required to take a risk-based approach <u>may use the requirements in 6.1 actions to address risk and its effects</u> to determine the type and extent of controls appropriate to particular external providers and externally provided products and services.	TAP
3014	UY	1691	A.8	We suggest delete this paragraph because the risk-based approach should be considerer in all processes. We think that this paragraph was including in the CD 9001, when the risk evaluation was specifically mentioned in "control of externally provided product and services" clause.	Delete the paragraph.	TN
3015	JP 177	1691	A.8	"Risk-based approach" To be consistent with the description in 0.5.	Change to "Risk-based thinking."	TAF
3016	PH/	1694	Annex B	Inclusion of the 7 quality management principles		Annex deleted

	BPS	-1762		in the text can provide ready access to users of additional references that can lead to their clearer understanding of the requirements declared in the main clauses.		
3017	AU	1694	Annex B	The text of the quality management principles in this Annex differs from the text in ISO 9000. Why didn't someone synchronise the two documents?	Synchronise with 9000 and refer to the principles agreed to by SC 1 & 2 during the voting process.	Annex deleted
3018	FR	1698	B.1	The link between the QMP's and the requirements of ISO 9001 is not explicit.	Add a table showing the link between the QMP's and the requirements of ISO 9001	Annex deleted
3019	SE	1699 -1703	Annex B	There is no reference to ISO 9000, sub-clause 2.3, where also "Key benefits" and "Actions you can take" are described for each principle.	Add after line 1703: "The quality management principles are more fully given in ISO 9000 sub-clause 2.3, where also "Key benefits" and "Actions you can take" are described for each principle."	Annex deleted
3020	IR	1699	B.1 of Annex B	The word "document" used in the first sentence of clause A.1 "This document introduces the seven quality management principles..." is to be replaced by the word "annex", as this annex is not a separate document.	Replace the word "document" by the word "annex" as follows: This document annex introduces the seven quality management principles...	Annex deleted
3021	JP 178	1699	B.1	"portfolio of" Is this necessary? The sentence is understandable without "portfolio of."	Delete "portfolio of" to simplify.	Annex deleted
3022	IT	1703	B.1	Make a reference to ISO 9000 for further information about QMPs.	Add the following sentence: <i>For further information on QMPs see ISO 9000.</i>	Annex deleted
3023	NO	1704 - 1754	Annex B	The acronym "QMP" is generally understood as "Quality Management Plan" and is used extensively within NATO-defense supplier management systems. The introduction of "QMP" as "Quality Management Principles" feels lacking and at fault. Also, the use of an undefined acronym in the headings seem unnecessary.	Replace "QMP" with "Quality Management Principles" in lines 1704, 1713, 1720, 1731, 1739, 1745 and 1754.	Annex deleted
3024	SE	1704 , 1713, 1720, 1731, 1739, 1745, 1754	Annex B	In ISO 9000 sub-clause 2.3 there is no numbering of the principles as such; there are only ordinary sub-clause numbers.	Delete the designations "QMP 1" through "QMP 7" in the titles of the principles. Use lower case letter in the beginning of all words except the first in the titles.	Annex deleted
3025	PT	1716	B.3	Text	Different from DIS 9000:2014	Annex deleted

				... the quality objectives of the organization	... the organization's quality objectives	
3026	PT	1716	B.3	Text ... the quality objectives of the organization	Different from DIS 9000:2014 ... the organization's quality objectives	Annex deleted
3027	IR	1718	B.3	The first part of item b) Rationale of clause B.3 is to be modified for the sake of consistency with the item a).	Read item b) as follows: Creation of unity of purpose, direction and engagement of people enable an organization...	Annex deleted
3028	CH	1718	B.3	Creation of ... enable an organization ... Check grammar.	Creation of ... enables an organization ...	Annex deleted
3029	NZ	1722	Annex B	This first paragraph does not appear in the ISO/DIS 9000 version of the QMPs. It does not appear to add to the 2 nd paragraph.	Delete P1	Annex deleted
3030	PT	1724 / 1725	B.4		The statement text differs from the text in DIS 9000:2014	Annex deleted
3031	IR	1727	B.4	The verb used in the title and item a) of clause B.4 QMP 3 – Engagement of People is "to engage". Hence, for the sake of consistency with the item a) the word "involve" in item b) is to be replaced by the word "engage".	Read item b) as follows: To manage an organization effectively and efficiently, it is important to involve engage all people at all levels and to respect them as individuals.	Annex deleted
3032	PT	1729	B.4	Text ... the objectives of the organization	Different from DIS 9000:2014 ... the organization's quality objectives	Annex deleted
3033	PT	1736 / 1738	B.5		The rationale text differs from the text in DIS 9000:2014	Annex deleted
3034	CH	1739	B	The important new aspect ' <u>Risk-based approach</u> ' is very significant, and should now be addressed as a <u>new QM Principle</u> , immediately following QMP-4, 'Process Approach'	After QMP-4 ('Process Approach') <u>add a new QMP</u> with the title 'RISK-BASED APPROACH' and transfer in text taken from Annex A.4 <u>plus</u> other suitable text.	Annex deleted
3035	SG	1745	Annex B B.7	More guidance required to clearly define what is evidence based.	To clearly identify what is evidence based: type of evidence e.g. mode or type to be valid	Annex deleted
3036	PL	1754	B 8	We suggest to add to the title" supplier" so the statement would be much more clear or "Interested party relationship management" The text of the statement saying clearly that it is about suppliers, so when we add this word, the title would be better understood, not so artificial	B 8. QMP 7 <u>Supplier</u> relationship management Or B8. QMP 6 <u>interested party</u> relationship management	Annex deleted
3037	HU	1764 -1847	Annex C	It is not clear why are not used the correct titles of ISO 10000 portfolio's standards. Sometimes the	It is suggested using the correct and full title of	TAF

				reference to the type of the standard is misleading, e.g ISO 10012 is requirement and not a guidance (see the Bibliography)	each standard detailed in the Bibliography	
3038	AT	1764	Annex C	There is no need for a description of The ISO 10000 portfolio of quality management standards. It is also against the principle of a requirement standard to provide guidance on this portfolio. No added value and inconsistent definitions in Annex C, etc.!	Delete Annex C	TN
3039	EOQ	1764	Annex C	This Annex does not add value but can cause confusion: it could create the impression, that this guidance needs to be considered, when fulfilling the requirements. Also there are errors in the table!.	Delete Annex C	TN
3040	TC4 6/SC 11 Liais on (FR)	1764	Annex C Informative	Add refs to ISO15489 and ISO30300's		TN
3041	AU	1766	Annex C	Needs to be changed as it includes standards other than the 10000 series and also includes a technical report	Change to: 'Quality Management Guidance Standards and Reports'	TAP
3042	JP 179	1767	Annex C	"portfolio of"	Change to "series."	TN
3043	MX	1775	Annex A	Use of correct and complete title of standard	ISO 10001, Quality management -- Customer satisfaction -- Guidelines for codes of conduct for organizations	EAF
3044	BE	1775	Annex C	ISO 10001, ISO 10002, ISO 10003 and ISO 10004 might be integrated in 1 document in the future.	Update overview based on ballot results according ISO 10001/2/3/4.	TN
3045	CA- 83	1775	Annex C	The full title of ISO 10001 should be used.	Add "for organizations" after "conduct".	EAF
3046	CA- 84	1776	Annex C	The term "customer satisfaction provisions" is unclear, as the word "code", included in the text of ISO 10001 between "satisfaction" and "provisions", is missing from the term.	Add "code" after "customer satisfaction" to read "customer satisfaction code provisions".	TN
3047	JP 180	1778	Annex C	Grammatical error	Change to: Its use can enhance customer confidence in an organization and improve customer understanding of what to expect from an organization, thereby	TAP

					reduce the likelihood of misunderstandings and complaints.	
3048	MX	1780	Annex A	Use of correct and complete title of standard	ISO 10002, <i>Quality management -- Customer satisfaction -- Guidelines for complaints handling in organizations</i>	EAF
3049	CA-85	1780	Annex C	The full title of ISO 10002 should be used.	Replace "Guidelines for handling complaints" with "Guidelines for complaints handling in organizations".	EAF
3050	DE	1782	Annex C	It provides an open ... For improved readability and translatability, replace "it" by "This International Standard".	ISO 10002 provides an open ...	EAF
3051	CH	1782	C	It provides an open ... For improved readability and translatability, replace "it" by "This International Standard".	This International Standard provides an open ...	EAP
3052	MX	1784	Annex A	Use of correct and complete title of standard	ISO 10003, <i>Quality management -- Customer satisfaction -- Guidelines for dispute resolution external to organizations</i>	EAF
3053	CA-86	1784	Annex C	The full title of ISO 10003 should be used.	Replace current title with "Measurement management systems – Requirements for measurement processes and measuring equipment".	EAF
3054	AU	1785-7		Move the last sentence to the second sentence	Change to: 'dispute resolution for product related complaints. Most complaints can be resolved successfully by the organisation without adversarial procedures. However dispute resolution gives an avenue of redress when organisations do not remedy a complaint internally'	EN
3055	MX	1788	Annex A	Use of correct and complete title of standard	ISO 10004, <i>Quality management -- Customer satisfaction -- Guidelines for monitoring and measuring</i>	EAF
3056	CA-87	1788	Annex C	The full title of ISO 10004 should be used.	Move "customer satisfaction" to after "ISO 10004", capitalize "C" in "customer" and add a hyphen after "satisfaction".	EAF
3057	MX	1792	Annex A	Use of correct and complete title of standard	ISO 10005, <i>Quality management systems -- Guidelines for quality plans</i>	EAF
3058	AU	1794		The words 'product realization' are leftover from the 2008 version of 9001. Need to be replaced.	Change 'product realization' to 'the provision of products and/or services'	TN
3059	MX	1797	Annex A	Use of correct and complete title of standard	ISO 10006, <i>Quality management systems -- Guidelines for quality management in projects</i>	EAF

3060	AU	1797			Change 'are' to 'is' as this refers to the standard not the guidelines.	EAF
3061	AU	1798			Change 'They' to 'The guidelines'. The way it is currently written seems to indicate that the 'They' refers to the 'projects'	EAP
3062	JP 181	1800	Annex C	"portfolio of" Is this necessary? The sentence is understandable without "portfolio of."	Delete "portfolio of" to simplify.	EAF
3063	MX	1801	Annex A	Use of correct and complete title of standard	ISO 10007, Quality management systems -- Guidelines for configuration management	EAF
3064	MX	1810	Annex A	Use of correct and complete title of standard	ISO 10012, Measurement management systems - Requirements for measurement processes and measuring equipment	EAF
3065	CA-88	1810	Annex C	The full title of ISO 10012 should be used.	Replace "external dispute resolution" with "dispute resolution external to organizations".	EAF
3066	JP 182	1812	Annex C	"compliance" Should it be "conformity?"	Change "compliance" to "conformity."	EN
3067	DE	1817	Annex C	This Technical Report may be used ... According to ISO/IEC Directives, Part 2, Annex H, the use of "may" states that it is permitted to use this TR for other managements systems. However, it is most likely that the intention was not give a formal permission, rather than to point out that ISO/TR 10013 can be used (as an option or a possibility) for other management systems. Therefore the use of "may" in this context is wrong.	Replace "may" by "can"!	EAF
3068	CH	1817	C	This Technical Report may be used ... According to ISO/IEC Directives, Part 2, Annex H, the use of "may" states that it is permitted to use this TR for other managements systems. However, it is most likely that the intention was not give a formal permission, rather than to point out that ISO/TR 10013 can be used (as an option or a possibility) for other management systems. Therefore the use of "may" in this context is	Replace "may" by "can"!	EAF

				wrong.		
3069	JP 183	1817	Annex C	Use of "may"	Change to "can."	EAF
3070	JP 184	1817	Annex C	"portfolio of" Is this necessary? The sentence is understandable without "portfolio of."	Delete "portfolio of" to simplify.	EAF
3071	MX	1820	Annex A	Use of correct and complete title of standard	ISO 10014, Quality management -- Guidelines for realizing financial and economic benefits	EAF
3072	DE	1825	Annex C	It may be used ... According to ISO/IEC Directives, Part 2, Annex H, the use of "may" states that it is permitted to apply this IS. However, it is most likely that the intention was not give a formal permission, rather than to point out that ISO 10015 can be applied.	Replace "may" by "can"!	EAF
3073	CH	1822	C	This standard is about the application of quality management principles (see previous sentence in the text).	It facilitates application of <i>quality</i> management principles ...	TN
3074	CH	1825	C	It may be used ... According to ISO/IEC Directives, Part 2, Annex H, the use of "may" states that it is permitted to apply this IS. However, it is most likely that the intention was not give a formal permission, rather than to point out that ISO 10015 can be applied.	Replace "may" by "can"!	EAF
3075	AU	1823			Change 'sustainable' to 'sustained'	TN
3076	MX	1824	Annex A	Use of correct and complete title of standard	ISO 10015, Quality management -- Guidelines for training	EAF
3077	AU	1824			Change 'and addressing' to 'to address'	EAP
3078	JP 185	1825	Annex C	Use of "may"	Change to "can."	EAF
3079	JP 186	1826	Annex C	"portfolio of" Is this necessary? The sentence is understandable without "portfolio of."	Delete "portfolio of" to simplify.	EAF
3080	SE	1829	Annex C	"...and outcome of processes..."	"...and result of processes..."	EAF

				See also general comment.		
3081	MX	1833	Annex A	Use of correct and complete title of standard	ISO 10018, Quality management -- Guidelines on people involvement and competence	EAF
3082	MX	1838	Annex A	Use of correct and complete title of standard	ISO 10019, Guidelines for the selection of quality management system consultants and use of their services	EAF
3083	AU	1844		This does not apply to one specific management system but to any management system	Change 'the management' to 'a management'	EAF
3084	DE	1845	Annex C	It is intended to apply to ... For improved readability and translatability, replace "it" by "This International Standard".	ISO 19011 is intended to apply to ...	EAF
3085	CH	1845	C	It is intended to apply to ... For improved readability and translatability, replace "it" by "This International Standard".	This International Standard is intended to apply to ...	TAP
3086	IT	1853 -1855	C.1	We appreciate Annex C and Table C.1 but we deem that some references could be more specific (too much "all" in the table).	Improve/expand Table C.1 with more specific references to ISO 10000 family of standards, also considering adding notes in specific clauses of the draft, as appropriate.	EN
3087	IN	1853 -54	Annex C	Clause No 8.4.4 does not exist in ISO/DIS 9001:2014 (E) so 8.4.4 has no relation with ISO 10007	Table C.1 needed to be reviewed for adequacy & correctness of relationship among the ISO 9001 clauses, sub-clauses and cross reference supporting technologies(ISO 10000 portfolio of quality management standards) The applicable clause is to be indicated.	EAP
3088	IN	1853 -54	Annex C	Table C.1 shows that only clause 8.4 of ISO/DIS 9001:2014 has relationship with ISO 10019. This is not adequate Since There organisations that needed assistance in various other clauses of ISO 9001 while establishing and implementing quality management system.	Table C.1 needed to be reviewed for adequacy & correctness of relationship among the ISO 9001 clauses, sub-clauses and cross reference supporting technologies(ISO 10000 portfolio of quality management standards) The applicable clause is to be indicated.	EAP
3089	IN	1853	Annex C (Table C.1)	8.2.4 clause does not exist in ISO/DIS 9001:2014 which shows any relation with ISO 10001	-Table C.1 needed to be reviewed for adequacy & correctness of relationship among the ISO 9001 clauses, sub-clauses and cross reference supporting technologies(ISO 10000 portfolio of quality management standards) The applicable clause is to be indicated.	EAP
3090	IN	1853	Annex C (Table C.1)	8.2.4 clause does not exist in ISO/DIS 9001:2014 which shows any relation with ISO 10002	Table C.1 needed to be reviewed for adequacy & correctness of relationship among the ISO 9001 clauses, sub-clauses and cross reference	EAP

					supporting technologies(ISO 10000 portfolio of quality management standards) The applicable clause is to be indicated.	
3091	TN	1853	Annexe C	Add at this table other management standards such as ISO 14001, ISO 22000 and more compatibility to facilitate the integrity of these standards		TN
3092	CA-89	1853	Annex C	In Table C.1, ISO 10005 is identified as related to §5.3 of ISO/DIS 9001. The Introduction to ISO 9005:2005 states: “quality plans provide a means of relating specific requirements of the process, product, project or contract to work methods and practices that support product realization.” Further, in §1, <i>Scope</i> of ISO 9005:2005. it states: “This International Standard is applicable to quality plans for a process, product, project or contract, any product category (hardware, software, processed materials and services) and any industry. It is focused primarily on product realization and is not a guide to organizational quality management system planning.” However, §5.3 of ISO/DIS 9001 is about “Organizational roles, responsibilities and authorities”, and only mentions ‘planning’ in regard to: “...changes to the <u>quality management system are planned...</u>”, and there is no mention of planning in regard to product and service realization, which is the focus of ISO 9005.	Remove §5.3 entry, against ISO 9005, in Table C.1	EN
3093	CA-90	1853	Annex C	In Table C.1, ISO 10005 is identified as related to §10.2 of ISO/DIS 9001. ISO/DIS 9001 §10.2, <i>Nonconformity and corrective action</i> does not use the term “plan” or any variant. Presumably, there would be some planning in relation to resolution of nonconformities and implementing corrective actions, but that is not explicitly stated in this clause. Further, if such planning was performed, it generally would not be in the form of a documented Quality Plan, as addressed by ISO 9005:2005.	Remove §10.2 entry, against ISO 9005, in Table C.1	EN
3094	CZ	1854	Table C.1	7.1.4	7.1.5	EAF

3095	MX	1854	Annex C	ISO 10012 is related to the clause 7.1.5 Monitoring and measuring resources, not to the 7.1.4 Environment for the operation of processes.	Correct to read. 7.1.5	EAF
3096	TC4 6/SC 11 Liaison (FR)	1854	Table C.1	Add refs to ISO15489 and ISO30300's		TN
3097	CA-91	1854	Annex C	Issues with the relationships indicated against various ISO standards: 1. §10.2, <i>Nonconformity and corrective actions</i> is identified against ISO 10005 (Plans), but there is nothing in the clause about planning 2. §8.4.4 is identified against ISO 10007 (Config, Mgmt.) but no such clause number exists. §8.5.2, <i>Identification and traceability</i> does address some aspects of CM 3. §7.1.4, <i>Environment for the operation of processes</i> is identified against ISO 10012, (Measurement). §7.1.5, <i>Monitoring and measuring resources</i> should be the reference 4. §7.5.1, <i>General</i> is identified for ISO/TR 10013 (Sys. Docs.). 10013 addresses preparation, control and changes to documentation, so clauses 7.5.2 and 7.5.3 also have a relationship. 5. §7.2, <i>Competence</i>, is identified for ISO 10015 (Training) but there are aspects of training ("to obtain the knowledge required") in §7.1.6, <i>Organizational knowledge</i>, as well	1. remove §10.2 against ISO 10005 2. change §8.4.4 to §8.5.2, against ISO 10007 3. change §7.1.4 to §7.1.5, against ISO 10012 4. change §7.5.1 to §7.5, against ISO/TR 10013 5. add §7.1.6 against ISO 10015	EAP
3098	CA-92	1854	Annex C	For ISO 10001, "8.2.4" is included, although it does not exist in ISO/DIS 9001. Possibly a typo referring to an earlier draft of ISO 9001. Instead, it could be "8.2.1" or the whole "8.2" (since ISO 10001 also relates to 8.2.2 and 8.2.3).	In the "ISO 10001" row, replace "8.2.4" with "8.2.1" (or with "8.2").	EAP
3099	CA-93	1854	Annex C	For ISO 10002 (just like for ISO 10001), "8.2.4" is included, although it does not exist in ISO/DIS 9001. "Complaints" are specifically mentioned in 8.2.1	In the "ISO 10002" row, replace "8.2.4" with "8.2.1".	EAF
3100	CA-	1854	Annex C	For ISO 10004, it is unclear why "9.1.1" is given,	In the "ISO 10004" row, replace "9.1.1" with	EAF

	94			when other customer satisfaction standards are linked to 9.1.2 and the text in 9.1.2 seems to clearly relate to the content of ISO 10004.	"9.1.2".	
3101	CA-95	1854	Annex C	ISO 10012 should be related to 7.1.5 instead of 7.1.4.	In the "ISO 10012" row, replace "7.1.4" with "7.1.5".	EAF
3102	CA-96	1858	Bibliography	Besides ISO/IEC 90003, the following standards also relate to ISO 9001, and should be added: ISO/IEC/TR 90005:2008 and ISO/IEC/TR 90006:2013	Add: <i>ISO/IEC/TR 90005:2008, Systems engineering – Guidelines for the application of ISO 9001 to system life cycle processes</i> <i>ISO/IEC/TR 90006:2013, Information technology - Guidelines for the application of ISO 9001:2008 to IT service management and its integration with ISO/IEC 20000-1:2011</i>	EN
3103	SE	1858	Bibliography	To address risk is a very difficult and complicated process. To help users of this standard to understand what risk is and how to address risk there should be a reference to ISO 31000 not only in para 0.5 but also in the Bibliography from this standard.	Add ISO 31000 to Bibliography.	EAF
3104	FR	1858	Bibliographie	Add ISO 31000 et ISO 26000.	Add ISO 31000 et ISO 26000.	EAP
3105	TC4 6/SC 11 Liaison (FR)	1881	Bibliography	Add refs to ISO15489 and ISO30300's		EN
3106	TC4 6/SC 11 Liaison (RU)	1881	Bibliography	Incorrect reference, see http://webstore.iec.ch/Webstore/webstore.nsf/ArtNum_PK/50049!openDocument	Replace "IEC 60300-1, Dependability management - Part 1: Dependability management systems " with "IEC 60300-1 Dependability management – Part 1: Guidance for management and application"	EAF
3107	TC6 9	1885	Bibliography	ISO 22514 series on Statistical methods in process management is missing	Add: ISO 22514 series maybe not listing each part but name it as series: "ISO 22514 (all parts)"	EN
3108	NZ	1886	Biblio	Risk management references not included but relevant to risk-based thinking.	Add ISO 31000 (and ISO Guide 73?)	EAP
3109	DE	1891	Bibliography	Please specify the source of supply for [24] and	Please add source.	EAF

		, 1893		[26].		
3110	MX	1893	Bibliography	Lack literature referenced in standard: This is mentioned in the line 478 of the page 14. This is mentioned in the line 670 of the page 19.	Add: [27] ISO Guide 73: 2009 [28] ISO 1087-1: 2000	EN
3111	IT	1893	Bibliography	The list should also make reference to ISO 31000.	Add the following reference [27] Risk management - Principles and guidelines	EAF
3112	CA-97	1894	Bibliography	Include reference to risk management ISO Guide 73.	Add: ISO/IEC Guide 73, Risk management. Vocabulary. Guidelines for use in standards	EN
3113	CQI	Annex D (New)		Add a new annex to give an alphabetical listing of terms	See below	See ISO 9000
3114	BIS	Annex D (New)		The ISO 9001 Standard shall be incorporating a risk based approach to quality for the first time. Unlike other risk based standards (ISO 14001, 27001) which are contextual and where related risks can be easily identified, ISO 9001 is generic and cuts across business sectors. It may be difficult for implementers of the revised ISO 9001 to understand and readily identify the risks to quality. It is therefore proposed that an Informative Annex may be provided in ISO 9001 for the guidance on identification of risks during various stages of the product / service lifecycle.	A document for the proposed informative annex is being submitted as a part of this comment. The document uses the approach of risk identification that appears as a requirement in Clause 5.1.2 – '(Top management shall ensure) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed' ; and clause 6.1.1 'determine the risks and opportunities that need to be addressed to: prevent, or reduce, undesired effects'. The paper identifies the typical and generic risks that may appear at six stages of the product / service lifecycle and the undesired effects it may have on the organization, customers and other interested parties.	TN
3115	DE	0.3 Fig 1		Annex 1: Figure for process approach	See below	TAF
3116	DE			Annex 2: process requirement matrix	See below	TN