

EAC – EAL General Requirements for Bodies Providing Accreditation of Inspection Bodies

PURPOSE

The purpose of this document is to lay down the general requirements for bodies providing accreditation of inspection bodies, until a European standard or an international guide covering this field has been established. This document is intended to facilitate the establishment of mutual recognition agreements between the bodies providing accreditation of inspection bodies.

EAC/EAL-G28 * ACCREDITATION OF INSPECTION BODIES

Authorship

This publication has been produced by a joint working group consisting of experts from the inspection field and from accreditation bodies representing the European Accreditation of Certification (EAC) and the European cooperation for Accreditation of Laboratories (EAL).

Official language

The text may be translated into other languages as required. The English language version remains the definitive version.

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Guidance Publications

This document represents a consensus of EAL and/or EAC member opinion and preferred practice on how the relevant clauses of the accreditation standards might be applied in the context of the subject matter of this document. The approaches taken are not mandatory and are for the guidance of accreditation bodies and their accredited organisations. Nevertheless, the document has been produced as a means of promoting a consistent approach to accreditation amongst EAL and EAC member bodies, particularly those participating in Multilateral Agreement.

Further information

For further information about this publication, contact your National member of EAL or EAC:

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1 Scope

- 1.1 This document sets out the general requirements for bodies providing accreditation of inspection bodies so that the accreditations granted and the services covered by the accreditations may be recognised at a national or an international level and the body operating the accreditation system may be recognised at national or international level as competent and reliable. Users of accreditation, other than the inspection body, may require compliance with requirements additional to those specified in this document.
- 1.2 The object of this document is to provide the basis for the setting up and operation of an accreditation body and to facilitate agreements, between such bodies, on mutual recognition of accreditation of inspection bodies.

Note: It is recognised that agreements on mutual recognition of accreditations aiming at the removal of barriers to across-border trade may have to cover other aspects not explicitly specified in these general requirements, such as exchange of any relevant information between inspection bodies, exchange of staff or training programmes. In particular, with a view to creating confidence and harmonising the interpretation and implementation of standards, each accreditation body should encourage technical cooperation and exchange of experience among inspection bodies accredited by it, and it should be prepared to exchange information on accreditation procedures and practices with other accreditation bodies.

- 1.3 This document is based on European Standard EN 45003, *Calibration and testing laboratory accreditation systems - General requirements for operation and recognition* (March 1995), and on ISO/IEC Guide 61:1996, *General requirements for assessment and accreditation of certification/registration bodies*. To facilitate a comparison between requirements on bodies that accredit inspection bodies, testing laboratories and certification bodies, an extensive cross-reference table between the clauses of this document and the corresponding clauses of the two above-mentioned documents was prepared. This working document is available on request.

2 Normative references

- 2.1 This document incorporates, by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this document only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

EN 45004 : 1995 *General criteria for the operation of various types of bodies performing inspection*

EN 45020 : 1993 *General terms and their definitions concerning standardization and related activities*

EN 30011-2 : 1993 *Guidelines for auditing quality systems - Part 2: Qualification criteria for quality systems auditors*

3 Definitions

- 3.1 The relevant definitions contained in EN 45020 are applicable. In addition, the following definitions apply for the purposes of this document:

Inspection

Examination of a product design, product, service, process or plant, and determination of their conformity with specific requirements or, on the basis of professional judgement, general requirements

Note 1. Inspection of processes includes personnel, facilities, technology and methodology.

Note 2. The results of inspection may be used to support certification.

Inspection body

Body that performs inspection

Note. A body can be an organisation or part of an organisation.

Accreditation

Procedure by which an authoritative body gives formal recognition that a body is competent to carry out specific tasks.

4 Accreditation body

4.1 General provisions

- 4.1.1 (a) The procedures under which the accreditation body operates shall be administered in a non-discriminatory manner.
- (b) Access to an accreditation system operated by an accreditation body shall not be conditional upon the size of the inspection body, the number of inspection bodies already accredited or membership of any association or group, nor shall there be undue financial conditions to restrict participation.
- 4.1.2 The competence of an applicant inspection body shall be assessed by the accreditation body against the requirements of EN 45004.
- 4.1.3 The requirements of EN 45004 may have to be interpreted for specific fields of inspection by the accreditation body. These interpretations shall be formulated by relevant and impartial committees [see 4.2.1 (m) and (n)] possessing the necessary technical competence. They shall be published by the accreditation body.

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

4.2 Organisation of the accreditation body

4.2.1 The accreditation body shall:

- (a) be impartial;
- (b) be responsible for its decisions relating to accreditation, including the granting, maintaining, extending, reducing, suspending and withdrawing of accreditation;
- (c) be a legally identifiable entity;
- (d) ensure that each decision on accreditation is taken by a person or by persons different from those who carried out the assessment;
- (e) have rights and responsibilities relevant to its accreditation activities;
- (f) have adequate arrangements to cover liabilities arising from its operations and/or activities;
- (g) have the financial stability and resources required for the operation of an accreditation system;
- (h) have and make available on request a description of the means by which it receives its financial support;
- (i) employ a sufficient number of personnel having the necessary education, training, technical knowledge and experience for handling the type, range and volume of work performed, under the responsibility of a senior executive;
- (j) have a quality system, including an organisational structure, that enables it to give confidence in its ability to satisfactorily operate a system of accreditation of inspection bodies;
- (k) have documented policies and procedures for the operation of the quality system that include:
 - (i) policies and decision-making procedures that distinguish between accreditation activities and any other activities in which the body is engaged;
 - (ii) policies and procedures for the resolution of complaints and appeals received from inspection bodies about the handling of accreditation matters, or from users of services about accredited inspection bodies or any other matters,

- (l) 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;
 - (m) have formal rules and structures for the appointment and operation of committees involved in the accreditation process; such committees shall be free from any commercial, financial and other pressures that might influence decisions or shall have a structure where members are chosen to provide impartiality through a balance of interests where no single interest predominates;
 - (n) establish one or more technical committees, each responsible, within its scope, for advising the accreditation body on the technical matters relating to the operation of its accreditation system;
 - (o) not offer consultancies or other services such as inspection which may compromise the objectivity of its accreditation process and decisions;
 - (p) have arrangements to preserve confidentiality at all times in accordance with 4.3.9 of this document.
- 4.2.2 The accreditation body shall have arrangements for controlling the ownership, use and display of the accreditation documents and/or controlling the manner in which an accredited inspection body may refer to its accredited status, in accordance with section 7 of this document.

4.3 Quality system

4.3.1 Policy for quality

The top management of the accreditation body 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 organisation.

4.3.2 Availability, implementation and responsibility

The accreditation body shall operate a quality system appropriate to the type, range and volume of work performed. This system shall be documented and the documentation shall be available for use by the accreditation body staff. The accreditation body shall ensure effective implementation of the documented quality system procedures and instructions. The accreditation body shall designate a person having direct access to its highest executive level, to take responsibility for the quality system and its improvement and the maintenance of the quality documentation.

4.3.3 Documentation of the quality system

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;
- (c) the names, qualifications, experience and terms of reference of the senior executive and other accreditation personnel, affecting the quality of the accreditation function;
- (d) a description of the organisational structure of the accreditation body, including an organisation 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) the operational and functional duties and services pertaining to quality, so that each person concerned will know the extent and the limits of their responsibility;
- (f) administrative procedures including document control;
- (g) policies and procedures to implement the accreditation process;
- (h) arrangements for feedback and corrective actions whenever discrepancies are detected;
- (i) the policy and procedures for dealing with appeals, complaints and disputes;
- (j) the policy and procedures for conducting internal audits;
- (k) the policy and procedures for conducting management reviews of the quality system;
- (l) the policy and procedures for the recruitment and training of assessors and accreditation body personnel and monitoring their performance;

4.3.4 Internal audits

The person designated as having the responsibility for the quality system has to ensure that internal audits are conducted covering all procedures in a planned and systematic manner, to verify that the quality system is being implemented and is effective. This person shall ensure that:

- (a) personnel responsible for the area audited are informed of the outcome of the audit;

- (b) corrective and, when necessary, preventive action is taken in a timely and appropriate manner;
- (c) the results of the audit are documented.

4.3.5 Management reviews

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

4.3.6 Document control

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 authorised 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, applicants and accredited bodies.

4.3.7 Maintenance of records

The accreditation body shall maintain records to demonstrate that accreditation procedures have been effectively fulfilled, particularly with respect to application forms, assessment reports, and reports relating to granting, maintaining, extending, suspending or withdrawing accreditation. These accreditation documents shall form part of the record.

4.3.8 Retention and access to records

The accreditation body shall have a policy and procedures for retaining records for a period consistent with its contractual and legal obligations. The accreditation body shall have a policy and procedures concerning access to these records consistent with 4.2.1 (p) of this document.

4.3.9 Confidentiality

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 organisation, including committees and external bodies or individuals acting on its behalf. Except as required in this document, information about a particular inspection 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 inspection body shall be informed of the information provided.

4.3.10 Appeals, complaints and disputes

The accreditation body shall have documented procedures for dealing with appeals, complaints and disputes brought before the accreditation body by inspection bodies or other parties. In particular, the accreditation body shall:

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

4.4 Granting, maintaining, extending, suspending and withdrawing accreditation

4.4.1 The accreditation body shall specify the conditions for granting, maintaining and extending accreditation and the conditions under which accreditation may be suspended or withdrawn, partially or in total for all or part of the inspection body's scope of accreditation.

4.4.2 The accreditation body shall have arrangements to grant, maintain, suspend or withdraw accreditation, increase or reduce the scope of accreditation or require re-assessment in the event of changes affecting the activity and operation of the inspection body, such as changes in personnel or equipment, or if analysis of a complaint or any other information indicates that the inspection body no longer complies with the requirements of the accreditation body.

The accreditation body shall have arrangements relating to the transfer of accreditation when significant changes in the status of the accredited inspection body occur.

4.5 Documentation

4.5.1 The accreditation body shall provide (through publications, electronic media or other means), update at adequate intervals, and make available on request:

- (a) information about the authority under which the accreditation body operates;
- (b) a document containing its requirements for accreditation;
- (c) a document stating the arrangements for granting, maintaining, extending, suspending and withdrawing accreditation;
- (d) information about the assessment and accreditation process;
- (e) general information on the fees charged to applicant and accredited inspection bodies;

- (f) a description of the rights and duties of accredited inspection bodies as specified in 8.1, 8.2 and 8.3 of this document, including requirements, restrictions or limitations on the use of the accrediting body's logo and on the ways of referring to the accreditation granted;
 - (g) information on procedures for handling complaints, appeals and disputes.
- 4.5.2 The accreditation body shall publish periodically a directory of accredited inspection bodies describing the accreditations granted.

5 Personnel involved in the accreditation process

5.1 General

- 5.1.1 The personnel involved in the accreditation process shall be competent for the functions they perform.
- 5.1.2 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.

5.2 Requirements for assessors

- 5.2.1 The assessor(s) appointed to assess an inspection body 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 fields and types of inspection for which accreditation is sought and, where relevant, with the associated sampling procedures;
 - (d) be able to communicate effectively, both in writing and orally;
 - (e) be free of any commercial, financial or other pressures or conflicts of interest that might cause assessor(s) to act in other than an impartial or non-discriminatory manner;
 - (f) not have offered consultancies to inspection bodies which might compromise their impartiality in the accreditation process and decisions.

Note.

According to the above, the overall function of an *assessor* is to assess the competence of an inspection body. This is in accordance with the designation used for a person who assesses laboratories, see EN 45003 where such a person in general terms is called an *assessor*.

Assessment of quality systems, as defined in sub-clause 2.2.2.2 of ISO/IEC Guide 61 and sub-clause 3.3 of EN 30011-1, is performed by *auditors*. An auditor who is designated to manage a quality audit (lead a team of auditors) is called a *lead auditor* (see Note 9 to sub-clause 3.3 and sub-clause 4.2.1.3 of EN 30011-1).

In laboratory accreditation it is customary to discriminate between (*technical*) *assessors* and *lead assessors*. The latter are well-experienced assessors who perform the same type of tasks as lead auditors. They usually have technical competence in specified fields.

In this document the terms (*technical*) *assessor* and *lead assessor* are used in the same sense as for laboratory accreditation.

5.3 Qualification procedures for assessors

5.3.1 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.

Note Guidance on personal attributes of assessors may be obtained from EN 30011-2 clause 7.

5.3.2 The accreditation body shall have procedures for:

- (a) qualifying assessors, comprising an assessment of their training, and attendance at one or more actual assessments with a qualified assessor;
- (b) qualifying assessors as lead assessors to assess quality systems, to lead assessment teams and to carry out specified technical assessments within their competency (cf. 6.2.4);
- (c) monitoring the performance of assessors.

5.4 Contracting of assessors

5.4.1 The accreditation body shall require the external assessors 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 association with inspection bodies to be assessed.

5.5 Assessor records

5.5.1 The accreditation body shall possess and maintain up-to-date records on assessors consisting of:

- (a) name and address;
- (b) organisation affiliation and position held;
- (c) educational qualification and professional status;

- (d) work experience;
- (e) training in inspection, quality assurance and assessment;
- (f) experience in inspection body assessment, together with field of competence;
- (g) results of regular performance monitoring;
- (h) date of most recent updating of record.

5.6 Procedures for assessors

- 5.6.1 Assessor(s) shall be provided with an up-to-date set of procedures giving assessment instructions and all relevant information on accreditation arrangements.

6 Accreditation process

6.1 Application for accreditation

- 6.1.1 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 inspection bodies (including fees to be paid by applicant and accredited bodies) shall be maintained up-to-date and given to applicant inspection bodies.
- 6.1.2 Additional relevant information shall be provided to applicant inspection bodies on request.
- 6.1.3 A duly authorised representative of the applicant inspection body shall be required to sign an official application form, in which or attached to which:
 - (a) the scope of the desired accreditation is clearly defined;
 - (b) the applicant's representative agrees to fulfil the accreditation procedure, especially to receive the assessor(s), to pay the fees charged to the applicant inspection body whatever the result of the assessment may be, and to accept the charges of subsequent maintenance of the accreditation of the inspection body;
 - (c) the applicant agrees to comply with the requirements for accreditation and to supply any information needed for the evaluation of the inspection body.
- 6.1.4 The following minimum information shall be provided by the applicant inspection body prior to the on-site assessment:
 - (a) the general features of the applicant inspection body (corporate entity, name, address, legal status, human and technical resources);

- (b) general information concerning the inspection body covered by the application, such as type of body as defined in EN 45004, primary function, relationship in a larger corporate entity and, if applicable, physical location of sites involved;
- (c) the field, type and range of inspection performed and reference to the methods and procedures used, such as EC directives or regulations, standard specifications or internal procedures;
- (d) a copy of the inspection body's quality manual and, where required, the associated documentation.

6.1.5 The information provided as under 6.1.4 shall be treated with appropriate confidentiality.

6.2 *Assessment process*

- 6.2.1 The accreditation body shall select assessor(s) meeting the requirements of section 5 to evaluate all material collected from the applicant and to conduct the assessment on its behalf. The assessment shall take place at the premises of the inspection body and on a representative sample of sites and shall include the assessment of performance of the types and ranges of inspections for which accreditation is sought. The assessment shall be carried out in accordance with a programme that has been agreed with the applicant inspection body in advance.
- 6.2.2 To ensure that a comprehensive and correct assessment is carried out, each assessor shall be provided with the appropriate working documents.
- 6.2.3 The applicant inspection body shall be informed of the name(s) of the qualified assessor(s) selected to carry out the assessment, with sufficient notice so that the inspection body is given an opportunity to object, with reasons, against the appointment of any particular assessor. The accreditation body shall give its reasons for not accepting an objection.
- 6.2.4 A lead assessor and any assessor(s) needed shall be formally appointed before the assessment process commences. The lead assessor shall, whenever possible, have the necessary technical competence for the field of inspection to be assessed. If the lead assessor does not have such competence, he has to be accompanied by an appropriate number of technical assessors. The mandate given to the assessor(s) shall be clearly defined and made known to the applicant inspection body.
- 6.2.5 The assessor(s) shall conduct an assessment of the competence of the applicant inspection body covered by the proposed scope against all the applicable accreditation requirements.

6.3 *Sub-contracting of assessment*

- 6.3.1 The accreditation body shall normally undertake the assessments on which accreditation is based. If an accreditation body decides to sub-contract the

assessment of an inspection body to another body, a properly documented agreement covering the arrangements, including confidentiality and conflict of interest, shall be drawn up. The accreditation body shall:

- (a) take full responsibility for the sub-contracted assessments, whether these be for granting, maintaining, extending, reducing, suspending or withdrawing accreditation;
- (b) ensure that any body to which assessment has been delegated is competent and complies with the applicable provisions of this document;
- (c) list all its sub-contractors used for assessment and maintain details of the procedures for assessing, recording, and monitoring their competence;
- (d) obtain the applicant's or accredited body's consent.

6.4 Assessment report

6.4.1 Accreditation bodies may adopt different reporting procedures but as a minimum these procedures shall ensure that:

- (a) a meeting takes place between the assessor(s) and the inspection body's management prior to leaving the inspection body, at which a written or oral report on the compliance of the applicant with the accreditation requirements is provided to the inspection body;
- (b) the assessor(s) provide(s) the accreditation body with a detailed assessment report containing all relevant information concerning the ability of the applicant inspection body to comply with all of the accreditation requirements;
- (c) a report on the outcome of the assessment is promptly brought to the applicant inspection body's notice by the accreditation body, identifying any non-compliances that have to be discharged in order to comply with all of the accreditation requirements. The inspection body shall be invited to present its comments on this report and to describe the specific actions taken, or planned to be taken within a defined time, to remedy any non-compliances with the accreditation requirements identified during the assessment.

6.4.2 The report authorised by the accreditation body and submitted to the inspection body shall include as a minimum:

- (a) date(s) of assessment(s);
- (b) the name(s) of the person(s) responsible for the report;
- (c) the names and addresses of all the sites assessed;
- (d) the assessed scope of accreditation or reference thereto;
- (e) comments of the assessor(s) on the compliance of the applicant inspection body with the accreditation requirements.

6.4.3 The report should take account of:

- (a) the technical qualification, experience and authority of the staff encountered, especially the person(s) responsible for the technical content of inspection reports and certificates;
- (b) the adequacy of the internal organisation and procedures adopted by the applicant body to give confidence in the quality of its services, having regard to the volume of work undertaken;
- (c) any other information that may assist in determining the technical competence of the applicant;
- d) when applicable, the actions taken to correct any non-compliances identified at a previous assessment.

6.5 Decision on accreditation

6.5.1 The decision whether or not to accredit an inspection body shall be taken by the accreditation body on the basis of the information gathered during the accreditation process according to section 6.

6.5.2 The accreditation body shall not delegate its responsibility for granting, maintaining, extending, suspending or withdrawing accreditation.

6.5.3 In response to an application for amendment to a 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.

6.6 Granting accreditation

6.6.1 The accreditation body shall transmit to each accredited inspection body formal accreditation documents such as a letter or a certificate signed by an officer who has been assigned such responsibility. These formal accreditation documents shall permit identification of:

- (a) the name and address of the inspection body that has been accredited;
- (b) the scope of the accreditation, including:
 - (i) the type of inspection body as defined in EN 45004;
 - (ii) the field of inspection for which accreditation has been granted;
 - (iii) the type and range of inspection;
 - (iv) the methods and procedures used;
- (c) the effective date of accreditation, and the term of the accreditation if applicable;
- (d) the accredited inspection body by a unique number.

6.7 Surveillance and re-assessment of accredited inspection bodies

- 6.7.1 The accreditation body shall have an established documented programme consistent with the accreditation granted for carrying out periodic surveillance and re-assessment at sufficiently close intervals to ensure that its accredited inspection bodies continue to comply with the accreditation requirements.

Note: In most cases it is unlikely that a period greater than one year would satisfy the surveillance requirements of this clause and a period greater than five years the re-assessment requirements of this clause.

- 6.7.2 Surveillance and re-assessment procedures shall be consistent with those concerning the assessment of inspection bodies as described in this document.
- 6.7.3 Surveillance visits may be less comprehensive in scope than re-assessments but should be planned so that the accreditation body can maintain confidence in the technical competence of the inspection body and its compliance with the accreditation requirements. The programme shall be designed so that all fields and types of inspection are surveyed at least once between re-assessments.

7 References to accredited status

- 7.1 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.
- 7.2 The accreditation body shall take suitable action to deal with incorrect references to the accredited status of the inspection body or misleading use of accreditation logos by the inspection body in advertisements, catalogues, etc.
- 7.3 The accreditation body shall have a policy that defines the circumstances in which accredited inspection bodies are permitted to include, in inspection reports and inspection certificates, the results of inspections for which accreditation is not held and the results of sub-contracted inspections.

8 Relationship between accreditation body and inspection body

- 8.1 The accreditation body shall have arrangements to ensure that the inspection body and its representatives afford such accommodation and cooperation as is necessary to enable the accreditation body to verify compliance with the

requirements for accreditation. These arrangements shall include provision for examination of documentation and access to the locations where inspection is undertaken, records and personnel for the purposes of assessment, surveillance, re-assessment and resolution of complaints.

- 8.2 The accreditation body shall require that an accredited inspection body:
- (a) at all times complies with the relevant provisions of this document;
 - (b) claims that it is accredited only in respect of activities for which it has been granted accreditation;
 - (c) pays such fees as shall be determined by the accreditation body;
 - (d) does not use its accreditation in such a manner as to bring the accreditation body into disrepute and does not make any statement relevant to its accreditation which the accreditation body may consider misleading or unauthorised;
 - (e) upon suspension or withdrawal of its accreditation (however determined) forthwith discontinues its use of all advertising matter that contains any reference thereto and returns any certificates of accreditation to the accreditation body;
 - (f) does not use its accreditation to imply product approval by the accreditation body;
 - (g) endeavours to ensure that no report or certificate nor any part thereof is used in a misleading manner;
 - (h) in making reference to its accreditation status in communication media such as advertising, brochures or other documents, complies with the requirements of the accreditation body.
- 8.3 The accreditation body shall give due notice of significant changes it intends to make in its requirements for accreditation (see 9.2).

9 Notification of change

- 9.1 The accreditation body shall have arrangements to ensure that an accredited inspection body informs it without delay of changes in any aspect of the inspection body's status or operation that may affect the inspection body's accredited status, e.g. its:
- (a) legal, commercial or organisational status;
 - (b) organisation and management, e.g. key managerial staff;
 - (c) policies or procedures, where appropriate;
 - (d) premises;

- (e) personnel, equipment, facilities, working environment or other resources, where significant

or other such matters that may affect the inspection body's capability, or scope of accredited activities, or compliance with the requirements in this document or any other relevant criteria of competence specified by the accreditation body.

- 9.2 Upon receipt of due notice of any intended changes relating to the requirements of this document, the relevant criteria of competence and any other requirements prescribed by the accreditation body, the accreditation body shall ensure that the inspection body carries out the necessary adjustments to its procedures within an agreed time-scale. The inspection body shall notify the accreditation body when such adjustments have been made.

Appendix A

Cross-reference list between the clauses of document EAL-G28, EN 45003 (March 1995) and ISO/IEC Guide 61:1996

- A1 The EAC-EAL general requirements for bodies providing accreditation of inspection bodies are mainly based on the corresponding requirements for bodies providing accreditation of laboratories as given in EN 45003 (March 1995) and bodies providing accreditation of certification bodies as given in ISO/IEC Guide 61:1996. Whenever possible, in the EAC-EAL document the same wording has been used as in one (or both) of the source documents. The introduced changes reflect factual differences in the accreditation process of the concerned bodies and the ambition to amend statements that were found to be ambiguous.
- A2 This cross-reference table was prepared to facilitate a comparison between requirements on bodies that accredit inspection bodies, testing laboratories and certification bodies. It contains reference to the clauses of the EAC-EAL document and the corresponding clauses of EN 45003 and ISO/IEC Guide 61. Some of the requirements of EN 45003 and ISO/IEC Guide 61 are irrelevant for accreditation of inspection bodies. However, for completeness they are inserted at appropriate places of the table, using smaller script than for the requirements of the EAC-EAL document.
- A3 In many cases the wording of the clauses of EN 45003 and ISO/IEC Guide 61 is identical. In other cases there are more or less subtle differences and the two documents are not identical in scope. For that reason it is impossible to give an exact characterisation of the actual requirements by short descriptors of the type used in the table. It was found impracticable to indicate cases where the wordings are identical, let alone to classify the degree of conformity. The reader is invited to consult the source documents for the exact contents of each particular requirement.
- A4 Section headings are given in bold script in the table. In these entries a dash indicates that an equivalent *heading* does not exist in the considered document. However, corresponding *requirements* may well exist. They are shown by entries under the heading in question.
- A5 Where one numbered (sub)clause contains more than one paragraph, the symbol ¶ followed by a number is used as paragraph number.

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General provisions	4	4	2.1
<i>Accreditation body</i>	4.1	4.1	2.1.1
procedures administered in a non-discriminatory manner	4.1.1 ¶ 1	4.1.1 ¶ 1	2.1.1.1
procedures non-discriminatory	–	–	2.1.1.1
procedures not to be used to impede or inhibit access	–	–	2.1.1.1
unconditional access to system	4.1.1 ¶ 2	4.1.1 ¶ 2	2.1.1.2
services accessible to all applicants	–	–	2.1.1.2
assessment criteria	4.1.2	4.1.2	2.1.1.3
interpretation of requirements	4.1.3	4.1.3	2.1.1.3
request for accredited bodies to maintain impartiality and integrity	–	4.1.4	–
confinement of requirements	4.1.4	4.1.5	2.1.1.4
<i>Organisation of the accreditation body</i>	4.2	4.2	2.1.2
structure to give confidence	–	–	2.1.2 ¶ 1
impartiality	4.2.1 (a)	–	2.1.2 ¶ 2 a) 2.1.2 ¶ 2 e)
responsibility for decisions	4.2.1 (b)	–	2.1.2 ¶ 2 b)
identification of responsible management	–	–	2.1.2 ¶ 2 c)
legal identification	4.2.1 (c)	4.2.1 a)	2.1.2 ¶ 2 d)
structure safeguarding impartiality	–	–	2.1.2 ¶ 2 e)
separate decision-making function	4.2.1 (d)	–	2.1.2 ¶ 2 f) 2.3.1
relevant rights and responsibilities	4.2.1 (e)	4.2.1 b)	2.1.2 ¶ 2 g)
adequate liability arrangements	4.2.1 (f)	4.2.1 c)	2.1.2 ¶ 2 h)
financial stability and resources	4.2.1 (g)	4.2.1 d)	2.1.2 ¶ 2 i)
description of financial support	4.2.1 (h)	4.2.1 e)	2.1.7.1 d)

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sufficient number of appropriately qualified personnel	4.2.1 (i)	4.2.1 f)	2.1.2 ¶ 2 j)
quality system, including organisational structure, to give confidence	4.2.1 (j)	4.2.1 g)	2.1.2 ¶ 2 k)
policies and procedures for the operation of the quality system:	4.2.1 (k)	4.2.1 h)	2.1.2 ¶ 2 l)
– distinguish between accreditation and other activities	4.2.1 (k)(i)	4.2.1 h) -1	2.1.2 ¶ 2 l)
– resolution of complaints and appeals	4.2.1 (k)(ii)	4.2.1 h) -2	2.1.2 ¶ 2 p)
freedom from undue pressure	4.2.1 (l)	4.2.1 i)	2.1.2 ¶ 2 m)
rules and structure for committees	4.2.1 (m)	4.2.1 j)	2.1.2 ¶ 2 n)
advisory technical committees	4.2.1 (n)	4.2.1 k)	-
repudiation of consultancy	4.2.1 (o)	4.2.1 l)	2.1.2 ¶ 2 o) 2)
integrity with respect to related bodies	–	–	2.1.2 ¶ 2 o)
preservation of confidentiality	4.2.1 (p)	4.2.1 m)	2.1.2 o)
arrangements for controlling the use of accreditation documents	4.2.2	4.2.2	-
<i>Quality system</i>	4.3	4.3	2.1.4
policy for quality	4.3.1	–	2.1.4.1
availability, implementation and responsibility	4.3.2	4.3.1	2.1.4.2
responsibility to establish, implement and maintain the quality system and to report	–	–	2.1.4.2 a) 2.1.4.2 b)
documentation of the quality system:	4.3.3	4.3.2	2.1.4.3
– quality policy statement	4.3.3 (a)	4.3.2 a)	2.1.4.3 a)
– legal status	4.3.3 (b)	–	2.1.4.3 b)
– data on accreditation personnel	4.3.3 (c)	–	2.1.4.3 c)
– organisational structure	4.3.3 (d)	4.3.2 b)	2.1.4.3 d)
– organisation	–	–	2.1.4.3 e)

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– duties and services	4.3.3 (e)	4.3.2 c)	2.1.4.3 h)
– administrative procedures	4.3.3 (f)	4.3.2 d)	2.1.4.3 g)
– accreditation process	4.3.3 (g)	4.3.2 e)	2.1.4.3 l)
– feedback and corrective action	4.3.3 (h)	4.3.2 f)	2.1.4.3 k)
– appeals, complaints, disputes	4.3.3 (i)	4.3.2 g)	2.1.4.3 m)
– internal audits:	4.3.3 (j)	4.3.2 h)	2.1.4.3 n)
– management reviews	4.3.3 (k)	4.3.2 i)	2.1.4.3 f)
– recruitment and training	4.3.3 (l)	4.3.2 j)	2.1.4.3 i)
internal audits:	4.3.4	4.3.3	2.1.6.1
– information on outcome	4.3.4 (a)	-	2.1.6.1 a)
– corrective and preventive action	4.3.4 (b)	-	2.1.6.1 b)
– results documented	4.3.4 (c)	-	2.1.6.1 c)
management reviews	4.3.5	4.3.3	2.1.6.2
document control	4.3.6	-	2.1.7.2
record system to suit the circumstances	-	-	2.1.8.1
maintenance of records	4.3.7	4.3.4	2.1.8.1
identification, management and disposal to ensure integrity and confidentiality	-	-	2.1.8.1
retention and access to records	4.3.8	4.3.5	2.1.8.2
retention period has to ensure confidence	-	-	2.1.8.1
confidentiality:	4.3.9	4.2.1 m)	2.1.9
safeguards	4.3.9	4.2.1 m)	2.1.9.1
non-disclosure	4.3.9	-	2.1.9.2
procedures for appeals, complaints and			

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disputes:	4.3.10	–	2.6.1
– records	4.3.10 (a)	–	2.6.2 a)
– corrective and preventive action	4.3.10 (b)	–	2.6.2 b)
– actions taken documented and their effectiveness assessed	4.3.10 c)	–	2.6.2 c)
<i>Granting, maintaining, extending, suspending and withdrawing accreditation</i>	4.4	4.4	2.1.5
specification of conditions	4.4.1	4.4.1	2.1.5.1
arrangements for accreditation	4.4.2	4.4.2	2.1.5.2
arrangements for transfer of accreditation	4.4.3	4.4.3	-
<i>Documentation</i>	4.5	4.5	2.1.7
documents available on:	4.5.1	4.5	2.1.7.1
– authority of accreditation body	4.5.1 (a)	4.5 a)	2.1.7.1 a)
– specification on voluntary or mandatory nature of system	–	4.5. a)	-
– requirements for accreditation	4.5.1 (b)	4.5 b)	2.1.7.1 b)
– arrangements for accreditation	4.5.1 (c)	4.5 c)	2.1.7.1 b)
– assessment and accreditation process	4.5.1 (d)	4.5 d)	2.1.7.1 c)
– fees	4.5.1 (e)	4.5 e)	2.1.7.1 d)
– rights and duties of accredited bodies	4.5.1 (f)	4.5 f)	2.1.7.1 e)
– procedures for handling complaints, appeals and disputes	4.5.1 g)	–	2.1.7.1 f)
directory of accredited bodies	4.5.2	7.4	2.1.7.1 g)
Personnel involved in the accreditation process	5	5	2.2
<i>General</i>	5.1	–	2.2.1
competency of personnel	5.1.1	–	2.2.1.1

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information on qualifications, training and experience	5.1.2	–	2.2.1.2
up-to-date instructions available describing duties and responsibilities	–	–	2.2.1.3
<i>Requirements for assessors</i>	<i>5.2</i>	<i>5.1</i>	<i>2.2.3.2</i>
teams with appropriate skills	–	–	2.2.3.2
familiarity with regulations, procedures and requirements	5.2.1 (a)	5.1 a)	2.2.3.2 a)
knowledge of assessment method	5.2.1 (b)	5.1 b)	2.2.3.2 b)
technical knowledge of the field	5.2.1 (c)	5.1 c)	2.2.3.2 c)
sufficient understanding to assess the competence	–	–	2.2.3.2 d)
ability to communicate effectively	5.2.1 (d)	5.1 d)	2.2.3.2 e)
freedom from pressures and conflicts of interest	5.2.1 (e)	5.1 e)	2.2.3.2 f)
non-participation in consulting activities compromising impartiality	5.2.1 (f)	5.1 f)	2.2.3.2 f)
<i>Qualification procedures for assessors</i>	<i>5.3</i>	<i>5.2</i>	<i>2.2.2</i>
definition of criteria for competence	5.3.1	–	2.2.2.1
assessors to meet international requirements –	–	–	2.2.2.2
technical experts need not meet the requirements for assessors	–	–	2.2.2.3
adequate procedure for:	5.3.2	5.2	2.2.3.1
– selecting assessors	–	–	2.2.3.1 a)
– qualifying assessors	5.3.2 (a)	5.2 a)	-
– qualifying lead assessors	5.3.2 (b)	–	-
– monitoring the performance	5.3.2 (c)	5.2 b)	2.2.3.1 b)
<i>Contracting of assessors</i>	<i>5.4</i>	<i>5.3</i>	<i>2.2.4</i>
contract with the assessors	5.4.1	5.3	2.2.4

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sub-contracted assessors to fulfil all requirements	–	–	2.2.4
<i>Assessor records</i>	5.5	5.4	2.2.5
data on assessors on records:	5.5.1	5.4	2.2.5.1
– name and address	5.5.1 (a)	5.4 a)	2.2.5.1 a)
– affiliation and position	5.5.1 (b)	5.4 b)	2.2.5.1 b)
– qualification and status	5.5.1 (c)	5.4 c)	2.2.5.1 c)
– work experience	5.5.1 (d)	5.4 d)	-
– training in the field to be assessed	5.5.1 (e)	5.4 e)	2.5.5.1 d)
– training in quality assurance and assessment	5.5.1 (e)	5.4 e)	-
– experience in assessment in a particular field	5.5.1 (f)	5.4 f)	-
– results of performance monitoring	5.5.1 (g)	–	2.5.5.1 f)
– date of latest updating	5.5.1 (h)	5.4 g)	2.2.5.1 e)
<i>Procedures for assessors</i>	5.6	5.5	2.2.6
provision of up-to-date procedures	5.6.1	5.5	2.2.6
Accreditation process	6	6	3
Application for accreditation	6.1	6.1	3.1
maintenance of description of assessment and accreditation procedure	6.1.1	6.1.1	3.1.1.1
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signed application form containing:	6.1.3	6.1.3	3.1.2.1
– the scope	6.1.3 (a)	6.1.3 a)	3.1.2.1 a)
– agreement to fulfil the procedure	6.1.3 (b)	6.1.3 b)	-
– agreement to comply with requirements	6.1.3 (c)	6.1.3 c)	3.1.2.1 b)

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– general features of the body	6.1.4 (a)	6.1.4 ¶ 1 a)	3.1.2.2 ¶ 1a)
– general information concerning the body	6.1.4 (b)	6.1.4 ¶ 1 b)	3.1.2.2 ¶ 1 b)
– field, type and range of work	6.1.4 (c)	6.1.4 ¶ 1 c)	3.1.2.2 ¶ 1 c)
– quality manual	6.1.4 (d)	6.1.4 ¶ 1 d)	3.1.2.2 ¶ 1 d)
information to be treated confidentially	6.1.5	6.1.4 ¶ 2	3.1.2.2 ¶ 2
<i>Assessment process</i>	<i>6.2</i>	<i>6.2</i>	<i>3.2, 3.3</i>
review before assessment	–	–	3.2.1
plan for assessment activities	6.2.1	–	3.2.2
selection of assessors, their task	6.2.1	6.2.1	3.2.3
assessment of the performance at a representative sample of sites to witness inspections	6.2.1	–	3.3.2
provision of working documents	6.2.2	6.2.2	3.2.5
agreement on date	6.2.1	6.2.3	3.2.5
possibility to object against an assessor	6.2.3	6.2.3	3.2.4
appointment of assessors, definition of their mandate	6.2.4	6.2.4	3.2.5
assessment conducted against applicable accreditation requirements	6.2.5	–	3.3.1
<i>Sub-contracting of assessment</i>	<i>6.3</i>	<i>6.3</i>	<i>2.1.3</i>
sub-contracting not a normal procedure	6.3.1	–	-
for sub-contracting a documented agreement needed	6.3.1	–	2.1.3
accreditation body responsible	6.3.1 a)	6.3.1	2.1.3 a)
sub-contractor competent	6.3.1 b)	6.3.2	2.1.3 b)
impartiality not compromised	–	–	2.1.3 b)

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list of sub-contractors, procedures for assuring their competence	6.3.1 (c)	–	2.1.4.3 j), 2.2.5.2
accredited body's consent	6.3.1 (d)	–	2.1.3 c)
<i>Assessment report</i>	<i>6.4</i>	<i>6.4</i>	<i>3.4</i>
reporting procedures shall ensure that:	6.4.1	6.4.1	3.4.1
during visit applicant informed on compliance with requirements	6.4.1 (a)	6.4.1 a)	3.4.1 a)
accreditation body provided with detailed assessment report	6.4.1 (b)	6.4.1 b)	3.4.1 b)
applicant given a report on the outcome of assessment	6.4.1 (c)	6.4.1 c)	3.4.1 c)
applicant invited to present comments on the assessment report	6.4.1 (c)	6.4.1 c)	3.4.1 d)
minimum contents of the report issued by the accreditation body	6.4.2	6.4.2	3.4.1 e)
– date(s) of assessment	6.4.2 (a)	6.4.2 a)	3.4.1 e) 1)
– name of responsible person	6.4.2 (b)	6.4.2 b)	3.4.1 e) 2)
– identification of assessed sites	6.4.2 (c)	6.4.2 c)	3.4.1 e) 3)
– assessed scope	6.4.2 (d)	6.4.2 d)	3.4.1 e) 4)
– comments on compliance	6.4.2 (e)	6.4.2 e)	3.4.1 e) 5)
– differences from information presented at visit	–	–	3.4.1 e) 6), 3.4.2 ¶ 1
the report should take account of:	6.4.3	6.4.3	3.4.2 ¶ 2
– qualification, experience and authority of staff	6.4.3 (a)	6.4.3 a)	3.4.2 ¶ 2 a)
– adequacy of organisation and procedures	6.4.3 (b)	6.4.3 b)	3.4.2 ¶ 2 b)
– programmes for comparison of results	6.4.3 (c)	6.4.3 c)	-
– actions taken to correct non-compliances	6.4.3 (d)	6.4.3 d)	3.4.2 ¶ 2 c)

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<i>Decision on accreditation</i>	6.5	6.5	2.3
based on information gathered	6.5.1	6.5.1	2.3.1
responsibility not delegated	6.5.2	6.5.2	2.3.2
procedure for amendment of scope	6.5.3	–	2.3.4
<i>Granting accreditation</i>	6.6	6.6	-
transmission of accreditation documents, with identification of:	6.6.1	6.6.1	2.3.3
– name and address	6.6.1 (a)	6.6.1 a)	2.3.3 a)
– scope, including:	6.6.1 (b)	6.6.1 b)	2.3.3 b)
type of body	6.6.1 (b) (i)	–	2.3.3 b) 1)
field of activity	6.6.1 (b) (ii)	6.6.1 b) 1)	2.3.3 b) 2)
type and range of activity	6.6.1 (b) (iii)	6.6.1 b) 2) 6.6.1 b) 3)	2.3.3 b) 3)
used methods and procedures	6.6.1 (b) (iv)	6.6.1 b) 4)	2.3.3 b) 4)
– persons responsible for reports	–	6.6.1 c)	-
– date and term of accreditation	6.6.1 (c)	6.6.1 d)	2.3.3 c)
– unique number of accreditation	6.6.1 (d)	6.6.1 e)	-
<i>Surveillance and re-assessment of accredited bodies</i>	6.7	6.7	3.5
programme for periodic surveillance and re-assessment	6.7.1	6.7.1	3.5.1
procedures consistent with those for assessment	6.7.2	6.7.2	3.5.2
scope of surveillance visits	6.7.3	–	-
participation in proficiency testing	–	6.8	-
References to accredited status	7	–	2.4
policy governing the use of logos	7.1	–	2.4.1, 2.4.2
reference to accredited status	7.1	6.9.1	2.4.1

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action to deal with incorrect reference or misleading use of logos	7.2	–	2.4.3
policy for inclusion of non-accredited results in reports	7.3	6.9.2	–
Relationship between accreditation body and accredited body	8	7	–
affording accommodation and cooperation	8.1	7.1	–
access to documentation, locations, records and personnel	8.1	7.1	3.1.1.2 b)
accredited body shall:	8.2	7.2	3.1.1.2
– comply with present provisions	8.2 (a)	7.2 a)	3.1.1.2 a)
– claim to be accredited only for actually accredited activities	8.2 (b)	7.2 b)	3.1.1.2 c)
– pay fees as determined	8.2 (c)	7.2 c)	–
– not discredit the accreditation body or act misleadingly	8.2 (d)	7.2 d)	3.1.1.2 d), 2.4.3
– upon termination of accreditation stop referring to it	8.2 (e)	7.2 e)	3.1.1.2 e)
– not use accreditation to imply product approval	8.2 (f)	7.2 f)	3.1.1.2 f), 2.4.2
– ensure that reports are not used in a misleading manner	8.2 (g)	7.2 g)	3.1.1.2 g)
– comply with the requirements when referring to its status	8.2 (h)	7.2 h)	3.1.1.2 h), 2.4.3
due notice of changes to accreditation requirements	8.3	–	2.5
account of external views before making changes to accreditation requirements	–	–	2.5
Notification of change	9	7.3	–
arrangements to be informed on changes affecting accredited body's:	9.1	7.3.1	3.5.3

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– status	9.1 (a)	7.3.1 a)	3.5.3 ¶ 1 a)
– organisation and management	9.1 (b)	7.3.1 b)	3.5.3 ¶ 1 b)
– policies or procedures	9.1 (c)	7.3.1 c)	3.5.3 ¶ 1 c)
– premises	9.1 (d)	7.3.1 d)	3.5.3 ¶ 1 d)
– personnel or other resources	9.1 (e)	7.3.1 e)	3.5.3 ¶ 1 e)
– staff authorised to sign reports	–	7.3.1 f)	-
or other matters affecting capability, scope or compliance	9.1	7.3.1	3.5.3 ¶ 2, 2.1.5.1
arrangements to ensure that accredited body adjusts its procedures	9.2	7.3.2	2.5