



Oxebridge Quality Resources, Inc.

# Ensure A Fair Registration Audit With These Contractual Obligations For Your Registrar <sup>v0</sup>

## **First Edition**

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## **YOU ARE THE BOSS.**

### ***NOT YOUR REGISTRAR.***

ISO 9001 certification/registration bodies (CRB's, or "registrars") are subject to the rules of both ISO 19011 – the standard for auditing – and ISO/IEC Guide 62 – the standard that defines what CRB's must do to become accredited. A third document, called the International Accreditation Forum Guidance Document 2 (IAF GD2) further elaborates on those requirements. Unfortunately, most ISO 9001 end user organizations do not understand or even know of these three important documents, even though their intent is to protect the auditee and ensure an objective, fact-based audit.

In a survey<sup>1</sup> 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 CRB's to abide by the requirements of either ISO 19011 or ISO Guide 62. Specific violations reported by the companies included failures of the CRBs to abide by audit schedules, failures to record evidence on nonconformance reports, making auditees uncomfortable and prescriptive auditing styles by auditors.

***Accredited registrars are required to abide by ISO 19011. Yet six out of the top ten most reported problems with registrars were various failures to abide by 19011.***

ISO 19011:2002 *Guidelines for Quality and/or Environmental Management Systems Auditing* is an important document in that it specifically defines how audits – both internal and external – should be carried out and reported. While basing an organization's internal audit program on ISO 19011 is optional, accredited registrars of systems such as ISO 9001 and AS9100 are required to abide by ISO 19011 as a part of their accreditation, because Guide 62 directly requires ISO 19011 compliance of the CRB.<sup>2</sup> Simply put, failing to follow ISO 19011 could lead to de-accreditation of the CRB.

It becomes valuable, therefore, to ensure that an organization's registrar is abiding by ISO 19011. That means you should not only purchase a copy of ISO 19011 (from ISO or your country's ISO member body) but also understand it. It is also beneficial to purchase a copy of ISO/IEC Guide 62 (also from ISO); you can obtain the IAF GD2 for free from [www.IAF.nu](http://www.IAF.nu).

But if registrars are already required to abide by ISO 19011 and, as the survey suggests, simply not doing so, what can be done? Another requirement of ISO Guide 62 is that registrars maintain a robust complaints handling process; this becomes a critical tool for reporting ISO 19011 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,

<sup>1</sup> Available online at [www.oxebridge.com/registrars.asp](http://www.oxebridge.com/registrars.asp)

<sup>2</sup> Likewise, ISO/IEC Guide 65 mandates compliance to ISO 19011 for ISO 14001 environmental management system auditors.



the ANSI/ASQ National Accreditation Board (ANAB) only receives a dozen or so complaints per year, according to data posted on [www.ANAB.org](http://www.ANAB.org).

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 19011 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, ISO 9001 requires companies to fully define their requirements to vendors, and registration companies are vendors.

*Clearly, waiting for registrars to break the rules is not palatable to most companies, and not particularly fair to the registration company.*

### ISO 19011: YOUR NEW BEST FRIEND

ISO 19011 assumes a model that is antithetical to how most people view the ISO 9001 registration audit process. The 19011 standard puts the end user of the audit – the auditee – in control of the entire audit, not the auditor. CRB’s will admit 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 CRB 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.

This is not how ISO 19011 defines the ideal auditor/auditee relationship. Instead, ISO 19011 Clause 5.1 plainly puts the authority within the hands of the auditee: “*The organization’s top management should<sup>3</sup> grant the authority for managing the audit program. Those assigned ... should (a) establish, implement, monitor and review the audit program and (b) identify the necessary resources and ensure they are provided.*” Note the roles given to the company’s management, and not ceded to the registrar:

- Establish the audit program
- Implement the audit program
- Monitor the audit program
- Review the audit program

In simple English, ISO 19011 says the ISO 9001 *end user organization* determines who will manage the audit. Handing over this responsibility to the registration company is a mistake, and one that can lead to significant problems later on, up to and including a failure to achieve registration.

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<sup>3</sup> (A note on the word “should”: ISO 19011 does not use the word “shall” because it is considered a “guidance document,” not a standard. However, because ISO Guide 62 *mandates* that registrars abide by 19011, the “shoulds” thus become “shalls” which the registrars must abide by as part of their accreditation.)



Instead, the organization's top management must assign someone (typically the Management Representative) to control (manage) the audit process, including the activities of the CRB. Of course, such control should not hinder the registrar's objectivity or ability to conduct a proper audit and report findings – but more on that in a moment.

It is necessary for the organization to establish control at the very beginning, before a contract with a CRB is even signed. When deciding on which registrar to use, organizations are encouraged to make their intent to enforce ISO 19011 known, and to clearly spell out their expectations for audits. It should – theoretically – be impossible to find an accredited registrar who balks at following ISO 19011, 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 19011 *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.

*Such control should not hinder the registrar's objectivity or ability to conduct a proper audit and report findings.*

## **EASY RIDERS**

When a company signs on with a registrar, the CRB 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 CRB's existing contracts – you ensure you have properly transmitted your requirements to the CRB.

Citing specific ISO 19011 requirements is critical. The contractual language should include the following general requirements:

- The CRB agrees to adhere to the requirements of ISO Guide 62<sup>4</sup> and the IAF GD2 during all audits and activities conducted with our organization.
- The CRB agrees to adhere to the requirements of ISO 19011 during all audits and activities conducted with our organization.
- The CRB acknowledges that the audit program and auditing activities are to be managed by our organization's selected representative, including development of audit scope, objectives, schedule, delegation of escorts, selection of CRB auditors, and other requirements as deemed necessary.

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<sup>4</sup> At some point in the near future ISO Guide 62 will be replaced by ISO 17021; make sure any contractual language you develop is updated when this happens.



- The CRB agrees to notify our organization if and when these requirements conflict with established rules under ISO Guide 62, IAF GD2 and/or ISO 19011, 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 CRB that the audit itself no longer meets the necessary criteria for a legitimate audit. For example, a Management Representative could not mandate that the CRB “find nothing wrong during the audit.”

In addition to general language, some specific citations of ISO 19011 are in order. These seek to address many reported disconnects between auditor behavior, CRB 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 CRB 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)
- Standards to be used
- Clauses to be audited (if not all)
- Languages to be used (in reports and in verbal communication)

Remember, however, that you cannot pick and choose which clauses you want to apply to your company; the scope of your business determines what clauses you are subject to. So do not misinterpret this article as granting your company authority to exclude pertinent clauses.

Your contract should also include a statement on the scope, or activities that are not to be included in the audit:

- The CRB agrees to not engage in auditing of any of the following activities which are deemed out of the scope of the audit:

Here you may want to make a short list of activities that are outside of the quality management system. Some examples may include:

- Safety issues unrelated to the safety of the auditors themselves
- Accounts payable
- Activities or processes not included in the scope of the quality system



Now some will argue that these concepts should be included in an overall quality management system, but that decision is up to the end user organization itself.<sup>5</sup> It is then the registrar's responsibility to notify the company if the intended narrowing of scope hinders their ability to provide a full audit that will result in a certificate.

## KNOW YOUR AUDIT OBJECTIVES

Once the audit scope is determined, the audit objectives must be determined and defined. ISO 19011 spends a good deal of time on audit objectives, yet this is a concept that is routinely ignored by CRB's who typically establish the objectives for the auditee. This is backwards, of course. The organization must tell the registrar what it wants; no company, CRB or otherwise, should ever assume customer requirements. Specifically, ISO 19011 clause 6.2.2 says:

*The audit objectives define what is to be accomplished by the audit and may include the following: (a) determination of the extent of conformity of the auditee's management system, or parts of it, with audit criteria; (b) evaluation of the capability of the management system to ensure compliance with statutory, regulatory and contractual requirements; (c) evaluation of the effectiveness of the management system in meeting its specified objectives; (c) identification of areas for potential improvement of the management system.*

Again, it is up to **the auditee** to determine the objectives, not the CRB to assume that the sole objective is to obtain or maintain ISO 9001 registration.

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 CRB 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)

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<sup>5</sup> 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 CRB 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 CRB into litigation. For example, we have seen cases where QMS auditors write up findings on the control of MSDS records; however, the Federal labor laws governing the content and use of MSDS's 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 CRB 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. CRB 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 CRB that proves otherwise.



- Written submission of a completed audit report in accordance with the CRB's 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).
- 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.

## **MISCELLANY IS GOOD FOR THE SOUL**

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

- The CRB 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 CRB acknowledges that its audit activities are to be conducted in accordance with ISO 19011:2002.
- The CRB agrees to the definitions of terms as listed in clause 3 of ISO 19011:2002.
- The CRB agrees to the principles of auditing as listed in clause 4 of ISO 19011:2002.
- The CRB 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 CRB agrees that exchange of documentation for the purposes of documentation review may be done electronically.
- The CRB agrees to populate its audit team in accordance with the requirements of clause 6.2.4 of ISO 19011:2002, with auditors knowledgeable in our industry, SIC codes and the standards listed in the Scope; where such auditors are not available, the CRB shall receive our waiver for this requirement in advance.
- The CRB shall provide our organization with the credentials, certifications and/or resumes of its proposed audit team members within sufficient time so that if our organization requires a change in audit team, there are no scheduling conflicts or fees incurred by the CRB for modifying the proposed audit team.
- The CRB shall not send auditors, trainees or observers who have not been pre-approved by our organization, with the exception of witness auditors from the CRB's accreditation body.
- CRB auditors agree to act in accordance with the requirements of ISO 19011, and refrain from actions which may be seen as combative, argumentative, intimidating or in any other way counterproductive to the audit process.



- CRB auditors agree not to be prescriptive in their auditing technique; i.e., to infer or require the implementation of specific methods for compliance.
- CRB auditors agree not to make conclusions or assumptions about our organization's quality management system on the basis of previous experience.
- The CRB 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 19011:2002 clause 6.5.3. (a) through (e).
- The CRB agrees to provide a written report of the documentation review portion of the audit (*x*) weeks prior to the first day of on-site audit activities. This report must list specific nonconformities found during the documentation review, in accordance with the nonconformity reporting requirements below. Failure to provide this report within the allotted time may result in our organization rescheduling the on-site audit activities at the full expense of the CRB.
- If the audit activities result in a recommendation for (or maintenance of) certification to the standards referenced, the CRB 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, CRB 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 19011 which requires that auditing be an “evidence-based” activity (clause 4) and that findings be verifiable.

*When auditors write a nonconformity beginning with the phrase “there is no objective evidence that...,” it means the auditor stopped auditing prematurely.*

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.

ISO 19011 clause 6.5.4 mandates that “*only information that is verifiable may be audit evidence,*” and clause 6.5.5 specifically requires that “*nonconformities and their supporting audit evidence*” be recorded. 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.

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.”<sup>6</sup>

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

- When writing findings, the CRB 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 CRB’s 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 19011 and rejected by our organization.
- Our organization reserves the right to reject such nonconforming findings during the audit itself or at a later date.
- The CRB shall agree to immediately reject findings that do not comply with this convention and not require the rejection to undergo the CRB’s appeals process.
- 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.

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 19011 and Guide 62.

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<sup>6</sup> [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, Inc., and has been implementing ISO 9001 systems since 1988.

Mr. Paris originally worked as a chemical process engineer for The Mearl Corporation (now Engelhard) where he worked on mica-based pigments, and Pure Tech, Inc., 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.

Mr. Paris is 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 member of the International Federation of Standards Users (IFAN), and a former RAB-certified auditor of quality management systems.

Mr. Paris’ articles on ISO 9001 and A9100 have been translated into numerous languages throughout the world, and praised for their simplicity and clarity. He lives near Orlando, Florida, and may be reached at [cparis@oxebridge.com](mailto:cparis@oxebridge.com).



## **About Oxebridge Quality Resources**

Oxebridge Quality Resources, Inc. was founded in 1999 with the intent of providing companies in all sectors affordable, practical implementations of ISO 9001 and related quality system programs. Since that time, the Oxebridge “Rapid ISO” program has assisted numerous companies in achieving ISO 9001 registration in less than 40 days, with the development of custom, lean systems that limit unnecessary documentation and provide for swift improvement returns. Oxebridge boasts the highest success rate of its clients, with 100% achieving registration on their first attempt, and 100% maintaining that registration through years of surveillance.

Using the same common-sense approaches as in its ISO 9001 implementation services, Oxebridge has become a leader in the implementation of other systems, including AS9100, the aerospace quality system standard.

For more information on Oxebridge, as well as other articles on ISO 9001 implementation methods, visit the company’s website at [www.Oxebridge.com](http://www.Oxebridge.com).