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TBT/W/84
16 September 1985

Special Distribution

GENERAL AGREEMENT ON TARIFFS AND TRADE

Committee on Technical Barriers to Trade

ISO/IEC GUIDES 38, 39 AND 40

In accordance with the request made by the Committee in the context of its discussion of the matter of testing and inspection at its meeting on 6-10 May 1985 (TBT/M/19 and Corr. 1, paragraph 11), the following three Guides of the International Organization for Standardization and the International Electro-technical Commission are being circulated in the attachment[1].

ISO/IEC Guide 38-1983 - "General Requirements for the Acceptance of Testing Laboratories" (Pages 2-9)

ISO/IEC Guide 39-1983 - "General Requirements for the Acceptance of Inspection Bodies" (Pages 10-16)

ISO/IEC Guide 40-1983 - "General Requirements for the Acceptance of Certification" (Pages 17-19)

[1] English and French only.

ISO/IEC GUIDE 38 - 1983

General requirements for the acceptance of testing laboratories

This Guide is one of a series covering the requirements for the acceptance of testing laboratories (ISO/IEC Guide 38), the acceptance of inspection bodies (ISO/IEC Guide 39) and the acceptance of certification bodies themselves (ISO/IEC Guide 40).

0 Introduction

0.1 When a testing laboratory's technical competence is acceptable to an appropriate body, that body may grant it recognition for such competence. Such recognition signifies a judgement that the testing laboratory has demonstrated an acceptable level of technical competence in providing the testing services identified in the recognition and further has agreed to comply with the requirements of this Guide.

0.2 Recognition should not be regarded as in any way diminishing the normal contractual responsibilities between testing laboratory and its clients. While recognition will normally be a sound indicator of the technical competence of the testing laboratory, it cannot be taken to constitute a guarantee by the body granting recognition that the testing laboratory always maintains a particular level of performance.

0.3 Considerations of competence, impartiality and integrity are fundamental to the acceptability of a testing activity. Users of testing services must be guided by this fact in making the choice of testing laboratories that they employ.

1 Scope and field of application

The object of this Guide is to set forth the general procedures and administrative conditions necessary for a system of assessment and acceptance of testing laboratories.

Additional requirements and information which must be disclosed for assessing technical competence or for determining compliance with other criteria may be specified by the organization or authority granting the recognition, depending upon the specific character of the task of the laboratory. As used herein, a testing laboratory refers to that facility which is operated at or from a specifically designated location.

This Guide may be used by accrediting bodies, certification bodies, and other governmental or non-governmental bodies concerned with the acceptance, recognition or approval of testing laboratories.

NOTES

1 This Guide should be read in conjunction with ISO/IEC Guide 25.

2 The testing laboratory or the function it performs could be an integral part of a certification or other body, or it could be a separate entity.

3 When a testing laboratory carries out its function on behalf of a certification body, it is required to work to the specific instructions of the certification body.

2 References

ISO Guide 2, *General terms and their definitions concerning standardization, certification and testing laboratory accreditation.*

ISO/IEC Guide 25, *Guidelines for assessing the technical competence of testing laboratories.*

3 Definitions

The relevant definitions contained in ISO Guide 2 are applicable.

As used in this Guide, the term "client" refers to any organization or person who employs a testing laboratory for any purpose. This term can thus refer to a commercial customer or to a certification body who uses the services of the testing laboratory.

4 Procedures for granting and withdrawing recognition

4.1 The body granting recognition shall specify the procedures by which application for recognition should be made (see the annex as a recommendation as to how some of the documentation may be provided), the conditions for the granting, maintenance and renewal of recognition and the conditions under which recognition may be refused or withdrawn.

4.2 The body granting recognition may, at its discretion, withdraw recognition, reduce the scope of recognition or require reassessment, in the light of changes in personnel, equipment or scope of activity or if a complaint or any other information is received which indicates that the technical competence of the testing laboratory is insufficient.

5 Organization

5.1 The testing laboratory shall have an organizational structure intended to ensure its capability in terms of its technical competence, including the level of accuracy in its tests and measurements, the accuracy of its observations, and the reporting and recording of test results.

5.2 The testing laboratory shall have an organizational structure to ensure compliance with the requirements of ISO/IEC Guide 25.

5.3 In addition to the information shown in the annex, the testing laboratory may be required to provide information on the following items :

a) the history of its testing in the specific area in which recognition is sought;

b) the geographical area currently served by the testing laboratory and the categories of customers which use its services, e.g. manufacturers, government agencies, etc.;

c) any other technical services provided by the testing laboratory in the areas for which it seeks recognition, with particular reference to any product development or consulting services;

d) details of recognition granted by other bodies to the testing laboratory;

e) the ownership and legal status of the testing laboratory.

6 Staff

The qualifications of staff and the management structure shall be such as to demonstrate compliance with the requirements of ISO/IEC Guide 25.

7 Assessment of competence

The testing laboratory shall satisfy the body granting recognition that it meets the requirements outlined in ISO/IEC Guide 25 as related to the type of recognition it is seeking and additional requirements prescribed at the discretion of the body granting recognition. For example, a certification body may require evidence that the testing laboratory adequately understands the standards to be applied under its instruction.

8 Other requirements to be met by a testing laboratory

8.1 The granting, maintenance and renewal of recognition will apply only to a testing laboratory which complies with these requirements and other criteria specified by the body granting recognition, and which provides such documentation as may be required. (See the annex, as an example of how some of the documentation may be provided.)

8.2 The testing laboratory shall demonstrate that it has the ability to communicate effectively with the body granting recognition and with clients in the relevant geographical area. Where required, competency in appropriate languages, including translation facilities, must be demonstrated.

8.3 The testing laboratory shall be willing to observe terms and conditions to provide for confidentiality and security of its practices as required by the users of its services.

8.4 Testing laboratories shall themselves normally perform the testing which they contract to undertake. Where, exceptionally, a testing laboratory sub-contracts any part of the testing, this work shall be placed with another testing laboratory complying with these requirements. The testing laboratory shall ensure and be able to demonstrate that his sub-contractor is competent to perform the services in question and complies with the same criteria of competence and, where applicable, the same regulations as the testing laboratory in respect of the work being sub-contracted. The testing laboratory shall advise the client of its intention to sub-contract any portion of the testing to another party. The sub-contractor shall be acceptable to the body granting recognition and to the client where competitive situations exist.

NOTE — In some cases, the body granting recognition may require that the sub-contractor also holds recognition in its own rights.

8.5 The testing laboratory shall record and retain details of its investigation of the competence and compliance of its sub-contractors and maintain a register of all sub-contracting. These details shall be available on demand to the body granting recognition.

8.6 The testing laboratory shall afford the client or his representative co-operation to enable him to monitor the performance of the testing laboratory in relation to the work to be performed. This co-operation shall include

a) affording the client or his representative access to relevant areas of the testing laboratory, for the witnessing of tests performed for the client. It is understood that such access shall by no means come into conflict with rules of confidentiality of work for other clients;

b) preparation, packaging and dispatch of test pieces, samples or other items needed by the client for verification purposes.

8.7 The testing laboratory shall afford the body granting recognition and its representative such co-operation as is necessary, to enable the body granting recognition to monitor compliance with these requirements and other criteria. This co-operation shall include

a) affording the representative access to relevant areas of the testing laboratory, for the witnessing of tests;

b) undertaking any reasonable check tests to enable the body granting recognition to verify the testing capability of the testing laboratory;

c) preparation, packaging and dispatch of test pieces, samples or other items needed by the body granting recognition for verification purposes;

d) participation in any appropriate programme of proficiency testing or comparison testing that the body granting recognition may reasonably deem to be necessary;

e) permitting scrutiny by the body granting recognition of the results of the testing laboratory's own internal audits or proficiency tests.

8.8 A recognized testing laboratory shall

a) at all times comply with these requirements and with other criteria prescribed by the body granting recognition;

b) claim that it is recognized only in respect of testing services for which it has been granted recognition and which are carried out in accordance with these requirements and other criteria prescribed by the body granting recognition;

c) pay such fees for application, membership, assessment, surveillance and other services as shall be from time to time determined by the body granting recognition having regard to the costs involved;

d) not use its recognition in such a manner as to bring the body granting recognition into disrepute and shall not make any statement relevant to its recognition which the body granting such recognition may reasonably consider to be misleading;

e) upon the termination of its recognition (however determined) forthwith discontinue its use and all advertising matters which contain any reference thereto;

f) make it clear in all contracts with its clients that the laboratory's recognition or any of its test reports by themselves in no way constitutes or implies product approval by the body granting recognition or any other body;

g) endeavour to ensure that no test report nor any part thereof shall be used by a client, or be authorized for use by a client, for promotional or publicity purposes, if the body granting recognition considers such use to be misleading. In any case, the test report shall not be reproduced except in full without the approval of both the body granting recognition and the testing laboratory.

8.9 In making reference to its recognition status in communication media such as documents, brochures or advertising, the testing laboratory shall use the following phrase as appropriate : "a (type)* testing laboratory recognized by (body granting recognition) for the testing of (product, services or field of testing for which recognition has been granted) and identified by registration number(s)...*".

The testing laboratory shall require that its clients who refer to use of a recognized testing laboratory shall use the following phrase as appropriate : "Tested by (name of testing laboratory) which is recognized by (body granting recognition) for the testing services described herein and identified by registration number(s)...*".

The testing laboratory shall, upon withdrawal of recognition, take steps to ensure that no further use of the reference occurs.

8.10 A testing laboratory shall retain on record all test reports, original observations, calculations and derived data, for a period of 6 years or as otherwise specified by the body granting recognition.

9 Notification of change

9.1 The body granting recognition shall be informed immediately by the testing laboratory of any changes bearing on its compliance with these requirements and other criteria affecting the testing laboratory's capability or scope of activity.

9.2 Recognition may be relinquished by a testing laboratory upon giving one month's notice (or other time period agreed upon between the parties) in writing to the body granting recognition.

* Optional with the body granting recognition.

ANNEX TO ISO/IEC GUIDE 38 - 1983

Information recommended to be provided by a testing laboratory in applying for recognition

1 Applicant's name and address :

Telephone No. :

Telex No. :

2 Test Laboratory* name and address
(if different from paragraph 1) :

Telephone No. :

Telex No. :

3 Senior management

3.1 Names and titles of the senior executives of the Test Laboratory* and of the testing laboratories for which recognition is being sought :

3.2 Name and title of the person responsible for the Quality Management System in the testing laboratory :

3.3 Name and title of the principal contact nominated by the testing laboratory, and of his deputy :

3.4 Operating departments of the testing laboratory for which recognition is being sought. (Show on a separate sheet to be attached either as a list or as an organization chart of the Test Laboratory*.) :

4 Employees

4.1 Total number in Test Laboratory* :

4.2 Total number in testing laboratory for which recognition is being sought :

4.3 Total number of professionally qualified staff (see also ISO/IEC Guide 25) in the area for which recognition is being sought :

5 Equipment

List on a separate sheet the major items of test equipment available for use in the area for which recognition is being sought.

6 Test facilities and services

6.1 List on a separate sheet the testing services for which recognition is being sought, indicating for each service any limits between which it will operate, and the published specifications against which the testing will be performed.

6.2 If recognition by other bodies or authorities are held in the area for which recognition is being sought, please give details.

6.3 What type of testing is to be subcontracted in respect of the recognition being sought?

7 Other information

7.1 Document, where applicable, how the testing laboratory may be related to external organizations or to components within its own parent organization.

7.2 Give any other information which you consider could be of assistance to the assessment team (on a separate sheet if necessary).

* "Test Laboratory" refers here to the corporate entity having final authority over the "testing laboratory" seeking recognition. In some cases this may be the same body.

	Yes/No	Particulars (where appropriate)
8 Quality Management Policy		
8.1 Are policy and procedures for the operation of the testing laboratory contained in a document such as a Quality Manual?		
8.2 Has the person responsible for quality management the responsibility and authority to identify quality problems and initiate effective solutions?		
8.3 Does the Quality Manual contain procedures for the supervision of any unqualified staff (see also ISO/IEC Guide 25)?		
8.4 Is there a prescribed audit procedure for checking quality management functions?		
9 Work instructions		
9.1 Are manuals, work instructions and regulations to be used by staff readily available?		
9.2 Is there a system for updating, implementing and recording changes to these documents?		
9.3 Are documents available for each testing operation?		
9.4 Are documents and reference data maintained in an up-to-date condition?		
9.5 Is obsolete data promptly removed from documents, etc.?		
10 Personnel		
10.1 Have standards of professional ability, skills and job descriptions been prescribed where necessary?		
10.2 Are training methods applied to attain and maintain skills with due attention to quality requirements?		
11 Test equipment and calibration		
11.1 Does the Quality Management System specify that the equipment is of an accuracy compatible with the testing undertaken?		
11.2 Is a record maintained of all test equipment, including calibration results?		
11.3 Are facilities and appropriate environments provided for calibration, handling, control, storage and maintenance of all testing and measuring equipment?		
11.4 Are there documented procedures for calibrating all equipment and reference standards, which include method, periodicity, sealing after calibration, etc.?		
If not, explain calibration system used :		
11.5 Are reference standards used for calibration traceable to national or international standards of measurement?		
12 Test procedures		
12.1 Are test methods and procedures recorded which are not called up in specifications, manuals, etc.?		
12.2 Are the environments in which tests are conducted and results recorded suitable to ensure their accuracy?		

	Yes/No	Particulars (where appropriate)
12.3 Do environmental test facilities exist?		
12.4 Is there control of access to the testing areas?		
12.5 Is there a prescribed system for detecting deficiencies in testing and their causes, and for correcting unfavourable trends?		
13 Handling and storage		
13.1 Are work and inspection instructions prescribed and implemented for the handling, storage and return to the client of materials and samples?		
13.2 Are appropriate storage areas arranged to prevent deterioration or damage to the products concerned?		
13.3 Are storage methods prescribed, including special environments?		
13.4 Are there procedures for the inspection of samples in storage?		
13.5 Are storage areas accessible only to authorized persons?		
13 6 Is provision made to ensure that all samples to be stored or returned to the client are adequately identified and labelled?		
14 Records		
14.1 Is there a prescribed system for recording the method and results of testing activities?		
14.2 Are observations and calculations recorded and stored as to provide a permanent test record?		
14.3 Are there arrangements for ensuring that records are current, complete, accurate and held confidential where required?		
15 Test reports		
15.1 Do test reports contain all the information required for such by ISO/IEC Guide 25?		
15.2 Is the testing laboratory prepared to make arrangements to send copies of test reports to the body granting recognition, where required, on a strictly confidential basis?		
16 Preparedness for assessment		
16.1 Are you satisfied that you can meet all the requirements prescribed herein?		
16.2 At what date will the testing laboratory be ready for assessment?		
16.3 Is there any special urgency for assessment?		
If so, what is the reason?		

Applicant's name .....

Signature of person authorized to sign for the Applicant .....
(Title)

Date .....

Application for assessment as a recognized testing laboratory

Name of applicant : .....

Address : .....

.....

.....

.....

Name of contact : .....

Title : .....

Name and address of testing laboratory if different :

.....

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.....

.....

Name of contact : .....

Title : .....

Test or series of tests for which recognition is sought : .....

.....

.....

.....

The testing laboratory hereby agrees to undertake

a) to conform to the requirements for a recognized testing laboratory;

b) to pay all costs connected with assessment and admisnistration in the pre-recognition stage irrespective of the eventual granting of recognition.

Signed : .....
(Title)

Date : .....

ISO/IEC GUIDE 39 - 1983

General requirements for the acceptance of inspection bodies

This Guide is one of a series covering the requirements for the acceptance of testing laboratories (ISO/IEC Guide 38), the acceptance of inspection bodies (ISO/IEC Guide 39) and the acceptance of certification bodies themselves (ISO/IEC Guide 40).

0 Introduction

The services offered by inspection bodies will be of benefit to individual users, national government, local government, certification and other bodies.

Inspection is an important component, associated with other activities, including certification, that assist in national and international trade. Considerations of competence, impartiality and integrity are fundamental to the acceptability of the inspection process. Users of the inspection service must be guided by this fact in making the choice of inspection bodies that they employ. This judgement must be seen to be exercised in an acceptable manner.

1 Scope and field of application

The object of this Guide is to set forth the criteria, the observance of which is intended to ensure that the services of inspection bodies are conducted with technical competence and thoroughness, careful observation and accurate reporting by competent qualified staff.

NOTES

1 The inspection body or the functions it performs could be an integral part of a certification or other body, or it could be a separate entity.

2 Where an inspection body carries out its function on behalf of a certification body, it is normally required to work to the specific instructions of the certification body.

2 Reference

ISO Guide 2, *General terms and their definitions concerning standardization, certification and testing laboratory accreditation.*

3 Definitions

3.1 **inspection body** : An impartial body having the organization, staffing, competence and integrity to perform to specified criteria functions such as assessing, recommending for acceptance and subsequent audit of manufacturers' quality control operations, and selection and evaluation of products on site or in factories or elsewhere as directed, to specified criteria.

The other relevant definitions contained in ISO Guide 2 are applicable.

4 Organization

An inspection body shall*

a) be legally identifiable;

b) have a technical manager, however named, who is qualified and experienced in the operation of the inspection body and who has overall responsibility for ensuring that the specified aims and the criteria contained herein are met;

c) provide procedures for clear demarcation between actual inspection services and any auxiliary or unrelated functions;

d) limit its actitivities, while performing an inspection, to those functions for which it is specifically directed;

e) clearly define the areas of technology to be covered by its inspection services and for which it is qualified;

f) ensure that inspection procedure and other matters shall be continuously coordinated with the certification or other bodies using these services.

* A recommended format for providing this information is given in the annex.

5 Staff

5.1 Adequate technically qualified staff shall be available, some of whom are trained in the practice and principles of quality assurance. One or more of the staff shall be nominated to supervise the inspection body in the absence of the technical manager.

5.2 Staff having responsibility for making initial recommendations for acceptance of manufacturer's quality assurance systems on products shall be

a) qualified in appropriate disciplines;

b) experienced for at least two years in the practical application of quality assurance, inspection techniques and production methods.

5.3 Staff having responsibility for subsequent monitoring of a manufacturer's quality control, if not professionally/academically qualified, shall be supervised by qualified staff, and the requirements of 5.2 a) shall be met. The proportion of such staff to qualified staff shall be such as not to degrade the work undertaken.

5.4 All staff shall be aware of the extent and any limitations of their responsibilities.

6 Recognition and financial stability

The inspection body shall preferably be recognized for conducting work on at least a national basis within its own country and shall be soundly supported financially as well as being free from commercial or any other influence which might affect its integrity.

7 Communication capability

The inspection body shall demonstrate that it has the ability to communicate effectively with the body granting recognition and with clients in the relevant geographical area. Where required, competency in appropriate languages, including translation facilities, must be demonstrated.

8 Records

8.1 The inspection body shall maintain a record system to suit its particular circumstances and the requirements of the body granting recognition.

8.2 The inspection body, the certification body, and any other body involved which has legitimate access to the records shall ensure that at all times such records are maintained confidential and secure for an appropriate period.

9 Report

9.1 The work carried out by the inspection body shall be covered by a report to its clients which shall be in accordance with the rules of the body granting recognition and which accurately, clearly and unambiguously conveys the results of the investigation.

9.2 All reports should normally be approved or reviewed by inspection bodies staff at appropriate supervisory level.

9.3 The inspection body, the certification body and any other body involved which has legitimate access to the reports shall ensure that at all times such reports are maintained confidential and secure for an appropriate period.

10 Confidentiality and security

10.1 The inspection body shall be willing to observe terms and conditions to provide for confidentiality and security of its practices as required by the users of its services.

10.2 Inspection bodies may in the course of their duties receive information such as manufacturing processes, market information, volume or value of production, which is of a secret nature or confidential. It is of the greatest importance that this confidentiality is respected at all times and is the subject of a clear understanding between the body granting recognition, the inspection body and the manufacturer subject to inspection.

10.3 All inspection staff shall be made aware of the need for confidentiality and security of their work. The distribution of confidential information within the staff shall be limited to those persons whose job requires that they have such information.

10.4 All staff engaged on the job of inspection shall be issued with positive distinct identification.

11 Facilities

Suitable and adequate facilities shall be maintained at the inspection body to permit all needed activities associated with inspection services to be carried out, e.g. offices, typing, check testing, storage of samples from factory visits and the market place.

12 Additional requirements to be met by the inspection body

12.1 Inspection bodies shall themselves normally perform the inspection which they contract to undertake. Where, exceptionally, an inspection body sub-contracts any part of the inspection, this work shall be placed with another inspection body complying with these requirements. The inspection body shall ensure and be able to demonstrate that his sub-contractor is competent to perform the services in question and complies with the same criteria of competence and, where applicable, the same regulations as the inspection body in respect of the work being sub-contracted. The inspection body shall advise the client of its intention to sub-contract any portion of the inspection to another party. The sub-contractor shall be acceptable to the body granting recognition.

12.2 The inspection body shall record and retain details of its investigation of the competence and compliance of its sub-contractors and maintain a register of all sub-contracting. These details shall be available on demand to the body granting recognition or its representative.

12.3 The inspection body shall afford the client or his representative reasonable co-operation to enable him to monitor the performance of the inspection in relation to his contract.

12.4 The inspection body shall afford the body granting recognition and its representatives such reasonable co-operation as necessary, to enable the body granting recognition to monitor compliance with these requirements and other criteria.

12.5 A recognized inspection body shall

a) at all times comply with these requirements and with other criteria prescribed by the body granting recognition;

b) claim that it is recognized only in respect to inspection services for which it has been granted recognition and which are carried out in accordance with these requirements and other criteria prescribed by the body granting recognition;

c) pay such fees for application, membership, assessment, surveillance and other services as shall be from time to time determined by the body granting recognition having regard to the costs involved;

d) not use its recognition in such manner as to bring the body granting recognition into disrepute and shall not make any statement relevant to its authority which the body granting recognition may reasonably consider to be misleading;

e) upon the termination of its recognition (however determined) forthwith discontinue its use and all advertising matters which contain any reference thereto;

f) make it clear in all contracts with its clients that the inspection body's recognition or any of its inspection reports by themselves in no way constitute nor imply product or system approval by the body granting recognition or by any other body;

g) endeavour to ensure that no inspection report nor any part thereof shall be used by a client, or be authorized by a client for use, for promotional or publicity purposes, if the body granting recognition may reasonably consider such use to be misleading.

12.6 In making reference to its recognition status in communication media such as documents, brochures or advertising, the inspection body shall use only the following phrase as appropriate : "an inspection body recognized by [body granting recognition] for the inspection of (product, services or field of inspection for which recognition has been granted) identified by registration number(s) ...*"

The inspection body shall, upon withdrawal of recognition, take steps to ensure that no further use or reference occurs.

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* Optional with the body granting recognition.

ANNEX TO ISO/IEC GUIDE 39 - 1983

Information recommended to be provided by the inspection bodies

A Introduction and instructions

A.1 This document together with a contract will form the basis under which inspection/surveillance visits will be carried out.

A.2 All sections of this document should be completed and supplements should be included where it is necessary.

A.3 The statements should relate to the facilities available at the date of completion of this form.

B General

B.1 Inspection body's name and address :

.....

Telephone : .....

Telex : .....

B.2 The inspection body should appoint a person who will be the contact with the body granting recognition and shall also appoint other persons who may be contacted in absence of main appointee.

Nominee and title : .....

Deputies : .....

B.3 State if inspection body is recognized nationally/internationally.

.....

B.4 Detail any existing recognitions by certification or other bodies.

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.....

B.5 Detail areas of technologies covered by above recognitions and indicate clearly those areas covered by this assessment.

.....

.....

B.6 Detail geographical areas covered by above recognitions and indicate clearly if any limitations exist in area of operation.

.....

.....

C Organization

C.1 Name technical manager(s) (however named) who has (have) overall responsibility for ensuring aims and criteria are met.

.....

C.2 Basic organization of inspection body

C.2.1 Describe how areas of technology are defined and made known to staff.

.....

C.2.2 Describe how staff are made aware of the extent and limits of their responsibilities.

.....

C.2.3 Describe how co-ordination of interpretation and operating procedures is observed.

.....

C.2.4 Describe how supervision of staff is achieved.

.....

C.2.5 Describe lines of demarcation between actual inspection operation and any auxiliary/unrelated functions.

.....

C.2.6 Give any other information on basic organizations.

.....

.....

C.3 Are appropriate technical and managerial staff under direct control of inspection body and are they appropriate to declared areas of technology — see B.5?

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.....

C.4 If inspection body is part of a larger organization, show its relationship to that organization.

.....

.....

C.5 How are staff protected from commercial or other influences?

.....

.....

C.6 State any other considerations affecting organization.

.....

.....

D Staffing

D.1 Total number of staff : .....

D.2 a) Provide organizational chart showing staff structure.

b) Provide list of job qualifications for each position shown on organizational chart.

c) List under appropriate job those persons who exercise supervision of the functions shown on the organizational chart.

D.3 Identify any staff with responsibilities for assessment and/or recommending acceptance or subsequent supervision of manufacturer's quality control who have less than two years practical experience in quality assurance.

.....

D.4 Indicate extent of non-qualified staff and describe how supervision of this category of staff is achieved.

.....

D.5 Language — are staff fluent in ... [language to be specified by body granting recognition]? If not, do adequate interpretation/translation facilities exist?

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E Records and reports

E.1 Indicate documentation used by inspection body, methods of scheduling inspection visits.

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E.2 How are records maintained?

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E.3 Indicate report format to be used.

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E.4 Designate staff having responsibility for signing inspection reports.

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.....

F Confidentiality and security

F.1 Are staff made aware of confidentiality affecting their work? .....

F.2 Are staff assessed for their security rating? Is there a security bond or clauses in contracts covering security?

.....

F.3 What actions are taken in respect of security and confidentiality of documentation relating to any sub-contract work?

.....

F.4 Are staff issued with an identification card or equivalent means of identification by the inspection body?

.....

G Other requirements

G.1 Does inspection body accept that there will be supervision and monitoring on a continuing basis by the body granting recognition?

.....

G.2 Detail any other considerations which may have a bearing on the recognition of the inspection body, such as possible reciprocal agreements, local legal or operating practices and the like.

.....

.....

H Authentication

The information contained in this declaration is true and accurate.

Name of inspection body : .....

Date : .....

Authorized officer : .....
(Signature) (Title)

ISO/IEC GUIDE 40 - 1983

General requirements for the acceptance of certification bodies

This Guide is one of a series covering the requirements for the acceptance of testing laboratories (ISO/IEC Guide 38), the acceptance of inspection bodies (ISO/IEC Guide 39) and the acceptance of certification bodies themselves (ISO/IEC Guide 40).

1 Scope and field of application

1.1 The object of this Guide is to set forth criteria, the observance of which is intended to ensure that certification bodies possess the necessary competence and reliability to operate a third-party certification system and thereby facilitate their acceptance or recognition on a national or international basis.

1.2 The Certification Body may operate its own testing and inspection activities or oversee these activities carried out on its behalf by other bodies.

2 References

ISO Guide 2, *General terms and their definitions concerning standardization, certification and testing laboratory accreditation.*

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

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

3 Definitions

The relevant definitions contained in ISO Guide 2 are applicable.

4 General requirements

4.1 The Certification Body shall be able to provide procedures and perform the functions specified in ISO/IEC Guide 28 and ISO Guide 27.

4.2 Access to the services of the Certification Body shall not be conditional upon membership in any association or group, nor shall there be undue financial conditions to restrict participation. The procedures under which the body operates shall be administered in a non-discriminatory manner.

5 Administrative structure

The Certification Body shall have

a) a structure which permits the choosing of members of the governing board from among those interests involved in the process of certification without any single interest predominating;

b) a permanent staff under the senior full-time executive responsible to the governing board to carry out the day-to-day operations in such a way as to be free from control by those who have a direct commercial interest in the products or services being certified.

6 Terms of reference of the governing board

The governing board shall be responsible for

a) the formulation of policy matters relating to the operation of the Certification Body;

b) an overview of the implementation of its policies;

c) an overview of the finances of the Certification Body;

d) the setting up of committees as required, to which defined activities are delegated.

7 Organization structure

The Certification Body shall have and make available on request

a) an organization chart showing clearly the responsibility and reporting structure of the organization;

b) a description of the means by which the organization obtains financial support;

c) a documented statement of its certification systems (including its rules and procedures for obtaining certification), which shall be in accordance with ISO/IEC Guide 28;

d) documentation clearly identifying its legal status.

8 Staff instructions

The staff of the Certification Body shall have available to them clear documented instructions pertaining to their duties and responsibilities. These instructions shall be maintained up to date.

9 Documentation and change control

The Certification Body shall maintain a system for the control of all documentation relating to the certification system such as

a) to ensure that the current issues of the appropriate documentation is available at all relevant locations;

b) to ensure that all changes of documents or amendments to documents are covered by the correct authorization and processed in a manner which will ensure direct and speedy action at the effective point;

c) to ensure that superseded documents are removed from use throughout the organization and its agencies;

d) to ensure that licensees and other users or participants in its certification schemes are notified of changes*.

10 Records

The Certification Body shall maintain records to demonstrate the way in which each certification procedure was applied including test and inspection reports (see clause 11).

The records shall be retained for a pre-determined period and shall be available to those persons whom it is considered by the Certification Body to have a right of access to these records.

* This may be accomplished by direct mailing or by issuance of a periodic publication.

11 Testing and inspection facilities required by the Certification Body

11.1 When the Certification Body operates its own testing and inspection activities, these activities shall conform to the relevant clauses of the documents for the acceptance of testing and inspection bodies (ISO/IEC Guides 38 and 39).

11.2 Where testing and inspection are carried out on its behalf by external bodies, the Certification Body shall ensure that these bodies conform to the requirements of the documents mentioned in 11.1.

12 Confidentiality

The Certification Body shall ensure the confidentiality of its activities and those of the testing and inspection bodies it commissions.

13 Publications

13.1 The Certification Body shall publish and update as necessary a Directory of certified products. Each product mentioned in the list shall be accompanied by identification of the licensee. The list shall be available to the public.

13.2 A description of the certification system(s) shall be available in published form.

14 Appeals

The Certification Body shall have provision for the consideration of appeals against its decisions.