INTERNATIONAL STANDARD

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

Part 1:

iTeh STANDARD PREVIEW

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

Partie 1: Exigences 015

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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, ISO and IEC develop joint ISO/IEC documents under the management of the ISO Committee on Conformity assessment (ISO/CASCO).

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO and IEC shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword Supplementary information

ISO/IEC 17021-1 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 first edition of ISO/IEC 1702111 cancels and replaces ISO/IEC 17021:2011, which has been technically revised.

ISO/IEC 17021 consists of the following parts, under the general title *Conformity assessment* — *Requirements for bodies providing audit and certification of management systems*:

- Part 1: Requirements
- Part 2: Competence requirements for auditing and certification of environmental management systems [Technical Specification]
- Part 3: Competence requirements for auditing and certification of quality management systems [Technical Specification]
- Part 4: Competence requirements for auditing and certification of event sustainability management systems [Technical Specification]
- Part 5: Competence requirements for auditing and certification of asset management systems [Technical Specification]
- Part 6: Competence requirements for auditing and certification of business continuity management systems [Technical Specification]
- Part 7: Competence requirements for auditing and certification of road traffic safety management systems [Technical Specification]

Introduction

Certification of a management system, such as the environmental management system, quality management system or information security 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, products and services, in line with the organization's policy and the requirements of the respective international management system standard.

This part of ISO/IEC 17021 specifies requirements for bodies providing audit and certification of management systems. It gives generic requirements for such bodies performing audit and certification in the field of quality, the environment and other types of management systems. Such bodies are referred to as 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 part of ISO/IEC 17021 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;
- c) is effectively implemented Teh STANDARD PREVIEW

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

Clause 4 describes the principles on which credible certification is based. These principles help the user to understand the essential nature of certification and they are a necessary prelude to Clauses 5 to 10. These principles underpin the requirements in this part of ISO/IEC 17021, 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 part of ISO/IEC 17021 through the establishment of a management system by the certification body.

Certification activities are the individual activities that make up the entire certification process, from application review to termination of certification. Annex E provides an illustration of the way in which many of these activities can interact.

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 usually a certification document or a certificate.

This part of ISO/IEC 17021 is applicable to the auditing and certification of any type of management system. It is recognized that some of the requirements, 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 part of ISO/IEC 17021, the following verbal forms are used:

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

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

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

Part 1:

Requirements

1 Scope

This part of ISO/IEC 17021 contains principles and requirements for the competence, consistency and impartiality of bodies providing audit and certification of all types of management systems.

Certification bodies operating to this part of ISO/IEC 17021 do not need to offer all types of management system certification.

Certification of management systems is a third-party conformity assessment activity (see ISO/IEC 17000:2004, 5.5) and bodies performing this activity are therefore third-party conformity assessment bodies.

NOTE 1 Examples of management systems include environmental management systems, quality management systems and information security management systems.

NOTE 2 In this part of ISO/IEC 17021 certification of management systems is referred to as "certification" and third-party conformity assessment bodies are referred to as "certification bodies".

NOTE 3 A certification body can be non governmental or governmental, with or without regulatory authority. https://standards.itely.aycatalog/standards/sist/8b0c5333-a473-43ad-9175-

NOTE 4 This part of ISO/IEC 170211can be used as a criteria document for accreditation, peer assessment or other audit processes.

2 Normative references

The following 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 9000, Quality management systems — Fundamentals and vocabulary

ISO/IEC 17000, 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

presence of objectivity

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

Note 2 to entry: Other terms that are useful in conveying the element of impartiality include "independence", "freedom from conflict of interests", "freedom from bias", "lack of prejudice", "neutrality", "fairness", "openmindedness", "even-handedness", "detachment", "balance".

3.3

management system consultancy

participation in establishing, implementing or maintaining a management system

EXAMPLE 1 Preparing or producing manuals or procedures.

EXAMPLE 2 Giving specific advice, instructions or solutions towards the development and implementation of a management system.

Note 1 to entry: 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; i.e. the trainer should not provide client-specific solutions.

Note 2 to entry: The provision of generic information, but not client specific solutions for the improvement of processes or systems, is not considered to be consultancy. Such information may include:

- explaining the meaning and intention of certification criteria;
- identifying improvement opportunities;
- explaining associated theories, methodologies, techniques or tools;
- sharing non-confidential information on related best practices;
- other management aspects that are not covered by the management system being audited.

3.4

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certification audit

audit carried out by an auditing organization independent of the client and the parties that rely on certification, for the purpose of certifying the client's management system ^{43ad-9175-}
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Note 1 to entry: In the definitions which follow, the term "audit" has been used for simplicity to refer to third-party certification audit.

Note 2 to entry: Certification audits include initial, surveillance, re-certification audits, and can also include special audits.

Note 3 to entry: Certification audits are typically conducted by audit teams of those bodies providing certification of conformity to the requirements of management system standards.

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

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

Note 6 to entry: 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 and its intended results

Note 1 to entry: See Note to 7.1.2.

3.11

nonconformity

non-fulfilment of a requirement

3.12

major nonconformity

nonconformity (3.11) that affects the capability of the management system to achieve the intended results

Note 1 to entry: Nonconformities could be classified as major in the following circumstances:

- if there is a significant doubt that effective process control is in place, or that products or services will meet specified requirements; I en S ANDARD I E VIII CONTROL OF STATE OF
- a number of minor nonconformities associated with the same requirement or issue could demonstrate a systemic failure and thus constitute a major nonconformity.

ISO/IEC 17021-1:2015

minor nonconformity/standards.iteh.ai/catalog/standards/sist/8b0c5333-a473-43ad-9175-

nonconformity (3.11) that does not affect the capability of the management system to achieve the intended results

3.14

technical expert

person who provides specific knowledge or expertise to the audit team

Note 1 to entry: Specific knowledge or expertise is that which relates to the organization, the process or activity to be audited.

3.15

certification scheme

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

3.16

audit time

time needed to plan and accomplish a complete and effective audit of the client organization's management system

3.17

duration of management system certification audits

part of *audit time* (3.16) spent conducting audit activities from the opening meeting to the closing meeting, inclusive

Note 1 to entry: Audit activities normally include:

- conducting the opening meeting;
- performing document review while conducting the audit;

— communicating during the audit;
— assigning roles and responsibilities of guides and observers;
 collecting and verifying information;
— generating audit findings;
— preparing audit conclusions;
 conducting the closing meeting.
4 Principles
4.1 General
4.1.1 The principles described in this clause provide the basis for the subsequent specific performance and descriptive requirements in this part of ISO/IEC 17021. This part of ISO/IEC 17021 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 standards.iteh.ai)
b) the customers of the organizations whose management systems are certified;
c) governmental authorities; //standards.iteh.ai/catalog/standards/sist/8b0c5333-a473-43ad-9175- 13103b1deae6/iso-iec-17021-1-2015
d) non-governmental organizations;
e) consumers and other members of the public.
4.1.3 Principles for inspiring confidence include:
— impartiality;
— competence;
— responsibility;
openness;
confidentiality;
 responsiveness to complaints;

NOTE This part of ISO/IEC 17021 sets out the principles of certification in <u>Clause 4</u>; the corresponding principles related to auditing can be found in ISO 19011:2011, Clause 4.

4.2 Impartiality

risk-based approach.

4.2.1 Being impartial, and being perceived to be impartial, is necessary for a certification body to deliver certification that provides confidence. It is important that all internal and external personnel are aware of the need for impartiality.

- **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 may include but are not limited to the following.
- a) Self-interest: 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 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 that arise from a person or body being too familiar with or trusting of another person instead of seeking audit evidence.
- d) Intimidation: 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

- **4.3.1** Competence of the personnel of the certification body in all functions involved in certification activities is necessary to deliver certification that provides confidence.
- **4.3.2** The competence also needs to be supported by the management system of the certification body. $\frac{1SO/IBC}{17021-12015}$
- https://standards.iteh.ai/catalog/standards/sist/8b0c5333-a473-43ad-9175-4.3.3 It is a key issue for the management of the certification body to have an implemented process for the establishment of competence criteria for the personnel involved in the audit and other certification activities and to perform evaluation against the criteria.

4.4 Responsibility

- **4.4.1** The certified client, and not the certification body, has the responsibility for consistently achieving the intended results of implementation of the management system standard and 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, maintaining of certification, expanding or reducing the scope of certification, renewing, suspending or restoring, 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.

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 does not disclose any confidential information.

Responsiveness to complaints 4.7

Parties that rely on certification expect to have complaints investigated and, if these are found to be valid, should have confidence that these complaints will be appropriately addressed and that a reasonable effort will be made by the certification body to resolve them. 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.

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

Risk-based approach iteh STANDARD PREVIEW 4.8

Certification bodies need to take into account the risks associated with providing competent, consistent and impartial certification. Risks may include but are not limited to, those associated with:

- the objectives of the audit:
- ISO/IEC 17021-1:2015
- the sampling used in the audit process, i/catalog/standards/sist/8b0c5333-a473-43ad-9175-
 - 3103b1deae6/iso-iec-17021-1-2015
- real and perceived impartiality;
- legal, regulatory and liability issues;
- the client organization being audited and its operating environment;
- impact of the audit on the client and its activities;
- health and safety of the audit teams;
- perception of interested parties;
- misleading statements by the certified client;
- use of marks.

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 that 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 with each client for the provision of certification activities in accordance with the relevant requirements of this part of ISO/IEC 17021. 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 the client that covers all the sites within the scope of the certification.

NOTE An agreement can be achieved through multiple agreements that reference or otherwise link to one another.

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, refusing, maintaining of certification, expanding or reducing the scope of certification, renewing, suspending or restoring following suspension, or withdrawing of certification.

5.2 Management of impartiality

- **5.2.1** Conformity assessment activities shall be undertaken impartially. The certification body shall be responsible for the impartiality of its conformity assessment activities and shall not allow commercial, financial or other pressures to compromise impartiality.
- **5.2.2** The certification body shall have top management commitment to impartiality in management system certification activities. The certification body shall have a policy 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.
- **5.2.3** The certification body shall have a process to identify, analyse, evaluate, treat, monitor, and document the risks related to conflict of interests arising from provision of certification including any conflicts arising from its relationships on an ongoing basis. Where there are any threats to impartiality, the certification body shall document and demonstrate how it eliminates or minimizes such threats and document any residual risk. The demonstration shall cover all potential threats that are identified, whether they arise from within the certification body or from the activities of other persons, bodies or organizations. 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.

Top management shall review any residual risk to determine if it is within the level of acceptable risk.

The risk assessment process shall include identification of and consultation with appropriate interested parties to advise on matters affecting impartiality including openness and public perception. The consultation with appropriate interested parties shall be balanced with no single interest predominating.

- NOTE 1 Sources of threats to impartiality of the certification body can be based on ownership, governance, management, personnel, shared resources, finances, contracts, training, marketing and payment of a sales commission or other inducement for the referral of new clients, etc.
- NOTE 2 Interested parties can include personnel and clients of the certification body, customers of organizations whose management systems are certified, representatives of industry trade associations, representatives of governmental regulatory bodies or other governmental services, or representatives of non-governmental organizations, including consumer organizations.
- NOTE 3 One way of fulfilling the consultation requirement of this clause is by the use of a committee of these interested parties.
- **5.2.4** A certification body shall not certify another certification body for its quality management system.

- **5.2.5** The certification body and any part of the same legal entity and any entity under the organizational control of the certification body [see <u>9.5.1.2</u>, bullet b)] shall not offer or provide management system consultancy. This also applies to that part of government identified as the certification body.
- NOTE This does not preclude the possibility of exchange of information (e.g. explanation of findings or clarification of requirements) between the certification body and its clients.
- **5.2.6** The carrying out of internal audits by the certification body and any part of the same legal entity to its certified clients is a significant threat to impartiality. Therefore, the certification body and any part of the same legal entity and any entity under the organizational control of the certification body [see 9.5.1.2, bullet b)] shall not offer or provide internal audits to its certified clients. A recognized mitigation of this threat is that the certification body shall not certify a management system on which it provided internal audits for a minimum of two years following the completion of the internal audits.
- NOTE See Note 1 to <u>5.2.3</u>.
- **5.2.7** Where a client has received management systems consultancy from a body that has a relationship with a certification body, this is a significant threat to impartiality. A recognized mitigation of this threat is that the certification body shall not certify the management system for a minimum of two years following the end of the consultancy.
- NOTE See Note 1 to 5.2.3.
- **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 <u>7.5</u>). This does not apply to individuals contracted as auditors covered in <u>7.3</u>. (**standards.iteh.al**)
- **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 links or statements by any consultancy organization stating or implying that certification would be simpler, easier, faster or less expensive if a specified consultancy organization were used.
- **5.2.10** In order 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. A recognized mitigation of this threat is that personnel shall not be used for a minimum of 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 can present them or the certification body with a conflict of interests. Certification bodies shall record and 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 interest.

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 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, duties, responsibilities and authorities of management and other personnel involved in certification 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** Certification activities shall be structured and managed so as to safeguard impartiality.
- **6.1.3** 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 and establishment of processes and procedures relating to its operations;
- b) supervision of the implementation of the policies, processes and procedures; https://standards.iteh.ai/catalog/standards/sist/8b0c5333-a473-43ad-9175-
- c) ensuring impartiality; 13103b1deae6/iso-jec-17021-1-2015
- d) supervision of its finances;
- e) development of management system certification services and schemes;
- f) performance of audits and certification, and responsiveness to complaints;
- g) decisions on certification;
- h) delegation of authority to committees or individuals, as required, to undertake defined activities on its behalf;
- i) contractual arrangements;
- j) provision of adequate resources for certification activities.
- **6.1.4** 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 Operational control

6.2.1 The certification body shall have a process for the effective control of certification activities delivered by branch offices, partnerships, agents, franchisees, etc., irrespective of their legal status, relationship or geographical location. The certification body shall consider the risk that these activities pose to the competence, consistency and impartiality of the certification body.