Guidance Document:

Ensure A Fair Registration Audit With These Contractual Obligations For Your ISO 9001 Registrar

Second Edition

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YOU ARE THE BOSS.

NOT YOUR REGISTRAR.

ISO 9001 certification bodies (CBs, or “registrars”) are subject to the rules of ISO 17021, the standard that defines what CBs must do to become accredited. CBs are audited annually by their Accreditation Body (AB) who is tasked with ensuring they comply with ISO 17021. Unfortunately, ABs are paid by their CBs, so overlook most violations, since enforcing the rules would impact on their revenue. Furthermore, most ISO 9001 end users do not even know of the accreditation rules, even though their intent is to protect the auditee and ensure an objective, fact-based audit.

In a survey[1] of over sixty US ISO 9001 registered companies, six of the top ten most common concerns with registrars were related to various failures by the CBs to abide by the requirements of either ISO 17021. Specific violations included failures of the CBs to abide by audit schedules, failures to record evidence on nonconformance reports, making auditees uncomfortable and prescriptive auditing styles by auditors. In a single 2013 incident, a poor audit by an accredited CB had been witnessed by the company’s customers, and resulted in the company having its risk rating increased, causing it to lose out on a billion – with a “b” --- dollar contract. Layoffs resulted, and real people lost their jobs, not because of inadequacies of the client’s QMS, but because the inadequate CB auditing led the customers to question the validity of the certification.

It becomes valuable, therefore, to ensure that an organization’s registrar is abiding by ISO 17021. That means you should not only purchase a copy of ISO 17021 (from ISO or your country’s ISO member body) but also understand it.

But if registrars are already required to abide by ISO 17021 and, as the survey suggests, simply not doing so, what can be done? Another requirement of ISO 17021 is that registrars maintain a robust complaints handling process; this becomes a critical tool for reporting ISO 17021 disconnects with the registrar. Unfortunately, ISO 9001 end user organizations are often too timid about filing complaints with registrars. Evidence bears this out: of some 50,000 registered companies in the US, the ANSI/ASQ National Accreditation Board (ANAB) only receives a dozen or so complaints per year, according to data posted on www.ANAB.org. That’s not even possibly accurate.

Clearly, waiting for the registrar to break the rules, and then reporting it, is not palatable to most companies. It is not particularly fair to the registration companies, either. Instead, it is important to invoke key points within ISO 17021 beforehand, to ensure that the registrar intends to stick to the rules, and to provide a pre-established baseline for resolving issues that may arise later. Remember,

Accredited registrars are required to abide by ISO 17021. Yet six out of the top ten most reported problems with registrars were various failures to abide by these rules.

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[1] Conducted by OQRI in 2006. A similar study was conducted of 50 companies in 2013 and found identical results.
ISO 9001 requires companies to fully define their requirements to vendors, and registration companies are vendors. You have the right to assess your CB as any other supplier, and then hold them accountable when they fail to uphold their requirements.

ISO 17021: YOUR NEW BEST FRIEND

ISO 17021 assumes a model that is antithetical to how most people view the ISO 9001 registration audit process. The 17021 standard puts the end user of the audit – the auditee – in control of the entire audit, not the auditor. CBs will say that this is the way it should be done, but day-to-day practice and real world experience tell us a different story. Instead, clients sign up with a registrar and then let that CB drive the audit process. The client accepts the auditor’s schedule without question, sits back during the opening meeting, and passively participates in the audit by fetching information and individuals to suit the auditor. They even run around and get coffee.

Tip: show the auditor where the coffee machine is. If an auditor can’t get his own coffee, the rest of the audit is only going to go downhill.

It is necessary for the organization to establish control at the very beginning, before a contract with a CB is even signed. When deciding on which registrar to use, organizations are encouraged to make their intent to enforce ISO 17021 known, and to clearly spell out their expectations for audits. It should – theoretically – be impossible to find an accredited registrar who refuses to follow ISO 17021, but in the event that one encounters such a company, it is best to let them know they can get their business elsewhere. Enforcing ISO 17021 enhances objectivity and fact-based auditing, and reduces opportunities for miscommunication, complaints or arguments; registrars should respect this reality, especially since it is part of their accreditation requirements.

EASY RIDERS

When a company signs on with a registrar, the CB will require the company to sign a contract. The registrar’s typical contract will include a lot of language on what your company must do, but rarely do these terms and conditions include language on what rules or requirements the registration body itself must abide by. Therefore, the contract becomes the easiest means by which to transmit your company’s wishes. By developing a contractual rider – one that becomes part of the purchase order agreement with the registrar, and takes precedence over any “stock” language in a CB’s existing contracts – you ensure you have properly transmitted your requirements to the CB. And – the best part – it is legally enforceable.

Citing specific ISO 17021 requirements is critical. The contractual language should include the following general requirements:
The CB agrees to adhere to the requirements of ISO 17021 during all audits and activities conducted with our organization.

The CB acknowledges that the audit scope, objectives and processes are to be defined by our organization’s selected representative.

The CB agrees to notify our organization in writing if and when these requirements conflict with established rules under ISO 17021, to the extent that such requirements would invalidate or threaten the validity of the audit or resulting certification.

The last sentence gives some power back to the registrar, because it is conceivable that a company could begin issuing so many requirements on the CB that the audit itself no longer meets the necessary criteria for a legitimate audit. In such cases, the rider language puts the onus on the CB to define and defend such cases.

In additional to general language, some specific citations of ISO 17021 are in order. These seek to address many reported disconnects between auditor behavior, CB management or other issues that could hinder an effective audit. The first thing is to establish a scope of the audit, and define it clearly in the contract:

- The CB agrees to limit its activities to the following scope of the audit:

Your audit scope is not the same as your scope of business (or scope of certification) but is the overall set of parameters of the audit itself. It should include the following information:

- Sites included (if not all)
- Departments included (if not all)
- QMS Processes included
- Standards to be used
- Clauses to be excluded (per the permissible allowances defined in the standard)
- Languages to be used (in reports and in verbal communication)

Regarding the processes, it is a recurring complaint that CB auditors do not abide by the processes as defined by their customer, but instead use process breakdowns they have developed ahead of time, usually in worksheets they have made that divide the ISO 9001 clauses into logical chunks, making their jobs easier. When these don’t align with the actual processes of the client, the auditor will usually just defer to his/her own list. This is not allowed. The CB auditor must audit to your processes, not his/her own. To ensure they comply with this, therefore, you must provide your process breakdown to the auditor ahead of time. That’s only fair. If the auditor nevertheless ignores your process structure, and audits against his/her own idea of what a process is, now you have legal grounds to enforce your rights.
Your contract should also include a statement on the scope, or activities that are not to be included in the audit:

- The CB agrees to not engage in auditing of any of the following activities which are deemed out of the scope of the audit:
  - Safety issues unrelated to the safety of the auditors themselves
  - Accounts payable
  - Employee personal protected information or data
  - Union rules
  - Activities or processes not included in the scope of the quality system

**KNOW YOUR AUDIT OBJECTIVES**

Once the audit scope is determined, the audit objectives must be determined and defined. This is a concept that is routinely ignored by CBs who typically establish the objectives for the auditee by assuming what they want. This is backwards, of course. The organization must tell the registrar what it wants; no company, CB or otherwise, should ever assume customer requirements.

Objectives should include a plainly-stated goal for the audit, and detailed definitions of the types of acceptable outputs for the audit. Here are some examples:

- The CB agrees that the objectives for the audit are limited to the following:
  - Audit of our organization’s quality management system against the standards listed in the Scope (above) for the purposes of obtaining/maintaining registration to those standards.
  - Auditing in accordance with the other conditions defined in Scope (above)
  - Written reporting of nonconformities between the QMS and the requirements listed in Scope (above)
  - Written submission of a completed audit report in accordance with the CBs normal format, to be submitted to our organization within (x) number of weeks.
  - Written reporting of opportunities for improvement, where such opportunities are discovered by the auditor so long as such opportunities are constrained to the Scope (above).

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2 Safety is a particularly common, and problematic, issue that comes up during audits, typically defended by the auditor as being an extension of “statutory or regulatory requirements.” We often see CB auditors write up safety issues if the quality system documentation makes the most passing reference to OSHA, for example; however, such citations are clearly out of the scope of the audit and could lead the CB into litigation. For example, we have seen cases where QMS auditors write up findings on the control of SDS records; however, the Federal labor laws governing the content and use of SDSs are complex, and there are certain elements of the ISO 9001 document/record control requirements which could actually put a company in noncompliance with the law, or (worse) risk a catastrophic incident affecting worker health. Clients hire the CB for its expertise on quality systems, and do not typically vet the auditor for their expertise in occupational health, industrial safety, or the laws behind either. Furthermore, we know of no accredited registrar that provides training of their QMS auditors on safety… nor are they required to. Finally, auditing of safety issues takes valuable time away from auditing things that are in scope. CB auditors should be strongly discouraged from writing safety issues up during a quality management system audit, unless this is agreed to in advance of the audit, or unless some compelling evidence can be provided by the CB that proves otherwise.
Documented statement of recommendation or denial of recommendation for registration to the standards listed in Scope (above) to be provided upon the close of the audit.

Approximate date(s) for any surveillance or follow-up audit activities.

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The end user organization should also provide the CB with a detailed listing of other expectations and requirements, all of which are enforceable as part of the purchase agreement.

- The CB shall use as its point of contact the following authorized representative of the organization: [name and contact information of representative].
- In the event that the authorized representative is not available, the following secondary representative is to be used: [name and contact information of secondary representative].
- The CB acknowledges that its audit activities are to be conducted in accordance with ISO 17021.
- The CB agrees to the definitions of terms as listed in ISO 17021 and ISO 9000.
- The CB agrees to the principles of auditing as listed in ISO 17021.
- The CB shall provide to our organization a written proposed audit schedule, defining which clauses and processes are to be audited on which dates. This schedule must be received at least two weeks before the first audit day.
- Our organization reserves the right to review and revise the proposed audit schedule so that it better aligns with our organization’s specific processes and process approach, provided that such revision does not invalidate the scope or objectives of the audit.
- The CB agrees that exchange of documentation for the purposes of documentation review may be done electronically.
- The CB agrees to populate its audit team with auditors knowledgeable in our industry, SIC codes and the standards listed in the Scope; where such auditors are not available, the CB shall request a waiver for this requirement in advance.
- The CB shall provide our organization with the credentials, certifications and/or resumes of its proposed audit team members within sufficient time so that our organization may request alternate auditors if we deem a selected auditor is not adequate.
- The CB shall not send auditors, trainees or observers who have not been pre-approved by our organization, with the exception of witness auditors from the CB’s accreditation body.
- CB auditors agree to act in accordance with the requirements of ISO 17021, and refrain from actions which may be seen as combative, argumentative, intimidating or in any other way counterproductive to the audit process.
- CB auditors agree not to be prescriptive in their auditing technique; i.e., to infer or require the implementation of specific methods for compliance.
- CB auditors agree not to make conclusions or assumptions about our organization’s quality management system on the basis of previous experience.
- CB auditors agree not to provide consulting during audits in any form, whether by providing specific solutions, or by providing examples of concepts the auditor has seen at other companies.
- CB auditors agree not to disclose to any other client or third party any intellectual property, whether viewed visually or through documentation or other means, without explicit written
permission from our organization, regardless of whether the CB auditor does so without naming our organization specifically. Transmission of our intellectual property and confidential information is protected by law, and will be vigorously enforced.

- The CB agrees to acknowledge the full responsibilities and authorities of company representatives selected by our organization as escorts, points of contact, authorities and representatives during the on-site audit activities, including any contract personnel so assigned by our organization. The activities of these individuals shall be in accordance with the requirements of ISO 17021.

- The CB agrees to provide a written report of the Stage 1 portion of the audit \((x)\) weeks/days prior to the first day of Stage 2 activities. This report must list specific nonconformities or concerns found during the Stage 1 event, in accordance with the nonconformity reporting requirements below. Failure to provide this report within the allotted time may result in our organization rescheduling the Stage 2 activities at the full expense of the CB.

- If the audit activities result in a recommendation for (or maintenance of) certification to the standards referenced, the CB agrees to provide this certificate within \((x)\) weeks of the last day of the on-site audit activities.

THE RIGHT WAY TO WRITE WRONGS

The writing of findings, especially nonconformities, continues to be a problem reported by ISO 9001 end users. Many times, CB auditors write nonconformances that “make sense at the time” but which cannot be comprehended later, after the auditor has left. This is because some auditors have gotten into the habit of writing the finding one way, and then verbally explaining it and adding context during the closing meeting. This practice, however innocent-looking, is a severe violation of ISO 17021 which requires that auditing be an “evidence-based” activity and that findings be verifiable.

Another bad practice is illustrated when auditors write a finding beginning with the phrase “there is no objective evidence that….” Auditors routinely write findings with this preface when they do not – or cannot – find evidence to prove compliance to a requirement. However, it must not be overlooked by the auditee that this means the auditor cannot find evidence to disprove it either. Imagine the district attorney who prosecuted criminals on the merits of having no evidence.

There is no allowance for writing up the absence of evidence as a finding. If the auditor has not found evidence, this does not mean there is a nonconformity; it means, rather, that the auditor stopped following the audit trail prematurely. In the end, any finding written up with the words “there is no objective evidence” is an admission by the auditor that he/she did not do their job. Such audit findings should be rejected by the auditee wholesale.

When auditors write a nonconformity beginning with the phrase “there is no objective evidence that…,” it means the auditor stopped auditing prematurely.
The industry expert coalition ISO 9001 Auditing Practices Group, founded by ISO and IAF, agrees. In a recently released guidance document on the writing of nonconformities, APG wrote, “If there is no audit evidence, there is no non-conformance.”

Instead, auditors must corroborate each finding with evidence. In order to ensure this, the following language should be included in the contract with the CB:

- When writing findings, the CB must adhere to the following convention:
  - Clearly record the nonconformity
  - Indicate the clause under which the nonconformity falls
  - Clearly state the objective evidence that supports the nonconformity
  - Indicate whether the nonconformity is a major or minor, using definitions of those terms as defined by the CBs procedures
  - Review the nonconformity, and revise as necessary, to ensure that it is written in a way that is verifiable at a later date without any further request for information.

- Findings that do not follow all the requirements of this convention will be considered to be nonconforming against ISO 17021 and rejected by our organization until corrected.

- If a finding cannot be corrected by the auditor upon such a rejection, the nonconformity will be voided.

- The rejection of findings under these conditions shall in no way delay or hinder the receipt of all other objectives, including certification to the applicable standards, if applicable.

- Signing of nonconformities during the CB audit shall constitute acknowledgment of the receipt of nonconformity, and shall not be construed as acceptance of the nonconformity, nor shall it negate our right to appeal the nonconformity. This rule shall trump any language present on the CB’s nonconformity form where such language contradicts this clause.

Once again, this may look ominous to a registrar (or their legal department!) but should pose no obstruction to their ability to provide your company service, since this convention follows the requirements of ISO 17021.

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3 [http://www.irca.org/inform/issue7/APGnon-conformity_reports.htm](http://www.irca.org/inform/issue7/APGnon-conformity_reports.htm)
About the Author

Christopher Paris is founder of Oxebridge Quality Resources International LLC, and has been implementing ISO 9001 systems since 1988.

Mr. Paris originally worked as a chemical process engineer for The Mearl Corporation (now BASF) where he worked on mica-based pigments, and Pure Tech, Inc. (now Williams Advanced Materials) , developing high tech ceramic and exotic alloy materials for physical vapor deposition. In both companies Mr. Paris spearheaded ISO 9001 implementations, doing so in high-volume working environments that prohibited any production shutdowns or extensive management meetings.

Using methods drawn from those real-world practical experiences, Mr. Paris formed Oxebridge in 1999 and developed a “Rapid ISO 9001 Implementation Program” that emphasized the use of simple, intuitive solutions that did not rely on heavy documentation, and did not impact management performance or production performance. In 2013, Mr. Paris opened the company’s first international office in Peru, South America.

Mr. Paris was a voting member of the US Technical Advisory Group to TC 176, the ISO technical committee responsible for development of the ISO 9000 family of standards. He is also a former member of the International Federation of Standards Users (IFAN), and a former RAB-certified auditor of quality management systems. He is currently trained by A2LA in ISO 17025 laboratory competency assessment. His clients have included Lufthansa, JetBlue Airways, SpaceX, L3 Communications, Northrup Grumman, NASA and nearly 200 small to medium suppliers in manufacturing, IT services and aerospace.

Mr. Paris is the President of the M3 Development Council, developing standards for management maturity models. He recently announced formation of the National Advisory Council on Accreditation (NACA) to provide guidance on accreditation activities.

A satirist, Mr. Paris has written the world’s only parody standards, Eyesore 9001 and DumbAS 9100, available for free download at www.oxebridge.com.

Mr. Paris’ articles on ISO 9001 and A9100 have been translated into numerous languages throughout the world, and praised for their simplicity and clarity. A bicontinental, he lives in Orlando FL and Lima Peru and may be reached at chris@oxebridge.com.