



GUIDE 61

**General requirements for
assessment and accreditation of
certification/registration bodies**

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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.

Draft Guides adopted by the responsible Committee or Group are circulated to national bodies for voting. Publication as a Guide requires approval by at least 75 % of the national bodies casting a vote.

ISO/IEC Guide 61 was prepared by the Committee on Conformity Assessment (CASCO).

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Introduction

The requirements contained in this Guide are written, above all, to be considered as general requirements for bodies operating accreditation systems. This Guide, however, is in three sections so that if used by organizations other than accreditation bodies concerned with recognition of competence, Sections 1 and 3 apply, and users need simply replace "accreditation" by "recognition".

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General requirements for assessment and accreditation of certification/registration bodies

Section 1: General

1.1 Scope

This Guide specifies general requirements for a body to follow if it is to be recognized at a national or international level as competent and reliable in assessing and subsequently accrediting certification bodies or registration bodies. Conformity to the requirements of this Guide will promote equivalence of national systems and facilitate agreements on mutual recognition of accreditations between such bodies.

The primary objective of this Guide is to describe accreditation as providing, by means of assessment and subsequent surveillance, an assurance that the market can rely on certificates issued by the accredited bodies. However, organizations other than accreditation bodies, concerned with recognition of competence, may also use it by replacing "accreditation" by "recognition".

In some countries, bodies which verify conformity of products, processes, services or systems to specified standards are called "certification bodies", in other countries "registration bodies", and in still others "assessment bodies". For ease of understanding, this Guide always refers to such bodies as "bodies". This should not be understood to be limiting, as this Guide may also be applicable to the assessment and accreditation of conformity assessment bodies other than certification or registration bodies, such as inspection bodies.

NOTE 1 It is recognized that agreements on mutual recognition of accreditations aiming at the removal of barriers to cross-border trade may have to cover other aspects not explicitly specified in these general requirements, such as

the exchange of staff or training programmes. In particular, with a view to create confidence and harmonize the interpretation and implementation of standards, each accreditation body should encourage technical cooperation and exchange of experience among bodies accredited by it, and it should be prepared to exchange information on accreditation procedures and practices with other accreditation bodies. Certification and certification/registration body standards often contain non-specific requirements such as "staff shall be competent". Mutual recognition of accreditation requires harmonization of interpretation of such clauses.

1.2 References

ISO/IEC Guide 2:1996, *General terms and their definitions concerning standardization and related activities*.

ISO/IEC Guide 25:1990, *General requirements for the competence of calibration and testing laboratories*.

ISO/IEC Guide 27:1983, *Guidelines for corrective action to be taken by a certification body in the event of misuse of its mark of conformity*.

ISO/IEC Guide 28:1982, *General rules for a model third-party certification system for products*.

ISO/IEC Guide 40:—1), *General requirements for bodies operating product certification systems*.

1) To be published. (Revision of ISO/IEC Guide 40:1983)

ISO/IEC Guide 62:1996, *General requirements for bodies operating assessment and certification/registration of quality systems.*

ISO 8402:1994, *Quality management and quality assurance — Vocabulary.*

ISO 10011-1:1990, *Guidelines for auditing quality systems — Part 1: Auditing.*

ISO 10011-2:1991, *Guidelines for auditing quality systems — Part 2: Qualification criteria for quality systems auditors.*

1.3 Definitions

For the purposes of this Guide, the relevant definitions given in ISO/IEC Guide 2 and ISO 8402 apply.

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Section 2: Requirements for accreditation bodies

2.1 Accreditation body

2.1.1 General provisions

2.1.1.1 The policies and procedures under which the accreditation body operates shall be non-discriminatory, and they shall be administered in a non-discriminatory manner. Procedures shall not be used to impede or inhibit access by applicant bodies other than as specified in this Guide.

2.1.1.2 The accreditation body shall make its services accessible to all applicants whose activities fall within its declared field of operation. There shall not be undue financial or other conditions. Access shall not be conditional upon the size of the applicant body or membership of any association or group, nor shall accreditation be conditional upon the number of bodies already accredited.

2.1.1.3 The accreditation criteria against which the competence of an applicant body is assessed shall be those outlined in the ISO/IEC Guides 40 and 62 or other normative documents relevant to the function performed. If an explanation is required as to the application of these documents to a specific accreditation programme, it shall be formulated by relevant and impartial committees or persons possessing the necessary technical competence, and published by the accreditation body.

2.1.1.4 The accreditation body shall confine its requirements, assessment and decisions on accreditation to those matters specifically related to the scope of the accreditation being considered.

2.1.2 Organization

The structure of the accreditation body shall be such as to give confidence in its accreditations.

In particular, the accreditation body shall

- a) be impartial;
- b) be responsible for its decisions relating to the granting, maintaining, extending, reducing, suspending and withdrawing of accreditation;
- c) identify the management (committee, group or person) which will have overall responsibility for all of the following:

- 1) performance of assessment and accreditation as defined in this Guide,
- 2) formulation of policy matters relating to the operation of the accreditation body,
- 3) decisions on accreditation,
- 4) supervision of the implementation of its policies,
- 5) supervision of the finances of the accreditation body,
- 6) delegation of authority to committees or individuals, as required, to undertake defined activities on its behalf;
- d) have documents which demonstrate that it is a legal entity;
- e) have a documented structure which safeguards impartiality, including provisions to assure the impartiality of the operations of the accreditation body; this structure shall enable the participation of all parties significantly concerned in the development of policies and principles regarding the content and functioning of the accreditation system;
- f) ensure that each decision on accreditation is taken by a person or persons different from those who carried out the assessment;
- g) have rights and responsibilities relevant to its accreditation activities;
- h) have adequate arrangements to cover liabilities arising from its operations and/or activities;
- i) have the financial stability and resources required for the operation of an accreditation system;
- j) employ a sufficient number of personnel having the necessary education, training, technical knowledge and experience for performing accreditation functions relating to the type, range and volume of work performed, under a responsible senior executive;
- k) have a quality system, as outlined in 2.1.4, giving confidence in its ability to operate an accreditation system for certification/registration bodies;
- l) have policies and procedures that distinguish between accreditation and any other activities in which the accreditation body is engaged;

- m) together with its senior executive and staff, be free from any commercial, financial and other pressures which might influence the results of the accreditation process;
- n) have formal rules and structures for the appointment and operation of any committees which are involved in the accreditation process; such committees shall be free from any commercial, financial and other pressures that might influence decisions (see note 2);
- o) ensure that activities of related bodies do not affect the confidentiality, objectivity or impartiality of its accreditations and shall not offer or provide, directly or indirectly,
 - 1) those services that it accredits others to perform,
 - 2) consulting services to obtain or maintain accreditation,
 - 3) services to design, implement or maintain a certification scheme (see note 3);
- p) have policies and procedures for the resolution of complaints, appeals and disputes received from bodies or other parties about the handling of accreditation or any related matters.

NOTES

2 A structure where members are chosen to provide a balance of interests, where no single interest predominates, will be deemed to satisfy this provision.

3 Other products, processes or services may be offered, directly or indirectly, provided they do not compromise confidentiality or the objectivity or impartiality of its accreditation process and decisions.

2.1.3 Subcontracting

When an accreditation body decides to subcontract work related to accreditation (e.g. audits) to an external body or person, a properly documented agreement covering the arrangements, including confidentiality and conflict of interests, shall be drawn up. The accreditation body shall

- a) take full responsibility for such subcontracted work and maintain its responsibility for granting, maintaining, extending, reducing, suspending or withdrawing accreditation;
- b) ensure that the subcontracted body or person is competent and complies with the applicable provisions of this Guide and is not involved, either directly or through its employer, with the design, implementation or maintenance of a certification or certification/registration scheme in such a way that impartiality could be compromised;

- c) obtain the consent of the applicant or accredited body.

NOTE 4 Requirements a) and b) are also relevant, by extension, when an accreditation body uses, for granting its own accreditation, work provided by another accreditation body with which it has signed an agreement.

2.1.4 Quality system

2.1.4.1 The management of the accreditation body with executive responsibility for quality shall define and document its policy for quality, including objectives for quality and its commitment to quality. The management shall ensure that this policy is understood, implemented and maintained at all levels of the organization.

2.1.4.2 The accreditation body shall operate a quality system in accordance with the relevant elements of this Guide and appropriate to the type, range and volume of work performed. This quality system shall be documented and the documentation shall be available for use by the staff of the accreditation body. The accreditation body shall ensure effective implementation of the documented quality system procedures and instructions. The accreditation body shall designate a person with direct access to its highest executive level who, irrespective of other responsibilities, shall have defined authority to

- a) ensure that a quality system is established, implemented and maintained in accordance with this Guide;
- b) report on the performance of the quality system to the management of the accreditation body for review and as a basis for improvement of the quality system.

2.1.4.3 The quality system shall be documented in a quality manual and associated quality procedures, and the quality manual shall contain or refer to at least the following:

- a) a quality policy statement;
- b) a brief description of the legal status of the accreditation body, including the names of its owners, if applicable, and, if different, the names of the persons who control it;
- c) the names, qualifications, experience and terms of reference of the senior executive and other accreditation personnel influencing the quality of the accreditation function;
- d) an organization chart showing lines of authority, responsibility and allocation of functions stemming from the senior executive and, in particular, the relationship between those responsible for the assessment and those taking decisions regarding accreditation;

- e) a description of the organization of the accreditation body, including details of the management (committee, group or person) identified in 2.1.2 c), its constitution, terms of reference and rules of procedure;
- f) the policy and procedures for conducting management reviews;
- g) administrative procedures including document control;
- h) the operational and functional duties and services pertaining to quality, so that the extent and limits of each person's responsibility are known to all concerned;
- i) the policy and procedures for the recruitment and training of accreditation body personnel (including auditors) and monitoring their performance;
- j) a list of its subcontractors and details of the procedures for assessing, recording and monitoring their competence;
- k) its procedures for handling nonconformities and for assuring the effectiveness of any corrective actions taken;
- l) the policy and procedures for implementing the accreditation process, including
 - 1) the conditions for issue, retention and withdrawal of accreditation documents,
 - 2) checks of the use and application of documents used in the accreditation,
 - 3) the procedures for assessing and accrediting applicants,
 - 4) the procedures for surveillance and re-assessment of accredited bodies;
- m) the policy and procedures for dealing with appeals, complaints and disputes;
- n) the procedures for conducting internal audits based on the provisions of ISO 10011-1.

2.1.5 Conditions for granting, maintaining, extending, reducing, suspending and withdrawing accreditation

2.1.5.1 The accreditation body shall specify the conditions for granting, maintaining, extending and reducing accreditation, and the conditions under which accreditation may be suspended or withdrawn, partially or in total, for all or part of the accredited body's scope of accreditation. In particular, the accreditation body shall require the body to notify it promptly of any intended changes to the quality system or other changes which may affect conformity.

2.1.5.2 The accreditation body shall have procedures to

- a) grant, maintain, withdraw and suspend accreditation;
- b) extend or reduce the scope of accreditation;
- c) conduct reassessment in the event of changes significantly affecting the activity and operation of the accredited body (such as change of ownership, changes in personnel or equipment), or if analysis of a complaint or any other information indicates that the accredited body no longer complies with the requirements of the accreditation body.

2.1.6 Internal audits and management reviews

2.1.6.1 The accreditation body shall conduct periodic internal audits covering all procedures in a planned and systematic manner, to verify that the quality system is being implemented and is effective. The accreditation body shall ensure that

- a) personnel responsible for the area audited are informed of the outcome of the audit;
- b) corrective action is taken in a timely and appropriate manner;
- c) the results of the audit are documented.

2.1.6.2 The top management of the accreditation body shall review its quality system at defined intervals sufficient to ensure its continuing suitability and effectiveness in satisfying the requirements of this Guide and the stated quality policy and objectives. Records of such reviews shall be maintained.

2.1.7 Documentation

2.1.7.1 The accreditation body shall document, update at regular intervals, and make available (through publications, electronic media or other means), on request,

- a) information about the authority under which the accreditation body operates;
- b) a documented statement of its accreditation system, including its rules and procedures for granting, maintaining, extending, reducing, suspending and withdrawing accreditation;
- c) information about the assessment and accreditation process;
- d) a description of the means by which the accreditation body obtains financial support, and general information on the fees charged to applicants and accredited bodies;

- e) a description of the rights and duties of applicants and accredited bodies, as specified, including requirements, restrictions or limitations on the use of the accreditation body's logo and on the ways of referring to the accreditation granted;
- f) information on procedures for handling complaints, appeals and disputes;
- g) a directory of accredited bodies including their locations, describing the scope of accreditation granted to each.

2.1.7.2 The accreditation body shall establish and maintain procedures to control all documents and data that relate to its accreditation functions. These documents shall be reviewed and approved for adequacy by appropriately authorized and competent personnel prior to issuing any documents following initial development or any subsequent amendment or change being made. A listing of all appropriate documents with the respective issue and/or amendment status identified shall be maintained. The distribution of all such documents shall be controlled to ensure that the appropriate documentation is made available to personnel of the accreditation body, or applicants and accredited bodies, when required to perform any function relating to the activities of applicants and accredited bodies.

2.1.8 Records

2.1.8.1 The accreditation body shall maintain a record system to suit its particular circumstances and to comply with existing regulations. The records shall demonstrate that accreditation procedures have been effectively fulfilled, particularly with respect to application forms, assessment reports, and other documents relating to granting, maintaining, extending, reducing, suspending or withdrawing accreditation. The records shall be identified, managed and disposed of in such a way as to ensure the integrity of the process and confidentiality of the information. The records shall be kept for a period of time so that continued confidence may be demonstrated for at least one full accreditation cycle, or as required by law.

2.1.8.2 The accreditation body shall have a policy and procedures for retaining records for a period consistent with its contractual, legal or other obligations. The accreditation body shall have a policy and procedures concerning access to these records consistent with 2.1.9.1.

2.1.9 Confidentiality

2.1.9.1 The accreditation body shall have adequate arrangements, consistent with applicable laws, to safeguard confidentiality of the information obtained in the course of its accreditation activities at all levels of

its organization, including committees and external bodies or individuals acting on its behalf.

2.1.9.2 Except as required in this Guide, information about a particular body shall not be disclosed to a third party without the written consent of the body. Where the law requires information to be disclosed to a third party, the body shall be informed of the information provided, as permitted by the law.

2.2 Accreditation body personnel

2.2.1 General

2.2.1.1 The personnel of the accreditation body involved in accreditation shall be competent for the functions they perform.

2.2.1.2 Information on the relevant qualifications, training and experience of each member of the personnel involved in the accreditation process shall be maintained by the accreditation body. Records of training and experience shall be kept up to date.

2.2.1.3 Clearly documented instructions shall be available to the personnel describing their duties and responsibilities. These instructions shall be maintained up to date.

2.2.2 Qualification criteria for auditors and technical experts

2.2.2.1 In order to ensure that assessments are carried out effectively and uniformly, the minimum relevant criteria for competence shall be defined by the accreditation body.

2.2.2.2 Auditors shall meet the requirements of the appropriate international documentation. For the assessment of quality systems, the relevant guidelines for auditing are those defined in ISO 10011-1, and the relevant criteria for auditors are those defined in ISO 10011-2.

2.2.2.3 Technical experts are not required to comply with the requirements for auditors covered in ISO 10011-2. Guidance on their personal attributes may be obtained from ISO 10011-2:1991, clause 7.

2.2.3 Selection procedure

2.2.3.1 Selection of auditors and technical experts, in general

The accreditation body shall have a procedure for

- a) selecting auditors and, if applicable, technical experts on the basis of their competence, training, qualifications and experience;
- b) initially assessing the conduct of auditors and technical experts during assessments, and subsequently monitoring the performance of auditors and technical experts.

2.2.3.2 Assignment for a specific assessment

When selecting the audit team to be appointed for a specific assessment, the accreditation body shall ensure that the skills brought to each assignment are appropriate. The team shall

- a) be familiar with the relevant legal regulations, accreditation procedures and accreditation requirements;
- b) have a thorough knowledge of the relevant assessment method and assessment documents;
- c) have appropriate technical knowledge of the specific activities for which accreditation is sought and, where relevant, with associated procedures and their potential for failure (technical experts who are not auditors may fulfil this function);
- d) have a degree of understanding sufficient to make a reliable assessment of the competence of the body to operate within its scope;
- e) be able to communicate effectively, both in writing and orally, in the required languages;
- f) be free from any interest that might cause team members to act in other than an impartial or non-discriminatory manner, for example
 - 1) audit team members or their organization shall not have provided consulting services to the applicant or accredited body which compromise the accreditation process and decision,
 - 2) in accordance with the directives of the accreditation body, the audit team members shall inform the accreditation body, prior to the assessment, about any existing, former or envisaged link between themselves or their organization and the body to be assessed.

2.2.4 Contracting of assessment personnel

The accreditation body shall require the personnel involved in the assessment to sign a contract or other document by which they commit themselves to comply with the rules defined by the accreditation body, including those relating to confidentiality and those relating to independence from commercial and other interests, and any prior and/or present link with

the bodies to be assessed. The accreditation body shall ensure that, and document how, any subcontracted assessment personnel satisfy all the requirements for personnel outlined in this Guide.

2.2.5 Assessment personnel records

2.2.5.1 The accreditation body shall possess and maintain up-to-date records on personnel conducting assessments, consisting of

- a) name and address;
- b) affiliation and position held in the organization;
- c) educational qualifications and professional status;
- d) experience and training in each field of competence of the accreditation body;
- e) date of most recent updating of record;
- f) performance appraisal.

2.2.5.2 The accreditation body shall ensure, and verify, that any subcontracted body maintains records, which satisfy the requirements of this Guide, of assessment personnel who are subcontracted to the accreditation body.

2.2.6 Procedures for assessment teams

Assessment teams shall be provided with up-to-date assessment instructions and all relevant information on accreditation arrangements and procedures.

2.3 Decision on accreditation

2.3.1 The decision whether or not to accredit a body shall be taken on the basis of the information gathered during the accreditation process and any other relevant information. Those who make the accreditation decision shall not have participated in the audit.

2.3.2 The accreditation body shall not delegate authority for granting, maintaining, extending, reducing, suspending or withdrawing accreditation to an outside person or body.

2.3.3 The accreditation body shall provide to each of its accredited bodies accreditation documents such as a letter or a certificate signed by an officer who has been assigned such responsibility. These accreditation documents shall identify, for the body and each of its sites covered by the accreditation,

- a) the name and address;
- b) the scope of the accreditation granted, including as appropriate
 - 1) the type of certification/registration scheme,

- 2) the standards and/or other normative documents and regulatory requirements against which products, services or systems are certified or registered,
 - 3) industry sectors,
 - 4) product categories;
- c) the effective date of accreditation and, as applicable, the term for which the accreditation is valid.

2.3.4 In response to an application for an amendment to the scope of an accreditation already granted, the accreditation body shall decide what, if any, assessment procedure is appropriate to determine whether or not the amendment should be granted and shall act accordingly.

2.4 References to accredited status

2.4.1 An accreditation body which is proprietor or licensee of a symbol or logo, intended for use under its accreditation programme, shall have a policy governing its use. It shall normally allow an accredited body to refer to its accreditation in certificates, reports, and stationery and publicity material relating to accredited activities.

2.4.2 The accreditation body shall not allow use of its mark or logo in any way which implies that the accreditation body itself approved a product, service or system certified or registered by an accredited body. Where a supplier is certified/registered only with respect to its quality system, the symbol or logo shall not be used on a product or in any other way that may be interpreted as denoting product conformance. Where the supplier's products are certified under product conformance arrangements, the symbol or logo may appear on the product if permitted by the rules of the accreditation body.

2.4.3 The accreditation body shall take suitable action to deal with incorrect references to the accreditation system, or misleading use of accreditation logos found in advertisements, catalogues, etc.

NOTE 5 Such action could include corrective action, withdrawal of certificate, publication of the transgression and, if necessary, other legal action.

2.5 Change in the accreditation requirements

The accreditation body shall give due notice of any changes it intends to make in its requirements for accreditation. It shall take account of views expressed by interested parties before deciding on the precise form and effective date of the changes. Following a decision on, and publication of, the changed requirements, it shall verify that each accredited body carries out any necessary adjustments to its procedures within such time as, in the opinion of the accreditation body, is reasonable.

2.6 Appeals, complaints and disputes

2.6.1 Appeals, complaints and disputes brought before the accreditation body by certification/registration bodies or other parties shall be subject to the procedures of the accreditation body.

2.6.2 The accreditation body shall

- a) keep a record of all appeals, complaints and disputes, and remedial actions relative to accreditation;
- b) take appropriate corrective and preventive action;
- c) document the actions taken and assess their effectiveness.

2.7 Access to records of appeals, complaints and disputes

The accreditation body shall require each applicant and accredited body to make available to it, when requested, the records of all complaints, appeals and disputes, and subsequent actions.

Section 3: Requirements for assessment

3.1 Application for accreditation

3.1.1 Information on the procedure

3.1.1.1 A detailed description of the assessment and accreditation procedure, the documents containing the requirements for accreditation, and documents describing the rights and duties of accredited bodies shall be maintained up to date as specified in 2.1.7.1 and shall be provided to applicants and accredited bodies.

3.1.1.2 The accreditation body shall require that a body

- a) always complies with the relevant provisions of this Guide;
- b) makes all necessary arrangements for the conduct of the assessment, including provision for examining documentation and the access to all areas, records (including internal audit reports) and personnel for the purposes of assessment, surveillance, reassessment and resolution of complaints;
- c) only claims that it is accredited with respect to those activities for which it has been granted accreditation;
- d) does not use its accreditation in such a manner as to bring the accreditation body into disrepute, and does not make any statement regarding its accreditation which the accreditation body may consider misleading or unauthorized;
- e) upon suspension or withdrawal of its accreditation (however determined), discontinues use of all advertising matter that contains any reference thereto and returns any accreditation documents as required by the accreditation body;
- f) does not allow the fact of its accreditation to be used to imply that a product, process, system or person is approved by the accreditation body;
- g) ensures that no accreditation document, mark or report, or any part thereof, is used in a misleading manner;
- h) in making reference to its accreditation status in communication media such as documents, brochures or advertising, complies with the requirements of the accreditation body.

3.1.1.3 When the desired scope of accreditation is related to a specific programme, any necessary explanation shall be provided to the applicant.

3.1.1.4 If requested, additional application information shall be provided to the body.

3.1.2 The application

3.1.2.1 The accreditation body shall require an official application form, duly completed and signed by a duly authorized representative of the applicant, in which or attached to which

- a) the scope of the desired accreditation is defined;
- b) the applicant agrees to comply with the requirements for accreditation and to supply any information needed for its evaluation.

3.1.2.2 At least the following information shall be provided by the applicant prior to the on-site assessment:

- a) the general features of the applicant body, such as corporate entity, name, addresses, legal status and, where relevant, human and technical resources;
- b) general information concerning the body covered by the application, such as its functions, and its relationship in a larger corporate entity, and its physical locations;
- c) a description of the systems or products it registers or certifies, and the standards or other normative documents applicable to each;
- d) a copy of its quality manual and, where required, the associated documentation.

The information gathered may be used for the preparation of on-site assessment and shall be treated with appropriate confidentiality.

3.2 Preparation for assessment

3.2.1 Before proceeding with the assessment, the accreditation body shall conduct, and maintain records of, a review of the request for accreditation to ensure that

- a) the requirements for accreditation are clearly defined and documented;
- b) any difference in understanding between the accreditation body and the applicant is resolved;
- c) the accreditation body has the capability to perform the accreditation service with respect to the scope of the accreditation sought, the location of the applicant's operations, and any special re-

quirements such as the language used by the applicant.

3.2.2 The accreditation body shall prepare a plan for its assessment activities to allow for the necessary arrangements to be made.

3.2.3 The accreditation body shall nominate a qualified audit team to evaluate all material collected from the applicant and to conduct the audit on its behalf. Experts in the areas to be assessed may be attached to the accreditation body's team as advisers.

3.2.4 The body shall be informed of the names of the members of the audit team who will carry out the assessment, with sufficient notice to appeal against the appointment of any particular auditors or experts.

3.2.5 The audit team shall be formally appointed and provided with the appropriate working documents. The plan for and the date of the audit shall be agreed with the body. The mandate given to the audit team shall be clearly defined and made known to the body, and shall require the audit team to examine the structure, policies and procedures of the body, and confirm that these meet all the requirements relevant to the scope of accreditation, and that the procedures are implemented and are such as to give confidence in the certifications or registrations of the body.

3.3 Assessment

3.3.1 The audit team shall assess all services of the body covered by the defined scope against all applicable accreditation requirements.

3.3.2 The accreditation body shall witness fully the on-site activities of one or more assessments or audits conducted by an applicant body before an initial accreditation is granted for any function requiring on-site activity by the applicant.

3.4 Assessment report

3.4.1 The accreditation body may adopt reporting procedures that suit its needs but, as a minimum, these procedures shall ensure that

- a) a meeting takes place between the audit team and the body's management prior to leaving the premises, at which the audit team provides a written or oral indication on the conformity of the applicant body with the particular accreditation requirements and provides an opportunity for the body to ask questions about the findings and their basis;
- b) the audit team provides the accreditation body with a report of its findings as to the body's conformity to all of the accreditation requirements;

- c) a report on the outcome of the assessment is promptly brought to the body's attention by the accreditation body, identifying any nonconformity to be discharged in order to comply with all of the accreditation requirements;
- d) the accreditation body shall invite the body to comment on the report and to describe the specific actions taken, or planned to be taken within a defined time, to remedy any nonconformity with the accreditation requirements identified during the assessment, and shall inform the body of the need for full or partial reassessment or whether a written declaration to be confirmed during surveillance will be considered adequate;
- e) the report shall contain as a minimum
 - 1) the date(s) of the audit(s),
 - 2) the name(s) of the person(s) responsible for the report,
 - 3) the names and addresses of all sites audited,
 - 4) the assessed scope of accreditation or reference thereto,
 - 5) comments on the conformity of the applicant body with the accreditation requirements and, where applicable, any useful comparisons with the results of previous assessment of the body,
 - 6) an explanation of any differences from the information presented to the body at the closing meeting.

3.4.2 If the final report authorized by the accreditation body differs from the report referred to in 3.4.1 c) and e), it shall be submitted to the body with an explanation of any differences from the previous report.

The report shall take into consideration

- a) the qualification, experience and authority of the staff encountered;
- b) the adequacy of the internal organization and procedures adopted by the body to give confidence in the quality of its services;
- c) the actions taken to correct identified nonconformities including, where applicable, those identified at previous assessments.

3.5 Surveillance and reassessment procedures

3.5.1 The accreditation body shall have an established documented programme, consistent with the accreditation granted, for carrying out periodic surveil-