USING ISO 19011 AND ANSI/ASQ QE 19011S:
A PRACTITIONER’S PERSPECTIVE

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SUMMARY

In October 2002, the International Organization for Standardization (ISO) published ISO 19011:2002, Guidelines on Quality and/or Environmental Management Systems Auditing, which replaced six previous ISO standards pertaining to the quality management systems (QMS) and environmental management systems (EMS) auditing. ISO 19011:2002 provides guidance on establishing an audit program for organizations, implementing audits of management systems, and determining and evaluating the competence of auditors. The guidance includes a description of its principal elements and some discussion of its applicability to internal and external audits of quality and environmental management systems. ISO 19011:2002 was intended to apply to the full range of auditing situations, but it emphasizes external third-party audits and does not appear to be effective in addressing internal and supplier audit applications. Throughout the development of ISO 19011:2002, the U.S. expressed concerns that the full scope of the standard was not being addressed adequately. Attempts by the U.S. to correct these problems were unsuccessful.

The development of ANSI/ASQ QE 19011S, the U.S. Supplement to ISO 19011:2002, was caused largely from the insufficient guidance in the standard in areas pertaining to internal and supplier audit programs and audits and guidance in the use of the standard by small-to-medium enterprises or organizations. No other alternative seemed viable and the U.S. believed that the market place could not afford to wait until ISO 19011 was revised.

ANSI/ASQ QE 19011S provides additional guidance to that in ISO 19011:2002; that is, it includes additional guidance in those clauses where the ISO text was found to be insufficient or inadequate. The Supplement format follows the ISO style and adopted the format employed in ISO 9004:2000 in which the ISO text is placed in boxes and is followed by the Supplement text for internal (first-party) audits, supplier (second-party) audits, and use by small organizations. Completion of the Supplement is expected by early summer 2004.

INTRODUCTION

ISO 19011:2002, Guidelines on Quality and/or Environmental Management Systems Auditing, is an international consensus standard currently nearing completion that provides guidance on auditing quality management system as well as environmental management systems. ISO 19011:2002 provides guidance on establishing an audit program for organizations, implementing audits of management systems, and determining and evaluating the competence of auditors. The guidance includes a description of its principal elements and some discussion of its applicability to internal and external audits of quality and environmental management systems. ISO 19011:2002 was intended to apply to the full range of auditing situations, but its text emphasizes external third-party audits and does not appear to be effective in addressing internal and supplier audit applications.

Despite repeated efforts by the U.S. delegation to the ISO 19011 Joint Working Group (JWG) that developed the standard, no additional text or clarifications were included. (The JWG was comprised of country experts from ISO/TC 176 on Quality Management and ISO/TC 207 on Environmental Management and was empowered by both Technical Committees to develop a single auditing standard for QMS and EMS auditing.) Upon finalization of ISO 19011:2002, the U.S. Technical Advisory Groups (TAGs) to both ISO Technical Committees considered several options in order to provide the U.S. market with adequate guidance for the full range of audit activities. It was concluded that the best option would be to develop a supplement to ISO 19011:2002 to add the needed guidance. Since this supplement would be an American National Standard, the task of developing the document was given to the Z1 Accredited Standards Committee of the American National Standards Institute (ANSI). The Quality and Environmental Management Subcommittees formed the Joint Task Group (JTG) on Auditing to undertake the task of developing ANSI/ASQ QE 19011S, Guidelines on Quality and/or Environmental Management Systems Auditing - U.S. Version with Supplemental Guidance Added.

In the discussions to follow, ISO 19011:2002 and ANSI/ASQ QE 19011S will be described, and areas where
additional guidance has been developed will be highlighted. The Supplement is not intended to supplant ISO 19011:2002. There are many elements of ISO 19011 that are applicable to the full range of audit activities without further change. The purpose of the Supplement is to augment the ISO text with the needed text to provide clear and useful guidance for internal (first-party) audits, supplier (second-party) audits, and use by small organizations.

THE ISO 19011 AUDITING STANDARD

ISO 19011 is intended to provide guidelines for auditing ISO 9001-based quality management systems (QMS) and ISO 14001-based environmental management systems (EMS), but it is also be sufficiently general that it can be applied to any QMS or EMS, and to other management systems such as health and safety. The standard replaced the following ISO auditing standards:

- ISO 10011-1, -2, -3, Guidelines for Auditing Quality Systems
- ISO 14010, Guidelines for Environmental Auditing - General Principles
- ISO 14011, Guidelines for Environmental Auditing - Audit Procedures - Auditing of Environmental Management Systems
- ISO 14012, Guidelines for Environmental Auditing - Qualification Criteria for Environmental Auditors

ISO 19011 reflects the changes made to ISO 9001:2000, Quality Management Systems - Requirements, which was issued in December 2001, including the new business model for the standard. ISO 19011 is intended to apply to both internal and external auditing, and may be used as part of auditor certification and training.

The structure of ISO 19011 is as follows:

0 Introduction
1 Scope
2 Normative References
3 Terms and Definitions
4 Principles of Auditing
5 Managing an Audit Program
6 Audit Activities
7 Competence and Evaluation of Auditors

Clause 0, Introduction, assists the reader in understanding the reason for the standard and who might use it. Clause 1, Scope, defines the scope and applicability of the standard which extends beyond QMS and EMS auditing. Clause 2, Normative References, cites the two reference standards on QMS and EMS vocabulary that are incorporated into the standard by reference and made a part of it. Clause 3, Terms and Definitions, provides additional unique terms not covered by the normative references that are necessary to ISO 19011 and its use. Clause 4, Principles of Auditing, provides some general principles on auditing to aid first-time users of the standard. Clause 5, Managing an Audit Program, provides guidance on establishing, managing, and evaluating different types of audit programs that an organization might need. Clause 6, Audit Activities, addresses the process of planning, conducting, and evaluating individual audits within a specific audit program. Clause 7, Competence and Evaluation of Auditors, addresses the personal attributes and knowledge and skills needed to assure auditor competence, including the initial selection and on-going evaluation of auditors.

The standard includes several diagrams and practical help boxes to aid users in understanding and using the guidance. Much of the ISO text addressing guidance to and internal auditors was typically found in these practical help boxes.

ISO 19011:2002 is a guideline standard which means its use is not mandatory unless it is invoked as part of a multiple party agreement, such as contract or other legal agreement. As a guideline standard, its implementation is generally not auditable because the elements of the standard are not requirements and because there may be others ways of accomplishing the same objectives. Of course, when the standard is invoked as a requirement, such as by a certification/registration body, its guidance becomes specifications for conformity assessment.

DESCRIPTION OF ISO 19011 AND QE 19011S

The need for a Supplement to ISO 19011:2002 resulted from the failure of the ISO standard to satisfy its original
objective to cover the full range of auditing activities (e.g., first-, second-, and third-party audits). The design of ISO 19011:2002 approached auditing as a process. The core of the standard lies in Clauses 5, 6, and 7. It was decided that Clause 4 would be included to provide new users with some basic principles of auditing that would support the guidance in the remaining clauses.

The format used in the Supplement followed the same order as the ISO standard. The Supplement presented the ISO text in a box and followed the box with the supplemental guidance in three sub-clauses, one each for internal (first-party) audits, supplier (second-party) audits, and use by small organizations. In those clauses in which the ISO text is sufficient, the Supplement notes that no additional guidance is needed. The format and its use are described in the Introduction to QE 19011S.

The placement of the ISO text in boxes was done so for several reasons. First of all, it was important to distinguish clearly between the ISO text and the Supplement text. This had been in ISO 9004:2000, Quality Management Systems - Guidelines for Performance Improvements, with the ISO 9001 requirements placed in boxes and followed by the ISO 9004 guidance. Second, the JTG had no authority to modify the ISO text; therefore, the ISO text had to remain intact and any deviations from the text would be presented in the Supplement’s guidance.

Clause 1 - Scope

The ISO text focuses on the applicability of the standard to QMS and EMS, and notes that it may be applied to other types of management systems as well. The Supplement adds clarification of the concept of small organizations to include consideration of the complexity of the management system; that is, the Supplement would apply to large organizations if they have simple management systems, simple products and processes, etc.

Clause 2 - Normative References


Clause 3 - Terms and Definitions

While the Supplement does not add new definitions or changes those in Clause 3, it does note that the term “competence” is used in the context of auditor competence. The current definition of “competence” in ISO 9000:2000 is slightly different from the one in ISO 19011 and adds “personal attributes” to the definition. This difference is not yet resolved in ISO 9000:2000; however, the JWG was empowered to modify terms and definitions in ISO 9000:2000 that pertained to auditing.

Clause 4 - Principles of Auditing

The standard provides a brief summary of some important auditing principles in Clause 4. These principles are to be used to drive the establishment and implementation of the audit process for an organization. Key among the principles cited for auditor behavior are:

- ethical conduct - the foundation of professionalism,
- fair presentation - the obligation to report truthfully and accurately, and
- due professional care - the application of diligence and judgement in auditing.

Two other principles of auditing relate to the audit process primarily. They are

- independence - the basis for impartiality and objectivity of the audit conclusions, and
- evidence-based approach - the rational method for reaching reliable and reproducible audit conclusions in a systematic audit process.

The Supplement stresses the importance of audit and auditor independence, adding that “auditors should not audit their own work.” The value of the audit principles to supplier (second-party) audits and to use by small organizations is also discussed.
Clause 5 - Managing an Audit Program:

Clause 5 provides guidance for those who need to establish and maintain an ongoing audit program for an organization. Such audit programs could include third-party certification audits, but could also include internal (first-party) audits and supplier (second-party) audits. Most clauses in this section of the standard have supplemental guidance to distinguish among the different types of audit programs. In particular, the Supplement emphasizes the differences between internal and external audits.

The standard utilizes the Plan-Do-Check-Act cycle to describe management of the audit program. Some of the key actions addressed are:

- establishing the authority for the audit program;
- establishing the audit program itself, including the objectives and extent, responsibilities, resources, and procedures;
- ensuring the implementation of the audit program,
- monitoring and reviewing the audit program to improve its efficiency and effectiveness, and
- improving the audit program.

Because the standard may be applied to internal and external auditing, setting the objectives and extent of the audit program is a critical early step in defining the audit program for a particular organization or application. Any audit program should be managed by persons having appropriate authorities and resources to implement the program.

The audit program may also address the possibility of “combined audits” and “joint audits.” A “combined audit” occurs when a QMS and EMS are audited at the same time by the same audit team. A “joint audit” occurs when two audit teams cooperate to audit an organization during the same period with one team auditing the QMS and the other team auditing the EMS. Such audits are more typically found in external (third-party) audits, but combined internal QMS and EMS audits are possible.

The ISO standard notes that any audit program should be monitored and reviewed to ensure its ongoing effectiveness in meeting the needs of the organization. Adjustments to the audit program should be made when needed in order foster improvements. The Supplement again emphasizes the differences between external and internal audits in how audit programs are managed and in the involvement of the organization’s management in the programs. In addition, the Supplement suggests that audit program review should also consider the performance of the audit program in meeting the needs of the organization and the contribution of the audit program to the improvement of the management system.

Clause 6 - Audit Activities

The Supplement adds important guidance for audit team leaders for internal (first-party) audits and supplier (second-party) audits not covered by the ISO text. In general, Clause 6 describes the six general steps in planning and conducting an audit. These steps include:

- initiating the audit,
- conducting document review,
- preparing for the on-site audit activities,
- conducting on-site audit activities,
- preparing, approving, and distributing the audit report, and
- completing the audit (including any follow-up activity that may be needed).

Initiating an audit requires consideration of several factors and actions, including:

- appointing a appropriate audit team leader,
- having defined audit objectives, scope, and criteria,
- determining that the audit is feasible,
- selecting a satisfactory audit team, and
- establishing the initial contact with the auditee.

The Supplement provides extensive added guidance to cover internal (first-party) audits and supplier (second-party) audits
not covered by the ISO text, including the audit team review of any available documents pertaining to the audit and preparation for the on-site phase of the audit. Such preparation for the on-site audit activities would also include:

- creating an audit plan to document how the audit will be conducted,
- assigning specific work or responsibilities to audit team members, and
- developing work documents such as checklists and sampling plans.

Whether a QMS or EMS audit, or internal (first-party) audits, supplier (second-party) audits, or external (third-party) audits, the on-site activities are similar and include:

- conducting an opening meeting with the auditee,
- communicating with the auditee and others during the audit,
- defining the roles and responsibilities of guides (as needed),
- collecting and verifying information,
- generating audit findings,
- preparing audit conclusions, and
- conducting the closing meeting.

The Supplement emphasizes the particular differences between internal and external audits and how they are conducted. For example, an opening meeting may less formal for an internal audit and communication during the audit can be simpler. The Supplement notes, however, that a formal meeting is always appropriate in supplier (second-party) audits. In all cases, a reliance on objective evidence is key.

Reporting on the audit results is a critical step and should accurately reflect what transpired during the audit regardless of type. The standard emphasizes the need to address the extent of conformance to the audit criteria, the effectiveness of the management system implementation, and the ability of the management review process to assure the continuing suitability and effectiveness of the management system. This is a significant difference from QMS audit criteria in the past when auditors frequently commented on the suitability and effectiveness of the management system itself. This was inappropriate for two reasons: (1) management is responsible for assessing the value (i.e., “suitability and effectiveness”) of the management system and (2) the auditors may lack critical knowledge about the organization’s operations in order to assess the value of the management system. Clearly, internal auditors have more flexibility in presenting opportunities for improvement inasmuch as they are stakeholders in the organization. External certification auditors, however, must remain mindful of most codes of ethics which prohibit consulting.

The ISO standard and the Supplement provide specific guidance for audit completion and follow-up as needed to confirm that all non-conformities have been addressed. In most cases, the audit will be completed when all activities described in the audit plan have been completed; however, there may be occasions when follow-up by the same audit team will be necessary, for example, in an internal audit.

**Clause 7 - Competence and Evaluation of Auditors**

Clause 7 in ISO 19011:2002 represented a significant change from looking at “auditor qualifications” to “auditor competence.” Auditors must be competent to perform their assigned tasks and the standard described a consistent process for initially selecting and continually evaluating the competence of auditors. Competence is based on the demonstration of personal attributes and the ability to apply requisite knowledge and skills obtained through education, work experience, auditor training, and audit experience. Auditor competence expectations and the evaluation process are described in Clause 7.

The ISO standard describes the general knowledge, skills, and personal attributes needed for an auditor and an audit team leader. An auditor should have knowledge and skills in audit principles, procedures, and techniques in order to be able to implement the audit. Similarly, the auditor needs to understand the scope of the audit and concepts of management systems in order to apply audit principles effectively. An audit team leader needs to have these same knowledge and skills as well as have the appropriate organizational and leadership skills to be able to implement the audit consistent with the goals of the audit program. In addition, the auditor and audit team leader will need knowledge and skills pertaining to QMS and their applications and EMS and their applications, as appropriate. When combined audits are required, knowledge and skills in both areas will be necessary.
There is also a need for auditors to have appropriate education, work experience, auditor training, and auditing experience consistent with the needs of the audit program. Typically, the levels of education, training, and experience will vary according to the specific goals and objectives of the audit program. For example, the levels of education, training, and experience needed for internal (first-party) auditors will very likely differ significantly from those for third-party, certification auditors. In a practical manner, these levels should be set by the “owner” of the audit program or by an appropriate accreditation body. For ISO 19011, there was an extensive debate about what these levels should be and who should set them. The ISO standard includes Table 1, which gives numeric levels for education, training, audit experience, and overall work experience. Table 1 was completely arbitrary and was reported based on a survey of certification auditors in the United Kingdom in the early 1990s. That Table 1 could be interpreted as a consensus recommendation and considered as a de facto requirement was the principal concern for the U.S. regarding Clause 7.

In contrast, sentiments were strong among some countries that Table 1 was needed “to raise the bar of excellence” for auditors professionally, but representatives of some developing countries expressed concern that the levels in Table 1 were too burdensome for them. The U.S. believed that this table was inappropriate for this standard and infringes upon the authorities of international and national certification bodies. The table is certainly inconsistent with the ANSI/RAB National Accreditation Programs for registrars for ISO 9001 and ISO 14001. Moreover, the U.S. feared that some users could be influenced to apply the table to other audit situations, including internal (first-party) audits and supplier (second-party) audits.

The Supplement provides an alternative approach to determining and evaluating the competence of auditors based on the scope of the audit program. Practical considerations show that the competence needed for certification/registration auditors would logically be greater than that for internal auditors. These and other differences between internal audit programs and external audit programs form the basis the Supplement’s approach to competence, and the Supplement provides extensive guidance to the user in this regard. While some people might argue that the size of the guidance be kept as small as possible, the U.S. believed that completeness and usability of the guidance should be the driving force.

The ISO standard and the Supplement together provide a process to guide the initial selection of auditors commensurate with the needs of the audit program and to provide for their continuing evaluation. Since some audit programs may be long term in nature and auditors may be used over an extended period of time, the they also describe a four-step process for the on-going evaluation of auditor competence. These are to:

1. identify the personal attributes and the types and extent of knowledge and skills to meet the needs of the audit program,
2. set the evaluation criteria (reflecting the nature of the audit program),
3. select an appropriate evaluation method, and
4. conduct the evaluation.

This process is illustrated in a table for an evaluation of internal auditors, which provides added guidance for such applications as well. The guidance also presents several types of evaluation methods that may be used.

Last, Clause 7 also provides guidance on the maintenance of auditor competence. This is typically achieved through continuing professional development, such as through additional training, participation in conferences and seminars, and additional auditing experience. The Supplement offers some examples of sources of continuing professional development that may be helpful to the user. As before, the amount of additional audit experience expected should be appropriate to the audit program for which the auditor is being considered.

**PRACTICAL USE OF ISO 19011 AND QE 19011S**

Now, it is important to re-emphasize the value of ISO 19011:2002 as an auditing standard, even though its primary application seems to be for third-party audits and certification/registration audits in particular. ISO 19011 introduces several new, important auditing concepts, including combined and joint audits. After the completion of ISO 14001:1996, there has been growing evidence of organizations seeking joint certifications to ISO 9001 and ISO 14001 and through combined audits to save time and costs.

As the development of QE 19011S as an American National Standard progressed, its existence became known to
other countries currently using ISO 19011 and several countries have expressed their support for its completion based upon their need for more guidance on internal audits and use by small organizations and businesses. As the director of the standards-setting body for a Middle Eastern country said, “We are a nation of small businesses.” These and other words of encouragement suggest that the U.S. was correct in creating QE 19011S in response to an unfilled need.

Since QE 19011S contains the full text of the ISO version, it may be more broadly applicable to users.

The nature of auditing continues to evolve as audit program managers and auditors are confronted with a constantly changing management systems landscape. New applications for management systems, such as occupational health and safety and corporate social responsibility, are continuing to emerge, and with the come the challenge of being able to audit them for conformity effectively. Together, ISO 19011:2002 and QE 19011S provide a practical and helpful tool for auditing all types of management systems.

CONCLUSION

While ISO 19011:2002 provides new and more effective guidance for auditing QMS and EMS, its value is only fully realized by an auditing organization through the use of ANSI/ASQ QE 19011S, the U.S. Supplement to the ISO standard. The Supplement contains the full text of the ISO standard and provides the added guidance necessary to manage audit programs, plan and conduct individual audits, and select and evaluate auditors. The Supplement expands the applicability of ISO 19011 beyond its emphasis on external (third-party) audits to encompass internal (first-party) audits, supplier (second-party) audits, and use by small organizations.

ANSI/ASQ QE 19011S is expected to be completed and issued by early summer 2004. It is expected that the Supplement will be provided to the ISO 19011 JWG for consideration during the first revision of ISO 19011:2002, which should occur by 2006 or 2007.

ACKNOWLEDGMENT

The author wishes to acknowledge the contributions to QE 19011S by John Stratton and Bart Solomon as fellow U.S. Experts to the ISO 19011 Joint Working Group on Auditing and by the members of the ANSI Z1 Joint Task Group. The support of the development of QE 19011S by the U.S. TAG to ISO/TC 176 and the U.S. TAG to ISO/TC 207 is also greatly appreciated.

REFERENCES

