Successful preparation and conducting of audits

The ISO 19011:2011
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Bibliographic information from the German National Library
The German National Library lists this publication in the German National Bibliography.
Detailed bibliographic data is available on the Internet at http://dnb.d-nb.de

ISBN 978-3-8249-1666-5
© by TÜV Media GmbH, TÜV Rheinland Group, 1st edition Cologne 2012
www.tuev-media.de

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Both males and females are meant by the professional designations used in the text, such as audit program manager or auditor.
Concerning use of the e-book

This e-book provides practical support for the planning, preparation, and conducting of management system audits. It will help you to integrate the regulations of ISO 19011:2011 into the audit process. You can then optimize existing audit processes, and introduce newly defined audit processes with a high degree of efficiency.

Section 1 includes a general introduction to the objective and purpose of audits. The brief profile in Section 2 will familiarize you with the structure of the ISO 19011:2011 standard. The main part of the brochure in Sections 3–6 clearly explains the most important requirements of the ISO 19011:2011 and supplements these by practical tips. The conclusion of the brochure in Section 7 shows how you can prepare your company for a certification procedure and for auditing in accordance with ISO/IEC 17021:2011.

The paperclip symbols included in the text refer to work aids which will support you in implementing the requirements of the standard; we have provided these for downloading:

- fb_19011_01.doc Sample text “Appointment of audit program manager”
- fb_19011_02.xls Example of a tabular audit program – minimal
- fb_19011_03.xls Example of a tabular audit program – extended
- fb_19011_04.doc Example of an audit program risk matrix
- fb_19011_05.doc Example of an audit assignment (individual audit)
- fb_19011_06.doc Example of a document review
- fb_19011_07.doc Example of an audit plan
- fb_19011_08.doc Example of a text analysis
- fb_19011_09.doc Example of an audit checklist
- fb_19011_10.doc Form “Audit notes”
- fb_19011_11.doc Form “Audit participant list”
- fb_19011_12.xls Example of an audit report
- fb_19011_13.doc Example of an audit evaluation
- fb_19011_14.doc Example of a competence matrix “Auditor”

The work aids are available for downloading at:

www.tuev-media.de/download/91665.php

Password: 12189

You can edit the documents as desired and match them to your own company requirements.
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1 Objective and purpose of audits

In accordance with ISO 9000:2005, an audit is a “systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled”. In connection with management systems, a distinction is usually made between

- internal audits,
- supplier audits, and
- certification audits.

The objective of an internal system audit (first party audit) is to systematically evaluate the complete installed QM system of a company and to improve it. The audit is usually conducted by trained employees of the company responsible for carrying out the internal audit. When performing a system audit, the complete operational and organizational structure of a company are checked to see whether the standard requirements of the regulations are fulfilled and that the own quality objectives can be achieved.

If the complete QM system of a company is checked by regular audits, quality deviations can be recognized early and corrected in sufficient time. This not only reduces the error rates and thus the error costs. Since quality audits also include the objective of finding possibilities for improvement, even if the operating procedures function relatively smoothly, these regular checks can also be used to continuously increase the quality level in a company. The focal point of an internal audit is the search for potentials for improvement to support further development of the management system and of business processes. Fulfillment of the standard requirements, in contrast to a certification audit, only plays a subordinate role.

In accordance with the definition of ISO 9000:2005, a supplier is a “producer, distributor, retailer or vendor of a product, or provider of a service or information or assembly worker providing the customer with a product”. The term includes products as well as services. Therefore the supplier is the organization used by a customer company to obtain material or intangible services.

Supplier audits are used for supplier selection and evaluation. During the supplier audit, the customer checks the quality capability of his supplier, i.e. makes sure that the supplier company is always able to provide services of perfect quality. Supplier audits are usually a mixture of process and system audits. Process audits because the customer questions the procedures and risks in the production or service processes with which his orders are handled. They are system audits at the same time because the sample also always considers supporting/leading processes of the complete organization.

Since two parties are therefore involved in this type of audit, namely the customer and the supplier, the supplier audit is also referred to as a second party audit. The term “customer audit” is also occasionally used in the literature since the audit is initiated by the customer. However, the term “supplier audit” is normally used.

The customer can carry out the external quality audit himself or have it carried out by an assigned department or person. This is particularly important if the supplier has his headquarters far away overseas.

In addition to the supplier audits, the external quality audits also include the so-called certification audit. Since this is carried out neither by the customer (second party) nor by the supplier company itself (first party), but by a third completely independent review authority, the certification audit is also referred to internationally as a third party audit. A certification audit is frequently a system audit. The certification audit checks, as a system audit,
whether the complete QM system of a company fulfills the specified requirements.

The requirements to be fulfilled by a QM system in order to obtain a corresponding test certificate are usually defined by a so-called system standard. This can be a sector-specific or sector-independent reference standard, such as the quality standard ISO 9001.

In the case of a certification audit, all areas of a company affected by the requirements of the standard are systematically investigated and assessed to establish whether the necessary quality management measures have been defined and are effective, and whether these measures are also complied with and carried out. If this is the case, the official QM certificate confirms the quality capability of a company. However, this is only the test with regard to a minimum standard (the standard to be applied) and does not provide any information concerning the maturity level of the management system.

The standard ISO 19011 was developed to prepare and conduct internal audits and supplier audits which are considered in detail in the following Sections 2 to 6.

The management of certification audits is regulated in the standard ISO/IEC 17021. Section 7 explains how a company can prepare for a certification audit.

Figure 1 provides an overview of the audit types, their names, and their normative assignment.

<table>
<thead>
<tr>
<th>Audit types</th>
<th>Internal audit</th>
<th>External audit</th>
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<tbody>
<tr>
<td></td>
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<td>Supplier audit</td>
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<tr>
<td>Alternative names</td>
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<tr>
<td>Application of the standards</td>
<td>ISO 19011</td>
<td>ISO/IEC 17021</td>
</tr>
</tbody>
</table>

Fig. 1: Audit types, names, and applications of the standards ISO 19011 and ISO/IEC 17021
2 ISO 19011:2011 – a brief profile

The current edition was published under the name

ISO 19011:2011 –

Guidelines for auditing management systems (ISO 19011:2011); German and English version EN ISO 19011:2011


Revision of the ISO 19011 was carried out because the diversity of management system standards had increased since the first edition in 2002. It therefore became necessary to consider a broader scope for the auditing of management systems and to provide guidelines applicable to management systems in general.

The following significant changes were made compared to ISO 19011:2002:

• The area of application was extended from the auditing of quality and environmental management systems to the auditing of all types of management systems;
• Figures were revised;
• Literature references were revised;
• The relationship between ISO 19011 and ISO/IEC 17021 has been clarified. The application of ISO 19011:2011 refers to first party audits (internal audits) and second party audits (supplier audits). The application for third party audits (certification audits) is possible as support to ISO/IEC 17021:2011;
• Clauses 5, 6 and 7 have been reorganized;
• The embedded text boxes labeled “Practical help” were removed, some of the contents have been transferred to the text of the standards or to the new Annex B;
• Additional guidelines are available at the following website: www.iso.org/19011auditing;
• Confidentiality of information was introduced as a sixth principle of auditing;
• Remote audit methods were introduced (methods which do not require the physical presence of the auditor on site);
• A risk concept was introduced with regard to the risks which endanger the reaching of the audit objectives;
• The terms and definitions (Clause 3) were extended and revised;
• The principles of auditing (Clause 4) were extended;
• Clause 5 “Managing an audit program” and Clause 6 “Audit activities” were modified and extended;
• Clause 7 “Competence and evaluation of auditors” was modified and extended;
• Illustrative examples of discipline-specific knowledge and skills of auditors were presented in a new Annex A;
• Additional information for audit preparation and for conducting the audit were included in a new Annex B;
• The standard provides guidance for all users, including small and medium-sized organizations, and concentrates on what are commonly termed ‘internal audits’ and ‘audits conducted by customers on their suppliers’. Those involved in management system certification audits and following
the requirements of ISO/IEC 17021:2011 may also find the guidance in this standard useful.

- The standard does not state requirements, but provides guidance on the management of an audit program, on the planning and conducting of a management system audit, as well as on the competence and evaluation of auditors and audit team leaders.
- The guidance in this standard can also be used for the purpose of self-declaration, and can also be used by organizations involved in auditor training or personnel certification.
- Use of the standard can differ depending on the size and level of maturity of an organization’s management system and on the nature and complexity of the organization to be audited, as well as on the objectives and scope of the audits to be conducted.
- The standard introduces the concept of risk assessment to management system auditing. The approach adopted relates both to the risk of the audit process not achieving its objectives and to the potential of the audit to interfere with the auditee’s activities and processes.

The standard adopts the approach that when two or more management systems of different disciplines are audited together, this can be also carried out as a combined audit. Where these systems are integrated into a single management system, the principles and processes of auditing are the same as for a combined audit.

The standard is structured in seven main sections – as with the previous version – and two annexes with examples of the required competence of auditors and with assistance for auditing in practice. Figure 2 shows the structure of the sections in ISO 19011:2011.

The main part of the standard (Clauses 4 to 7) contains the following sections:

4 Principles of auditing
5 Managing an audit program
   5.1 General
   5.2 Establishing the audit program objectives
   5.3 Establishing the audit program
   5.4 Implementing the audit program
   5.5 Monitoring the audit program
   5.6 Reviewing and improving the audit program
6 Performing an audit
   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
7 Competence and evaluation of auditors
   7.1 General
7.2 Determining auditor competence to fulfill the needs of the audit program
7.3 Establishing the auditor evaluation criteria
7.4 Selecting the appropriate auditor evaluation method
7.5 Conducting auditor evaluation
7.6 Maintaining and improving auditor competence

Fig. 2: Overview of the structure of the sections in ISO 19011:2011
3 Fundamentals of the audit process – the principles of auditing

In order to meet the requirements of a good audit, ISO 19011:2011 defines fundamental principles – see Clause 4 in the standard. These refer to principles for the auditor and principles for conducting the audit. Adherence to these principles is a prerequisite for enabling auditors, working independently from one another, to reach similar conclusions in similar circumstances. Figure 3 represents the principles of auditing of ISO 19011:2011 as the pillars of an efficient audit process.

![Diagram of the six principles of auditing](image)

Fig. 3: The six principles of auditing of ISO 19011:2011

3.1 Principles for the auditor

Personal integrity of the auditor

- Integrity is the foundation of professionalism (formerly referred to as ethical behavior). Auditors as well as those managing an audit program should:
  - perform their work with honesty, diligence, and responsibility;
  - observe and comply with any applicable legal requirements;
  - demonstrate their competence while performing their work;
  - perform their work in an impartial manner, i.e. remain fair and unbiased in all their dealings;
  - be sensitive to any influences that may be exerted on their judgment while conducting an audit.

Fair presentation

Fair presentation as the obligation to report truthfully and accurately. This means that audit findings, audit conclusions and audit reports should reflect truthfully and accurately the audit activities. Significant obstacles encountered during the audit and unresolved diverging opinions between the audit team and the auditee can be reported.

The communication must be truthful, accurate, objective, timely, clear and complete.
Due professional care

3. Principle

Due professional care means the application of diligence and judgment in auditing. The auditors should exercise due care in accordance with the importance of the task they perform and the confidence placed in them by the audit client and other interested parties.

An important factor in carrying out their work with due professional care is having the ability to make reasoned judgments in all audit situations (formerly only reference to qualification).

3.2 Principles for conducting the audit

Confidentiality of information

4. Principle

Confidentiality is understood as the security of confidential/secret information. The auditors should exercise discretion in the use and protection of information acquired in the course of their duties. Audit information should not be used inappropriately for personal gain by the auditor or the audit client, or in a manner detrimental to the legitimate interests of the auditee. This concept includes the proper handling of sensitive or confidential information.

Independence of the auditors

5. Principle

Independence is the basis for the impartiality of the audit and objectivity of the audit conclusions. Auditors should be independent of the activity being audited, and should act as far as possible in a manner that is free from bias and conflicts of interest.

For internal audits, auditors should be independent from the operating managers of the function being audited.

Auditors should maintain objectivity throughout the audit process to ensure that the audit findings and conclusions are based only on the audit evidence.

For small organizations, it may not be possible for internal auditors to be fully independent of the activity being audited, but every effort should be made to remove bias and encourage objectivity.

Evidence-based approach

6. Principle

An evidence-based approach is the rational basis for reaching reliable and reproducible audit conclusions in a systematic audit process.

Audit evidence should be verifiable. It is based on samples of the information available, since an audit is conducted during a limited period of time and with finite resources. The appropriate use of sampling is closely related to the confidence that can be placed in the audit conclusions.