INTERNATIONAL STANDARD

ISO/IEC 17021

Conformity assessment — Requirements for bodies providing audit and certification of management systems

Évaluation de la conformité — Exigences pour les organismes procédant à l'audit et à la certification des systèmes de management

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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 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.

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 17021 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.

This second edition cancels and replaces the first edition (ISO/IEC 17021:2006), which has been revised to expand the scope. The first edition is provisionally retained for a period of one year until the systematic review of this second edition.

This International Standard has also been published in an unofficial, marked version indicating changes from the previous edition.

Introduction

Certification of a management system, such as a quality or environmental management system of an organization, is one means of providing assurance that the organization has implemented a system for the management of the relevant aspects of its activities, in line with its policy.

This International Standard specifies requirements for certification bodies. Observance of these requirements is intended to ensure that certification bodies operate management system certification in a competent, consistent and impartial manner, thereby facilitating the recognition of such bodies and the acceptance of their certifications on a national and international basis. This International Standard serves as a foundation for facilitating the recognition of management system certification in the interests of international trade.

Certification of a management system provides independent demonstration that the management system of the organization

a) conforms to specified requirements,

b) is capable of consistently achieving its stated policy and objectives, and

c) is effectively implemented.

Conformity assessment such as certification of a management system thereby provides value to the organization, its customers and interested parties.

In this International Standard, Clause 4 describes the principles on which credible certification is based. These principles help the reader to understand the essential nature of certification and they are a necessary prelude to Clauses 5 to 10. These principles underpin all the requirements in this International Standard, but such principles are not auditable requirements in their own right. Clause 10 describes two alternative ways of supporting and demonstrating the consistent achievement of the requirements in this International Standard through the establishment of a management system by the certification body.

This International Standard is intended for use by bodies that carry out audit and certification of management systems. It gives generic requirements for such certification bodies performing audit and certification in the field of quality, environmental and other forms of management systems. Such bodies are referred to as certification bodies. This wording should not be an obstacle to the use of this International Standard by bodies with other designations that undertake activities covered by the scope of this document.

Certification activities involve the audit of an organization's management system. The form of attestation of conformity of an organization's management system to a specific management system standard or other normative requirements is normally a certification document or a certificate.

The publication of this International Standard includes the text of ISO/IEC 17021:2006, including amendments to delete relevant references to ISO 19011, with new text adding specific requirements for third-party certification auditing and the management of competence of personnel involved in certification.

Specific market needs have already been identified, resulting from a lack of specific and recognized requirements for third-party auditors of management systems, such as quality management systems, environmental management systems or food safety management systems. The lack of requirements for auditor competence and the way in which these auditors are managed and deployed has been identified by key interested parties, including industry interested parties, as being a drawback.

This International Standard provides a set of requirements for management systems auditing at a generic level, aimed at providing a reliable determination of conformity to the applicable requirements for certification, conducted by a competent audit team, with adequate resources and following a consistent process, with the results reported in a consistent manner.

This International Standard is applicable to the auditing and certification of any type of management system. It is recognized that some of the requirements, and in particular those related to auditor competence, can be supplemented with additional criteria in order to achieve the expectations of the interested parties.

In this International Standard, the word "shall" indicates a requirement and the word "should" a recommendation.

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Conformity assessment — Requirements for bodies providing audit and certification of management systems

1   Scope

This International Standard contains principles and requirements for the competence, consistency and impartiality of the audit and certification of management systems of all types (e.g. quality management systems or environmental management systems) and for bodies providing these activities. Certification bodies operating to this International Standard need not offer all types of management system certification.

Certification of management systems (named in this International Standard "certification") is a third-party conformity assessment activity (see ISO/IEC 17000:2004, 5.5). Bodies performing this activity are therefore third-party conformity assessment bodies (named in this International Standard "certification body/bodies").

NOTE 1   Certification of a management system is sometimes also called "registration", and certification bodies are sometimes called "registrars".

NOTE 2   A certification body can be non-governmental or governmental (with or without regulatory authority).

NOTE 3   This International Standard can be used as a criteria document for accreditation or peer assessment or other audit processes.

2   Normative references

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

ISO 9000:2005, *Quality management systems — Fundamentals and vocabulary*

ISO/IEC 17000:2004, *Conformity assessment — Vocabulary and general principles*

3   Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000, ISO/IEC 17000 and the following apply.

3.1
certified client
organization whose management system has been certified

3.2
impartiality
actual and perceived presence of objectivity

NOTE 1   Objectivity means that conflicts of interest do not exist or are resolved so as not to adversely influence subsequent activities of the certification body.

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NOTE 2   Other terms that are useful in conveying the element of impartiality are: objectivity, independence, freedom from conflict of interests, freedom from bias, lack of prejudice, neutrality, fairness, open-mindedness, even-handedness, detachment, balance.

3.3
management system consultancy
participation in designing, implementing or maintaining a management system

EXAMPLES

a)   preparing or producing manuals or procedures, and

b)   giving specific advice, instructions or solutions towards the development and implementation of a management system.

NOTE   Arranging training and participating as a trainer is not considered consultancy, provided that, where the course relates to management systems or auditing, it is confined to the provision of generic information that is freely available in the public domain; i.e. the trainer should not provide company-specific solutions.

3.4
third-party certification audit
audit carried out by an auditing organization independent of the client and the user, for the purpose of certifying the client's management system

NOTE 1   In the definitions which follow, the term "audit" has been used for simplicity to refer to third-party certification audit.

NOTE 2   Third-party certification audits include initial, surveillance, re-certification audits, and can also include special audits.

NOTE 3   Third-party certification audits are typically conducted by audit teams of those bodies providing certification of conformity to the requirements of management system standards.

NOTE 4   A joint audit is when two or more auditing organizations cooperate to audit a single client.

NOTE 5   A combined audit is when a client is being audited against the requirements of two or more management systems standards together.

NOTE 6   An integrated audit is when a client has integrated the application of requirements of two or more management systems standards into a single management system and is being audited against more than one standard.

3.5
client
organization whose management system is being audited for certification purposes

3.6
auditor
person who conducts an audit

3.7
competence
ability to apply knowledge and skills to achieve intended results

3.8
guide
person appointed by the client to assist the audit team

3.9
observer
person who accompanies the audit team but does not audit

3.10
technical area
area characterized by commonalities of processes relevant to a specific type of management system

4 Principles

4.1 General

4.1.1   These principles are the basis for the subsequent specific performance and descriptive requirements in this International Standard. This International Standard does not give specific requirements for all situations that can occur. These principles should be applied as guidance for the decisions that may need to be made for unanticipated situations. Principles are not requirements.

4.1.2   The overall aim of certification is to give confidence to all parties that a management system fulfils specified requirements. The value of certification is the degree of public confidence and trust that is established by an impartial and competent assessment by a third-party. Parties that have an interest in certification include, but are not limited to

a)   the clients of the certification bodies,

b)   the customers of the organizations whose management systems are certified,

c)   governmental authorities,

d)   non-governmental organizations, and

e)   consumers and other members of the public.

4.1.3   Principles for inspiring confidence include

— impartiality,

— competence,

— responsibility,

— openness,

— confidentiality, and

— responsiveness to complaints.

4.2 Impartiality

4.2.1   Being impartial, and being perceived to be impartial, is necessary for a certification body to deliver certification that provides confidence.

4.2.2   It is recognized that the source of revenue for a certification body is its client paying for certification, and that this is a potential threat to impartiality.

4.2.3   To obtain and maintain confidence, it is essential that a certification body's decisions be based on objective evidence of conformity (or nonconformity) obtained by the certification body, and that its decisions are not influenced by other interests or by other parties.

4.2.4   Threats to impartiality include the following.

a)   Self-interest threats: threats that arise from a person or body acting in their own interest. A concern related to certification, as a threat to impartiality, is financial self-interest.

b)   Self-review threats: threats that arise from a person or body reviewing the work done by themselves. Auditing the management systems of a client to whom the certification body provided management systems consultancy would be a self-review threat.

c)   Familiarity (or trust) threats: threats that arise from a person or body being too familiar with or trusting of another person instead of seeking audit evidence.

d)   Intimidation threats: threats that arise from a person or body having a perception of being coerced openly or secretively, such as a threat to be replaced or reported to a supervisor.

4.3   Competence

Competence of the personnel supported by the management system of the certification body is necessary to deliver certification that provides confidence.

4.4   Responsibility

4.4.1   The client organization, not the certification body, has the responsibility for conformity with the requirements for certification.

4.4.2   The certification body has the responsibility to assess sufficient objective evidence upon which to base a certification decision. Based on audit conclusions, it makes a decision to grant certification if there is sufficient evidence of conformity, or not to grant certification if there is not sufficient evidence of conformity.

NOTE   Any audit is based on sampling within an organization's management system and therefore is not a guarantee of 100 % conformity with requirements.

4.5   Openness

4.5.1   A certification body needs to provide public access to, or disclosure of, appropriate and timely information about its audit process and certification process, and about the certification status (i.e. the granting, extending, maintaining, renewing, suspending, reducing the scope of, or withdrawing of certification) of any organization, in order to gain confidence in the integrity and credibility of certification. Openness is a principle of access to, or disclosure of, appropriate information.

4.5.2   To gain or maintain confidence in certification, a certification body should provide appropriate access to, or disclosure of, non-confidential information about the conclusions of specific audits (e.g. audits in response to complaints) to specific interested parties.

4.6   Confidentiality

To gain the privileged access to information that is needed for the certification body to assess conformity to requirements for certification adequately, it is essential that a certification body keep confidential any proprietary information about a client.

4.7   Responsiveness to complaints

Parties that rely on certification expect to have complaints investigated and, if these are found to be valid, should have confidence that the complaints will be appropriately addressed and that a reasonable effort will be made to resolve the complaints. Effective responsiveness to complaints is an important means of protection for the certification body, its clients and other users of certification against errors, omissions or unreasonable behaviour. Confidence in certification activities is safeguarded when complaints are processed appropriately.

NOTE   An appropriate balance between the principles of openness and confidentiality, including responsiveness to complaints, is necessary in order to demonstrate integrity and credibility to all users of certification.

5   General requirements

5.1   Legal and contractual matters

5.1.1   Legal responsibility

The certification body shall be a legal entity, or a defined part of a legal entity, such that it can be held legally responsible for all its certification activities. A governmental certification body is deemed to be a legal entity on the basis of its governmental status.

5.1.2   Certification agreement

The certification body shall have a legally enforceable agreement for the provision of certification activities to its client. In addition, where there are multiple offices of a certification body or multiple sites of a client, the certification body shall ensure there is a legally enforceable agreement between the certification body granting certification and issuing a certificate, and all the sites covered by the scope of the certification.

5.1.3   Responsibility for certification decisions

The certification body shall be responsible for, and shall retain authority for, its decisions relating to certification, including the granting, maintaining, renewing, extending, reducing, suspending and withdrawing of certification.

5.2   Management of impartiality

5.2.1   The certification body shall have top management commitment to impartiality in management system certification activities. The certification body shall have a publicly accessible statement that it understands the importance of impartiality in carrying out its management system certification activities, manages conflict of interest and ensures the objectivity of its management system certification activities.

5.2.2   The certification body shall identify, analyse and document the possibilities for conflict of interests arising from provision of certification including any conflicts arising from its relationships. Having relationships does not necessarily present a certification body with a conflict of interest. However, if any relationship creates a threat to impartiality, the certification body shall document and be able to demonstrate how it eliminates or minimizes such threats. This information shall be made available to the committee specified in 6.2. The demonstration shall cover all potential sources of conflict of interests that are identified, whether they arise from within the certification body or from the activities of other persons, bodies or organizations.

NOTE   A relationship that threatens the impartiality of the certification body can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing and payment of a sales commission or other inducement for the referral of new clients, etc.

5.2.3   When a relationship poses an unacceptable threat to impartiality (such as a wholly owned subsidiary of the certification body requesting certification from its parent), then certification shall not be provided.

NOTE   See Note to 5.2.2.

5.2.4   A certification body shall not certify another certification body for its management system certification activities.

NOTE   See Note to 5.2.2.

5.2.5   The certification body and any part of the same legal entity shall not offer or provide management system consultancy. This also applies to that part of government identified as the certification body.

5.2.6   The certification body and any part of the same legal entity shall not offer or provide internal audits to its certified clients. The certification body shall not certify a management system on which it provided internal audits within two years following the end of the internal audits. This also applies to that part of government identified as the certification body.

NOTE   See Note to 5.2.2.

5.2.7   The certification body shall not certify a management system on which a client has received management system consultancy or internal audits, where the relationship between the consultancy organization and the certification body poses an unacceptable threat to the impartiality of the certification body.

NOTE 1   Allowing a minimum period of two years to elapse following the end of the management system consultancy is one way of reducing the threat to impartiality to an acceptable level.

NOTE 2   See Note to 5.2.2.

5.2.8   The certification body shall not outsource audits to a management system consultancy organization, as this poses an unacceptable threat to the impartiality of the certification body (see 7.5). This does not apply to individuals contracted as auditors covered in 7.3.

5.2.9   The certification body's activities shall not be marketed or offered as linked with the activities of an organization that provides management system consultancy. The certification body shall take action to correct inappropriate claims by any consultancy organization stating or implying that certification would be simpler, easier, faster or less expensive if the certification body were used. A certification body shall not state or imply that certification would be simpler, easier, faster or less expensive if a specified consultancy organization were used.

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5.2.10   To ensure that there is no conflict of interests, personnel who have provided management system consultancy, including those acting in a managerial capacity, shall not be used by the certification body to take part in an audit or other certification activities if they have been involved in management system consultancy towards the client in question within two years following the end of the consultancy.

5.2.11   The certification body shall take action to respond to any threats to its impartiality arising from the actions of other persons, bodies or organizations.

5.2.12   All certification body personnel, either internal or external, or committees, who could influence the certification activities, shall act impartially and shall not allow commercial, financial or other pressures to compromise impartiality.

5.2.13   Certification bodies shall require personnel, internal and external, to reveal any situation known to them that may present them or the certification body with a conflict of interests. Certification bodies shall use this information as input to identifying threats to impartiality raised by the activities of such personnel or by the organizations that employ them, and shall not use such personnel, internal or external, unless they can demonstrate that there is no conflict of interests.

5.3   Liability and financing

5.3.1   The certification body shall be able to demonstrate that it has evaluated the risks arising from its certification activities and that it has adequate arrangements (e.g. insurance or reserves) to cover liabilities arising from its operations in each of its fields of activities and the geographic areas in which it operates.

5.3.2   The certification body shall evaluate its finances and sources of income and demonstrate to the committee specified in 6.2 that initially, and on an ongoing basis, commercial, financial or other pressures do not compromise its impartiality.

6 Structural requirements

6.1 Organizational structure and top management

6.1.1   The certification body shall document its organizational structure, showing duties, responsibilities and authorities of management and other certification personnel and any committees. When the certification body is a defined part of a legal entity, the structure shall include the line of authority and the relationship to other parts within the same legal entity.

6.1.2   The certification body shall identify the top management (board, group of persons, or person) having overall authority and responsibility for each of the following:

a)   development of policies relating to the operation of the body;

b)   supervision of the implementation of the policies and procedures;

c)   supervision of the finances of the body;

d)   development of management system certification services and schemes;

e)   performance of audits and certification, and responsiveness to complaints;

f)   decisions on certification;

g)   delegation of authority to committees or individuals, as required, to undertake defined activities on its behalf;

h)   contractual arrangements;

i)   provision of adequate resources for certification activities.

6.1.3   The certification body shall have formal rules for the appointment, terms of reference and operation of any committees that are involved in the certification activities.

6.2 Committee for safeguarding impartiality

6.2.1   The structure of the certification body shall safeguard the impartiality of the activities of the certification body and shall provide for a committee to

a)   assist in developing the policies relating to impartiality of its certification activities,

b)   counteract any tendency on the part of a certification body to allow commercial or other considerations to prevent the consistent objective provision of certification activities,

c)   advise on matters affecting confidence in certification, including openness and public perception, and

d)   conduct a review, at least once annually, of the impartiality of the audit, certification and decision-making processes of the certification body.

Other tasks or duties may be assigned to the committee provided these additional tasks or duties do not compromise its essential role of ensuring impartiality.

6.2.2   The composition, terms of reference, duties, authorities, competence of members and responsibilities of this committee shall be formally documented and authorized by the top management of the certification body to ensure

a)   representation of a balance of interests such that no single interest predominates (internal or external personnel of the certification body are considered to be a single interest, and shall not predominate),