



GUIDE 39

**General requirements for the
acceptance of inspection bodies**

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Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) together form a system for worldwide standardization as a whole. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work.

This second edition of Guide 39 was drawn up by the ISO Committee on conformity assessment, ISO/CASCO. It was approved by the IEC Council in August 1988 and by the ISO Council in September 1988.

The documents produced by CASCO are issued as Guides and follow the general rules for development and promulgation of ISO and IEC standards except that they are the result of a consensus reached within a Council committee, endorsed by the ISO Council and the IEC Council.

The work of ISO/CASCO in preparing Guides relating to certification, assessment and testing, uses as a basis the principles established in ISO/IEC Guide 16, *Code of principles on third party certification systems and related standards*.

Guide 16 recognizes that third party certification systems should, to the extent possible, be based on internationally agreed standards and procedures. While recognizing the major role of manufacturers' declaration of conformity through normal manufacturer/customer relationship, Council resolutions have emphasized the preparation of guidance documents on third party certification and assessment procedures in order that national systems may be compatible with one another so as to facilitate bilateral and multilateral agreements.

Whilst these documents are intended to provide guidance, it is hoped that any changes from the documents made in introducing systems nationally would be minimal. In recognizing that some countries may choose to adopt the Guides directly,

they are written to enable this to be done by including words such as "shall" to indicate those aspects which desirably would be mandatory. The overriding basis that the document is intended to provide guidance holds good.

While this emphasis on creating the infrastructure for mutual recognition covers most of the work of ISO/CASCO, notice has to be taken that a further objective is to create the basis for an international certification system in due course, if found to be required. Some ISO/CASCO documents relate to the development of rules for such a system.

It is recognized that there are already well established certification systems, e.g. in the electrotechnical field, which have been developed with the aim of facilitating trade and which are functioning satisfactorily in the spirit of relevant ISO/IEC Guides.



Introduction

Inspection is an important component, associated with other activities, including certification, that assists 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.

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General requirements for the acceptance of inspection bodies

1 Scope

This Guide sets out general criteria, the observance of which is intended to provide that the services of inspection bodies are conducted with technical competence, impartiality, confidentiality and thoroughness, careful observation and accurate reporting by competent qualified staff, and to serve the needs of individual users, national government, local government, certification, accreditation and other bodies, as they relate to certification and related activities.

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 References

ISO/IEC Guide 2 : 1986, *General terms and their definitions concerning standardization and related activities*.

ISO 8402 : 1986, *Quality — Vocabulary*.

3 Definitions

3.1 The relevant definitions contained in ISO/IEC Guide 2 and ISO 8402 are applicable.

3.2 For the purposes of this guide, the following definitions are also applicable.

3.2.1 inspection body : Third party impartial body having the organization, staffing, competence and integrity to perform inspection services to specified criteria. Inspection services are understood to include such functions as assessing, recommending for acceptance and subsequent audit of suppliers' production and testing facilities, personnel and quality control operations, and selection and evaluation of products on site or in factories, laboratories or elsewhere as directed.

3.2.2 client : Any party which employs an inspection body for any purpose. This term can thus refer to a commercial customer or to a certification body who uses the services of the inspection body.

4 Organization and operational procedures¹⁾

4.1 An inspection body shall

- a) be legally identifiable;
- b) have an organizational structure that enables it to maintain the capability to perform its technical functions satisfactorily;
- c) have a technical manager and a deputy, however named, who are appropriately qualified and experienced in the operation of the inspection body and who have overall responsibility for ensuring that the specified objectives and the criteria contained herein are met;
- d) clearly define the areas of technology to be covered by its inspection services and for which it is qualified;
- e) be able to demonstrate, on request, that it is capable of providing the required inspection services;
- f) be so organized as not to subject staff members to undue pressure or inducement that might influence their judgement or the results of their work;
- g) have no commercial interest, nor be part of an organization having direct commercial interest in the product, process or service to be inspected;
- h) not engage in, or have engaged in, any consultancy service that conflicts with its role as an inspection body.

4.2 An inspection body shall have procedures for

- a) clear demarcation between actual inspection services and any certification, auxiliary or unrelated functions;
- b) limiting its activities, while performing an inspection, to those functions for which it is specifically directed;

1) A recommended format for providing information on the inspection body is given in annex B, which is not an integral part of this Guide.

- c) ensuring that inspection procedures and other matters are continuously co-ordinated with the certification body or others using the services of the inspection body;
- d) ensuring that the integrity of inspection results and procedures are not compromised by external relationships;
- e) dealing with feedback and corrective action whenever inspection discrepancies are detected;
- f) dealing with technical complaints;
- g) the consideration and resolution of appeals against its decisions.

4.3 The inspection body may also be required to provide information on items such as

- a) if formal recognition is sought, the history of the inspection body's experience in the area for which recognition is sought;
- b) the geographical area currently served by the inspection body and the categories of clients which use its services, e.g. suppliers, government agencies, etc.;
- c) any other technical services provided by the inspection body in the areas for which it seeks recognition;
- d) if formal recognition is sought, details of recognition granted by other bodies to the inspection body;
- e) the ownership of the inspection body;
- f) the qualification of its managers and staff.

5 Quality system

5.1 The inspection body shall operate an effective internal quality system appropriate to the type, range and volume of work performed.

The quality system shall address all of the criteria contained in this Guide and shall be documented. The documentation shall be available for use by the staff of the inspection body. It shall be maintained relevant and current by a responsible member of the staff. A person or persons having responsibility for quality assurance within the inspection body shall be designated by the management of the inspection body and shall have direct access to top management.

5.2 The quality system shall be systematically and periodically audited and reviewed by or on behalf of management to ensure the effectiveness of the arrangements. Such audits and reviews shall be recorded together with details of any action taken.

5.3 The inspection body shall maintain a system for control of all documentation relating to its quality system so as

- a) to ensure that the current issues of the appropriate documentation are available at all relevant locations and to all relevant staff;

- 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 notify relevant parties of significant changes.

6 Staff

6.1 The inspection body shall have sufficient staff to carry out the work for which it claims to be competent. The staff shall have the necessary education, up-to-date training, technical knowledge and experience for their assigned functions, and shall be subject to effective supervision.

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

- a) qualified in appropriate disciplines;
- b) suitably experienced in the practical application of quality assurance, inspection techniques and production methods.

6.3 Staff having responsibility for subsequent monitoring of a supplier's quality assurance system, if not professionally or academically qualified, shall be supervised by qualified staff, and the requirements of 6.2a) shall be met. The proportion of such staff to qualified staff shall be such as not to degrade the work undertaken.

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

6.5 Remuneration of staff shall not be influenced by the frequency or the results of inspections.

6.6 There shall be a job description for each technical position category, which includes the necessary requirements for education, training, technical knowledge and experience.

7 Inspection methods and procedures

7.1 The inspection body shall use methods and procedures detailed in the requirements against which the inspection is to be performed. The requirements shall be available to staff performing the inspection.

7.2 The inspection body shall have and use adequate documented instructions on standard sampling and inspection techniques, where the absence of such instructions could jeopardize the efficacy of the inspection process. All instructions, standards or written procedures, worksheets, check lists and reference data relevant to the work of the inspection body shall be maintained up-to-date and be readily available to the staff.

7.3 When it is necessary to use methods and procedures which are not as required, any deviations, additions to or exclusions from the requirements shall be recorded.

8 Handling of samples

8.1 A system for identifying samples shall be applied, either through documents or through marking, to ensure that there can be no confusion regarding the identity of the samples or items.

8.2 A procedure shall exist for bonded storage of items when necessary.

8.3 At all stages of storing, handling and preservation of samples, precautions shall be taken to prevent damage to the items, for example by contamination, corrosion or the application of stresses, any of which would invalidate the later test or inspection results. Any relevant instructions provided with the item shall be observed.

8.4 There shall be clear rules for the receipt, retention and disposal of samples.

9 Financial stability

The inspection body shall be financially sound.

10 Communication capability

The inspection body shall be able to communicate effectively with the users of its services in the relevant geographical area. Where required, competency in appropriate languages, including translation facilities, shall be demonstrated.

11 Records

11.1 The inspection body shall maintain a record system to suit its particular circumstances and the requirements of other bodies with which it has contractual relationships involving inspection.

11.2 The inspection body shall retain on record all inspection reports, original observations, calculations and derived data and the final inspection report for a predetermined period.

The records for each inspection shall contain sufficient information to permit satisfactory repetition of the inspection.

NOTE — In some countries it may be necessary to maintain records for a period specified by law.

11.3 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.

12 Report

12.1 The work carried out by the inspection body shall be covered by a report to its clients which shall be in accordance with the requirements of the body utilizing its services and which accurately, clearly and unambiguously conveys the results of the investigation. All reports shall carry a distinctive identification.

12.2 All reports should normally be approved or reviewed by the inspection body's staff at an appropriate supervisory level.

12.3 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.

12.4 Consistent with the wishes of the party utilizing the services of the inspection body, particular care shall be given to the arrangement of inspection reports, especially with regard to the presentation of the inspection data and ease of assimilation by the reader. The format shall be specifically designed for each type of inspection carried out.

12.5 Corrections or additions to an inspection report after issue shall be made only by a further document suitably marked, e.g. "Supplement to inspection report serial number . . .".

13 Confidentiality and security

13.1 The inspection body shall have adequate security rules and measures for the protection of proprietary rights and confidential information.

13.2 The inspection body shall be willing to observe terms and conditions to provide for confidentiality and security of its practices as required by its clients.

13.3 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 be respected at all times and be subject to a clear understanding between the inspection body, its clients and the manufacturer subject to inspection.

13.4 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.

13.5 All staff engaged in field inspection work shall be issued with positive distinct identification.

14 Facilities and equipment

14.1 The inspection body shall have suitable and adequate facilities and equipment to permit all needed activities associated with the inspection services to be carried out.

14.2 The inspection staff shall, when applicable, be furnished with the equipment required for the performance of their services.

15 Sub-contracting

15.1 Inspection bodies shall themselves normally perform the inspection which they contract to undertake.

When an inspection body sub-contracts any part of the inspection, it shall ensure that its responsibilities and obligations for the inspection conducted on its behalf are fully met. The inspection body shall ensure and be able to demonstrate that its sub-contractor is competent to perform the services in question and where applicable complies with the criteria stipulated in this guide and with any additional requirements for the work being sub-contracted.

The inspection body shall advise and obtain agreement from its clients of its intention to sub-contract any portion of the inspection.

15.2 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 subcontracting. These details shall be available on demand to the body granting recognition.

16 Co-operation

16.1 The inspection body shall afford the client reasonable co-operation to enable him to monitor the performance of the inspection in relation to its contract.

16.2 The inspection body shall afford the body with which it has contractual relations involving inspection services such reasonable cooperation as necessary to assure compliance with these requirements and other criteria.

17 Formal recognition

Information regarding issuance of formal recognition of inspection bodies is contained in Annex A.

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Annex A

Recommendations for formal recognition of inspection bodies

A.1 As used here "recognition" signifies a formalized judgement granted by another body that the inspection body has demonstrated an acceptable level of competence in providing the inspection services identified in the recognition and further has entered into a written agreement to comply with the requirements of this Guide and all other requirements of the body granting recognition.

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

A.2 The following additional requirements shall be met by inspection bodies seeking recognition :

- 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 a manner as to bring the body granting recognition into disrepute and 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 or imply product or system approval by the body granting recognition or by any other body;

g) endeavour to ensure that no inspection report or 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.

A.3¹⁾ In making reference to its recognition status in communication media such as documents, brochures or advertising, the inspection body shall use 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) ...".

A.4¹⁾ The inspection body shall require that its clients who refer to use of a recognized inspection body shall use the following phrase as appropriate : "Inspected by [name of inspection body] which is recognized by [body granting recognition] for the inspection services described herein and identified by registration number(s) ...".

A.5 The body granting recognition shall be notified by the inspection body of any changes bearing on its competence with these requirements and other criteria affecting the inspection body's capability or scope of activity.

1) Inclusion of this clause is at the discretion of the body granting recognition.

B.3.7 Is there a prescribed system for detecting deficiencies in inspection and their cause, and for correcting unfavourable trends?

B.3.8 State any other considerations affecting organization.

B.4 Quality system

B.4.1 Name person responsible for the co-ordination of the quality system of the inspection body.

B.4.2 Are policy and procedures for the operation of the inspection body documented?

B.4.3 Have the persons responsible for quality management the responsibility and authority to identify quality problems and initiate effective solutions?

B.4.4 Does the documentation contain procedures for the supervision of any unqualified staff?

B.4.5 Is there a prescribed audit procedure for checking quality management functions?

B.5 Staffing

B.5.1 Total number of staff :

B.5.2 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.

B.5.3 Indicate practical experience in quality assurance of staff with responsibilities for assessment and/or recommending acceptance or subsequent supervision of manufacturer's quality control.

B.5.4 Indicate extent of non-qualified staff and describe how supervision of this category of staff is achieved.

B.5.5 Language — are staff fluent in (language to be specified by body granting recognition)? If not, do adequate interpretation/translation facilities exist?

B.5.6 Are training methods applied to attain and maintain skills with due attention to quality requirements?

B.6 Inspection methods and procedures

B.6.1 Are manuals, work instructions, regulations, standards, work sheets, check lists, etc. to be used by staff readily available?

B.6.2 Is there a system for updating, implementing and recording changes to these documents?

B.6.3 Are documents, including work sheets and check lists, available for each type of inspection work performed by the inspection body?

B.6.4 Are documents and reference data maintained in an up-to-date condition?

B.6.5 Is obsolete data promptly removed from documents, etc.?

B.6.6 Are there clearly documented procedures for the inspection work?

B.6.7 Are inspection methods and procedures recorded which are not called up in specifications, manuals, etc.?

B.7 Handling of samples

B.7.1 Are work and sampling instructions prescribed and implemented for the selection, preparation, handling, marking, storing and dispatch of samples?

B.7.2 Are appropriate storage areas arranged to prevent deterioration or damage to the items concerned?

B.7.3 Are storage methods prescribed, including special environments?

B.7.4 Are there procedures for the inspection of samples in storage?

B.7.5 Are storage areas accessible only to authorized persons?

B.7.6 Is provision made to ensure that all samples to be stored, packed or dispatched to testing laboratory or elsewhere are adequately identified and labelled?

B.8 Records and reports

B.8.1 Indicate documentation used by inspection body and the methods of scheduling inspection visits.

B.8.2 Are observations and calculations recorded and stored as to provide a permanent inspection record?

B.8.3 Are there arrangements for ensuring that records are current, complete, accurate and held confidential where required?

B.8.4 How are records maintained?

B.8.5 Indicate report format to be used.