TECHNICAL SPECIFICATION

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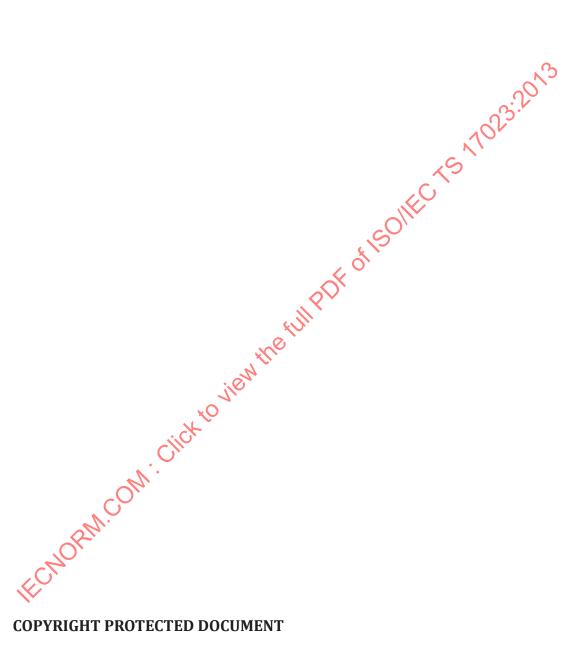
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Conformity assessment — Guidelines for determining the duration of management system certification audits

Évaluation de la conformité — Lignes directrices pour la détermination de la durée des audits de certification d'un système de management

Les audits de ca







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Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) form the specialized system for worldwide standardization. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work. In the field of conformity assessment, the ISO Committee on conformity assessment (CASCO) is responsible for the development of International Standards and Guides.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

Draft International Standards adopted 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 member bodies casting a vote.

In other circumstances, particularly when there is an urgent market requirement for such documents, a technical committee may decide to publish other types of document:

- an ISO/IEC Publicly Available Specification (ISO/IEC PAS) represents an agreement between technical experts in an ISO working group and is accepted for publication if it is approved by more than 50 % of the members of the parent committee casting a vote.
- an ISO/IEC Technical Specification (ISO/IEC TS) represents an agreement between the members of a technical committee and is accepted for publication if it is approved by 2/3 of the members of the committee casting a vote.

An ISO/PAS or ISO/TS is reviewed after three years in order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn. If the ISO/PAS or ISO/TS is confirmed, it is reviewed again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO/IEC TS 17023 was prepared by the ISO Committee on conformity assessment (CASCO).

It was circulated for voting to the national bodies of both ISO and IEC, and was approved by both organizations.

Introduction

This Technical Specification provides guidance on the application of the relevant requirements of ISO/IEC 17021:2011 for determining the duration of management system certification audits. It provides certification bodies with a framework for achieving a basic level of consistency for determining the duration of management system certification audits. It can be also considered for the determination of duration of other types of audits.

The growth in the number of management system standards and certification schemes has highlighted the need for a document providing guidance to ensure that the factors influencing the duration of management system certification audits are considered.

This Technical Specification enables clients of certification bodies and other interested parties (e.g. scheme owners, regulators, accreditation bodies) to understand how different factors contribute to the duration of management system certification audits.

This Technical Specification does not define tables, formulas, or other methods to calculate the duration of management system certification audits for specific schemes, but it identifies factors to be considered when such tables or formulas are developed.

In this Technical Specification, the following verbal forms are used:

- "should" indicates a recommendation;
- "may" indicates a permission;
- "can" indicates a possibility or a capability.

The verbal form "shall", which indicates a requirement, is not used in this Technical Specification because only guidance is provided.

Further details can be found in the ISO/IEC Directives, Part 2.

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Conformity assessment — Guidelines for determining the duration of management system certification audits

1 Scope

This Technical Specification provides guidelines for determining the duration of management system certification audits, to the bodies providing audit and certification of management systems and to those that develop and maintain certification schemes.

NOTE 1 This Technical Specification is also intended to address the needs of other interested parties (e.g. regulators, accreditation bodies) when determining the duration of management system certification audits.

NOTE 2 Where additional specific requirements related to the duration of management system certification audits have been established for a specific certification scheme (e.g. ISO/TS 22003 for food safety management systems) or other requirements as established by scheme owners or regulators, these can be applied.

2 Normative references

The following referenced documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/IEC 17000, Conformity assessment — Vocabulary and general principles

ISO/IEC 17021:2011, Conformity assessment—Requirements for bodies providing audit and certification of management systems

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC 17000, ISO/IEC 17021:2011 and the following apply.

3.1

scheme owner

person or organization responsible for developing and maintaining a specific certification scheme (3.2)

Note 1 to entry. The scheme owner can be the certification body itself, a governmental authority, a trade association, agroup of certification bodies or others.

[SOURCE: JSO/IEC 17065:2012, 3.11]

3.2

certification scheme

conformity assessment system related to management systems to which the same specified requirements, specific rules and procedures apply

[SOURCE: ISO/IEC 17000:2004, 2.8, modified]

3.3

client organization

entity or defined part of an entity operating a management system

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3.4

permanent site

location (physical or virtual) where a client organization (3.3) performs work or provides a service on a continuing basis

3.5

temporary site

location (physical or virtual) where a client organization (3.3) performs specific work or provides a service for a finite period of time and which is not intended to become a permanent site (3.4)

3.6

audit time

time needed to plan and accomplish a complete and effective audit of the *client organization* (3.3) management system

3.7

duration of management system certification audits

part of audit time (3.6) spent conducting audit activities from the opening meeting to the closing meeting, inclusive

Note 1 to entry: Audit activities normally include:

communicating during the audit; assigning roles and responsibilities of guides and observers; collecting and verifying information; generating audit findings; preparing audit conclusions; onducting the closing meeting. actors for the determination. Factors for the determination of the duration of management system certification audits

4.1 General

The following text is based on the aspects specified in the relevant clauses of ISO/IEC 17021:2011. The factors listed in 4.2 to 4.12 should be used when defining processes for the determination of the duration of management system certification audits. These factors can be used for the determination of the duration of management system certification audits for specific audits. The particular factors to be taken into account should depend on the type and scope of audit.

The time spent travelling to and from the site(s) is not included in the determination of the duration of management system certification audits.

Relevant management system standard(s) and other requirements

The duration of management system certification audits can depend on relevant management system standard(s) and certification scheme requirements and the type of audit (e.g. initial audit, surveillance, recertification, special audit, follow up audit, transfer audit).

When an audit is done in two stages, the duration of management system certification audits is the sum of stage one and stage two.

NOTE 2 Other audits (e.g. special audits, transfer audits) can be performed and the duration of such audits is usually established on a case by case basis depending on the objectives of such audits.

4.3 Size and location(s) of the client organization

- **4.3.1** The following factors can be relevant when determining the duration of management system certification audits:
- the physical size of the client organization (large or small);
- the number of people involved in the activities of the client organization in relation to the scope of the audit including, when relevant, part-time, seasonal contract and casual personnel;
- complicated logistics (e.g. university with various campuses, oil platforms);
- the number of sites to be audited.
- **4.3.2** The duration of management system certification audits may furthen be affected by:
- the level of central control;
- the commonalities of processes and products;
- the linked processes;
- seasonal and climate conditions.

4.4 Complexity of the client's organization and management system

The following factors can be relevant when determining the duration of management system certification audits:

- accessibility to management system documentation and records (e.g. remote or on-site);
- structure of the management system, including levels of controls, reporting and internal communication;
- the number and range of people representing various levels within the client organization to be interviewed;
- activities that require visiting temporary sites;
- complexity of the interaction between the client organization's activities;
- prior knowledge about the client organization (e.g. other management system certified by the same certification body);
- activities which are repetitive (commonality of processes or unique process);
- changes to the client organization (e.g. relocation, management change, merging);
- the control and type of shift work;
- the client organization's occupational health and safety and security conditions.

4.5 Technological and regulatory context

The following factors can be relevant when determining the duration of management system certification audits:

— the complexity and amount of applicable regulations (e.g. food, pharmaceutical, aerospace, nuclear power industries);

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- the complexity of the technology used in the client organization;
- the complexity of design processes;
- the level of automation.

4.6 Activities included in the scope of the management system

The following factors can be relevant when determining the duration of management system certification audits:

- the applicable requirements of the management system standard, including considerations of eligible exclusion of requirements;
- the scope of certification with respect to product, services, activities, processes and sites, including consideration of their complexity;
- the activities outsourced by the client organization (e.g. extent, level of control, significance, complexity).

4.7 Maturity and effectiveness of the management system

The following factors can be relevant when determining the duration of management system certification audits:

- the results and effectiveness of any prior audits performed by the certification body;
- the results and effectiveness of any prior external audits conducted by parties other than the certification body;
- the effectiveness of the client organization's internal audit and management review processes;
- the level of understanding and commitment to the management system within the client organization;
- existing certified management systems;
- reliable public information (e.g. media reports, customer feedback, regulatory information or sanctions);
- the period for which the management system has been in operation;
- the capacity of the client organization to achieve its management system objectives.

4.8 Risks associated with the products, processes or activities of the client organization

The following factors can be relevant when determining the duration of management system certification audits.

- the existence of hazardous processes, materials or work environment (e.g. sterilization with radiation, chemicals used in leather treatment process);
- the risk of non-conformities and their impact (e.g. in health service, food production, air traffic control);
- the level of vulnerability within processes and operations.

4.9 Culture

The following factors can be relevant when determining the duration of management system certification audits:

- different cultures and social behaviour (e.g. local customs, employment practices);
- the need for interpretation and translation;

- ease of communication within the client organization;
- transparency and openness of the client organization.

4.10 Integrated management system

The following factors can be relevant when determining the duration of integrated management system certification audits:

- the level of integration;
- the number of management systems included in the integrated management system;
- the complexity of the integrated management system compared with a single management system;
- the availability of auditors capable of auditing more than one management system.

4.11 Composition of the audit team

The following factors can influence the duration of management system certification audits:

- the need for translators or interpreters;
- the need for technical experts.

NOTE ISO/IEC 17021:2011 specifies that time spent by any team member that is not assigned as an auditor does not count in the established audit time.

4.12 Other considerations

When two or more certification bodies cooperate to audit a single client organization, the impact of different approaches or procedures used by the joint audit team should be taken into account.

When remote auditing techniques are being used, i.e. when the auditor is not physically present at the audit location, this should not lead to the reduction of the duration of management system certification audits.

5 Methodology for the calculation of the duration of management system certification audits

5.1 General

Where relevant generally accepted and published methodologies exist, these should be taken in consideration to calculate the duration of management system certification audits. Where no such methodology exists, the *scheme owners* (3.1) should be responsible for the development and maintenance of the appropriate calculation methodologies for the duration of management system certification audits.

NOTE It is important that any developed methodology can be applied impartially.

5.2 Development of a methodology

5.2.1 General

The result of the methodology development process should be a framework (e.g. formulas, tables, graphs) that enables certification bodies to establish the duration of a management system certification audit.