European co-operation for Accreditation

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EA Guidance On the Application of ISO/IEC TR 17010

PURPOSE

This document provides guidance on the application of ISO/IEC TR 17010. It has been produced to improve the harmonization within EA.

Authorship
This document has been prepared by the EA Laboratory Committee.

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

Further information
For further information about this publication, contact your national member of EA or the Chairman of the EA Laboratory Committee.

Please check our website for up-to-date information at http://www.european-accreditation.org.

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CONTENTS

0 *INTRODUCTION*

ISO/IEC TR 17010 sets out general requirements for bodies providing accreditation of inspection bodies. This document provides further guidance on some of the issues identified by the EA accreditation bodies in the light of experience gained in accrediting inspection bodies subsequent to the publication of ISO/IEC TR 17010 (and its predecessor EA-3/03 (formerly denominated EAC/EAL-G28 Edition 1-July 1997)). *Annex A* of this Guidance document is attached as an example and can be used by the accreditation bodies in determining sample size for the assessment of premises and sites. *Annex B* of this Guidance document is attached for information only.

If accreditation of inspection bodies is to be performed in a harmonised manner as complying with ISO/IEC TR 17010 some Guidance to the Technical Report is necessary. This guidance document provides it. One aim is to enable accreditation bodies to harmonise their application of the standard. This is an important step towards mutual recognition of accreditation.

For convenience, the headings and clause numbers from ISO/IEC TR 17010 are first printed in **bold;** Guidance where it is offered is, for ease of reference, identified with the letter ”G”.
This Guidance will form the basis of mutual recognition agreements between accreditation bodies, and is considered necessary for the consistent application of ISO/IEC TR 17010. Members of the EA Multilateral Agreement (MLA), and applicants for membership in that Agreement, will assess each others’ implementation of ISO/IEC TR 17010 and all of this Guidance is expected to be adopted by accreditation bodies as part of their general rules of operation.

The term ”shall” is used throughout this document to indicate those provisions which, reflecting the requirements of ISO/IEC TR 17010, are mandatory. The term ”should” is used to indicate those provisions which, although they constitute guidance for the application of the requirements, are expected to be adopted by an inspection body. Any variation from the guidance by an accreditation body shall be an exception. Such variations will only be permitted on a case by case basis after the accreditation body has demonstrated that the exception meets the requirements of the relevant clause of ISO/IEC TR 17010 and the intent of this Guidance in some equivalent way.

An accreditation body shall at all times maintain its impartiality as required by clause 4.2 of ISO/IEC TR 17010. Nevertheless, it shall be prepared to discuss this guidance and its interpretation with an applicant body, and, where appropriate, to respond to enquiries.

1 *SCOPE*

G1.1 There are no comments on this clause.

2 NORMATIVE REFERENCES

G2.1 There are no comments on this clause.

3 *TERMS AND DEFINITIONS*

G3.1 There are no comments on this clause.

4 ACCREDITATION BODY

G4.1 There are no comments on this clause.

5 PERSONNEL INVOLVED IN THE ACCREDITATION PROCESS

EA Guidance to clause 5.2.1

G.5.1 Technical experts - The clause 5.2.1 of ISO/IEC TR 17010 does not make reference to technical experts. Accreditation bodies may use technical experts, as a member of the assessment team to provide specific knowledge or expertise with respect to a particular technical subject assessed. Technical experts are distinct from assessors in that they do not have the qualifications, training and experience of assessors. Technical experts may not have a thorough knowledge of the assessment techniques.

Technical experts shall not conduct assessment activities unaccompanied by an assessor and it is always the assessors who shall take the responsibility for reporting any non-compliances.

6 *ACCREDITATION PROCESS*

EA Guidance to clause 6.2.1

G6.1 **Definitions**

Premises – Locations that belong to the inspection body with an involvement in inspection activities. Such locations may be owned, rented or leased by the inspection body.

Site - Any location where an inspection activity is being undertaken on a temporary or permanent basis.

G6.2 **Sampling**

The assessment shall cover all the premises of the inspection body within a defined cycle. Annex 1, *General Principles for the Assessment of Inspection Bodies,* may be used for determining the sample size for the assessment of premises and sites.

EA Guidance to clause 6.7

G6.3 *Frequency of surveillance and reassessment* - Accreditation bodies should follow the guidance given in EA document EA /GA (98) 77- Surveillance and reassessment of accredited organisations.

7 REFERENCES TO ACCREDITED STATUS

G7.1 Results issued by an accredited inspection body, without the accreditation mark or reference made to the accredited status, cannot be granted the presumption of conformity with the clauses of the standard EN 45004 nor with the provisions of the MLA.

8 RELATIONSHIP BETWEEN ACCREDITATION BODY AND INSPECTION BODY

G8.1 There are no comments on this clause.

9 *NOTIFICATION OF CHANGE*

G9.1 There are no comments on this clause.

ANNEX A

Preamble

This document is based on the United Kingdom Accreditation Service publication E1.

1 Introduction

1.1 One of the functions of accreditation bodies is to assess and accredit the competence of inspection bodies to carry out specified fields and types of inspection and subsequently to ensure by monitoring that the required standards are maintained. Each applicant inspection body provides basic information on its activities, equipment and staff in an application form and its quality documentation. Assessment of the competence of an inspection body is carried out using document review, visits to the inspection body's central administrative office and other locations and on-site assessment of inspections. The purpose of the assessment is to determine whether an inspection body complies with the requirements of EN 45004. European guidelines on the application of EN 45004 are provided in EAL-5/01.

1.2 The accreditation bodies use technical assessors with the relevant specialist knowledge to judge the competence of the inspection body to perform the inspections for which accreditation is sought. The assessors are required to maintain confidentiality, and to sign a Code of Conduct specifying the need to declare any potential for conflict of interest. Their activities will be confined to assessing the inspection body's activities for compliance with the requirements and reporting their findings to the inspection body and to the accreditation body.

1.3 All information obtained before, during or after assessment, including the fact that a particular inspection body has applied for accreditation, or that an application has been deferred or rejected, will be treated as strictly confidential by the accreditation bodies' staff and assessors.

1.4.1 This document outlines how the accreditation bodies plan and conduct assessment, surveillance and reassessment visits to inspection bodies working to EN 45004 on a four year cycle. It also refers to the assessment techniques normally used.

2 Definitions

2.1 **Site** Place at which inspection is being undertaken.

2.2 **Multi-location organisation** An organisation with a central office in which certain activities are performed or managed with a network of locations at which such activities are fully or partially carried out. All locations have a direct legal or contractual link with the central office of the organisation and are subject to a common quality system.

3 Application

3.1 (a) On receipt of an application for accreditation as an inspection body working to EN 45004, the accreditation body will appoint an assessment manager to be responsible for the accreditation process. The assessment manager will contact the inspection body to:

(i) seek agreement to the appointment of a specified external Lead Assessor, as appropriate;

(ii) confirm the detailed list of fields and type of inspection for which the organisation is seeking accreditation;

(iii) confirm the different locations from which the inspection service is managed and the activities which are carried out at each of these.

(b) Whenever it is necessary for the accreditation body to make use of external assessors or experts in the assessment of an inspection body, the agreement of the inspection body to the individuals concerned will always be sought.

3.2 Prior to any work being carried out, the accreditation body will provide an estimate of the effort (in man-days) which will be required to proceed to the next stage of the assessment process. The charges for the assessment activity are calculated by multiplying this effort by the daily rate in force at the time.

3.3 The inspection body's quality manual and procedures will be examined for compliance with EN 45004 and EA-5/01. If necessary the findings will be reported to the inspection body in order that any changes can be made.

4 Preassessment

4.1 (a) Although not mandatory, a pre-assessment visit would normally be carried out at a specified location (generally the central office) of the inspection body to:

(i) discuss any findings related to the documentation;

(ii) seek further information on the quality system;

(iii) briefly examine the systems which have been established and implemented;

(iv) discuss any arrangements which have been made to include multiple locations, inspectors working from home or abroad, subcontracted activities etc within the quality system;

(v) agree the proposed scope of accreditation;

(vi) determine whether any further technical assessors will be required.

(b) The preassessment visit will normally be completed within one day.

4.2 The inspection body may need to make changes to its policies, procedures and practices prior to the accreditation body undertaking the assessment.

4.3 If necessary, further technical assessors or technical experts will be identified and the agreement of the inspection body to their appointment will be sought.

5 Assessment

5.1 (a) Prior to assessment, the inspection body will provide the accreditation body with a list of current inspectors, the fields and types of activity and the locations (however named) at which they are currently operating. The Assessment Manager will determine, in conjunction with the inspection body, the sampling level of locations and which inspectors will be subject to on-site assessment (see 5.5) as part of the planning process.

(b) An assessment plan and a quotation will be forwarded to the inspection body in advance of the assessment; written acceptance of both of these will be needed before a visit can be undertaken.

(c) The time required for assessment, surveillance and reassessment will be dependent on the complexity of the

organisation, the geographical spread of its activities, the structure of the quality system and the proposed scope of accreditation.

(d) Following successful assessment, an estimate of the time required to maintain accreditation over the four year cycle, including the anticipated number of locations to be visited and on-site assessments of inspections, will be provided at the time of offering accreditation; this will be reviewed annually and in the light of any findings. Extensions to scope will be quoted separately.

(e) The nature of the initial assessment will be dependent upon the schedule of accreditation required by the inspection body and the complexity of the quality system that is being operated. However, the following elements will need to be covered:

(i) central office assessment

(ii) assessment of multiple locations (where applicable)

(iii) on-site assessments of inspections for different fields and types of inspection and inspectors

(f) The team for initial assessments will comprise a minimum of two persons, one of whom will normally be a permanent staff member of the accreditation body.

5.2 Central office assessment

5.2.1 The accreditation body assessment team will seek to establish through objective evidence and by using various techniques that:

(a) the quality system is appropriate to the inspection body's needs, organisational arrangements and methods of operation, including multiple location operations and number of inspectors;

(b) all of the requirements of EN 45004 have been satisfactorily addressed ;

(c) the inspection body has implemented all the requirements of the quality system effectively;

(d) the operational, administrative and technical procedures used to support the quality manual are complete, technically valid and appropriate.

5.2.2 The following techniques will be employed to establish that procedures are being correctly and fully implemented:

(a) questioning of management and staff who have an involvement in or bearing upon the quality of inspection

work;

(b) examination of records;

(c) examination of the suitability, maintenance, calibration, control and use of all equipment used for inspection work;

(d) examination of the arrangements for exercising control over subcontractors and suppliers.

5.2.3 All fields and types of inspection will be subject to an office assessment and technical review. The team will assess the technical competence of inspectors in each field or type of inspection covered by the schedule. This will be done through:

(a) the examination of the records outlined above;

(b) discussions with supervisors;

(c) assessment of the performance of the staff whilst conducting scheduled inspections (see 5.5).

5.2.4 A report will be provided to the inspection body at the time of the assessment; where corrective action by the inspection body is required, a maximum of 3 months will be allowed for provision of evidence that the action has been carried out. In most cases evidence can be provided by post although there may be situations where additional visits to the inspection body will be required. The accreditation body will review the evidence provided and decide upon its acceptability.

5.2.5 On completion of all actions, including those arising from visits to multiple locations and on-site assessment of inspections, to the accreditation body's satisfaction, a draft schedule of accreditation will be sent to the inspection body along with an offer of accreditation. When agreement is reached on the scope of accreditation as shown in the schedule and any outstanding fees have been paid, the inspection body will be granted accreditation and a certificate and schedule will be issued.

5.3 Multi-location organisations

5.3.1 (a) An applicant that operates from a central office through a number of locations may seek a single accreditation provided that the conditions as specified by the accreditation body are fulfilled.

(b) On application, the inspection body must indicate the number and range of locations being operated. At assessment, the accreditation body will visit selected locations taking into account:

(i) the results of internal audits from central office and locations

(ii) the results of management reviews

(iii) variations in the size of locations

(iv) complexity of the quality system

(v) complexity of the locations

(vi) variations in working practices including, where applicable, equipment used

(vii) variations in activities undertaken eg fields of inspection, types of inspection

(c) It will normally not be necessary to witness the full range of scopes for each selected location.

5.3.2 (a) The accreditation body will seek to establish through objective evidence and by using various techniques that:

(i) all locations are operating under the same quality system;

(ii) all locations are included in the internal audit programme and central review process.

(b) Temporary locations must be working to the same requirements and may be subject to assessment on a sampling basis as part of the accreditation process to provide evidence of the operation and effectiveness of the system.

(c) During the central office assessment, the accreditation body may need to see records of certain activities which are being carried out at different locations.

5.3.3 (a) If the accreditation body observes non-compliances at the central office or at any one of the locations of an organisation with multiple locations, the corrective action procedure shall apply to all locations where applicable. In the event that the results of any of the assessments of 'sample locations' reveal that there is a significant weakness or inconsistency in the application of the quality system, the accreditation body will review the assessment programme and may increase the number of locations to be assessed.

(b) Failure by one location to comply with requirements may lead to removal of the location from the schedule of accreditation. If the cause of non-compliance is the lack of central control then the corporate accreditation will be the subject of review by the accreditation body and may lead to suspension or withdrawal of accreditation from all locations.

5.3.4 Generally, each location from which an organisation is operating will be visited at least once during the four year assessment cycle.

5.3.5 The accreditation body must be advised of any changes to location addresses and activities. The establishment of any new locations from which the inspection body proposes to offer an accredited service must be notified to the accreditation body before these can be included in the scope of accreditation; the need for assessment of the new location will be reviewed, the schedule of accreditation will be amended as appropriate and the location will be included in the programme of surveillance and reassessment.

5.4 On-site assessment of inspections

5.4.1 On-site assessment of inspections is an essential part of the accreditation body assessment of inspection bodies to EN 45004. This is particularly important when the inspection body is performing inspections of such nature where the inspector's professional judgement is crucial to the outcome of inspection.

5.4.2 (a) When deciding on the number of on-site assessments of inspections needed the following aspects will be considered by the accreditation body:

(i) the fields and types of inspection on the accreditation schedule;

(ii) the inspection body's procedures for selecting, training, authorising and monitoring inspectors, having regard to the qualifications and experience required for different fields and types of inspection;

(iii) the internal auditing arrangements of the inspection body;

(iv) the locations from which inspectors operate;

(v) any statutory requirements;

(vi) the extent to which inspectors are required to exercise professional judgement

(b) The minimum number of on-site assessments of inspections at initial assessment will normally be two.

5.4.3 (a) When deciding on the types of inspection to be witnessed account will be taken of the following:

(i) variety of products, services, processes and plant covered by the inspection activities;

(ii) skills needed by inspector.

(iii) any statutory requirements;

(iv) the extent to which inspectors are required to exercise professional judgement

(b) As a minimum, one inspector carrying out inspections will be assessed on-site for the fields and types of inspection on the accreditation schedule.

5.4.4 (a) When deciding on which inspectors will be assessed account will be taken of:

(i) new recruits or new authorisations

(ii) qualifications and experience

(iii) location

(iv) any statutory requirements;

(v) the extent to which inspectors are required to exercise professional judgement

(b) If none of the inspectors can cover the entire scope of a specific field then more than one inspector will be assessed for that field. Where there is any evidence which casts doubt on the competence of inspection staff, the sample size of inspectors assessed on site may be increased.

5.4.5 It will be necessary to examine equipment and documentation, such as procedures and instructions, records, reports and planning arrangements. If an inspector operates from home, this examination will be arranged at a mutually acceptable location.

5.4.6 (a) The accreditation body's assessors will ensure that their role during on-site assessment of inspections is one of observer and they will not influence the inspection being performed.

(b) The team will be looking to see that as a minimum:

(i) the inspector has the competence for the inspection performed;

(ii) the inspector's competence is consistent with the records;

(iii) the inspector has been supplied with all necessary

documented inspection methods and procedures;

(iv) the procedures are up-to-date;

(v) the inspector implements the procedure in full and correctly ie no short-cuts, no personalised application where it is not permissible to do so;

(vi) records of all observations are made while on site as required by the procedure;

(vii) records clearly identify what has been inspected, using what method/procedure, and when;

(viii) all records are signed/initialled, as applicable;

(ix) all findings that indicate immediate or urgent action are reported as required to the client whilst on site;

(x) reports comply with the inspection body requirements and EN 45004 as amplified by EA-5/01;

(xi) facilities and equipment are fit for the inspection purpose.

6 Surveillance and reassessment

6.1 General

6.1.1 Following accreditation, the accreditation body will check for continuing compliance with requirements by carrying out surveillance visits to inspection bodies, initially six months after accreditation and then annually, with a reassessment in the fourth year. The level of sampling of locations and inspectors will depend on performance over the four year cycle, the extent of any changes which have taken place and the level of confidence which can be placed in the performance measures and control systems of the inspection body. Quotations will be provided prior to any work being undertaken by the accreditation body.

6.2 Surveillance

6.2.1 Surveillance visits will be planned to cover the whole of the schedule of accreditation over four yearly cycle. Any revisions to the quality system will be reviewed during these visits; extensive changes may require additional assessment time.

6.2.2 A report will be provided to the inspection body at the time of the surveillance; where corrective action by the inspection body is required, a maximum of one month will be allowed for provision of evidence that the action has been carried out. In most cases evidence can be provided by post although there may be situations where additional visits to the inspection body will be required. The

accreditation body will review the evidence provided and decide upon its acceptability.

6.3 Multi-location organisations

6.3.1 For multi-location organisations the central quality system and technical control will be subject to surveillance each year. It is anticipated that, in addition to the central office, at least one location will be visited each year, with a visit to each location generally taking place over the four year period. However, the level of sampling of locations and inspectors will depend on performance over the four year cycle, the extent of any changes which have taken place and the level of confidence which can be placed in the performance measures and control systems of the inspection body.

6.4 On-site assessment of inspections

6.4.1 On-site assessment of inspections will be carried out at each surveillance visit. The minimum number of on-site assessments of inspections at surveillance is one per year and the same criteria used for assessment will be considered when determining the number and type of inspections, and the inspectors to be witnessed.

6.5 Reassessment

6.5.1 Reassessment visits will involve a comprehensive re-examination of the inspection body's quality system and inspection activities and will be similar in format and content to the initial assessment. The same criteria used for assessment will be considered when determining the number and type of inspections, and the inspectors to be assessed.

7 Extensions to scope

7.1 (a) Following receipt of an application for extension to scope the accreditation body will determine whether or not there is a need for a central office and/or location assessment and/or on-site assessments of inspection to take place. Factors which will be taken into consideration will be the:

(i) existing scope of accreditation;

(ii) inspector competences within scopes;

(iii) the range of scopes;

(iv) the location at which the extension to scope is sought.

(b) Where possible and desirable, any additional work will be carried out at the next surveillance or reassessment visit; where

necessary, additional visits will be arranged. The estimated effort required for subsequent surveillance and reassessment will be reviewed and may be revised.

(c)

*8 Scope of accreditation**

8.1 The policy is to define the scope of an inspection body's accreditation as precisely as possible. Inspection bodies will therefore be asked to specify in detail the field, type and range of inspections for which accreditation is sought and the locations at which these activities are to be carried out; this scope will be agreed as far as possible before the assessment in order to determine the extent of the assessment activities.

References

1 EN 45004, *General Criteria for the Operation of Various Types of Bodies performing Inspection.*

2 EA-5/01, *Accreditation of Inspection Bodies - Guidelines on the application of EN 45004.*

ANNEX B

Cross-reference list between the clauses of the document *EAC-EAL general requirements for bodies providing accreditation of inspection bodies*, EN 45003 (March 1995) and ISO/IEC Guide 61:1996

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.

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.

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.

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.

Where one numbered (sub)clause contains more than one paragraph, the symbol ¶ followed by a number is used as paragraph number.

***Section of the EAC-EAL document*, description of detailed requirement**	**EAC-EAL document**	**EN 45003**	**ISO/IEC Guide 61**
General provisions	***4***	***4***	***2.1***
Accreditation body	***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
Organisation of the accreditation body	***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)
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)

(cont.)

***Section of the EAC-EAL document*, description of detailed requirement** *(continued)*	**EAC-EAL document**	**EN 45003**	**ISO/IEC Guide 61**
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) -1	4.2.1 h) -1	2.1.2 ¶ 2 l)
- resolution of complaints and appeals	4.2.1 k) -2	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	-
Quality system	***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)
- 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)

(cont.)

***Section of the EAC-EAL document*, description of detailed requirement** *(continued)*	**EAC-EAL document**	**EN 45003**	**ISO/IEC Guide 61**
- 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 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)
Granting, maintaining, extending, suspending and withdrawing accreditation	***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

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***Section of the EAC-EAL document*, description of detailed requirement** *(continued)*	**EAC-EAL document**	**EN 45003**	**ISO/IEC Guide 61**
arrangements for transfer of accreditation	4.4.3	4.4.3	-
Documentation	***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***
General	***5.1***	***-***	***2.2.1***
competency of personnel	5.1.1	-	2.2.1.1
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
Requirements for assessors	***5.2***	***5.1***	***2.2.3.2***
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)

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***Section of the EAC-EAL document*, description of detailed requirement** *(continued)*	**EAC-EAL document**	**EN 45003**	**ISO/IEC Guide 61**
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)
Qualification procedures for assessors	***5.3***	***5.2***	***2.2.2***
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)
Contracting of assessors	***5.4***	***5.3***	***2.2.4***
contract with the assessors	5.4.1	5.3	2.2.4
sub-contracted assessors to fulfil all requirements	-	-	2.2.4
Assessor records	***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)	-

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***Section of the EAC-EAL document*, description of detailed requirement** *(continued)*	**EAC-EAL document**	**EN 45003**	**ISO/IEC Guide 61**
- 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)
Procedures for assessors	***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
specific scopes to be explained	-	-	3.1.1.3
additional information on request	6.1.2	6.1.2	3.1.1.4
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)
information to be provided prior to on-site assessment:	6.1.4	6.1.4	3.1.2.2
- 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
Assessment process	***6.2***	***6.2***	***3.2, 3.3***
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

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***Section of the EAC-EAL document*, description of detailed requirement** *(continued)*	**EAC-EAL document**	**EN 45003**	**ISO/IEC Guide 61**
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
Sub-contracting of assessment	***6.3***	***6.3***	***2.1.3***
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)
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)
Assessment report	***6.4***	***6.4***	***3.4***
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)

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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)
Decision on accreditation	***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
Granting accreditation	***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)

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***Section of the EAC-EAL document*, description of detailed requirement** *(continued)*	**EAC-EAL document**	**EN 45003**	**ISO/IEC Guide 61**
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)	-
Surveillance and re-assessment of accredited bodies	***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
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)	-

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***Section of the EAC-EAL document*, description of detailed requirement** *(continued)*	**EAC-EAL document**	**EN 45003**	**ISO/IEC Guide 61**
- 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
- 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

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