

AMERICAN NATIONAL STANDARD

Guidelines for management systems auditing—U.S. Version with supplemental guidance added

AMERICAN SOCIETY FOR QUALITY
P.O. BOX 3005
MILWAUKEE, WI 53201-3005

(This page intentionally left blank)

AMERICAN NATIONAL STANDARD

Guidelines for management systems auditing— U.S. Version with supplemental guidance added

Approved as an American National Standard by:
ASC Z1 Subcommittees on
Quality Management and Environmental Management

May 19, 2008

American National Standards: An American National Standard implies a consensus of those substantially concerned with its scope and provisions. An American National Standard is intended as a guide to aid the manufacturer, the consumer, and the general public. The existence of an American National Standard does not in any respect preclude anyone, whether he or she has approved the standard or not, from manufacturing, purchasing, or using products, processes, or procedures not conforming to the standard. American National Standards are subject to periodic review and users are cautioned to obtain the latest edition.

Caution Notice: This American National Standard may be revised or withdrawn at any time. The procedures of the American National Standards Institute require that action be taken to reaffirm, revise, or withdraw this standard no later than five years from the date of publication. Purchasers of American National Standards may receive current information on all standards by calling or writing the American National Standards Institute.



COPYRIGHT PROTECTED DOCUMENT

© 2008 by ASQ

Copyright Protection Notice for the ANSI/ISO/ASQ QE19011S-2008 Standard.

This standard is subject to copyright claims of ISO, ANSI, and ASQ. Not for resale. No part of this publication may be reproduced in any form, including an electronic retrieval system, without the prior written permission of ASQ. All requests pertaining to the ANSI/ISO/ASQ QE19011S-2008 Standard should be submitted to ASQ.

Note: As used in this document, the term "International Standard" refers to the American National Standard adoption of this and other International Standards.

ASQ will consider requests for change and information on the submittal of such requests regarding this Standard. All requests should be in writing to the attention of the Standards administrator at the address below.

ASQ Mission: The American Society for Quality advances individual and organizational performance excellence worldwide by providing opportunities for learning, quality improvement, and knowledge exchange.

PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be viewed but shall not be edited or printed. In downloading this file, parties therein accept the responsibility of not infringing on Adobe's licensing policy. ASQ accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creating parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by our customers. In the unlikely event that a problem relating to it is found, please inform ASQ at the address below.

Published by:



Quality Press
600 N. Plankinton Avenue
Milwaukee, Wisconsin 53203
Call toll free 800-248-1946
Fax 414-272-1734
www.asq.org
<http://www.asq.org/quality-press>
<http://standardsgroup.asq.org>
E-mail: authors@asq.org

Also available from ASQ Quality Press:

The Internal Auditing Pocket Guide: Preparing, Performing, Reporting, and Follow-Up, Second Edition
J.P. Russell

The Management System Auditor's Handbook
Joe Kausek

The ASQ Auditing Handbook, Third Edition
J.P. Russell, editing director

The Process Auditing Techniques Guide
J.P. Russell

Quality Audits for Improved Performance, Third Edition
Dennis R. Arter

The Quality Toolbox, Second Edition
Nancy R. Tague

Managing the Customer Experience: A Measurement-Based Approach
Morris Wilburn

Lean Kaizen: A Simplified Approach to Process Improvements
George Alukal and Anthony Manos

Root Cause Analysis: Simplified Tools and Techniques, Second Edition
Bjørn Andersen and Tom Fagerhaug

The Certified Manager of Quality/Organizational Excellence Handbook, Third Edition
Russell T. Westcott, editor

Enabling Excellence: The Seven Elements Essential to Achieving Competitive Advantage
Timothy A. Pine

To request a complimentary catalog of ASQ Quality Press publications,
call 800-248-1946, or visit our Web site at <http://www.asq.org/quality-press>.

(This page intentionally left blank)

Contents

	Page
Foreword	viii
Introduction.....	ix
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 Principles of auditing	4
5 Managing an audit program	5
5.1 General	5
5.2 Audit program objectives and extent	8
5.3 Audit program responsibilities, resources, and procedures.....	10
5.4 Audit program implementation	12
5.5 Audit program records.....	13
5.6 Audit program monitoring and reviewing.....	14
6 Audit activities	15
6.1 General	15
6.2 Initiating the audit.....	17
6.3 Conducting document review	21
6.4 Preparing for on-site activities.....	22
6.5 Conducting on-site activities	24
6.6 Preparing, approving and distributing the audit report	33
6.7 Completing the audit.....	34
6.8 Conducting audit follow-up.....	35
7 Competence and evaluation of auditors	36
7.1 General	36
7.2 Personal attributes	39
7.3 Knowledge and skills	40
7.4 Education, work experience, auditor training and audit experience	47
7.5 Maintenance and improvement of competence	51
7.6 Auditor evaluation	52

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization. International standards are drafted in accordance with the rules given in the ISO/IEC Directives, part 3.

The main task of technical committees is to prepare International Standards. Draft international standards accepted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75% of the members casting a vote.

ISO 19011:2002 was prepared jointly by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 3, *Supporting technologies*, and Technical Committee ISO/TC 207, *Environmental management*, Subcommittee SC 2, *Environmental auditing and related environmental investigations*.

Attention is drawn to the possibility that some of the elements of ISO 19011 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. The first edition of ISO 19011:2002 canceled and replaced ISO 10011-1:1990, ISO 10011-2:1991, ISO 10011-3:1991, ISO 14010:1996, ISO 14011:1996, and ISO 14012:1996.

The American National Standard ANSI/ISO/ASQ QE19011-2002 contains the same text as the ISO version.

This Supplement, ANSI/ISO/ASQ QE19011S-2008, is modeled after ISO 9004:2004; that is, the verbatim text of QE19011 (ISO 19011) is given and is followed by supplemental guidance for first-party (internal) audits, second-party (supplier) audits, occupational health and safety audits, and for use by small organizations for the full range of audit activities.

Introduction

The ISO 9000 and ISO 14000 series of International Standards emphasize the importance of audits as a management tool for monitoring and verifying the effective implementation of an organization's quality and/or environmental policy. ANSI/AIHA Z10-2005 includes audits as an integral part of managing the effective implementation of an occupational health and safety management system (OHSMS). Audits are also an essential part of conformity assessment activities such as external certification/registration and of supply chain evaluation and surveillance.

The ISO 19011:2002 International Standard provides guidance on the management of audit programs, the conduct of internal or external audits of quality and/or environmental management systems, as well as competence and evaluation of auditors. It is intended to apply to a broad range of potential users, including auditors, organizations implementing quality and/or environmental management systems, organizations needing to conduct audits of quality and/or environmental management systems for contractual reasons, and organizations involved in auditor certification or training, in certification/registration of management systems, in accreditation or in standardization in the area of conformity assessment. The guidance in the ISO 19011:2002 International Standard is intended to be flexible. As indicated at various points in the text, the use of the guidelines can differ according to the size, nature and complexity of the organizations, as well as on the objectives and scopes of the audits to be conducted. Throughout the International Standard, supplementary guidance and examples on specific topics are provided in the form of practical help in boxed text. However, the U.S. determined that additional guidance was needed to apply the International Standard to the full range of audit activities, specifically first-party (internal) audits and second-party (supplier) audits, occupational health and safety management system (OHSMS) audits, and use by small organizations.

Since the definition of small organizations may vary, the concept of a small organization in this Supplement does not only relate to the size of the organization but also to the complexity of the management system, complexity of the product and processes, the organization's regulatory environment, and the effectiveness of communications within the organization. Therefore, the guidance given for small organizations may also apply to larger organizations with simple management systems, simple products and processes, little regulatory impact, and good communications processes among the personnel, functions and management levels. It is up to the organization's top management and the audit program manager to determine the application of ISO 19011:2002 and this Supplement to their organization and to the various types of audits they use.

Accordingly, this Supplement has been developed to provide the needed additional guidance. The format includes the complete text of ANSI/ISO/ASQ QE19011-2002 in boxed text followed by supplemental text as needed. No changes to the boxed text from ANSI/ISO/ASQ QE19011-2002 are made in this document. Where no supplemental text is needed, this is stated at the end of the boxed text. When additional text is needed, it is presented for first-party audits, second-party audits, OHSMS audits and use by small organizations as applicable. In some cases, the supplemental text provided for first-party and second-party audits may be also useful for small organizations.

Clause 4 describes the principles of auditing. These principles help the user to appreciate the essential nature of auditing and they are a necessary prelude to clauses 5, 6 and 7.

Clause 5 provides guidance on managing audit programs and covers such issues as assigning responsibility for managing audit programs, establishing the audit program objectives, coordinating auditing activities and providing sufficient audit team resources.

Clause 6 contains guidance on conducting audits of quality and/or environmental management systems, including the selection of audit teams. This Supplement uses a *graded approach* to

apply the guidance from the International Standard to all audit situations.

Clause 7 provides guidance on the competence needed by an auditor and describes a process for evaluating auditors. The guidance provided in the International Standard may be more appropriately suited for third-party audits, including certification/registration audits. This Supplement provides an alternative approach to determining and evaluating the competence of auditors. Rather than emphasizing one set of levels of work experience, education, and audit experience as provided in the International Standard, this Supplement focuses on defining the needed competence for auditors depending on the scope of the audit program. Also included in this Supplement is guidance on the competence needed by those auditing occupational health and safety management systems, a subject that is not addressed in the International Standard.

Where quality, environmental or occupational health and safety (OH&S) management systems are implemented by the same organization, it is at the discretion of the user of the International Standard and this Supplement as to whether the management system audits are conducted separately or together.

The International Standard applies to the auditing of quality and/or environmental management systems. This Supplement also applies to the auditing of occupational safety and health management systems. Users of this Supplement can adapt or extend the guidance provided herein to apply to audits of other types of management systems (for example, AS 9000 for aerospace quality, ASME NQA-1 for nuclear quality assurance) provided the regulatory and contractual audit requirements are met.

The International Standard and this Supplement provide only guidance; however, users can apply them to develop their own audit-related requirements.

In addition, any other individual or organization with an interest in monitoring conformance to requirements, such as product specifications or laws and regulations, may find the guidance in the International Standard and this Supplement useful.

Guidelines for management systems auditing – U.S. Version with supplementary guidance added

1 Scope

QE19011 Text:

This International Standard provides guidance on the principles of auditing, managing audit programs, conducting quality management system audits and environmental management system audits as well as the competence of quality and environmental management system auditors. It is applicable to all organizations having a need to conduct internal or external quality and/or environmental management system audits or manage an audit program.

The application of this International Standard to other types of audits is possible in principle but special consideration should be paid to identifying the competence needed by the audit team members in such cases.

S1 Scope

The supplemental text contained in this document provides additional guidance to users to augment the International Standard. In particular, additional guidance is provided for small organizations that may wish to consider its application to the full range of audit activities (i.e., first, second, and third-party audits) and for any users that wish to apply the standard to internal (first-party) audits and external supplier (second-party) audits.

Since the definition of small organizations may vary, the concept of a small organization in this Supplement relates not only to the size of the organization but also to the complexity of the management system, the complexity of the product and processes, the organization's regulatory environment, and the effectiveness of communications within the organization. Therefore, the guidance given for small organizations may also apply to larger organizations with simple management systems, simple products and processes, little regulatory impact, and good communication processes among the personnel, functions and management levels.

Supplemental guidance for first-party audits, second-party audits, use by small organizations and OHSMS audits has been added to individual sections of this Supplement as applicable.

The organization's top management and the audit program manager should determine the application of ISO 19011:2002 and this Supplement to their organization and their specific audit programs.

2 Normative references

QE19011 Text:

The following normative documents contain provisions, which, through references in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the normative documents indicated below. For undated references, the latest edition of the normative document referred to apply. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 9000:2000, *Quality management systems - Fundamentals and Vocabulary*.

ISO 14050:2002, *Environmental management – Vocabulary*.

3 Terms and definitions

QE19011 Text:

For the purposes of this International Standard, the terms and definitions given in ISO 9000:2000 and ISO 14050:2002 apply, unless superseded by definitions given below.

A term in a definition or note, which is defined elsewhere in this clause, is indicated by boldface followed by its entry number in parentheses. Such a boldface term may be replaced in the definition by its complete definition.

3.1 audit

systematic, independent and documented process for obtaining **audit evidence** (3.3) and evaluating it objectively to determine the extent to which **audit criteria** (3.2) are fulfilled

NOTE Internal audits, sometimes called first-party audits, are conducted by, or on behalf of, the organization itself for management review and other internal purposes and can form the basis for an organization's self-declaration of conformity. In many cases, particularly in smaller organizations, independence can be demonstrated by the freedom from responsibility for the activity being audited.

NOTE 2 External audits include those generally termed second- and third-party audits. Second-party audits are conducted by parties having an interest in the organization, such as customers, or by other persons on their behalf. Third-party audits are conducted by external, independent auditing organizations, such as those providing registration or certification of conformity to requirements of ISO 9001 and ISO 14001.

NOTE 3 When a quality management system and an environmental management system are audited together, this is termed a combined audit.

NOTE 4 When two or more auditing organizations co-operate to audit a single auditee, this is termed a joint audit.

3.2 audit criteria

set of policies, procedures, or requirements

NOTE Audit criteria are used as a reference against which **audit evidence** (3.3) is compared.

3.3 audit evidence

records, statements of fact or other information, which are relevant to the **audit criteria** (3.2) and verifiable

NOTE Audit evidence can be qualitative or quantitative.

3.4 audit findings

results of the evaluation of the collected **audit evidence** (3.3) against **audit criteria** (3.2)

NOTE Audit findings can indicate either conformity or nonconformity with audit criteria or opportunities for improvement.

3.5 audit conclusion

outcome of an **audit** (3.1), provided by the **audit team** (3.9) after consideration of the audit objectives and all **audit findings** (3.4)

3.6**audit client**

organization or person requesting an **audit** (3.1)

NOTE The client can be the auditee or any other organization which has the regulatory or contractual right to request an audit

3.7**auditee**

organization being audited

3.8**auditor**

person with the **competence** (3.14) to conduct an **audit** (3.1)

3.9**audit team**

one or more **auditors** (3.8) conducting an **audit** (3.1), supported if needed by **technical experts** (3.10)

NOTE 1 One auditor of the audit team is appointed as audit team leader.

NOTE 2 The audit team can include auditors-in-training.

3.10**technical expert**

person who provides specific knowledge or expertise to the **audit team** (3.9)

NOTE 1 Specific knowledge or expertise is that which relates to the organization, process or activity to be audited, or language or culture.

NOTE 2 A technical expert does not act as an **auditor** (3.8) in the audit team.

3.11**audit program**

set of one or more **audits** (3.1) planned for a specific time frame and directed toward a specific purpose

NOTE An audit program includes all activities necessary for planning, organizing and conducting the audits.

3.12**audit plan**

description of the activities and arrangements for an **audit** (3.1)

3.13**audit scope**

extent and boundaries of an **audit** (3.1)

NOTE The scope generally includes a description of the physical locations, organizational units, activities and processes, as well as the time period covered.

3.14**competence**

demonstrated personal attributes and demonstrated ability to apply knowledge and skills

S NOTE The definition of competence in clause 3.14 above pertains to the competence of auditors and not to any other application of competence within the auditing process.

3.15**interested party**

The term “**interested party**” is used in several places within the International Standard and this Supplement. For purposes of a quality management system audit, an “interested party” is defined in ISO 9000-2000 as a person or group having an interest in the performance or success of an organization, including customers, owners, people in the organization, suppliers, bankers, unions, partners or society. For purposes of an environmental management system audit, an “interested party” is defined in ISO 14001:2004 as a person or group concerned with or affected by the environmental performance of an organization. The term “interested party” is not used or defined in ANSI/AIHA Z10-2005. For purposes of an OHSMS audit and this Supplement, the term “interested party” is defined as a person or group, inside or outside the workplace, concerned with or affected by the OH&S performance of an organization.

Other terms and definitions applicable to an occupational health and safety management system (OHSMS) are set out in ANSI/AIHA Z10-2005, Occupational Health and Safety Management Systems.

4 Principles of auditing

QE19011 Text:

Auditing is characterized by reliance on a number of principles. These make the audit an effective and reliable tool in support of management policies and controls, providing information on which an organization can act to improve its performance. Adherence to these principles is a prerequisite for providing audit conclusions that are relevant and sufficient and for enabling auditors working independently from one another to reach similar conclusions in similar circumstances.

The following principles relate to auditors

a) **Ethical conduct** - *the foundation of professionalism*

Trust, integrity, confidentiality and discretion are essential to auditing.

b) **Fair presentation** - *the obligation to report truthfully and accurately*

Audit findings, audit conclusions and audit reports reflect truthfully and accurately the audit activities. Significant obstacles encountered during the audit and unresolved diverging opinions between the audit team and the auditee are reported.

c) **Due professional care** - *the application of diligence and judgement in auditing*

Auditors exercise care in accordance with the importance of the task they perform and the confidence placed in them by audit clients and other interested parties. Having the necessary competence is an important factor.

Further principles relate to the audit, which is by definition independent and systematic:

d) **Independence** - *the basis for the impartiality of the audit and objectivity of the audit conclusions*

Auditors are independent of the activity being audited and are free from bias and conflict of interest. Auditors maintain an objective state of mind throughout the audit process to ensure that the audit findings and conclusions will be based only on the audit evidence.

e) **Evidence-based approach** - *the rational method for reaching reliable and reproducible audit conclusions in a systematic audit process*

Audit evidence is verifiable. It is based on samples of the information available, since an audit is conducted during a finite 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.

The guidance given in the remaining clauses of this International Standard is based on the principles set out above.

S4.0 General

Independence of the audit and the auditors is important. The value of the audit outcome depends upon the audit and auditors being safeguarded from undue influences that could bias the results.

S4.1 First-party (internal) audits

In order to maintain independence, objectivity, and impartiality, auditors should not audit their own work.

S4.2 Second-party (supplier) audits

For second-party audits, the principles of auditing are important because of contractual situations and possible legal ramifications of audit results. Second party auditors should be selected such that they are sufficiently free from financial, scheduling, or other pressures that could potentially bias audit conclusions.

S4.3 Use by small organizations

These principles apply equally to small organizations as stated. There is no less emphasis on independence, professional care, and evidence-based approach for a single-person operation where audit results directly impact business than for a very large organization. In fact, the smallest organizations are often more sensitive to the need for independence and a factual based approach. For such organizations, it may not be possible for internal auditors to be wholly independent of the activity being audited.

5 Managing an audit program

5.1 General

QE19011 Text:

An audit program may include one or more audits, depending upon the size, nature and complexity of the organization to be audited. These audits may have a variety of objectives and may also include joint or combined audits (see Notes 3 and 4 to the definition of audit in 3.1).

An audit program also includes all activities necessary for planning and organizing the types and number of audits, and for providing resources to conduct them effectively and efficiently within the specified time frames.

An organization may establish more than one audit program.

The organization's top management should grant the authority for managing the audit program.

Those assigned the responsibility for managing the audit program should:

- a) establish, implement, monitor, review and improve the audit program, and

- b) identify resources and ensure they are provided.

Figure 1 illustrates the process flow for the management of an audit program.

S5.1.1 General

Audit programs may include programs for internal audits, supplier audits and other audits as appropriate for the organization.

S5.1.2 First-party (internal) audits

Internal audit program activities should include:

- a) Developing documented audit procedure(s) for internal audit program activities;
- b) Developing an audit schedule to meet management system needs;
- c) Defining the scope of each audit;
- d) Establishing competence requirements and identifying internal auditors (see Clause 7);
- e) Implementing and monitoring the audit program to ensure that effective audits are performed; and
- f) Reviewing audit results to determine opportunities for audit program improvement.

S5.1.3 Second-party (supplier) audits

An audit program for supplier audits may involve:

- a) Selecting those suppliers that are critical to the organization;
- b) Scheduling supplier audits as appropriate;
- c) Establishing competence requirements and identifying supplier auditors (see Clause 7);
- d) Monitoring the supplier audit program to ensure its effectiveness;
- e) Reviewing audit results to determine the need for additional action; and
- f) Reviewing and improving the audit program.

S5.1.4 Use by small organizations

For a small organization, the audit program may be managed and carried out by a very small group or an individual, and may consist of a single annual audit. It is still important to document the audit process in sufficient detail so that it can be managed by another competent individual if personnel changes are made.

QE19011 Text:

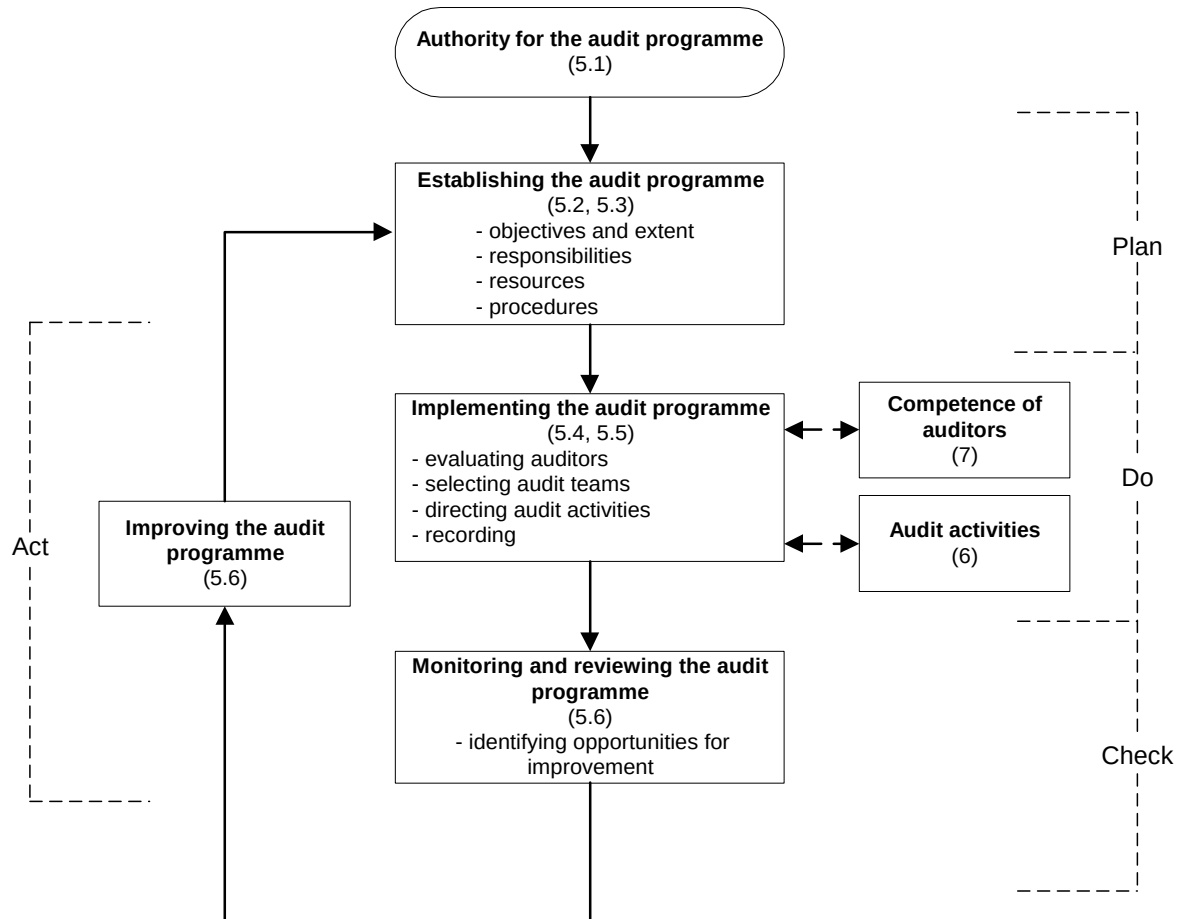


Figure 1 — Illustration of the process flow for the management of an audit program

NOTE 1 Figure 1 also illustrates the application of the Plan-Do-Check-Act methodology in this International Standard.

NOTE 2 The numbers in this and all subsequent figures refer to the relevant clauses of this International Standard.

If an organization to be audited operates both quality management and environmental management systems, combined audits may be included in the audit program. In such a case special attention should be paid to the competence of the audit team.

Two or more auditing organizations may cooperate, as part of their audit programs, to conduct a joint audit. In such a case, special attention should be paid to the division of responsibilities, the provision of any additional resources, the competence of the audit team and the appropriate procedures. Agreement on these should be reached before the audit commences.

Practical help – Examples of audit programmes

An audit programme includes appropriate planning, providing resources and establishing procedures to conduct audits within the programme.

Examples of audit programmes include the following:

- a) a series of internal audits covering an organization-wide quality management system for the current year;
- b) second-party management system audits of potential suppliers of critical products to be conducted within six months;
- c) certification/registration and surveillance audits conducted by a third-party certification/registration body on an environmental management system within a time period agreed contractually between the certification body and the client.

5.2 Audit program objectives and extent**5.2.1 Objectives of an audit program**

QE19011 Text:

Objectives should be established for an audit programme, to direct the planning and conduct of audits.

These objectives can be based on consideration of:

- a) management priorities;
- b) commercial intentions;
- c) management system requirements;
- d) statutory, regulatory and contractual requirements;
- e) need for supplier evaluation;
- f) customer requirements;
- g) needs of other interested parties;
- h) risks to the organization.

Practical help – Examples of audit programme objectives

Examples of audit programme objectives include the following:

- a) to meet requirements for certification to a management system standard;
- b) to verify conformance with contractual requirements;
- c) to obtain and maintain confidence in the capability of a supplier;
- d) to contribute to the improvement of the management system.

S5.2.1.1 First-party (internal) audits

First-party audits should be used by the organization to improve the management system, and may also be used as the basis for self-declaration of conformity and to satisfy requirements for third party registration. Internal audits should be closely aligned with the goals of the organization. For example, some organizations may expand the objectives of their internal audit program to include the identification of business improvement opportunities, opportunities to enhance customer loyalty, opportunities to minimize the organization's environmental impact and opportunities to reduce their OH&S risks. Input on these opportunities can be gathered throughout the audit process and, where supported by objective evidence, reported as opportunities for improvement.

S5.2.1.2 Second-party (supplier) audits

Primary objectives of the second-party audit may be to:

- a) Verify conformance of the supplier's management system with specified requirements;
- b) Obtain and maintain confidence in the supplier's capability to meet the organization's requirements; and
- c) Follow-up on corrective actions taken by the supplier.

S5.2.1.3 OHSMS audits

Objectives for an OHSMS audit program may also be based on, but not limited to, consideration of the frequency and severity of the injury or illness that may be caused by particular hazards as well as assessing whether the organization has appropriately applied and effectively implemented OHSMS elements, including identifying hazards and controlling risks.

5.2.2 Extent of an audit program

QE19011 Text:

The extent of an audit programme can vary and will be influenced by the size, nature and complexity of the organization to be audited, as well as by the following:

- a) the scope, objective and duration of each audit to be conducted;
- b) the frequency of audits to be conducted;
- c) the number, importance, complexity, similarity and locations of the activities to be audited;
- d) standards, statutory, regulatory and contractual requirements and other audit criteria;
- e) the need for accreditation or registration/certification;
- f) conclusions of previous audits or results of a previous audit programme review;
- g) any language, cultural and social issues;
- h) the concerns of interested parties;
- i) significant changes to an organization or its operations.

S 5.2.2.1 General

The extent of an audit program may also be influenced by the involvement of multiple organizations. For example, this situation is common at construction worksites. This may require cooperation or coordination between the auditor(s) and the various auditee organizations.

S5.2.2.2 First-party (internal) audits

The scope of the audit program and the individual audits should be clearly communicated to all applicable parties.

S5.2.2.3 Second-party (supplier) audits

The scope of each individual audit should be clearly communicated to all applicable parties.

S5.2.2.4 Use by small organizations

Small organizations may find it convenient to cover the entire management system with a single audit or with a number of very small audits.

5.3 Audit program responsibilities, resources and procedures**5.3.1 Audit program responsibilities**

QE19011 Text:

The responsibility for managing an audit programme should be assigned to one or more individuals with a general understanding of audit principles, of the competence of auditors and the application of audit techniques. They should have management skills as well as technical and business understanding relevant to the activities to be audited.

Those assigned the responsibility for managing the audit programme should:

- a) establish the objectives and extent of the audit programme,
- b) establish the responsibilities and procedures, and ensure resources are provided,
- c) ensure the implementation of the audit programme,
- d) ensure that appropriate audit programme records are maintained, and
- e) monitor, review and improve the audit programme.

S 5.3.1.1 General

Those assigned the responsibility for managing the audit program should ensure the adherence of auditors and audit program managers to proper ethical conduct.

5.3.2 Audit program resources

QE19011 Text:

When identifying resources for the audit programme, consideration should be given to:

- a) financial resources necessary to develop, implement, manage and improve audit activities; audit techniques,
- b) audit techniques,
- c) processes to achieve and maintain the competence of auditors,
- d) the availability of auditors and technical experts having competence appropriate to the particular audit programme objectives,
- e) the extent of the audit programme, and
- f) travelling time, accommodation and other auditing needs.

S5.3.2.1 General

Organizations may find it advantageous to contract out first-party and second-party audits. For example, reasons for contracting out may include the lack of available resources, cost considerations, and impartiality issues. They may also be able to cooperate with other organizations to provide audit resources to each other in order to implement effective audit programs.

S5.3.2.2 Use by small organizations

Cooperation with other organizations may be particularly useful to small organizations.

5.3.3 Audit program procedures

QE19011 Text:

Audit programme procedures should address the following:

- a) planning and scheduling audits,
- b) assuring the competence of auditors and audit team leaders,
- c) selecting appropriate audit teams and assigning their roles and responsibilities,
- d) conducting audits,
- e) conducting audit follow-up, if applicable,
- f) maintaining audit programme records,
- g) monitoring the performance and effectiveness of the audit programme,
- h) reporting to top management on the overall achievements of the audit programme.

For smaller organizations, the activities above can be addressed in a single procedure.

S 5.3.3.1 General

The audit program procedure(s) should take into account any applicable requirements of management system standards, the needs of the organization and items listed in 5.2.2.d.

Audit program procedures should take into account any applicable requirements set out in labor management agreements. This may include requirements associated with employee or employee representative participation in audit activities and the communication and reporting of audit results.

S5.3.3.2 First-party (internal) audits

The procedure(s) for an internal audit program may differ in complexity from one organization to another. An internal audit program may not need the level of formality found in external audit programs. For example, planning and scheduling of internal audits may be accomplished in a less formalized process and reporting to management may be done informally. Generally, all of the elements in 5.3.3 should be considered for internal audits, but the extent of their application and use may vary depending upon the needs of the audit program.

S5.3.3.3 Second-party (supplier) audits

Supplier audit procedure(s) may differ in requirements from an organization's internal audit procedure(s) in order to reflect the external nature of customer-supplier relationships. Such second-party audit programs may use auditors from within the organization or external to the organization. The audit program procedures may differ depending upon how the organization chooses to address second-party audits.

S5.3.3.4 Use by small organizations

The procedure(s) for a small organization may not need to be as detailed or comprehensive as those for a larger organization but should satisfy the audit program objectives for the organization and the capability of the organization to implement audit programs. Sufficient detail should be provided in the procedure(s) to assure understanding of the processes involved by all participants.

5.4 Audit program implementation

QE19011 Text:

The implementation of an audit programme should address the following:

- a) communicating the audit programme to relevant parties;
- b) coordinating and scheduling audits and other activities relevant to the audit programme;
- c) establishing and maintaining a process for the evaluation of auditors and their continual professional development, in accordance with 7.6 and 7.5;
- d) ensuring the selection of audit teams;
- e) providing necessary resources to the audit teams;
- f) ensuring the conduct of audits according to the audit programme;