



GUIDE 39

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General requirements for the acceptance of inspection bodies

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Foreword

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GUIDE 39-1983 (E)

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 activities, 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.

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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.

* Optional with the body granting recognition.

Annex

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 :

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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.

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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.

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

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C Organization

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

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C.2 Basic organization of inspection body

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

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

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

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C.2.4 Describe how supervision of staff is achieved.

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

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C.2.6 Give any other information on basic organizations.

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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.

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

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C.6 State any other considerations affecting organization.

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D Staffing

D.1 Total number of staff :

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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.

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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?

E Records and reports

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

E.2 How are records maintained?

E.3 Indicate report format to be used.

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

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?