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Conformity assessment — General requirements for peer assessment of conformity assessment bodies and accreditation bodies

Évaluation de la conformité — Exigences générales relatives à Teh ST l'évaluation par des pairs des organismes d'évaluation de la conformité ét des organismes d'accréditation

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ISO/IEC 17040:2005

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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

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Contents

Page

Forewo	ord	i\	
Introduction			
1	Scope		
2	Normative references		
3	Terms and definitions		
4	Structural requirements		
-	•		
5 5.1	Human resource requirementsQualifications and selection		
5.2	Languages — translation		
6	Information and documentation	3	
7	Peer assessment process requirements	4	
7.1	General	4	
7.2	Application for peer assessment or an extension of scope		
7.3	Review and acceptance of the application Preparation for the peer assessment process	5	
7.4	Preparation for the peer assessment processFN.P., Y	5	
7.5 7.6	Appointment of peer assessment team	ف	
7.6 7.7	On-site assessment		
7.8	Analysis of findings		
7.9	Peer assessment report itch ai/catalog/standards/sist/at/bc7a5c-adc5-4c39-8cdc	7	
7.10	Review of the peer assessment report	8	
7.11	Peer assessment in support of continuing membership of agreement group		
7.12	Notification of changes		
8	Confidentiality	9	
9	Complaints	9	
Annex	A (informative) Financial aspects	10	
Annex B (informative) Assessment techniques for use by peer assessment teams		11	
	C (normative) Information to be included in the peer assessment report		
	Ribliography		

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 national bodies for voting. Publication as an International Standard requires approval by at least 75 % of the national 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 17040 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. (standards.iteh.ai)

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Introduction

Peer assessment has been used for many years as a means of deciding upon whom to admit to a particular group of equals or peers. Membership of a professional institution, for example, can be decided by using a process that the existing members have established, involving the setting of requirements for membership and the assessment of candidates for conformity with those requirements. In the field of conformity assessment, groups of bodies conducting the same type of work, for example testing or accreditation, have used peer assessment in order that the work of each body can be assessed and found acceptable to all the other bodies.

The global economy has accelerated the need for mutual recognition amongst accreditation and conformity assessment bodies. Each group has developed a form of peer assessment appropriate to its activities. It became apparent when reviewing the methods used by the different groups that there were many aspects in common. It was felt that there would be benefits in creating an International Standard that gave generic requirements for an effective peer assessment process, while leaving it open to individual groups to adopt specific measures appropriate to their individual fields of activities.

This International Standard is intended to be used by groups of peers performing any conformity assessment activity (e.g. conformity assessment bodies, accreditation bodies). Such groups of peers have been described in various ways, and are called agreement groups in ISO/IEC Guide 68. That is not to say that other groups in different fields of work cannot use the peer assessment process. However, such groups would need to adopt suitable organizational and managerial arrangements to provide the right conditions for the peer assessment process to be carried out to the best effect. As a result, each group can achieve its desired outcomes with the expenditure of less resources. (standards iteh.a)

This International Standard is also intended to enhance the confidence of those who use or depend upon the results of conformity assessment that the work is being conducted in a competent and proper manner.

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In this International Standard a generic peer assessment process is illustrated in Figure 1.

The model shown in Figure 1 separates aspects of the peer assessment process that are covered in this International Standard. It starts with the presumption that there is a prospective applicant to join an agreement group. It is assumed that an agreement group exists, and that this group has some criteria or requirements that have to be met in order for a body to join. These aspects are not covered by this International Standard but are for the specific agreement group to decide for themselves, as are the decision on membership of the group and any appeal on that decision. The bulk of this International Standard focuses on the steps to be used within the peer assessment process, and only makes non-process requirements where absolutely necessary. It can be used in conjunction with ISO/IEC Guide 68, and for the peer assessment process that may be required in either regulatory or voluntary fields of conformity assessment.

The nature of a peer assessment is determined by the goal of the agreement group and the use to which the outcome of the peer assessment process will be applied. The goal of the agreement group could be one or more of the following:

- a) conformity of bodies with specified requirements;
- b) equivalence of results among bodies;
- c) acceptance of results from one body by other bodies for use in their conformity assessment activities.

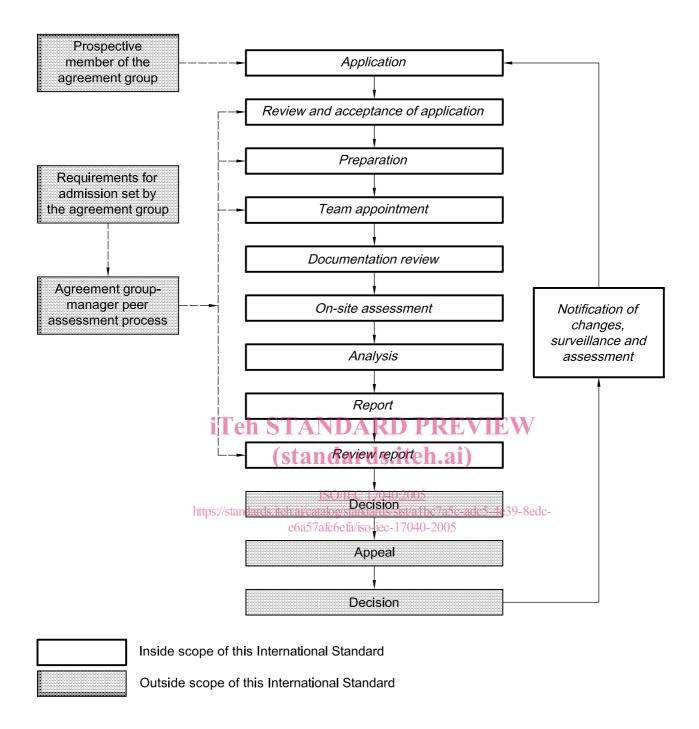


Figure 1 — Generic peer assessment process

Conformity assessment — General requirements for peer assessment of conformity assessment bodies and accreditation bodies

1 Scope

- **1.1** This International Standard specifies the general requirements for the peer assessment process to be carried out by agreement groups of accreditation bodies or conformity assessment bodies. It addresses the structure and operation of the agreement group only insofar as they relate to the peer assessment process.
- **1.2** This International Standard is not concerned with the wider issues of the arrangements for the formation, organization and management of the agreement group, and does not cover how the group will use peer assessment in deciding membership of the group. Such matters, which could for example include a procedure for applicants to appeal against decisions of the agreement group, are outside the scope of this International Standard.

NOTE 1 Further information on the wider issues is contained in ISO/IEC Guide 68.

- 1.3 This International Standard is applicable to peer assessment of conformity assessment bodies performing activities such as
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- a) testing, https://standards.iteh.ai/catalog/standards/sist/a1bc7a5c-adc5-4e39-8edc-e6a57afc6efa/iso-iec-17040-2005
- b) product certification,
- c) inspection,
- d) management system certification (sometimes also called registration), and
- e) personnel certification.

More than one type of activity can be included in a peer assessment process. This can be considered particularly appropriate when the body under assessment conducts combined assessments of multiple conformity assessment activities.

This International Standard is also applicable to peer assessment amongst accreditation bodies, which is also known as peer evaluation.

NOTE 2 Bodies that are members of an agreement group might wish to rely on the soundness of the peer assessment process for evaluating the competence of a peer body as a potential subcontractor.

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

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

peer assessment

assessment of a body against specified requirements by representatives of other bodies in, or candidates for, an agreement group

[ISO/IEC 17000:2004, definition 4.5]

NOTE 1 "Candidates" are included to cater for the situation where a new group is being formed, at which time there would be no bodies in the group.

NOTE 2 The term "peer evaluation" is used by some groups instead of "peer assessment".

3.2

applicant

body that is to be the object of the peer assessment process

NOTE The body can be applying for membership of the agreement group or can be an existing member applying for an extension of the scope of its membership. If the peer assessment process is used for continuing assurance of conformity (see 7.10), the term "applicant" refers to the body that is being assessed.

4 Structural requirements eh STANDARD PREVIEW

- **4.1** The requirements of this International Standard are Jimited to those necessary for the successful performance of the peer assessment process. ISO/IEC Guide 68 provides guidance on other aspects of the operation of the agreement group.

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- **4.2** A management committee or person shall be appointed with overall authority and responsibility for the peer assessment process, including the following activities:
- a) development of policies and procedures relating to the operation of the peer assessment process;
- b) implementation of the policies and procedures for the peer assessment process;
- c) financing of the peer assessment process (see Annex A);
- d) performance of the peer assessment process;
- e) reporting on the conformity of the assessed body with the requirements specified by the agreement group;
- f) controlling the resolution of nonconformities of the assessed body;
- g) advising the agreement group on matters relating to the peer assessment process.

The management committee or person may delegate authority to committees or persons to undertake defined activities on its behalf. Where this International Standard refers to "management committee or person", it includes any committee or person to whom authority has been delegated.

- **4.3** The duties and responsibilities of the management committee or person, and any committees or persons to whom authority has been delegated, shall be documented.
- **4.4** The management committee or person shall ensure that persons involved in the peer assessment process are competent and can perform their duties objectively.

5 Human resource requirements

5.1 Qualifications and selection

5.1.1 The qualification criteria shall be defined and documented for the people carrying out the peer assessment process.

Elements of ISO 19011:2002, Clause 7, may be adapted for use in various types of assessments.

- **5.1.2** The qualification criteria of the people carrying out the peer assessment process shall match the personal attributes and competence that would be required of a person performing the activity that is the object of the peer assessment.
- **5.1.3** Competence criteria shall match the nature of the peer assessments to be performed (see Introduction).
- **5.1.4** The process for the selection, training and continuing evaluation of the people required for the conduct of the peer assessment process shall be defined and documented.

5.2 Languages — translation

- **5.2.1** The basic documents that will be required for the peer assessment process shall be available in a language that can be understood by all members of the peer assessment team. The body under assessment may need to translate some documents into another language. The choice of basic documents shall be agreed between the members of the agreement group prior to any peer assessment process.
- **5.2.2** The language(s) in which the peer assessment process will be conducted shall be specified. If necessary, translation facilities shall be provided to make sure that all members of the peer assessment team understand the discussions.

 ISO/IEC 17040:2005

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6 Information and documentation

confidentiality,

The management committee or person shall provide applicants, the members of the agreement group and other interested parties with the following information and documentation, in language(s) agreed by the members.

a) The requirements for membership specified by the agreement group against which the peer assessments will be carried out.

These requirements should refer to the relevant International Standard or Guide. If a relevant International Standard or Guide does not exist, the requirements should include at least

	the structure,
	subcontracting,
	management system for the conformity assessment results,
_	internal audits and management reviews,
	documentation,
	records,

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- human resources, including personal attributes and competence criteria,
- facilities and equipment, where appropriate, and
- complaints and appeals.

Any additional documentation that may be necessary to supplement the International Standards or Guides should be formulated by relevant committees or persons possessing the necessary technical competence and should be endorsed by the members of the agreement group.

b) A clear and unambiguous definition of the type(s) and scope(s) of peer assessment.

NOTE The type of peer assessment refers to the assessment activities to be undertaken, as described in 7.1. The scope of the peer assessment refers to the range of the applicant's activities that will be assessed.

c) The total scope of membership in terms of the activities that the agreement group members undertake.

NOTE Members of the agreement group can undertake other activities outside the scope of the agreement group, and as such would be outside of the scope of the peer assessment.

- d) A detailed description of the peer assessment process.
- e) Any fees that may be required and reference to other charges that may be incurred for application, initial
 assessment and reassessment.
- f) An application form.

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7 Peer assessment process requirements

ISO/IEC 17040:2005

7.1 General

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The activities to be carried out in conducting each peer assessment process shall be defined and documented.

These activities may include

- a) reviewing documentation,
- b) assessment of records.
- c) interviewing personnel, including top management,
- d) assessment of the body's performance of its internal activities,
- e) witnessing the body performing its activities,
- f) witnessing the body performing its own witnessing of customer activities,
- g) reviewing the facilities required in the normative documents concerned,
- h) technical assessment of the conformity assessment activities, and
- i) reviewing the results of comparisons or proficiency-testing programmes where these are relevant to the validity of the activity.

For the purposes of this International Standard, the requirements given in 7.2 to 7.12 are deemed the minimum requirements for the peer assessment process. Agreement groups may add to these requirements to suit their individual circumstances.

7.2 Application for peer assessment or an extension of scope

- **7.2.1** A duly authorized representative of the applicant shall be required to sign an application form, in which the applicant
- a) defines the scope of its activities which are to be subjected to the peer assessment process,
- b) includes a summary of its current and previous activities, and of any related bodies,
- c) declares awareness of the manner in which the peer assessment process will be conducted,
- d) agrees to the peer assessment process, especially to accept the visit of the assessment team, and
- e) agrees to pay the fees, wherever applicable, charged to the applicant whatever the result of the assessment may be, and to accept the charges for subsequent monitoring wherever applicable.
- **7.2.2** At least the following information related to the desired scope of the peer assessment process shall be provided by the applicant, as required, prior to the on-site assessment:
- a) the governing rules of the applicant pertaining to issues such as confidentiality, objectivity, impartiality, independence, integrity and legal status;
- a description of the conformity assessment activities which the applicant performs, and standards or methods or procedures to which the applicant operates, including limits of capability as required by the agreement group;
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- c) a copy of its quality manual, lists of procedures and working instructions, and the associated documentation; (Standards.iteh.ai)
- d) as required by the agreement group, <u>information on any</u> other independent assessment of its conformity to relevant requirements, for example through accreditation or through another peer assessment.

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If the applicant's documents are confidential, the applicant should provide extracts that include the required information.

7.2.3 Records of applications for peer assessment shall be maintained by the management committee or person.

7.3 Review and acceptance of the application

- **7.3.1** Before the management committee or person starts to prepare for a peer assessment process, it shall review the application provided by the applicant to ensure that the applicant meets the basic conditions to undergo the peer assessment process.
- **7.3.2** The management committee or person shall inform the applicant of the result of the review.
- **7.3.3** Records of the reviews of applications for peer assessment shall be maintained by the management committee or person.

7.4 Preparation for the peer assessment process

- **7.4.1** The preparations required for a peer assessment process shall be specified in a document which, being internal to the operation of the agreement group, may be in the form of a confidential "operational document" or "guidelines", or however named.
- **7.4.2** If provided, evidence of other independent assessment (e.g. through accreditation or through another peer assessment presented by the applicant) shall be evaluated to determine the extent to which it can be used to demonstrate conformity with the requirements specified by the agreement group.