A Public Call for Temporary Cessation of Work on the Development of ISO 9001:2015

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PREAMBLE

Oxebridge is calling on ISO Technical Committee 176 to place a temporary hold on development of ISO 9001:2015 to consider the views of all stakeholders. This is based on observation of four critical points of convergence: first, that the current work to date was done without the guidance of the Quality Management Principles which are intended to act as the standard's foundation. Second, that early feedback on the ISO 9001:2015 Working Draft show a strong level of dissatisfaction with the direction and content the TC has taken with the standard. Third, that major international industrial sectors, including those for automotive and aerospace, are so frustrated by the development of 9001:2015 they have considered "decoupling" from ISO entirely. And, finally, that analysis of twenty years' of ISO Survey data shows decreasing usage and interest in ISO 9001, and increasing abandonment of it, indicating unmistakable user dissatisfaction.

POINT 1: LACK OF QUALITY MANAGEMENT PRINCIPLES

In May 2011, Chairman of TC 176 SC2 Nigel Croft mapped the design plan for the upcoming ISO 9001:2015 revision process, at the Tenth IRCA International Forum in Yokohama Japan. During that presentation, Dr. Croft indicated that possible – albeit by no means guaranteed – concerns would include:

- Risk management
- More emphasis on the Quality Management Principles
- Aligning product conformity and process effectiveness
- Recognizing different customer categories
- Knowledge management
- Life cycle management
- Improvement and innovation
- "Time/Speed/Agility"
- Technology advances
- Incorporation of 6σ, QFD, benchmarking etc.

He assured the conference attendees that work on the new standard "can only begin after the formal ISO systematic review process" and said, "we are doing a lot of strategic thinking and planning for the future."

Of special import were the Quality Management Principles, first introduced during development of ISO 9001:2000. At that time they provided the foundational elements for the development of ISO 9001, and Dr. Croft said they would do so again, after revision. He said that the QMP's must be one of the first tasks conducted, and so SC2 had met in Dec 2010 and formed ISO/TC 176/SC2/AHG01- TG QMPs, a special Task Group to be led by Prof. Iizuka of Japan, alongside several "high level strategic thinkers." Dr. Croft said the aim of the TG was "to review existing 8 QMP's" to determine their relevancy, and whether they should be amended, perhaps adding such concepts as ethics and organizational agility.

However, drafting of the standard had already begun before the work of the TG was completed. In November 2012, SC2 met in St. Petersburg and official records reveal that the QMPs were not complete, but that the intent was to complete them in April 2013… five months later.

> [The Task Group] *completed the definitions of the "titles", "statements" and "rationales" for the individual QMPs, which will provide an important input into the work of WG24 for the revision of ISO 9001. These will now be sent to the members for a confirmation ballot. The TG has yet to complete its work on the "key benefits" and "actions you can take" sections, and plans to meet in April to finish this task.*[1]

SC2 nevertheless pushed ahead without waiting for the final QMP's, with the objective that "WG24 during the St. Petersburg meeting was to achieve a first Working Draft of the new edition of ISO 9001." It reported that as a result, "by the end of the week it had achieved a skeleton draft that was edited following the meeting and then circulated to WG24's members as the first Working Draft."

[1] Source: http://isotc.iso.org/livelink/livelink/fetch/-8835848/8835872/8835883/Activities.html?nodeid=3554104

One needs not remind the members of TC176 or SC2 that the QMP's are to provide the foundation of the standard, and without the foundation, the work is built on sand. When 9001:2000 introduced the process approach, this was done to address the QMP's which defined that as a foundational element. Adding the foundational elements after the standard is drafted not only ensure that no new QMP's of any substance can be implemented, but this clearly contradicts Dr. Croft's public statements in 2011 that the new standard would improve the role of the QMP's, not lessen them.

To summarize: the Working Draft of the ISO 9001:2015 standard was developed at least five months before the Quality Management Principles were scheduled to be completed. Likewise, other than risk, virtually none of the other concepts discussed by Dr. Croft were included in the Working Draft. This is a dramatic missed opportunity.

POINT 2: EARLY USER FEEDBACK

Like it or not, the Working Draft was quickly leaked to the internet via an uploaded copy hosted on, first, a website in South Africa. It later spread from there.

Early feedback from users who have read the WD is almost universally derisive. Oxebridge will be conducting a sampled poll shortly, so at this time no statistical data is available and we must rely on anecdotal evidence; however this evidence must not be dismissed, as the anecdotes are so strongly negative, and the positive feedback almost nonexistent.

Oxebridge has found the comments to fall into the following buckets:

1. **Risk management is controversial.** This in itself is stirring debate, as about 50% of those who have a concern over it are also convinced that it will be impossible to audit and/or believe it should have been put into ISO 9004, not 9001. AS9100 is currently struggling with this, as it already includes a clause on risk. Furthermore, the ISO 9001 Working Draft abandons the approach and definitions of ISO 31000 on Risk Management, for entirely incomprehensible reasons. Rather than merely link to ISO 31000, the WD takes on its own approach, creating contradictions and competition between otherwise harmonious ISO standards.
2. **Other than risk, there are no new concepts.** No lean, no improvements in measurement and analysis methods, no forward thinking approaches. This is likely due to the lack of QMP's, as discussed.
3. **Paragraph re-shuffling.** By following a slavish adherence to the new Annex SL model, SC2 has apparently wasted time shoehorning existing 9001:2000/2008 requirements into the new paragraph structure, rather than using that time develop new concepts. Such "reshuffling" results in expensive, wasteful and time consuming labor for companies updating their systems to comply with the new documentation structure. Doing so while addressing new concepts adds value; merely renumbering old clauses does not.
4. **No input from the sectors, such as aerospace or automotive.** This will be discussed in Point 3 below.

Like a film receiving early negative reviews which later fails at the box office, ISO must consider this early user feedback as another reason to pause and solicit additional input. TC 176 must resist the urge to shrug off the criticism as being for a "Working Draft" as over 25 years' of history show us that the language of the Working Draft undergoes little substantive change through the various drafts to the final IS version. No major concepts can be added at this time, and the repairs needed will require major conceptual shifts.

TC 176 must also resist the tendency to worry more about the leak, rather than the feedback. The TC should consider this a blessing, and an early warning shot.

POINT 3: SECTOR ALIENATION

Previously, TC176 worked under a mandate from ISO *"work towards minimizing the proliferation of standards in the field of quality management developed externally to TC 176 using a joint and cooperative approach with the ISO/IEC TCs and other bodies involved."*[2]

As a participant in the ANSI US TAG to TC176 during the development of ISO 9001:2000 and ISO 9001:2008, the author saw firsthand the opposite occurring. Rather than polling the sectors – such as automotive and aerospace – as to their concerns and then working to incorporate those concerns, the US TAG promoted the offline work done by the sector organizations to develop their own standards externally to TC 176, literally violating ISO's mandate.

(Because so many of the resulting standards, including QS9000 (now ISO/TS16949), TL9000 and AS9100, originated from the US, the experience of the United States is valuable to focus on, even on the international stage of ISO.)

This "appeasement" approach did not work. During this period we saw the biggest growth in sector-specific ISO 9001 "variants" in history. The problem has reached such heights that even the ANSI/ASQ National Accreditation Board (ANAB), which shares senior management with the International Accreditation Forum (IAF) itself, has directly participated in the authoring of at least two such sector variants: "BA9001" for body armor manufacturers and "SN9001" for snow and ice management companies. Worsening matters is the fact that without the guidance of ISO, these new standards are being marketed under dubious and perhaps outright fraudulent claims; SN9001, for example, is being marketed as capable of reducing insurance premiums and preventing liability lawsuits. ISO 9001 and ISO as an organization will be tarnished when these claims inevitably fail to come to fruition.

This has led to a thinking that ISO 9001 is insufficient on its own, and must be tailored to suit every possible industrial sector in the world. In a discussion with ANAB, marketing representatives said there may be "thousands" of such possible standards, and they defended their role in developing them (again) externally to TC 176. The potential burden this places on end user organizations will be unsustainable.

Now, as the Working Draft has been released, new information has come forward that two critical international industries – the automotive industry currently operating under ISO/TS 16949, and aerospace operating under AS9100 – were considering "decoupling" from ISO entirely, and creating multiple individual standards completely separate from ISO 9001.

At an additional level – that of, admittedly, rumor – NASA is now considering dropping AS9100 because of that standard's ties to ISO 9001, and has already pulled certification as a requirement from one of its major contracts; an expansion of NASA 2nd party audits are underway, and NASA supplier quality engineers have expressed frustration with ISO/AS. Likewise, major automotive manufacturers are reported to be looking at the Volkswagen auditing schemes used in Europe as one replacement for ISO 9001 / TS 16949. The US Department of Defense is rumored to be considering ramping up its DoD certification program, instead of relying on ISO 9001. While these rumors may yet

[2] Previously from http://www.tc176.org/About176.asp - link now expired.

prove to be unsubstantiated, or may never mature, they are nevertheless a compounding problem when faced with the facts of industry dissatisfaction and decoupling. They should never have entered the discussion at all.

If decoupling is allowed to happen, this will throw ISO 9001 into chaos and virtually assure its international irrelevance. Tens of thousands of more companies will not only fall off the ISO 9001 rolls, but will then be subjected to a return to the days of multiple 2nd party audits, and all the increased costs and lost efficiencies thereof.

Even if decoupling does not occur at this time, the fact that this has entered into the debate, and that the sectors are so publicly vocal in their dissatisfaction with the work done to date by SC2 on ISO 9001:2015, the criticism must be considered. There would be nothing to stop such industries from decoupling *after* 9001:2015 is released, and the problem is locked into place for another decade or more.

As the next point will show, ISO 9001 is already in a deadly downward spiral, and any industry sector alienation will only quicken the fall.

POINT 4: DECADE OF DATA SHOWS ISO 9001'S DECLINING ACCEPTANCE

4.1 DATA USED FOR THIS STUDY

Data provided by the International Organization for Standardization (ISO), through "*The ISO Survey*" (formerly "*The Mobil Survey*") published annually since 1990, shows that ISO adoption rates are declining precipitously, with key nations showing particular declines since the release of ISO 9001:2000. Most of the data analyzed herein is derived from the ISO Surveys between 12th Cycle (2002) through to the latest published 21st Cycle (2011). The data goes back as far as 1993, however, providing us two decades of figures to review. Data for 2012 was not available at the time of this report. Data provided under the pre-ISO "Mobil Surveys" was also used to a lesser extent.

Some incorrect and missing data was found in the 2011 report, which was corrected using data from previous Survey cycles. This included erroneous entries for UK totals.

Oxebridge acknowledges two factors that cause some discontinuity in data:

1. ISO's reporting method was inconsistent during the transition between ISO 9001:1994 and ISO 9001:2000, and
2. ISO transitioned reporting to AC Nielsen in recent years, and it is unclear how the Nielsen methodologies differed from those conducted by ISO itself, and
3. ISO has also transitioned management of the ISO Survey to CASCO, and it is unclear how this may have affected the data or methods of reporting it.

Oxebridge maintains that these factors do not cause significant impact on the results, given the amount of data provided.

4.2 CRITICAL ANALYSIS OF ISO'S MARKETING

ISO's marketing of ISO 9001 has relied on overemphasizing positive trends, however small, and either dismissing or ignoring negative data.

In 2003, when *The ISO Survey* revealed shocking declines in both major regions and the worst growth rate in the entire history of the Survey, ISO's then Secretary General Alan Bryden nevertheless said:

> *"... it is certainly gratifying to note another growth year for certification to ISO's management system standards that underlines their increasing importance and use worldwide for the development and promotion of quality and environmental protection, not only in industry, but also in services and the public sector."* [3]

Likewise, the most recent *ISO Survey* (21st Cycle – 2011) includes equally deceptive language. With the data showing declining interest in all regions, ISO Secretary General Rob Steele issued this comment:

> *"A number of markets where certification took off in the early 1990s are showing signs of having reached maturity. For example, overall, this is the case of ISO 9001 certification in Europe, but the effect is not evenly spread for Italy is the country that experienced the highest growth in certificates. The East Asia and Pacific region has almost overtaken Europe for the regional share of ISO 9001 certificates.*[4]

In the above quote, Mr. Steele places on ISO 9001 a previously unheard of argument that the decline in interest in ISO 9001 can be attributed to "reaching maturity." Such a statement is not only false, it defies the very concepts embodied in ISO 9001 (such as continual improvement). Furthermore, the irresponsible statement paints the standard with a grossly toxic sheen that it may never shake off: that ISO 9001 has a limited use, and that dropping certification should be viewed as a sign of maturity. In short: ISO 9001 goes stale over time. If true, than Mr. Steele's reliance on "Asia and the Pacific region" will fade as well, as the standard decomposes in those regions; only then, there will be no other regions to pick up the slack, and ISO 9001 will be gone forever.

Although the statements are separated by nine years and two Secretaries General, the same spin tools are used to defend ISO 9001, in contradiction to the data presented.

4.3 ASIA

Much has been said by ISO and others about the growth of ISO 9001 in Asia; the meme being spread is that Asia is under massive growth, overshadowing (or, as Mr. Steele said, "overtaking") the rest of the world. This talking point is used to provide evidence of ISO 9001's ongoing international relevance.

The following chart shows ISO 9001 growth by region between the years 1993-2011, and supports this notion at first glance. The continent of Asia is the geographic region showing the greatest increase in ISO 9001 adoption rates, with Central and South America (a combined region under ISO reporting) showing a slight uptick.

[3] http://www.iso.org/iso/home/news_index/news_archive/news.htm?refid=Ref864
[4] The ISO Survey of Management System Standard Certifications – 2011

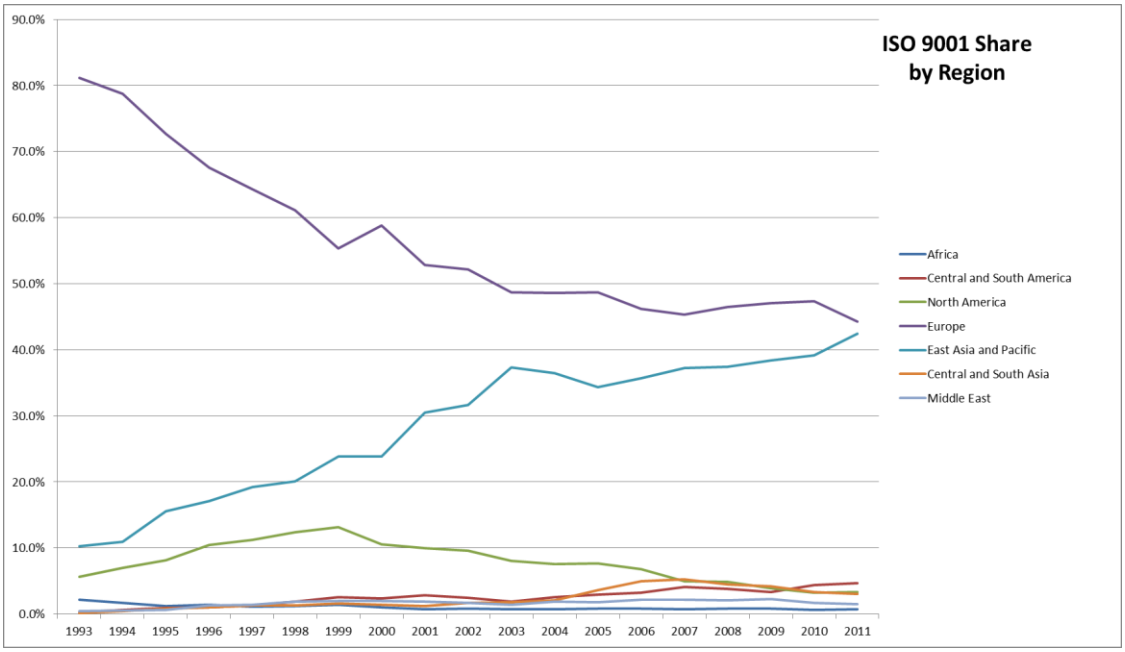


Chart: ISO 9001 by Regional Share

However, the chart reveals a troubling truth as well: in all other markets the rates are declining or flat, meaning that as a percentage, Asia's number only look good in the context of the poverty of ISO 9001 certificates everywhere else.

But the Asian numbers are mutated by the growth in certificates for only three countries: China, Japan and (slightly) South Korea. Other critical Asian nations, such as Australia, Taipei, Hong Kong and Vietnam are declining. It is therefore inaccurate at best to claim that "Asia" as a region is a factor to consider.

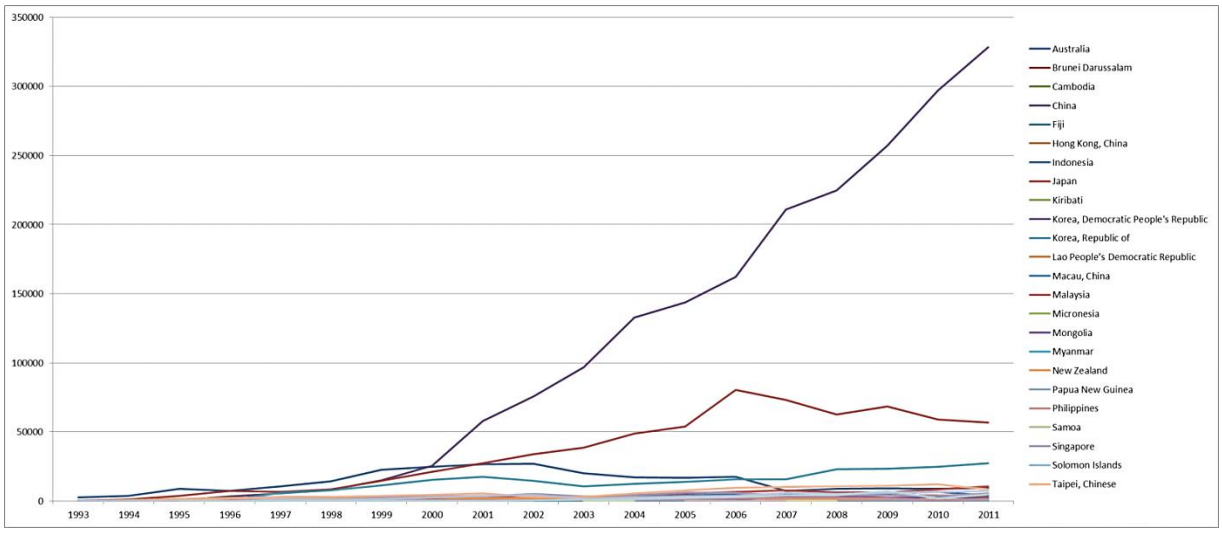


Chart: Asia Region Growth by Nation

Rate of growth is the most critical factor to consider when analyzing ISO 9001's perception in the market. Reviewing growth rates indicates current "acceptance and tolerance" levels for ISO 9001, and can be used as a moderately

accurate predictor. Using growth rates alone, in 2000 Oxebridge was able to accurately predict that by the 2002-2003 time frame, adoption rates of ISO 9001 certificates would achieve "negative growth" (less certificates than a previous year); this prediction was vehemently dismissed by Robert King of ANAB and Roger Frost of ISO, but nevertheless came true in 2003.

The examination of rates of growth also sidesteps marketing justifications which rely on merely having a higher number one year than in a previous year.

For example, despite so much emphasis being made on Asia, if one examines the actual growth *rates* in Asia's top economy – China – one clearly sees a declining interest in ISO 9001.

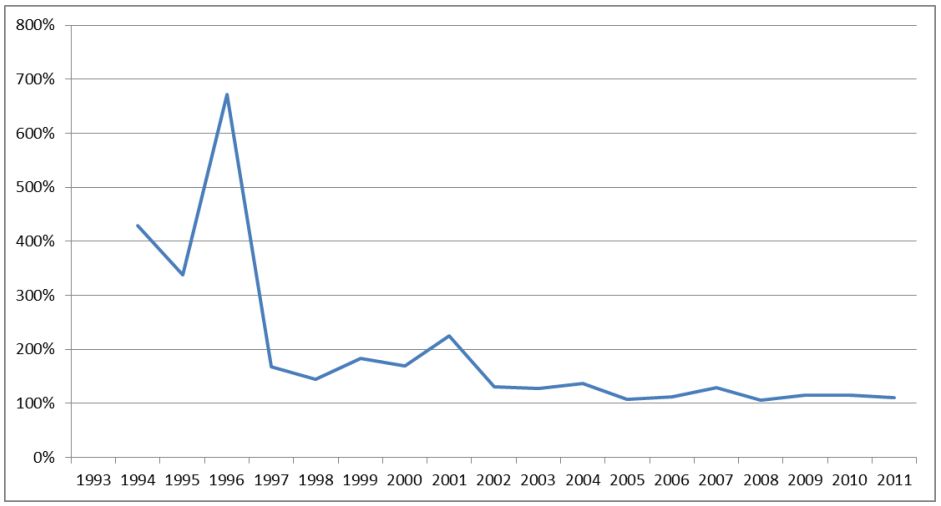


Chart: China Adoption Rage 1993 – 2011

Likewise there has been much talk about the growth of ISO 9001 in India, as part of the "Central and South Asia" geographic designation. This too is a red herring, when one examines India's overall growth pattern.

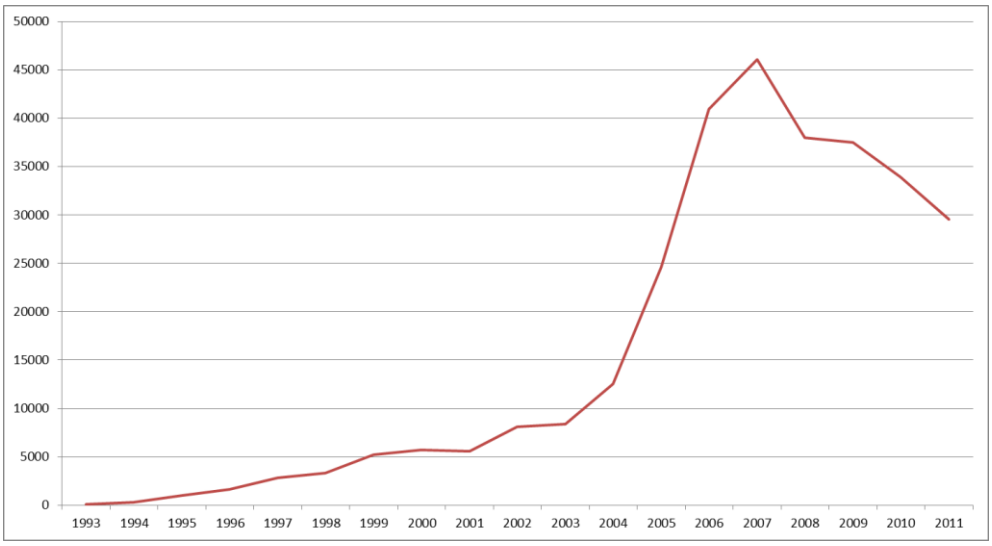


Chart: India Growth Rate Pattern 1993 - 2011

As we can see, 2007 marked the peak of ISO 9001 activity, and has declined ever since.

Using a different graphing approach, we can see the trends away from ISO 9001 a bit more clearly. Analyzing two ISO Surveys from 2002 and 2011, we find a shift in the "Top Ten" nations. The nations listed in 2002 were:

Australia	Japan
China	Spain
France	Switzerland
Germany	UK
Italy	USA

Since those nations represent heavy early adopters, it is worth reviewing their data specifically to try and understand if ISO 9001 usage results in abandonment over a period of time.

In the following chart, red color is applied to any year with less ISO 9001 certificates than the previous year, indicating "negative growth." By merely applying colors, trends become apparent.

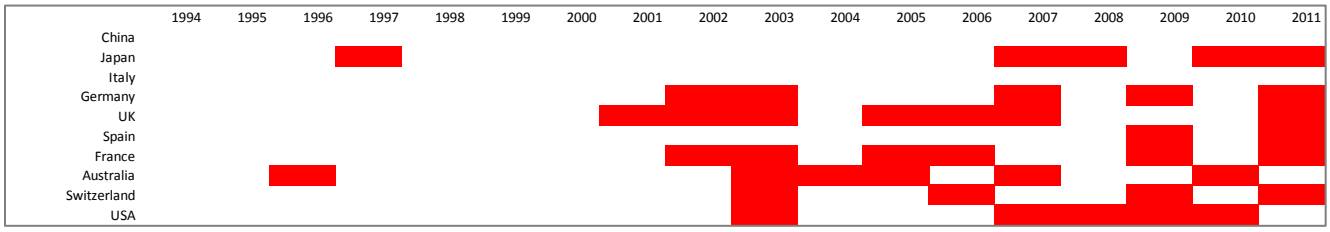


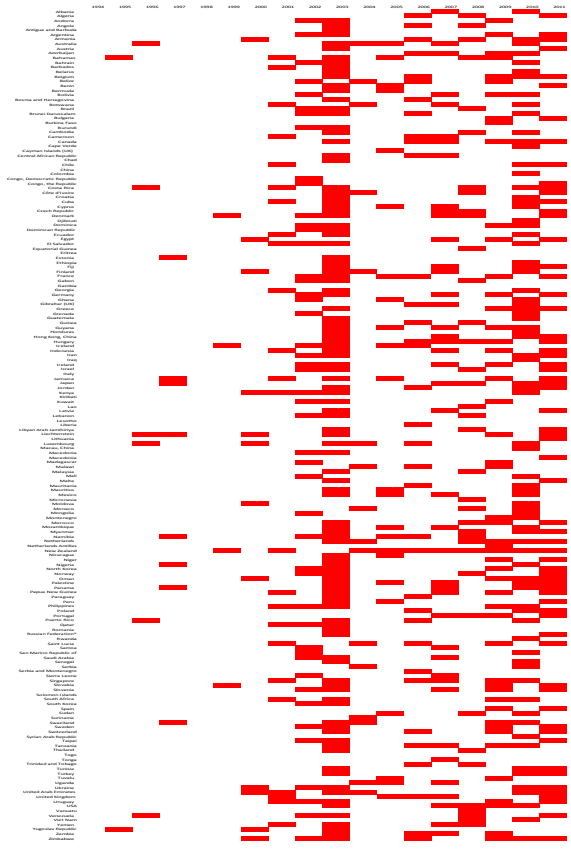
Chart: Graphical Representation of Negative Growth Rates
Red indicates less certificates than previous year (more withdrawals than certifications)

Prior to the release of the process-based ISO 9001:2000 revision, only two of the Top Ten countries had seen negative numbers. After its release, we find that eight now have routinely bad years for certification. Only China and Italy are outliers.

At right we see this same representation looks like when applied to the entire world.

The middle burst of red clearly highlights a sudden drop in ISO 9001 certifications in 2003: the exact year when ISO 9001:1994 was formally phased out, and mandatory transition to 9001:2000 was dictated. We can surmise from this that many companies across the entire world elected not to "upgrade" their systems, and instead let them lapse.

Looking further to the right of this graph we see a second set of bursts in the years 2010 and 2011, in what appears to be another buildup to a massive defection. This does not bode well for the 2015 revision.



4.4 THE MYTH OF MARKET SATURATION

In previous years, representatives of ASQ, US TAG, ISO and other organizations have dismissed flatlining within nations as "market saturation." When asked to present any data to support this notion, they have routinely failed to do so.

Data does exist to test this theory in at least one of the former Top Ten nations: the United States. Using 2010 US Census data we can determine a relative sense of the level of participation in ISO 9001's primary user demographic: business organizations. The data reported the following registered businesses:

22,614,000	Nonfarm proprietorships
3,146,000	Partnerships
5,847,000	Corporations
31,607,000	TOTAL

Using 31.6 million as the working figure, we then see that the US only had 25811 certificates in 2011. ***This represents 0.082% of the potential US business marketplace.***

Consider that the Census data does not include other potential organizations that may adopt ISO 9001, such as NGO's, labor unions, hospitals, educational facilities, municipalities, police, government agencies… when viewing this, it becomes clear that in the case of the United States, "market saturation" cannot be used as a descriptor for what is occurring.

These figures are likely repeated throughout the world.

CONCLUSION AND PATH FORWARD

Based on the convergence of these key four factors – lack of management principles, negative early user feedback, alienation of major international sectors and two decades of *ISO Survey* data showing declining interest – it is clear that ISO TC 176 must change course on ISO 9001:2015. TC 176 needs to practice what it preaches, rather than letting schedule take precedence over quality of the product.

Oxebridge sees a "reboot" as the only feasible corrective action. In order to achieve this, TC 176 must:

1. Abandon a dogged adherence to a deadline, and commit to producing a valuable, high-quality end product that meets the needs of stakeholders, rather than publishing a flawed document according to a timetable. This may be the most difficult step, as ISO rules forbid extended development periods for its products, but TC 176 must make the case to ISO to allow a one-time exception under such extraordinary conditions. ISO 9001 is ISO's flagship product, and should have an interest in ensuring it succeeds, rather than holding the Committee to an aging, arbitrary procedural requirement.
2. Initiate a "stop work" order on all development of ISO 9001:2015 immediately. The various SC's and working groups must be alerted to cease all work, and the cancellation of all scheduled meetings must be initiated. In order to do this, the TC may have to work with senior ISO officials to make the case for the necessity of this action, as it is not supported by any current ISO procedures. The TC 176 must make it clear that there is no

precedence for this action, and that following procedures will result in the decline not only of ISO 9001, but of ISO's stature in the world as a leading standards organization.

3. Create a new Working Group to develop and implement a new ISO 9001 survey, to be funded by ISO, which will gather feedback from industries across the world on the next ISO 9001 revision. The previous "User Survey" method must be abandoned entirely. Greater balance between users and non-users must be sought, especially to discover what keeps them away from the product. The new method must strive for far, far greater participation, using improved online methods to accomplish this without increasing costs. The survey must be far shorter than the previous iterations, and preferably developed by an appropriate 3rd party survey firm. The national member bodies must agree to promote the survey, at their cost, within their nations.
4. Conduct immediate meetings with key sectors such as automotive and aerospace, to gage their feedback directly, and to determine conclusive ways to include their feedback into the resulting work product.
5. Use modern technology – including social media and online program management tools – to ensure healthy participation by all those involved in development activities and committees, not merely those that can afford to attend, or are reimbursed for attending, physical meetings spread across the globe.
6. When re-convening the SCs and working groups, ensure that leadership and membership are representative of the stakeholders concerned, and specifically include users of ISO 9001, not only "high level strategic thinkers," and to age-balance the committees so they are not as negatively impacted when older members fall ill, pass away or retire.
7. Communicate its path forward in a positive way, emphasizing the need to "get things right, rather than get them fast."
8. Resume ISO 9001 development only once the feedback of stakeholders and Quality Management Principles are fully defined and understood.

Only by taking a temporary pause for reflection and correction can the decline of ISO 9001 be halted and reversed, but it requires a comprehensive understanding of the needs of the full spectrum of users and stakeholders.

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Oxebridge is seeking individuals or organizations as co-sponsors of this initiative. If you would like to support the temporary pause in development of ISO 9001:2015, contact Oxebridge at OQR@oxebridge.com.

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