

BONZA NEWS

ISO 19011:2011 Guidelines for Auditing Management Systems

By Keshav Ram Singhal

The International Organization for Standardization released ISO/FDIS 19011:2011 – Guidelines for auditing management systems in July 2011 to ISO members. It is expected that international standard ISO 19011:2011 will be published in October 2011.

ISO 19011:2002 is the current auditing standard that provides guidelines for auditing quality and/or environmental management systems. This standard was long overdue for revision and since the initial publication of ISO 19011 in 2002, a number of new management system standards have been published. This has resulted in a need to consider a broader scope of management system auditing as well as providing guidance that is more generic. This is now reflected in ISO 19011:2011 that has the revised title “Guidelines for auditing management systems” instead of “Guidelines for auditing quality and/or environmental management systems” as mentioned in the existing standard ISO 19011:2002.

ISO 19011:2011 will provide guidance for all users, including small and medium sized organizations and will concentrate on what are commonly termed internal (first party) and second party audits as often conducted by customers on their suppliers.

The International Organization for Standardization (ISO) has already published ISO 17021:2011, a standard for conformity assessment that provides requirements for bodies providing audit and certification of management systems. After publication of ISO 19011:2011, there will be two relevant standards:

- ISO 17021:2011, Conformity assessment – Requirements for bodies providing audit and certification of management systems
- ISO 19011:2011, Guidelines for auditing management systems

The publication of ISO 19011:2011 will provide auditors, organizations implementing management systems and organizations (including certification bodies) needing to conduct audits of management systems an opportunity to re-assess their own practices and identify improvement opportunities in conducting audits.

What are the changes within ISO 19011:2011?

ISO 19011 is being revised to provide persons involved in management system auditing with good audit practice guidance relevant to the present environment. Presently there are many organizations implementing management systems covering multiple disciplines, for example quality (ISO 9001), environment (ISO 14001), occupational health and safety (OHSAS 18001) and information security (ISO 27000) etc.



QUOTE

“Education is not preparation for life; education is life itself.”

John Dewey
(1859-1952)

GOOD NEWS

Bombardier Secures \$126M Q400 order

TORONTO, ON
Bombardier says it has secured an order for four Q400 NextG the national airline of the Grand Duchy of Luxembourg, valued at approximately US\$126 million.

The transaction also included options for an additional four Q400 NextGen aircraft.

Luxair had purchased three Q400 airliners in 2006 and a further two Q400 turboprop aircraft.

The Q400 is built at Toronto’s assembly plant.

Source: [Canadian Manufacturing](#)

The Principles of auditing on which the guidance is based are being revised and expanded to include the new auditing principle of 'Confidentiality – security of information'. This will be a principle that will require auditors to be prudent in the use and protection of information acquired in the course of their duties during auditing management systems.

The main body of ISO 19011:2011 will set out good practice for Managing an Audit Programme and Performing an Audit. The update will reflect current thinking and in parts is expanded significantly. These sections will provide detailed guidance; intended to be used flexibly according to the size, level of maturity of an organization's management system, and the nature and complexity of the organization to be audited. The concept of risk in auditing is being introduced. Some guidance will be provided on combined audits, where two or more management systems of different disciplines are audited together (for example QMS and EMS, EMS and OHSAS, QMS and OHSAS). Also, the use of technology in remote auditing will be acknowledged. Changes are being introduced in the guidance on Competence and evaluation of auditors. ISO 19011:2011 will address auditing management systems covering multiple disciplines. and some of these may be wide ranging. The significant changes include:

ISO 19011:2011 will identify that necessary auditor competence comprises generic knowledge and skills of management systems, plus discipline specific (for example, QMS) and sector specific (for example, aerospace) knowledge and skills. Annex A (informative) of the standard will provide examples of discipline-specific knowledge and skills of auditors, including:

- Transportation safety management
- Environmental management
- Quality management
- Records management
- Resilience, security, preparedness and continuity management
- Information security
- Occupational health and safety

ISO 19011:2011 will not include guidance on sector specific knowledge and skills of an auditor. These may be developed later and published separately by the International Organization for Standardization (ISO).

The existing standard ISO 19011:2002 provides guidance on education, work experience, auditor training and audit experience that contribute to development of the knowledge and skills needed to perform audits and lead audit teams. ISO 19011:2011 will also provide guidance on knowledge and skills of management system auditors and an audit team leader but it will not make reference to auditors having completed education, work experience, auditor training and audit experience. This change will recognize that education, work experience, training and audit experience are enablers to competence, which ISO 19001:2011 and ISO 17021:2011 define as 'ability to apply knowledge and skills to achieve intended results'. ISO 19011:2011 will recognize evaluation of competence needs, which may be carried out in a variety of ways, for example a combination of testing and examination, interview and observed audits.

1. **Scope** – There will be no significant changes.

2. **Informative references** – There will be no previous reference to terms and definitions given in ISO 9000 (QMS) and ISO 14050 (EMS).

3. **Terms and definitions** – New definitions for Observer, Guide and Risk are being introduced. The term risk will be used in ISO 19011:2011 in context of "risk-based auditing" and also "audit programme risks". The definition of competence is being revised and although the change in wording appears slight it will require

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organizations to determine competence to achieve intended results. The starting point for which will be to define the intended results for the various activities involved in managing an audit programme and performing audits. This change will be consistent with ISO 17021:2011, a standard on conformity assessment.

4. Principles of auditing – There will be six principles in ISO 19011:2011 instead of five in ISO 19011:2002. Principles (a) – (d) will relate to auditors and the person managing the audit programme. Principles (e) and (f) will relate to the audit.

(a) Integrity – The principle of integrity will replace and expand the principle of ethical conduct mentioned in ISO 19011:2002. The principle of integrity is the foundation of professionalism.

(b) Fair presentation – There will be a minor expansion that will include the obligation to report truthfully and accurately.

(c) Due professional care – the application of diligence and judgement in auditing. ‘Having the necessary competence is an important factor’ (in ISO 19011:2002) will be replaced with ‘An important factor in carrying out their work with due professional care is having the ability to make reasoned judgement in all audit situations’, in ISO 19011:2011.

(d) Confidentiality – security of information. It will be a new auditing principle, which will address the need for auditors to exercise discretion in the use and protection of information acquired in the course of their duties. The principle will refer to inappropriate use of such information for personal gain or in a manner detrimental to the legitimate interests of the auditee.

(e) Independence – the basis for the impartiality of the audit and objectivity of audit conclusions. ISO 19011:2011 will provide more specific guidance on the extent of independence that needs to be achieved, whilst recognizing that in small organizations it may be difficult for internal auditors to be fully independent. ISO 19011:2011 will refer to internal auditors being independent from the operating managers of the function being audited. ISO 19011:2011 will reflect the interpretation of independence that certification bodies generally apply.

(f) Evidence-based approach – There will be minor rewording in ISO 19011:2011 that will include the rational method for reaching reliable and reproducible audit conclusions in a systematic way.

5. Managing an audit programme – In this section ISO 19011:2011 will have considerable revision. The language of guidelines in this section will be easy to understand. There will be more clarity. Managing an audit programme guidelines will be structured in the following clauses:

5.1 - General

5.2 – Establishing the audit programme objectives

5.3 – Establishing the audit programme

5.4 – Implementing the audit programme

5.5 – Monitoring the audit programme

5.6 – Reviewing and improving the audit programme

5.1 General – This clause of the ISO 19011:2011 will recognize that an organization may implement a number of management system standards. Where the existing issue of ISO 19011:2002 refers to an organization establishing one or more audit programmes, ISO 19011:2011 will refer to an audit programme that can include audits considering one or more management system standards. Practically there will be little difference.

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In clause 5.1 of ISO 19011:2011 there will be guidance to allocate audit resources to audit those matters of significance within the management system. This concept is known as risk-based auditing.

5.2 Establishing the audit programme objectives – Title of this clause is being revised and also guidelines for structuring the content to follow the process flow guidance on the extent of an audit programme is being transferred to section 5.3.3.

5.3 Establishing the audit programme – ISO 19011:2002 states the title ‘Audit programme responsibilities, resources and procedures’ and this is being revised as new title ‘Establishing the audit programme.’. New to this issue is guidance on ‘Competence of the person managing the audit programme’. ISO 19011:2011 will add new guidance on ‘Identifying and evaluating audit programme risks’.

5.4 Implementing the audit programme – ISO 19011:2011 will provide more extensive guidance.

There will be sub-clause ‘Define the objectives, scope and criteria for an individual audit’. The sub-clause guidelines will identify that each audit should have a clear objective. This section will also highlight issues to consider when two or more management systems of different disciplines are audited together.

There will be a new sub-section ‘Selecting the audit methods’ and additional guidance on this issue will be provided in Annex B of ISO 19011.

Other sub-clauses will include: Selecting the audit team members, Assigning responsibilities for an individual audit to the team leader, Managing the audit programme outcome, Managing and maintaining audit programme records.

In short we can conclude that section 5.4 of ISO 19011:2002 is being revised to provide comprehensive guidance to what was previously a list of headline topics that needed to be addressed when implementing the audit programme. Section 5.5 of ISO 19011:2002 – Audit programme records will be part of section 5.4

5.5 – Monitoring the audit programme and 5.5 – Reviewing and improving the audit programme - These two sections will replace what is stated in ISO 19011:2002 in clause 5.6 – Audit programme monitoring and reviewing. There will be minor expansion and references to consider, such as, evaluate the performance of audit team members, consider as part of a review, alternative or new auditing methods, review the effectiveness of the measures to address the risks associated with the audit programme, review confidentiality and information security issues relating to the programme.

6. **Performing an audit** – The clause title in ISO 19011:2002 is ‘Audit activities’ which is being revised. In this clause of ISO 19011:2011 you will find improved guidance. The section will be structured to follow the audit process flow, as under:

- 6.1 General
- 6.2 Initiating the audit
- 6.3 Preparing audit activities
- 6.4 Conducting the audit activities
- 6.5 Preparing and distributing the audit report
- 6.6 Completing the audit
- 6.7 Conducting audit follow-up

There will be few changes in the guidelines in ISO 19011:2011.

7. **Competence and evaluation of auditors** – Some significant changes are being introduced in ISO 19011:2011. The new standard will address auditing management system covering multiple disciplines. New

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guidance will include: Determining auditor competence to fulfill the needs of the audit programme, Personal behaviour, Knowledge and skills. The clause 'Knowledge and skills' will comprise: Generic knowledge and skills of management system auditors, Discipline and sector specific knowledge and skills of management system auditor. ISO 19011:2002 provides guidance for quality management system and/or environmental management system auditors, each having its own section providing guidance on auditor knowledge and skill requirements. In ISO 19011:2011 these two sections of ISO 19011:2002 will be replaced by one that will identify knowledge and skills that need to be applied to all management systems, for example, knowledge of: Legal requirements relevant to the specific discipline, fundamentals of the discipline and the application of business and technical discipline-specific methods, techniques, processes and practices sufficient to enable the auditor to examine the management system and generate appropriate audit findings and conclusions, risk management principles, methods and techniques relevant to the discipline and sector to enable the auditor to evaluate and control the risks associated with the audit programme.

ISO 19011:2011 Annex A will provide guidance on discipline-specific knowledge and skills of auditors for: Transportation safety management, Environmental management, Quality management, Records management, Resilience, security, preparedness and continuity management, Information security, Occupational health and safety.

ISO 19011:2011 will provide guidance on Generic knowledge and skills of an audit team leader, that will include knowledge and skills to: balance the strengths and weaknesses of the individual audit team members, develop a harmonious working relationship among the audit team members, manage the uncertainty of achieving audit objectives

ISO 19011:2011 will provide guidance on knowledge and skills for auditing management systems addressing multiple disciplines, achieving auditor competence. Clause 7.6 of ISO 19011:2002 provides guidance on auditor evaluation, having sub-clauses, 7.6.1 – General and 7.6.2 – Evaluation process. ISO 19011:2011 will provide more clear guidance on auditor evaluation specifying guidance on establishing the auditor evaluation criteria, selecting the appropriate auditor evaluation method, conducting auditor evaluation, maintaining and improving auditor competence.

Thus we will find ISO 19011:2011 a useful guidance document that will enable auditors to have clearer guidelines on auditing any management systems. The whole process of revising and preparing ISO 19011:2011 is under the auspices of the ISO Joint Technical Co-ordination Group and administered by the ISO Technical Committee ISO/TC 176, ISO subcommittee ISO/TC 176/SC3, and also included interested parties for example ISO/TC 207, ISO/TC 34. ISO 19011:2011 will be the second edition of ISO 19011. The second edition of ISO 19011 will cancel and replace ISO 19011:2002 upon its publication.

Courtesy:

- ISO Website
- ISO 19011:2002
- ISO/FDIS 19011:2011
- IRCA Website

About the Author: *Keshav Ram Singhal is a Trainer, Writer, Speaker, Consultant and Social Worker based out of Ajmer, India. Keshav recently received a medallion in Mumbai: "NCQM sustaining member honour for continuing support to National Centre for Quality Management activities". He can be reached by email at ksinghal@rediffmail.com Linkedin Profile: http://www.linkedin.com/profile/view?id=14687263&trk=tab_pro Referenced Blog: <http://iso9001-2008awareness.blogspot.com>*

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Are you Ready for an FDA Audit?

By John Mahn

The Food and Drug Administration (FDA) is stepping up their focus and inspection activities concerning foreign manufacturers and distributors, exporting medical devices into the United States. They are attempting to conduct inspections of all foreign companies who export medical devices into the USA at least every two years. Some medical device manufacturers have become complacent in adhering to FDA requirements, since the probability of a FDA visit was quite low. This is about to change.

If terms like QSIT, DMR's, DHR's, 510K's and 483's sound unfamiliar to you then perhaps it's time to start preparing for the unexpected, an FDA visit. If you are exporting medical devices to the USA, regardless whether they are a class I, II or III device, you are required, at a minimum, to be in compliance with 21 CFR 820 regulations. You may also be required to comply with 21 CFR 803, 806 & 821 just to name a few.

Companies are required to conduct internal audits with trained auditors to the appropriate 21 CFR 8XX series regulations totally independent of any other internal audit. i.e.: audits to ISO 9001 or 13485 etc.

FDA investigators have the prerogative to show up at your facility without notice and conduct a level I or level II inspection. I have had clients who were given three months advance notice, but trust me if you are not in compliance today, then three months advance notice will not be enough time to prevent receiving the dreaded 483's.

Remember, when you are in violation of a FDA regulation, you are in violation of their Federal laws. This is a serious issue with potentially serious consequences.

Watch for future articles related to FDA requirements and how to survive an FDA visit.

About the author

John Mahn is president of M3M Systems, a consulting, auditing and training company, established in 1991. Specializing in ISO Standards including 9001, 13485, 14000, 17025, AS 9100 & FDA 820 regulations. John delivers over 26 course topics including internal auditing, core tools, problem solving, process mapping, DOE and many more. He currently provides a variety of training courses in partnership with Bonza Training Solu-

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