

ISO/IEC Guide 65
Compliance Audit Checklist / Working Document

4. Certification Body

4.1 General Provisions

4.1.1

Do the applicant's procedures support nondiscrimination?

Guidance: Look for nondiscrimination statement or artificial barriers to certification.

Are procedures used to impede access by applicants other than as provided under Guide 65?

4.1.2

Are services available to all applicants whose activities fall within the declared scope of operation?

Are there any apparent undue financial or other considerations?

Is access to services conditional upon the size of the supplier or membership in any association or group?

Is certification conditional upon the number of certificates already issued?

4.1.3

Are evaluation criteria as outlined in specified standards?

Guidance: Note referenced standards.

If applicable, are explanatory documents formulated by relevant and impartial committees or persons possessing the necessary technical competence?

If applicable, are explanatory documents published by the certification body?

4.1.4

Are requirements, evaluation and decisions regarding certification confined to matters specifically related to the scope of the certification being considered?

4.2 Organization

4.2.a

Does the structure of the organization allow it to make impartial evaluations and certification decisions?

4.2.b

Is the organization responsible for making decisions relating to granting, maintaining, extending, suspending and withdrawing of certification?

4.2.c.1

Is there a management committee, group or person identified as responsible for the performance of testing, inspection, evaluation and certification as defined in Guide 65?

Guidance: [Hard element. See management responsibilities.](#)

4.2.c.2

Is there a management committee identified as responsible for formulation of policy matters relating to the operation of the certification body?

Guidance: [Hard element. See management responsibilities.](#)

4.2.c.3

Is there a management committee identified as responsible for decisions on certification?

Guidance: [Hard element. See management responsibilities.](#)

4.2.c.4

Is there a management committee identified as responsible for supervision of policy implementation?

Guidance: [Hard element. See management responsibilities.](#)

4.2.c.5

Is there a management committee identified as responsible for supervision of the finances of the body?

Guidance: [Hard element. See management responsibilities.](#)

4.2.c.6

Is there a management committee identified as responsible for delegation of authority to committees or individuals as required to undertake defined activities on its behalf?

Guidance: [Hard element. See management responsibilities.](#)

4.2.c.7 Is there a management committee identified as responsible for defining the technical basis for granting certification?

Guidance: [Hard element. See management responsibilities.](#)

4.2.d

Does the applicant have documents that demonstrate it is a legal entity?

Guidance: [Hard element. Ask to see article of incorporation, business licenses, etc.](#)

4.2.e

Is there a documented structure that safeguards impartiality?

Guidance: [Hard element. See organization chart or other structure document.](#)

Does the structure of the body enable the participation of all parties significantly concerned in the development of policies and principles regarding the content and function of the certification system?

4.2.f

Is the decision on certification different than that person who conducted the evaluation?

Guidance: [See separation of responsibilities and identify as separate entities.](#)

4.2.g

Does the applicant have rights and responsibilities relevant to its certification activities?

4.2.h

Does the applicant have arrangements to cover its liabilities arising from its operations and/or certification activities?

Guidance: [Hard item. See liability insurance policy or statement of self-insurance.](#)

4.2.i

Does the applicant have the financial stability and resources required for the operation of a certification system?

Guidance: Ask to see financial statements/balance sheets and discuss financial logistics.

4.2.j

Does the applicant employ a sufficient number of qualified people for performing the volume, type, and range of work performed?

Guidance: Hard item. Check personnel rosters and dossiers.

4.2.k

Does the applicant have a quality system giving confidence in its ability to operate a certification system?

Guidance: Hard item. Review quality manual.

4.2.l

Does the applicant have policies and procedures that distinguish between product certification and other activities the applicant performs?

Guidance: Hard item. Review organizational chart or other document showing segregation of activities.

4.2.m

Is the organization free from commercial, financial or other pressures that may influence the results of its certification process?

Guidance: Note conflicting activities or apparent conflicts of interest.

4.2.n

Does the applicant have formal rules and policies for the appointment and operation of committees involved with the certification process?

Guidance: Hard item. See rules for appointing committee. Rules must support balance of interests.

Are committees free from commercial, financial, or other pressures that might influence decisions?

Guidance:

4.2.o

Does the applicant ensure that activities of related bodies do not affect the confidentiality, objectivity, and impartiality of its certifications?

Guidance: Check for conflicts of interest or potential sources of bias.

4.2.o.1

Does the applicant supply or design products of the type it certifies?

4.2.o.2

Does the applicant give advice or provide consultancy services to the applicant as to methods of dealing which are barriers to certification?

Guidance: Ask about consulting service policies or see non-consultancy policy.

4.2.o.3

Does the applicant provide any other products or services that could compromise the confidentiality, objectivity or impartiality of its certification process or decisions?

Guidance: Check for conflicts of interest or potential sources of bias.

4.2.p

Does the applicant have policies and procedures for the resolution of complaints, appeals and disputes received from suppliers or other parties about the handling of certification or any other related matters?

Guidance: Hard item. See appeals procedures. Review history of appeals and complaints and verify effective resolution.

4.3 Operations

Does the certification body take all steps necessary to evaluate conformance with the relevant product certification system?

Guidance: Observe performance or records of performing tests referenced in program testing manual.

Does the certification body specify relevant standards or parts thereof that form the basis for the applicable certification system?

When appropriate, does the applicant observe the requirements for the suitability and competence of bodies or persons carrying out testing, inspection and certification/registration as specified in ISO guides 25, 39 and 62?

4.4 Subcontracting

Are arrangements for subcontracting properly documented in agreements?

Guidance: Hard item. See agreements or contracts. Ensure all required issues are addressed and decision authority is retained.

4.4.a

Does applicant take full responsibility for subcontracted work?

Guidance: Hard item. See agreements or contracts. Ensure all required issues are addressed and decision authority is retained.

4.4.b

Does applicant ensure subcontracted body is competent and complies with the requirements of the guide?

4.4.c

Is there a signed agreement consenting to the subcontracting of services?

4.5 Quality System

4.5.1

Is the quality policy documented?

Guidance: Hard item. See quality policy statement.

Is the policy for quality understood at all levels?

Guidance: Interview personnel to determine level of understanding.

4.5.2

Is system effective and appropriate to the type, range, and volume of work?

Is there a designated person with direct access to the highest executive with the designated authority for (a) and (b) below?

Guidance: [Hard item. Identify quality system manager.](#)

4.5.2.a

Are all relevant elements of the guide established, maintained and implemented?

4.5.2.b

Is performance of the quality system reported to management to be incorporated into the quality system?

4.5.3

Is there a quality manual?

Guidance: [Review quality manual for all elements.](#)

4.5.3.a

Is there a quality policy statement?

Guidance: [Hard item.](#)

4.5.3.b

Is there a brief description of the legal status and ownership, including names of persons who own and control it?

Guidance: [Hard item.](#)

4.5.3.c

Are names, qualifications, and terms of reference of senior executives and other personnel listed?

Guidance: [Hard item.](#)

4.5.3.d

Is there an organizational chart showing lines of authority up to senior executive?

Guidance: Hard item.

4.5.3.e

Is there a description of the applicant's organization?

Guidance: Hard item.

4.5.3.f

Are there documented policies and procedures for management reviews?

Guidance: Hard item

4.5.3.g

Are there procedures for document control and other administrative procedures?

Guidance: Hard item.

4.5.3.h

Are all operational and functional duties and services that pertain to quality documented?

Guidance: Hard items.

4.5.3.i

Are there procedures for the recruitment, selection and training of certification body personnel?

Guidance: Hard item.

Are there procedures for monitoring their performance?

Guidance: Hard item.

4.5.3.j

Is there a list of approved subcontractors?

Is there a written procedure for assessing, recording, and monitoring their competence?

Guidance: Check quality system of subcontracted companies that may be referenced in the manual.

4.5.3.k

Are there procedures for handling nonconformities?

Are there procedures for assuring effectiveness of corrective/preventive actions?

Guidance: This pertains to internal quality, not of the certified suppliers.

4.5.3.1

Are there procedures for evaluating products and implementing the certification process?

Guidance: Hard item. Review certification procedures.

Are there written criteria for issue, retention and withdrawal of certification documents?

Guidance: Hard item.

Are there procedures for controlling use of certification documents.

Guidance: Review control of all documents and the use of certificates in marketing.

4.5.3.m

Are there policies for dealing with appeals, complaints and disputes?

Guidance: Hard item.

4.5.3.n

Are there procedures for conducting internal audits based on the provisions of ISO 10011-1?

Guidance: Copy of ISO 10011 not required, but procedures for internal audits should be comparable in nature to ISO 10011.

4.6 Conditions and procedures for granting, maintaining, extending, suspending and withdrawing certification?

4.6.1

Are conditions for granting, maintaining and extending certification specified?

Guidance: [Hard item.](#) [Review program approval criteria.](#)

4.6.2.a

Are there procedures for granting, maintaining, withdrawing, and suspending certification?

4.6.2.b

Are there procedures for extending or reducing the scope of the certification?

4.6.2.c

Are there procedures to reevaluate the program in the event of significant changes in program content, organizational structure, or management?

Guidance: [Hard item.](#) [Check procedures for reevaluation.](#)

4.7 Internal audits and management reviews

Are there plans to conduct internal audits?

Guidance: [Check internal audit procedures and schedule.](#)

4.7.1.a

Are personnel responsible for areas informed of the results of the internal audits?

4.7.1.b

Is corrective action taken in a timely manner?

4.7.1.c

Are the results of internal audits documented?

4.7.2

Are there procedures for the applicant's management to review the results of the quality system at intervals that are short enough to ensure continuing suitability?

Are there records of management reviews?

Guidance: Hard item. Review reports or minutes of meetings.

4.8 Documentation

4.8.1.a

Is there information about the authority under which the applicant operates?

4.8.1.b

Is there a documented statement of its certification system, rules, and procedures for granting, maintaining, extending, suspending and withdrawing certification?

Guidance: Hard items.

4.8.1.c

Is there information about the evaluation process related to each certification system?

Guidance: Hard item.

4.8.1.d

Is there a description of the means of financial support?

Guidance: Hard item.

4.8.1.e

Is there a description of the rights and duties of applicants regarding the use of the body's logo and ways to referring to certified status?

Guidance: Hard item.

Are requirements, restrictions and limitations clearly defined?

Guidance: [Hard item](#).

4.8.1.f

Is there information about procedures for handling complaints, appeals, and disputes?

Guidance: [Hard item](#).

4.8.1.g

Is there a directory of certified products and their suppliers?

Guidance: [Hard items](#).

4.8.2

Are there procedures to control all data and documents that relate to certification functions?

Guidance: [Hard item](#).

Are the procedures reviewed and approved by appropriately authorized and competent personnel?

Guidance: [Hard item](#).

Is there a list of documents and their appropriate version?

Guidance: [Hard item](#).

Is the distribution of documents controlled to ensure that the appropriate documentation is made available to personnel of the certification body?

4.9 Records

4.9.1

Does the record system meet its particular needs and comply with existing regulations?

Do records demonstrate the certification activities have been fulfilled?

Are records maintained for at least one full certification cycle or as required by law?

4.9.2

Are there policies and procedures for retaining records in compliance with contractual, legal, or other obligations?

Guidance: [Hard item.](#) [Review procedures.](#)

Is there a written policy and procedures concerning access to these documents?

Guidance: [Hard item.](#)

4.10 Confidentiality

4.10.1

Are there adequate arrangements to safeguard confidentiality of the information obtained in the course of its certification activities?

4.10.2

Are there policies requiring consent of the supplier to obtain permission prior to releasing information regarding a particular product or supplier?

Guidance: [Does not call for a particular document, but must somehow demonstrate the policy exists.](#)

5 Certification body personnel

5.1 General

5.1.1

Are personnel of the certification body competent for technical judgements, framing policies and implementing them?

Guidance: [Soft item.](#) [Review general backgrounds of key decision makers?](#)

5.1.2

Are there clearly documented instructions available to the personnel describing their duties and responsibilities?

Are these instructions maintained up to date?

5.2 Qualification criteria

5.2.1

Does the certification body define a minimum relevant criterion for the competence of the personnel?

5.2.2.a

Does the certification body require its personnel to sign an agreement in which they agree to comply with the rules of the certification body regarding confidentiality and conflicts of interests?

5.2.2.b

Does the certification body require its personnel to sign an agreement in which they declare any prior and/or present association with a supplier or designer of products for any evaluation or certification to which they are to be assigned?

5.2.3

Is information on each member of the certification staff maintained?

Are records of training and experience maintained regarding?

5.2.3.a

Name and address-

5.2.3.b

Organization affiliation and position held-

5.2.3.c

Educational qualification and professional status-

5.2.3.d

Experience and training in each field of the certification body's competence-

5.2.3.e

Date of most recent updating of records-

5.2.3.f

Performance appraisal-

6 Changes in the certification requirements

Does the body give due notice when making changes in its requirements?

Guidance: [Soft item. Check available historical documents.](#)

Does the body take into account the views expressed by interested parties before deciding on the precise form and effective date of changes?

Guidance: [Soft item.](#)

Does the body ensure each supplier makes appropriate change?

Guidance: [Soft item.](#)

7 Appeals, complaints, and disputes

7.1

Are appeals, complaints and disputes brought before the certification body by suppliers or other parties subject to the procedures of the certification body?

7.2.a

Are there records of all appeals, complaints and disputes and remedial actions?

7.2.b

Are there records of subsequent action?

7.2.c

Is the action taken and its effectiveness documented?

8 Application

8.1 Information on the procedure

Does the body provide detailed information relating to and descriptions of the evaluation and certification procedures?

8.1.2.a

Does the body require a supplier comply with all relevant provisions of the certification program?

8.1.2.b

Does the body require that a supplier make all necessary arrangements for the conduct of the evaluation?

8.1.2.c

Does the body require that the supplier make claims regarding certification only within the scope of the certified program?

8.1.2.d

Does the body require that the supplier not use its product certification in such a manner as to bring the body into disrepute or make misleading statements?

8.1.2.e

Does the body require that the supplier, upon suspension or cancellation of certification, discontinue its use of any advertising matter that contains any reference thereto and returns any certification documents as required by the certification body?

8.1.2.f

Does the body require that the supplier use certification only to indicate that products are certified as in conformity with specified standards?

8.1.2.g

Does the body endeavor to ensure no certificate is used in a misleading manner?

8.1.2.h

In referring to products, does the body require that the supplier comply with the requirements of the certifying body?

8.1.3

Is information on specific systems or types of systems operated by the applicant provided to the supplier when they are related to the applicant's scope of the certification?

Guidance: This item may relate to services provided by the body that relate to the scope of the supplier's system.

8.1.4

Is additional procedure provided when requested by the applicant?

Guidance: Soft item.

8.2 The application

Is there an official form signed by the duly authorized agent of the applicant?

Guidance: Hard item. Check application.

8.2.1.a

Does the application cover the scope of the certification?

8.2.1.b

Does the application include a statement that the applicant agrees to comply with the requirements for certification and supply any information needed for an evaluation of products to be certified?

8.2.2.a

On the application, does the applicant provide the corporate entity, name, address, and legal status?

8.2.2.b

On the application, does the applicant provide a definition of the products to be certified and the standards to which the products will be certified?

9 Preparation for evaluation

9.1.a

Before proceeding with evaluations, does the certification body conduct an evaluation, and maintain records, of a review of the application to ensure the requirements are clearly defined, documented, and understood?

9.1.b

Before proceeding with evaluations, does the certification body conduct an evaluation, and maintain records, of a review of the application to ensure any difference in understanding between the certification body and the applicant are resolved?

9.1.c

Before proceeding with evaluations, does the certification body conduct an evaluation, and maintain records, of a review of the application to ensure the certification body has the capability to perform the certification service with respect to the scope of the certification sought and if applicable, the location of the applicant's operations and any special requirements that must be met?

Guidance: Similar to contract review procedures in ISO 9000.

9.2

Does the certification body prepare a plan for its evaluation activities to allow for the necessary arrangements to be made?

9.3

Does the certification body assign appropriately qualified personnel for the specific evaluation?

Does the body ensure that the personnel assigned have not been involved with the design, supply, installation or maintenance of such products in a manner and within a time period which would conflict with impartiality?

9.4

Are certification personnel provided with appropriate working documents?

10 Evaluation

Does the certification body evaluate products -

- against the standards?

- covered in the scope?

- defined in its application?

- against all certification criteria specified in the rules of the scheme?

Guidance: Soft point. Observe evaluations as compared to above issues.

11 Evaluation report

Does the certification body have reporting procedures?

11.a

Does the report provide certification body with findings as to conformity with all requirements of certifications?

11.b

Do procedures ensure that the outcome of the evaluation is promptly brought to the applicants notice by the certification body?

Do the procedures ensure that the report identify any nonconformity that will have to be discharged in order to comply with the certification requirements?

Do the procedures ensure that the reports clearly state the extent of further evaluation or testing required?

12 Decision on certification

12.1

Are decisions made by the certification body based on information gathered during the evaluation process and other relevant information?

12.2

Does the certification body delegate authority for granting, maintaining, extending, suspending, or withdrawing certification to an outside person or body?

12.3.a

Does the certification body provide each supplier with an official certificate or letter signed by an officer who is assigned such responsibility?

Does the formal certification instrument include -

- the name and address of the supplier?

12.3.b.1

The scope of the certification, including products certified by type and range,

12.3.b.2

the product standards or other normative documents,

12.3.b.3

and the applicable certification system?

12.3.c

Does the certificate state the effective dates and term of the certification?

12.4

Does the certification body have procedures for determining approval of amendments?

13 Surveillance

13.1

Does the certification body have written surveillance procedures?

[Guidance: Hard item.](#)

13.2

Does the certification body require the supplier to inform it of changes cited in 4.6.2.c?

Does the certification body require withholding of products produced under the changed procedures pending review by the certification body?

13.3

Does the certification body document its surveillance report?

Guidance: [Hard item](#). [See surveillance reports](#).

13.4

Does the certification body, in the event of authorized ongoing approval, periodically evaluate the marked products to confirm that they continue to conform to the standards?

14 Use of licenses, certificates, and marks of conformity

14.1

Does the certification body exercise proper control over ownership, use and display of licenses, certificates and marks of conformity?

Guidance: [Soft item](#).

14.2

Guidance available from ISO/IEC Guide 23.

14.3

Are incorrect reference or misleading remarks related to the certification system dealt with by suitable action?

15. Complaints to suppliers

Does the certification body require suppliers to -

15.a

- keep a record of complaints to the supplier relating to a products compliance with requirements of the relevant standard and make those records available to the certification body upon request?

15.b

- take appropriate action with respect to such complaints and any deficiencies found in products or services that affect compliance with the requirements for certification?

15.c

- document actions taken?

Guidance: [Hard item](#).