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

*Évaluation de la conformité — Exigences générales relatives à
l'évaluation par des pairs des organismes d'évaluation de la conformité
et des organismes d'accréditation*

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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

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 Structural requirements	2
5 Human resource requirements	3
5.1 Qualifications and selection	3
5.2 Languages — translation	3
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	5
7.3 Review and acceptance of the application	5
7.4 Preparation for the peer assessment process	5
7.5 Appointment of peer assessment team	6
7.6 Documentation review	7
7.7 On-site assessment	7
7.8 Analysis of findings	7
7.9 Peer assessment report	7
7.10 Review of the peer assessment report	8
7.11 Peer assessment in support of continuing membership of agreement group	8
7.12 Notification of changes	9
8 Confidentiality	9
9 Complaints	9
Annex A (informative) Financial aspects	10
Annex B (informative) Assessment techniques for use by peer assessment teams	11
Annex C (normative) Information to be included in the peer assessment report	12
Bibliography	13

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.

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.

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.

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.

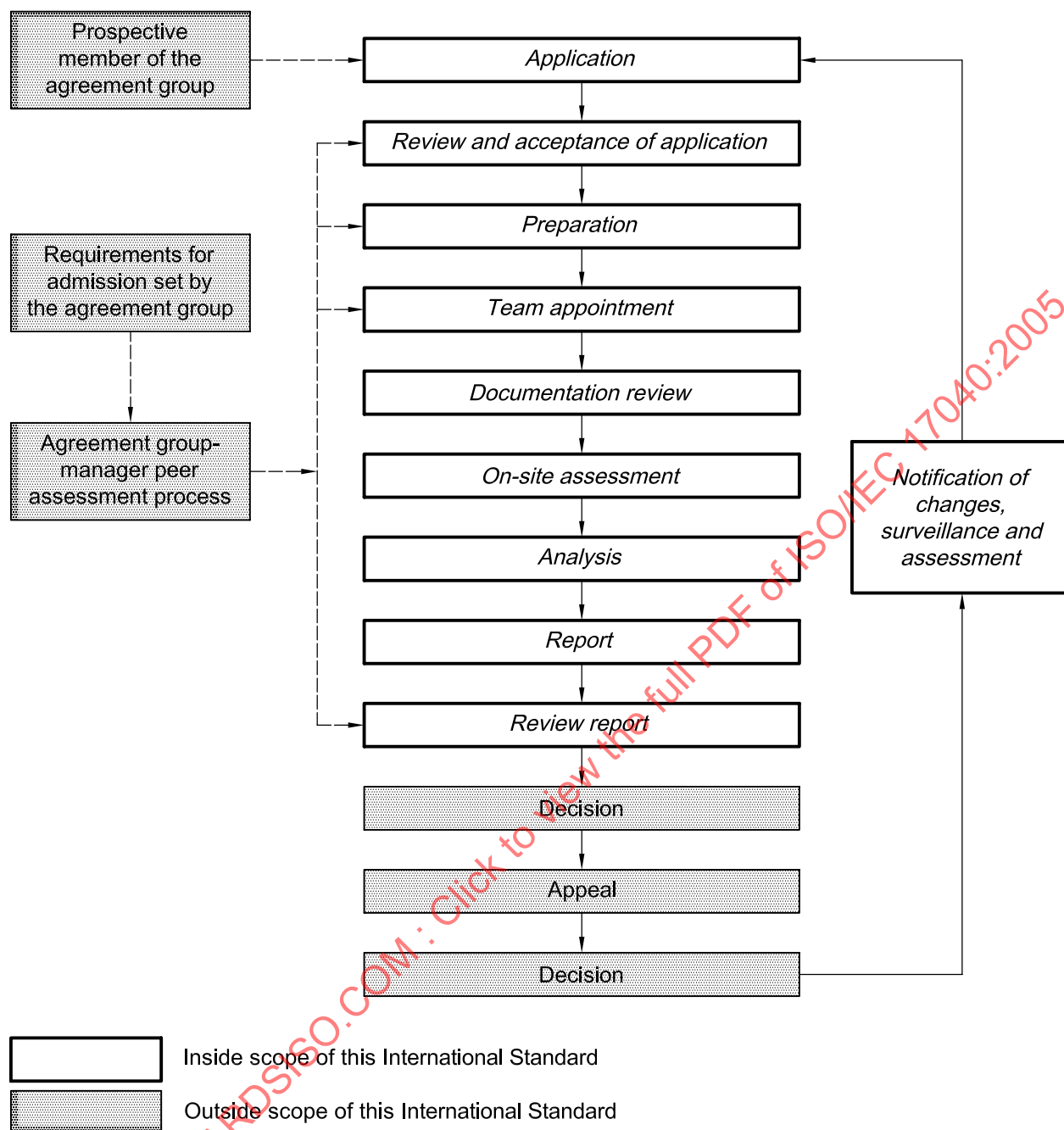


Figure 1 — Generic peer assessment process

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

- a) testing,
- 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

4.1 The requirements of this International Standard are limited 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.

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.

6 Information and documentation

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,
- confidentiality,

- 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.

7 Peer assessment process requirements

7.1 General

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;
- b) 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;
- c) a copy of its quality manual, lists of procedures and working instructions, and the associated documentation;
- d) as required by the agreement group, information on any other independent assessment of its conformity to relevant requirements, for example through accreditation or through another peer assessment.

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.

7.4.3 The applicant or the management committee or person may suggest that a pre-assessment visit be conducted by one or more members of the peer assessment team or the group. Before a pre-assessment visit is conducted, its purpose, the arrangements for its conduct, and any financial conditions shall be agreed between the applicant and the management committee or person.

Ideally, a pre-assessment visit should be carried out by the peer assessment team leader once appointed according to 7.5.2. If the pre-assessment visit is needed before the peer assessment team is appointed, the management committee or person should assign the task to a suitably qualified person.

7.4.4 When the necessary information has been obtained, the management committee or person shall provide the applicant with a proposal for the peer assessment process, including the proposed number of people conducting the assessment and their names and affiliations, the likely duration of the assessment, and an estimate of any costs to be borne by the applicant. The applicant's acceptance of the proposal shall be received before the management committee or person initiates the peer assessment process.

NOTE Guidance on the financial aspects of peer assessment is given in Annex A.

7.5 Appointment of peer assessment team

7.5.1 The management committee or person shall appoint a peer assessment team that is qualified to perform the peer assessment process.

7.5.2 One member of the team shall be appointed as team leader who will take full responsibility for the peer assessment process and related communications with the applicant and the management committee or person.

Depending upon the scale of the peer assessment process, a one-person team may be appointed; that is, the team leader may perform the entire peer assessment process.

7.5.3 The people assigned to conduct a particular peer assessment process shall have practical experience of the activities to be assessed.

7.5.4 Wherever possible, the team shall include people from a balanced selection of agreement group member bodies.

7.5.5 Assignment of people to the team shall take into account their ability to work together effectively.

7.5.6 Provision shall be made to assure the objectivity of team members, taking into account any conflicts of interests.

7.5.7 Any person from a body that had itself been assessed earlier by a person from the body currently under assessment shall not be assigned to the team, unless this reciprocal arrangement is explicitly intended and there is written agreement by both bodies.

NOTE The agreement group can specify a time limit for this requirement.

7.5.8 The management committee or person may, with the agreement of the team leader, assign one or more observers to accompany the team, for example, for the purposes of training or evaluating the people conducting the peer assessment process.

7.5.9 The management committee or person shall inform the applicant of the names and affiliations of the team members and observers. The applicant shall be given the opportunity to agree to the assignment of team members and observers, or to object to the assignment of any team member or observer, with reasons. The management committee or person shall have a procedure for resolving objections.

7.5.10 If it is necessary to use translators, the specific role of the translators shall be defined and documented. The responsibility for selection of translators and for the provision of translators shall be defined and documented. The need for objectivity, as well as competence in providing complete, technically accurate translations, shall be taken into account (see 5.2).

7.5.11 The management committee or person shall require the team members to give their assent and commitment to a document that defines the expectations and responsibilities of the team.

7.5.12 The management committee or person shall have a procedure which specifies that a plan shall be drawn up for each peer assessment process, and that the plan shall be understood and accepted by all parties including the applicant and the peer assessment team. The procedure shall include the action to be taken if it is subsequently found to be necessary to make changes to the plan.

7.6 Documentation review

The assessment team shall review the documentation supplied by the applicant to ascertain that it fulfils the requirements specified by the agreement group. If this review reveals that the documentation does not meet the requirements, further resources should not be expended until such concerns are resolved to the satisfaction of the assessment team and the applicant. The results of the documentation review shall be recorded.

7.7 On-site assessment

7.7.1 The peer assessment team shall commence the on-site assessment with an opening meeting with the relevant personnel of the applicant. At this meeting, the purpose of the peer assessment and the requirements specified by the agreement group shall be confirmed, along with the scope and plans for the on-site assessment.

7.7.2 The peer assessment team shall conduct the on-site assessment to gather objective evidence that, for the applicable scope, the applicant conforms to the requirements specified by the agreement group. Where applicable, the team may conduct the on-site assessment entirely at the primary site or, as necessary, at other sites where the operations of the applicant are located.

7.7.3 The peer assessment team shall assess the applicant's provision of the activities covered by the defined scope against the applicable requirements specified by the agreement group (see Annex B).

7.7.4 The peer assessment team shall witness a sufficient number of examples and files of the on-site activities of the applicant's personnel, using appropriate sampling techniques to ensure that their fulfilment of requirements is appropriately evaluated.

7.7.5 The peer assessment team shall evaluate a sufficient number and variety of the personnel of the applicant to provide assurance that the applicant fulfils the requirements.

7.8 Analysis of findings

The peer assessment team shall analyse all information and objective evidence gathered during the documentation review and the on-site assessment to determine the extent of conformity of the applicant with the requirements specified by the agreement group, and shall decide on any nonconformities. If the assessment team has doubt about a possible nonconformity, the team shall refer back to the responsible management committee or person for clarification.

NOTE Suggestions for improvement may also be identified and presented to the applicant provided that they cannot be construed as consultancy.

7.9 Peer assessment report

7.9.1 The management committee or person shall adopt procedures that suit its needs, but as a minimum these procedures shall ensure the following:

- a) a meeting shall take place between the peer assessment team and the applicant's top management prior to leaving the site, at which the assessment team presents a report on their findings, including any nonconformities to be discharged in order to conform with all of the requirements specified by the agreement group: opportunity shall be provided for the applicant to ask questions about the findings and their basis;

- b) a written report on the outcome of the peer assessment process shall be promptly brought to the attention of the applicant (see Annex C); if the report is copied by the applicant, it shall be copied only in its entirety;
- c) the applicant shall be invited to comment on the written report and to describe the specific actions taken or planned to be taken, within a defined time, to remedy any identified nonconformities;
- d) information about the corrective actions in relation to nonconformities, supplied by the applicant, shall be analysed by the team leader (and if necessary other members of the peer assessment team) to determine if actions are sufficient and effective;
- e) the applicant shall be informed by the team leader of the outcome of the analysis.

7.9.2 The team leader shall submit a written report to the management committee or person containing a conclusion or recommendation and sufficient information for them to judge the conformity of the applicant with the requirements specified by the agreement group. The management committee or person shall define and document the level of detail to be included in the report but it shall include the information given in Annex C.

NOTE The report prepared under 7.9.1 b) could be used, together with information on the action taken to resolve nonconformities.

7.10 Review of the peer assessment report

7.10.1 The management committee or person shall review the peer assessment report and any other relevant information. If the management committee or person has delegated this task, this task shall be performed by a person or group independent of the members of the assessment team. A person appropriately qualified on technical issues shall be involved in the review where necessary.

7.10.2 The review of the peer assessment report and other relevant information shall be performed to confirm the following:

- a) that the peer assessment process has been conducted in a consistent and competent manner in accordance with the requirements of this International Standard;
- b) that the information is reliable and is sufficient with respect to determining the conformity of the applicant with the requirements specified by the agreement group;
- c) that all nonconformities have been satisfactorily documented and addressed.

If the result of the review does not clearly indicate that the items above have been satisfied, then the report shall be dealt with in accordance with the applicable procedures of the agreement group.

7.10.3 The management committee or person shall have a procedure which specifies the action to be taken if the findings of the review are that the applicant fulfils the requirements specified by the agreement group.

NOTE The decision on admission of the applicant to membership of the agreement group and the procedure for the handling of appeals against that decision are outside the scope of this International Standard (see 1.2).

7.10.4 The management committee or person shall maintain records of assessment reports, reviews and related correspondence.

7.11 Peer assessment in support of continuing membership of agreement group

If the agreement group decides to use peer assessment to provide evidence that member organizations continue to conform to the requirements specified by the agreement group, the management committee or person shall have a documented procedure specifying how the requirements of this International Standard are to be applied.

The agreement group may use peer assessment in response to deficiencies discovered in the work of a particular member organization, or as a planned review of all member organizations.

7.12 Notification of changes

7.12.1 The agreement group shall give due notice of any changes it intends to make in its requirements for peer assessment. Before deciding on the precise form and effective date of the changes, the agreement group shall consult with parties having a significant interest in the effect of the changes. Subsequent to a decision on, and publication of, the changed requirements, it shall verify that each member of the agreement group carries out any necessary adjustments to its procedures within such time as, in the judgement of the agreement group, is reasonable.

7.12.2 Member bodies shall notify the agreement group promptly of any changes that could affect the conformity of the body with the requirements specified by the agreement group. The agreement group shall have a procedure for handling such notifications. The procedure may require the management committee or person responsible for peer assessment to evaluate the possible effects of the changes and, where necessary, to arrange a full or partial assessment of the member organization to be carried out in accordance with the requirements of this International Standard. A partial assessment might be appropriate where the change affects only a part of the member body or of its activities.

8 Confidentiality

The agreement group shall make appropriate arrangements to safeguard the confidentiality of the information obtained in the peer assessment process, and these shall be documented. These arrangements shall cover all individuals working within the agreement group, including committee members, and external bodies or individuals acting on its behalf. Such information shall not be disclosed to an unauthorized party without the written consent of the organization or individual from whom the information was obtained, except where the law requires such information to be disclosed. When the agreement group is required by law to release confidential information, the body shall, unless prohibited by law, be notified of the information provided.

9 Complaints

The agreement group shall have a policy and procedure for dealing with complaints regarding the peer assessment process. The procedure shall at least require

- a) establishing the validity of the complaint,
- b) ensuring that the complainant is informed of the outcome as far as confidentiality considerations permit,
- c) ensuring that any appropriate corrective action is taken,
- d) documenting the actions taken and assessing their effectiveness, and
- e) establishing and maintaining a record of all complaints.

NOTE A complaint-handling system compliant with the requirements of ISO 10002 is deemed to satisfy these requirements.

Annex A **(informative)**

Financial aspects

The peer assessment process involves the expenditure of considerable resources in order

- to set up the peer assessment process,
- to manage and maintain the process,
- to conduct individual peer assessment processes, and
- to conduct on-going activities to assure the conformity of agreement group members, where necessary.

The agreement group should decide how the resources are to be provided by the members. For example, if the group comprises members of similar size, experience and scope of activity, it might be decided that each member should provide the necessary resources in terms of people for the peer assessment teams and that no financial transactions should take place to compensate for the resources used. If, on the other hand, some members of the group should be called upon to provide a large proportion of the resources, then it could be decided that they should receive reimbursement of the expenditure which they incur. The reimbursement might cover only the actual expenditure on travelling and living costs, or might also include compensation for the time of the personnel provided by the member, at an agreed rate.

The agreement group should have a documented policy and procedure(s) covering the financial aspects related to peer assessment. The policy should recognize that the costs should be proportional to the risks from nonconformity with the requirements specified by the agreement group.