Telecom Technical
Regulations Assessment
Specifications

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Assessment Manual for Telecommunications Equipment Testing Laboratory Accreditation Bodies

Directorate General of Telecommunications,
Ministry of Transportation andCommunications

Contents

1.Introduction

The Directorate General of Telecommunications follows " the Assessment and Approval Guidelines for Testing Laboratory Accreditation Bodies " and establishes " the Assessment Team for the Testing Laboratory Accreditation Bodies (hereafter named assessment group)", conducts assessments of laboratory accreditation body . The assessment group shall pay attention to the following:

1、 to conduct assessment in the manner of impartiality and objectivity

2、 not to divulge the confidential information which is acquired by assessment

3、 to conduct on-site assessment in the way of sampling. The purpose of assessment is to find the defective evidence of the laboratory operation system, not to look for any mistakes intentionally. The assessment items in this manual are mentioned in principle, actual records could be added or deleted by assessors for the needs of on-site assessment.

4、 The assessors shall record briefly and clearly the facts and suggestions and shall sign for responsibility in observation reports and defect reports. The representative of the evaluated laboratory shall sign for confirmation, if necessary. The completed manual shall be kept by the evaluation group.

5、 Lead assessor shall submit the completed manual to evaluation group for review with two weeks after on-site assessment.

Cross-references between assessment items and documentation/place

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Directorate General of Telecommunications,
Ministry of Transportation and Communications

Non-conformance Report

organization name:_____ serial number of assessment/audit :_____
organization code:_____ report number:_____

assessment criteria :ISO/IEC Guide 58/ /
lead assessor: assessor:
assessment scope:
Assessment Result: There are _____ major non-conformances and _____ minor non-conformances details in the Assessment Observation Report and Assessment Defect Report after documentation review and on-site assessment. The initial decision of assessment teams is ☐ to suggest for approval ☐ to suggest laboratory to submit corrective action plan including deadline before _____(day/month/year) After verifying the corrective action plan of the laboratory accreditation body, ☐to suggest for approval, and to take these items involved in the corrective action as key items in the surveillance. ☐to arrange the other on-site assessment ☐to suggest to conduct a surveillance in _____ month(s) ☐not to suggest for approval Laboratory accreditation body who disagree the above decisions could submit its appeal in writing within one month. Beyond one month, the appeal is invalid.

the initial decision:	the person in charge(signature):
the reexamined decision :	the person in charge(signature):
the representative of the laboratory accreditation body	

date:_____(day/month/year)

Directorate General of Telecommunications,
Ministry of Transportation and Communications

Assessment Observation Report

Organization name:_____ serial number of assessment/audit :_____
organization code:_____ report number:_____

assessment criteria: ISO/IEC Guide 58/		
clause of assessment criteria	Observation	number of non-conformance record

the representative of the laboratory accreditation body:	assessor: lead assessor:

date:_____(day/month/year)

5. Accreditation Body

5.1 General Provisions

5.1.1 Are the accreditation boy‘s procedures administered in a nondiscrminatory manner?

_____

_____

Is access to the accreditation system made conditional upon the size of the laboratory or membership of any association or group?

_____

_____

Are there any undue financial conditions to restrict participation?

_____

_____

5.1.2 Is the competence of an applicant laboratory assessed against all of the requirements of ISO/IEC Guide 25?

_____

_____

5.1.3 Are the requirements of ISO/IEC Guide 25 interpreted by the accreditation body for a specific calibration, test or type of test or calibration? If so, how?

_____

_____

Are such interpretations formulated by relevant and impartial committees or persons possessing the necessary technical competence?

_____

_____

Are the interpretations published by the accreditation body?

_____

_____

5.1.4 Does the accreditation body require accredited laboratories to maintain impartiality, independence and integrity?

_____

_____

5.1.5 Does the accreditation body confine its requirements assessment and decision on accreditation to those matters specifically related to the scope of the accreditation being considered?

_____

_____

5.2 Organization of the accreditation body

5.2.1

a) Is the accreditation body a legally identifiable, public or private entity?

_____

_____

b) Does it have rights and responsibilities relevant to its accreditation activities?

_____

_____

c) Does it have adequate arrangements to cover liabilities arising from its operations and/or activities?

_____

_____

d) Does it have the financial stability and resources required for the operation of an accreditation system?

_____

_____

e) Does it have the make available on request a description of the means by which it receives its financial support?

_____

_____

f) Does it have sufficient personnel with necessary education, training, technical knowledge and experience for the type, range and volume of work performed?

_____

_____

Are they under a senior executive who is responsible to the organization, body or board to which it reports?

_____

_____

g) Does it have a quality system including an organizational structure, that enables it to

give confidence in its ability to operate a laboratory accreditation system satisfactorily?

_____

_____

h) Does it have documented policies and procedures for the operation of the quality system that include:

_____

_____

--policies and decision- making procedures that distinguish between laboratory accreditation and any other activities in which the body is engaged?

_____

_____

--policies and procedures for the resolution of complaints and appeals received from laboratories about the handling of accreditation matters, or from users of services about accredited laboratories or any other matters?

_____

_____

i) Is it, together with its senior executive and staff, free from any commercial, financial and other pressures which might influence the results of the accreditation process?

_____

_____

j) Does it have formal rules and structures for the appointment and operation of committees involved in the accreditation process?

_____

_____

Are such committees free form any commercial, financial and other pressures that might influence decisions?

_____

_____

Do they have a structure where members are chosen to provide impartiality through a balance of interests where no single interest predominates?

_____

_____

k) Has the accreditation body established 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?

_____

_____

l) Does the accreditation body offer consultancies or other services which may compromise the objectivity of its accreditation process and decisions?

_____

_____

m) Does the accreditation body have arrangements that are consistent with applicable laws, to safeguard, at all levels of its organization (including committees), confidentiality of the information obtained relating to application, assessments and accreditation of laboratories.

_____

_____

5.2.2 Does the accreditation body have arrangements for controlling the ownership, use and display of the accreditation documents and/or controlling the manner in which an accredited laboratory may refer to its accredited status, or both?

_____

_____

5.3 Quality System

5.3.1 Does the accreditation body operate a quality system appropriate to the type, range and volume of work performed ?

Is the system documented and available for use by the accreditation staff?

Has the accreditation body designated a person having direct access to its highest executive level, to take responsibility for the quality system and the maintenance of the quality documentation?

5.3.2 Is the quality system documented in a quality manual and associated quality procedures?

Does the quality manual contain or refer to at least the following:
a) a quality policy statement?

b) the organizational structure of the accreditation body?

c) 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?

d) administrative procedures including document control?

_____

_____

e) policies and procedures to implement the accreditation process?

_____

_____

f) arrangements for feedback and corrective actions whenever discrepancies are detected?

_____

_____

g) the policy and procedures for dealing with appeals, complaints and disputes?

_____

_____

h) the policy and procedures for conducting internal audits?

_____

_____

i) the policy and procedures for conducting quality system reviews?

_____

_____

i) the policy procedures for the recruitment and training of assessors and monitoring their performance?

_____

_____

5.3.3 Are the activities of the accreditation body audited to verify that they comply with the requirements of the quality system?

_____

_____

Is the quality system reviews to ensure its continued effectiveness?

_____

_____

Are audits and reviews carried out systematically and periodically and recorded together with details of any corrective actions taken?

_____

_____

5.3.4 Does the accreditation body maintain records to demonstrate that accreditation procedures have been effectively fulfilled?

_____

_____

Do application forms, assessment reports, and reports relating to granting, maintaining, extending, suspending or withdrawing accreditation form part of those records?

_____

_____

5.3.5 Does the accreditation body have a policy and procedures for retaining records for a period consistent with its contractual and legal obligations?

_____

_____

Dose the accreditation body have a policy and procedures concerning access to these records consistent with 5.2.1(m) of ISO/IEC Guide 58?

_____

_____

5.4 Granting, maintaining, extending, suspending and withdrawing accreditation

5.4.1 Does the accreditation body 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 laboratory‘s scope of accreditation?

_____

_____

5.4.2 Does the accreditation body have arrangements to grant, maintain, suspend or withdraw accreditation, increase or reduce the scope of accreditation or require reassessment, in the event of changes affecting the laboratory‘s activity and operation, such as changes in personnel or equipment, or if analysis of a complaint or any other information indicates that the laboratory no longer complies with the requirements of the accreditation body?

_____

_____

5.4.3 Does the accreditation body have arrangements relating to the transfer of accreditation when the legal status (e.g.ownership) of the accredited laboratory changes?

_____

_____

5.5 Documentation

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

a) information about the authority under which accreditation systems operated by the accreditation body were established, and specifying whether they are mandatory or voluntary?

_____

_____

b) a document containing its requirements for accreditation in accordance with ISO/IEC Guide 58?

_____

_____

c) a document stating the arrangement 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 laboratories?

_____

_____

f) a description of the rights and duties of accredited laboratories as specified in 8.1, 8.2 and 8.3 of ISO/IEC Guide 58, including requirements, restrictions or limitations on the use of the accrediting body‘s logo and on the ways of referring to the accreditation granted?

_____

_____

6. Laboratory Aessessors

6.1 Requirements for assessors

How does the accreditation body address the following questions:

a) Is the assessor or assessment team appointed to assess a laboratory familiar with the relevant legal regulations, accreditation procedures and accreditation requirements?

_____

_____

b) Do they have a thorough knowledge of the relevant assessment method and assessment documents?

_____

_____

c) Do they have appropriate technical knowledge of the specific calibration, tests or types of calibration or tests for which accreditation is sought and, where relevant, with the associated sampling procedures?

_____

_____

d) Are they able to communicate effectively, both in writing and orally?

_____

_____

e) Are they 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) Have they offered consultancies to laboratories which might compromise their impartiality in the accreditation process and decisions?

_____

_____

6.2 Qualification procedures

Does the accreditation body have an adequate procedure for:

a) qualifying assessors, comprising an assessment of then competence and training. and attendance at one or more actual assessments with a qualified assessor?

_____

_____

b) monitoring the performance of assessors?

_____

_____

6.3 Contracting of assessors

Does the accreditation body require 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 laboratories to be assessed?

_____

_____

6.4 Assessor records

Does the accreditation body possess and maintain up-to-date records on assessors consisting of:

a) name and address?

_____

_____

b) organization affiliation and position held?

_____

_____

c) educational qualification and professional status?

_____

_____

d) work experience?

_____

_____

e) training in quality assurance, assessment and calibration and testing?

_____

_____

f) experience in laboratory assessment, together with field of competence?

_____

_____

g) date of most recent updating of record?

_____

_____

6.5 Procedures for assessors

Are assessors provided with an up-to-date set of procedures giving assessment instructions and all relevant information on accreditation arrangements?

_____

_____

7. Accreditation process

7.1 Application for accreditation

7.1.1 Does the accreditation body maintain up-to-date:

• a detailed description of the assessment and accreditation procedure?

_____

_____

• documents containing the requirements for accreditation?

_____

_____

• documents describing the rights and duties of accredited laboratories including fees to be paid by applicant and accredited laboratories?

_____

_____

Are these given to applicant laboratories?

_____

_____

7.1.2 Is additional relevant information provided to applicant laboratories on request?

_____

_____

7.1.3 Is a duly authorized representative of the applicant laboratory required to sign an official application form, in which or attached to which:

a) the scope of the desired accreditation is defined?

_____

_____

b) the applicant representative agrees:

-- to fulfill the accreditation procedure?

_____

_____

-- to receive the assessment team?

_____

_____

-- to pay the fees charged to the applicant laboratory whatever the result of the assessment may be?

_____

_____

-- to accept the charges of subsequent maintenance of the accreditation of the laboratory?

_____

_____

c) the applicant agrees to comply with the requirement for accreditation and to supply any information needed for the evaluation of the laboratory?

_____

_____

7.1.4 Is the following minimum information provided by the applicant laboratory:

a) the general features of the applicant laboratory (corporate entity: name, address, legal status, human and technical resources) prior to on-site assessment?

_____

_____

b) general information concerning the laboratory covered by the application, such as primary function, relationship in a larger corporate entity and, if applicable, physical location of laboratories involved?

_____

_____

c) a definition, for the calibrations concerned, of the type of measurement performed. the measurement range and best measurement capability, and for tests, of the materials or products tested, the methods used and the tests performed?

_____

_____

d) a copy of the laboratory‘s quality manual and , where required, the associated documentation? Is the information gathered used for the preparation of on-site assessment?

_____

_____

Is it treated with appropriate confidentially?

_____

_____

7.2 Assessment

7.2.1 Does the accreditation body appoint qualified assessor(s) to evaluate all material collected from the applicant and to conduct the assessment on its behalf at the laboratory and any other sites where activities to be covered by the accreditation are performed?

_____

_____

7.2.2 Is each assessor provided with the appropriate working documents, to ensure that a comprehensive and correct assessment is carried out?

_____

_____

7.2.3 Is the date of assessment mutually agreed with the applicant laboratory?

_____

_____

Is the applicant laboratory informed of the name(s) of the qualified assessor(s) nominated to carry out the assessment? Is sufficient notice given so that the laboratory has an opportunity to appeal against the appointment of any particular assessor?

_____

_____

7.2.4 Are the assessor(s) formally appointed?

_____

_____

Is a lead assessor appointed, if relevant?

_____

_____

Is the mandate given to the assessor(s) clearly defined and made known to the applicant laboratory?

_____

_____

7.3 Sub-contracting of assessment

7.3.1 If an accreditation body decides to delegate fully or partially the assessment of a laboratory to another body ,does the accreditation body take full responsibility for such an assessment made on its behalf?

_____

_____

7.3.2 Does the accreditation body ensure that any body to which assessment has been dele-gated is competent and complies with the applicable provisions of ISO/IEC Guide 58?

_____

_____

7.4 Assessment report

7.4.1 Does the accreditation body adopt reporting procedures that ensure, as a minimum, that:

a) a meeting takes place between the assessor(s) or assessment team and the laboratory management prior to leaving the laboratory. At which the assessment team provides a written or oral report on the compliance of the applicant laboratory with the accreditation requirements?

_____

_____

b) the assessor(s) or assessment team provides the accreditation body with a detailed assessment report containing all relevant information concerning the ability of the applicant laboratory to comply with all of the accreditation requirements, including any which may come about from the results of proficiency testing?

_____

_____

c) a report on the outcome of the assessment is promptly brought to the applicant laboratory'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.

_____

_____

Is the laboratory 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?

_____

_____

7.4.2 If the final report authorized by the accreditation body and submitted to the laboratory is different, does it 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 laboratory sites assessed? d) the assessed scope of accreditation or reference thereto?

_____

_____

e) comments of the assessor(s) or assessment team on the compliance of the applicant laboratory with the accreditation requirements?

_____

_____

7.4.3 Do the reports take into consideration:

a) the technical qualifications, experience and authority of the staff encountered, especially the persons responsible for the technical validity of calibration certificate, test reports or test certificates?

_____

_____

b) the adequacy of the internal organization and procedures adopted by the applicant laboratory to give confidence in the quality of its services, the physical facilities, i.e. the environment and the calibration/test equipment of the laboratory including maintenance and calibration having regard to the volume of work undertaken? c) any proficiency testing performed by the applicant laboratory, the results of this proficiency testing. and the use of these results by the laboratory?

_____

_____

d) the actions taken to correct any non-compliances identified at previous assessments?

_____

_____

7.5 Decision on accreditation

7.5.1 Is the decision whether or not to accredit a laboratory taken by the accreditation body on the basis of the information gathered during the accreditation process?

_____

_____

7.5.2 Does the accreditation body delegate its responsibility for granting, maintaining, extending, suspending or withdrawing accreditation?

_____

_____

7.6 Granting accreditation

7.6.1 Does the accreditation body transmit to each accredited laboratory formal accreditation documents such as a letter or a certificate signed by an officer Who has been assigned such responsibility?

_____

_____

Do these format accreditation documents permit identification of:

a) the name and address of the laboratory that has been accredited?

_____

_____

b) the scope of the accreditation including:

- a list of calibrations or tests, or types of calibration or test for which accreditation has been granted?

_____

_____

- for calibrations, the type of measurement performed, the measurement range and best
  measurement capability?

_____

_____

- for tests, the materials or products tested, the method used and the tests performed?

_____

_____

- for specific calibrations and tests for which accreditation has been who has been assigned such responsibility?

_____

_____

Do these format accreditation documents permit identification of:

a) the name and address of the laboratory that has been accredited?

_____

_____

b) the scope of the accreditation including:

- a list of calibrations or tests, or types of calibration or test for which accreditation has been granted?

_____

_____

- for calibrations, the type of measurement performed, the measurement range and best measurement capability?

_____

_____

- for tests, the materials or products tested, the method used and the tests performed?

_____

_____

- for specific calibrations and tests for which accreditation has been granted, the methods used defined by written standards or reference documents that have been accepted by the accreditation body?

_____

_____

c) where appropriate, the persons recognize by the accreditation body as being responsible for the calibration certificates, test certificates or the test reports?

_____

_____

d) the effective date of accreditation, and the terms of the accreditation if applicable?

_____

_____

e) the accredited laboratory by a unique number?

_____

_____

7.7 Surveillance and reassessment of accredited laboratories

7.7.1 Does the accreditation body have an established, documented program consistent with the accreditation granted for carrying out periodic surveillance and reassessment at sufficiently close intervals to ensure that its accredited laboratories continue to comply with the accreditation requirements?

_____

_____

7.7.2 Are surveillance and reassessment procedures consistent with those concerning the assessment of laboratories as described in ISO/IEC Guide 58?

_____

_____

7.8 Proficiency testing

7.8.1 Are laboratories encouraged by the accreditation body to participate in proficiency testing?

_____

_____

7.8.2 Is proficiency testing (which may be organized by the accreditation body itself or by any other body judged competent) consistent with the provisions contained in ISO/IEC Guide 43?

_____

_____

7.8.3 Do accredited laboratories and applicant laboratories participate in proficiency testing or other interlaboratory comparisons as required by the accreditation body? Is it policy that performance in
such tests meet the requirements of the accreditation body?

_____

_____

7.9 Certificates or reports issued by accredited laboratories

7.9.1 Does the accreditation body normally allow an accredited laboratory to refer to its accreditation in calibration certificates, test reports and test certificates, that contain only the results of calibrations, tests or types of calibration or test for which accreditation is held?

_____

_____

7.9.2 Does the accreditation body have a policy that defines the circumstances in which accredited laboratories are permitted to include the results of calibrations or test for which accreditation is not held and the results of sub-contracted calibrations or tests?

_____

_____

8 Relationship between accreditation body and laboratory

8.1 Does the accreditation body have arrangements to ensure that the laboratory and its representatives afford such accommodation and cooperation as is necessary, to enable the accreditation body to verify compliance with the requirements for accreditation?

_____

_____

Do these arrangements include provision for examination of documentation and access to all calibration and testing areas, records and personnel for the purposes of assessment, surveillance, reassessment and resolution of complaints?

_____

_____

8.2 Does the accreditation body require that an accredited laboratory:

a) at all times comply with the relevant provisions of this document?

_____

_____

b) claim that it is accredited only in respect of services for which it has been granted accreditation and which are carried out in accordance with these conditions?

_____

_____

c) pay such fees as shall be determined by the accreditation body?

_____

_____

d) not use its accreditation in such a manner as to bring the accreditation body into disrepute, and not make any statement relevant to its accreditation which the accreditation body may consider misleading or unauthorized? e) upon suspension or withdrawal of its accreditation (however determined), forthwith discontinue its use of all advertising matter that contains any reference thereto, and return any certificates of accreditation to the accreditation body?

_____

_____

f) not use its accreditation to imply product approval by the accreditation body?

_____

_____

g) endeavour to ensure that no certificate or report nor any part thereof is used in a misleading manner?

_____

_____

h) in making reference to its accreditation status in communication media such as documents, borchures or advertising, comply with the replacements of the accreditation body?

_____

_____

8.3 Notification of change

8.3.1 Does the accreditation body have arrangements to ensure that an accredited laboratory informs it without delay of changes in any aspect of the laboratory‘s status or operation that affects the laboratory‘s:
a) legal, commercial or organizational status?

_____

_____

b) organization 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?

_____

_____

f) authorized signatories?

_____

_____

or other such matters that may affect the laboratory’s capability, or scope of accredited activities, or compliance with the requirements in ISO/IEC Guide 58 or any other relevant criteria of competence specified by the accreditation body?

_____

_____

8.3.2 Upon receipt of due notice of any intended changes relating to the requirements of ISO/IEC Guide 58, the relevant criteria of competence and any other requirements prescribed by the accreditation body, does the accreditation body ensure that the laboratory carries out the necessary adjustments to its procedures within such time as, in the opinion of the body, is reasonable?

_____

_____

Does the laboratory notify the body when such adjustments have been made?

8.4 Directory of accredited laboratories

Does the accreditation body produce periodically a directory of accredited laboratories describing the accreditation granted?

_____

_____

Directorate General of Telecommunications,
Ministry of Transportation and Communications

Non-conformance Record

Organization name:_____ serial number of assessment/audit :_____
Organization code:_____ record number:_____ page :____/_____

Category :major/ minor assessment criteria :ISO/IEC Guide 58/	
Clause of assessment criteria:	
Non-conformance:	
laboratory collective action plan including deadline (or comments)	
the representative of the laboratory accreditation body:	assessor: lead assessor:

date:_____(day/month/year)