

2004: The year of the ISO Teams



IN THIS ISSUE

We begin the sixth year of the Newsletter in a far more settled ISO 9000 environment than those that greeted our opening editions over the past three years.

At the beginning of 2001 we were trying to calculate the changes that would result from the introduction of the new ISO 9001:2000 Standard.

At the beginning of 2002, we responded to the precipitous drop in new ISO certifications with the theme: "ISO 9001:2000, Is It Worth It?"

Last year began with a review of readers' answers to a questionnaire about ISO 9001:2000. Some of these answers turned out to be surprisingly good guidelines to the ISO events of 2003.

Examples of this accurate feedback included:

- Customer demand would continue to be the driving force for certification.
- Companies would wait till the last minute to transition from ISO 9000:1994.
- Many companies that said they wouldn't change from ISO 9000:1994 to the new Standard kept their word (although a number of them put their resources into specialist Standards like ISO 13485 instead)
- The economy would be a big factor in smaller companies' decisions regarding ISO 9000: 1994 to 9001: 2000 transitions.

Some small companies never tried to transition.

Others started and just gave up.

■ ISO 9001 surprises during 2003 (pleasant and otherwise) that could have been foreseen from a closer examination of readers' responses included:

■ A "let it be" approach of some Certification Auditors

On a number of occasions during 2003, QRC was invited to explain ISO 9001:2000 to companies that had already transitioned. Although they were certified, they admitted they knew nothing about the new Standard, and they were not being modest

In some transitions, for example, the Certification Auditor limited the audit to checking out the revised Quality Manual. The result was cynicism on the part of some managers ("they want our business so bad, they wouldn't dare fail us"), and frustration on the part of many ISO 9001 Management Representatives.

This is not to suggest that all Certification bodies adopted this strategy. There were some first class audits of QRC clients, where the registrars were looking to use the Certification Audits to give added value to the Quality Management System.

New Certifications were often very thoroughly audited; leaving the successful companies with the impression that being certified was a worthwhile achievement.

■ Another hint of a trend came from the feedback of companies that had already certified and were encouraged by the positive changes that the new System was making.

At the time, we tended to fall into the trap of passing over these comments as examples of "good people doing a good job"

However, as 2003 progressed, it became apparent that there was a growing number of Management Representatives who expected more from ISO 9001 than just a "plaque on a wall".

Sometimes, these Management Representatives were not clear about the possibilities of their new Systems or what tools they needed.

However, they understood that ISO 9001:2000 could be a valuable business device, and they wanted to use it to make things better.

In response to this growing trend, the QRC Newsletter starts a series intended to help the "ISO TEAM," focusing, in particular, on:

■ Management Representatives who want to make their ISO 9001 Systems effective contributors to the success of their organizations

■ Internal Auditors who want their auditing skills to be a value added asset to their organizations.

"He that will not apply new remedies must expect new evils, for time is the greatest innovator."

Francis Bacon



KEEPING UP WITH THE STANDARDS

The number of specialist Standards seems to be growing by the week. A few examples of the Standards supported by the QRC Special Standards Service Unit are:

- ☞ ISO 13485 (Medical devices)
- ☞ ISO 14000 (Environmental)
- ☞ ISO 18000 (Occupational safety)
- ☞ AS 9100 (Aerospace)
- ☞ SQAP: 2000 (Flight simulators)
- ☞ TS 16489 (Automotive)

This year, every ISO 9001 team needs to be aware of **IAF Guidelines: 2002**.

These Guidelines will impact all ISO 9001 installations during 2004 and beyond.

Some Management Representatives have already expressed their surprise at the number of days being assigned for Certification or Surveillance Audits.

IAF Guidelines: 2002 are the reason.

Annex 2 of these Guidelines provides guidance to registrars on the amount of time required to assess organizations of differing sizes and complexities.

A Chart provides the average number of auditor days (initial audit) calculated on the number of employees.

Days can be added or subcontracted according to audit factors.

Multiple buildings, high degrees of regulation, multiple languages can all increase the length of an audit

Reduced scopes, small sites, repetitive tasks can reduce the time of the audit.

An even bigger impact of IAF Guidelines: 2002 is the recommendation that registrars audit to ISO 19011:2002 Standards by November 2004.

QRC is already noticing the impact of this recommendation.

Owing to our large number of clients, we are directly or indirectly involved in certification and surveillance audits on a continuing basis. These audits are conducted by a wide variety of registrars in an assortment of ways.

In the last few months, actual Level 2 and threatened Level 1 nonconformities have

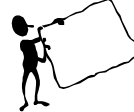
occurred on the topics of planning, conducting and reporting Internal Audits. This development was a nasty and unexpected surprise to companies that, for many years, had been happily auditing to ISO 10011-3, 1991 Standards and/or military Standards.

As registrars train their Certification Auditors in the requirements of ISO 19011:2002 Standards, Management Representatives and Internal Auditors can brace themselves for some shocks if they are not aware of the requirements of the new audit Standard.

At the beginning of the second Quarter of 2003, QRC changed its ISO 9001 Internal Auditor Training Courses and Workshops to reflect the requirements of ISO19011: 2002. If you attended one of our Courses or Workshops since that date, you were taught to the requirements of the new Standard. If not, the next segment may be of interest.

“Before everything else, getting ready is the secret of success”

Henry Ford



SOME HIGHLIGHTS OF ISO 19011:2002 STANDARDS

ISO 19011:2002 introduces itself as “guidance on the management of audit programs, on the conduct of internal or external audits and on the competence and evaluation of auditors”

From this it is reasonable to expect that Certification Auditors will evaluate:

How you manage your audit program in accordance with the 19011 guidelines

How you conduct internal and external audits according to the guidelines

What evidence is there that you evaluate the competence of your auditors?

Typical registrar strategies are to give a warning of new topics that will be addressed in future surveillance audits.

However, there is no certainty of such a warning, and, as we discovered in the early days of transitioning to ISO 9001:2000, when a Certification Auditor is trained in something new, he/she starts to use it.

To illustrate some of the changes of ISO 19011:2002, we include the following questions (with answers) taken from tests that we give after Internal Auditor training.

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These questions are some indication of the "coming attractions" of being audited to ISO 19011:2002 Standards.

- ① What are the key principles that relate to auditors?
- ② What are the key principles of an audit process?
- + List four considerations that should be made in creating objectives for an audit program
- ! List four considerations governing the extent of an audit program
- List four criteria that audit procedures should address
- List four pieces of information that should be included or referred to in the audit report
- ☞ What factors should be used when evaluating the effectiveness of an audit program?
- What should the Audit Scope include?
- X List four issues that the audit conclusions should deal with
- ? Whose property is the Audit Report?
(Answers in the next column)

Clause 7 of ISO 19011:2002 focuses on the competence and qualifications of audit team leaders and auditors.

Topics addressed include:

- Education (Secondary)
- Total work experience (5 years)
- Work experience in quality (2 years)
- Auditor training (40 hours)
- Audit experience (4 complete audits for a total of 20 days as an "auditor-in-training," within the last three consecutive years).

Let us hope that these issues are fed in gradually.

We know of many fine auditors who would not qualify, and more than a few small companies that could not staff an audit team under these conditions

As part of the "listening post" service we try to provide to our readers, could you let us know when your registrar starts to refer to ISO 19011:2000 requirements?

"If it isn't perfect, make it better"

Japanese saying quoted by D. T. Kearns



HELP US HELP YOU

We are still developing the topics for this

"ISO Team" Newsletter Series.

Some of the issues we are looking at as a result of customer requests are:

- Managing Change
- Customer satisfaction
- Continual improvement

If you have any other subjects you would like us to cover, please let us know.

The idea is that the 2004 Newsletters give support to the people who are developing their ISO 9001:2000 programs through the three stages of maturity we reviewed in the last issue.

Answers to test questions:

- ? The Audit Report is the property of the auditee
- X How well is the system implemented? How well is the system maintained? Is the system being improved? Is there evidence that the management review process is impacting the system?
- Physical locations to be audited; Organizational Units to be audited; Activities and processes to be audited; Time period for the audit
- ☞ The ability of the auditors to implement the plan; Conformity with audit schedules; Feedback from auditors and auditees; Consistency in performance by different auditors in similar situations
- Audit objectives; Audit scope; Unresolved issues between the auditor and the auditee; Statement of confidentiality
- Planning and scheduling; Assuring the competence of auditors; Assigning roles and responsibilities; Monitoring the effectiveness of the program
- ! Size and complexity of the organization; Scope and objectives of each audit; Regulatory and contractual requirements; Changes to the organization
- + Management priorities; Commercial intentions; Management system requirements; Regulatory and contractual requirements
- ☞ Effective and reliable; Capable of giving conclusions that are relevant and sufficient; A valid support of management policies and controls; A provision of consistent conclusions from auditors working independently of each other.
- ☞ Ethical conduct; Fair presentation; Due care; Independence; Evidence based evaluations