



Standard Guide for General Requirements for Bodies Operating Assessment and Certification/Registration of Quality Systems¹

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INTRODUCTION

Certification/registration of a supplier's quality system is one means of providing assurance that the certified/registered supplier is capable of supplying products or services that meet specified requirements.

This guide specifies requirements, the observance of which is intended to ensure that certification/registration bodies operate third-party certification/registration systems in a consistent and reliable manner, thereby facilitating their acceptance on a national and international basis. This guide should serve as a foundation for the recognition of relevant national systems in the interests of international trade.

This guide is intended for use by bodies, however described, which carry out the functions of assessment and certification/registration of quality systems. For convenience of drafting, such bodies are referred to as *certification/registration bodies*. This wording should not be an obstacle to the use of this guide by bodies with other designations which undertake activities which it covers. Indeed, this guide should be usable by any body involved in quality system assessment.

The requirements contained in this guide are written, above all, to be considered as general requirements for organizations operating quality system certification/registration programs, therefore the requirements may have to be supplemented when specific industrial or other sectors, for example, health and safety, make use of it.

Quality system certification/registration involves only the assessment of a supplier's quality system and not the certification of products, processes, or service. Evidence of conformity to the appropriate quality system standard and any supplementary documentation will be in the form of a certification/registration document or a quality system certificate.

While this guide is intended for use by bodies concerned with recognizing the competence of certification/registration bodies, many provisions contained herein may be useful in second-party assessment procedure.

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1. Scope

1.1 This guide specifies general requirements for a third-party body operating quality system certification/registration to meet if it is to be recognized as competent and reliable in the operation of quality system certification/registration.

NOTE 1—In some countries, the bodies which verify conformity of quality systems to specified standards are called *certification bodies*, in others *registration bodies*, in others *assessment and registration bodies* or *certification/registration bodies* and in still others *registrars*. For ease of understanding, this guide always refers to such bodies as *certification/registration bodies*. This should not be understood to be limiting. The

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2. Referenced Documents

2.1 ISO Standards:²

- ISO/IEC Guide 2:1996 General Terms and Their Definitions Concerning Standardization and Related Activities
- ISO 8402:1994, Quality Management and Quality Assurance—Vocabulary
- ISO 9000–1:1994, Quality Management and Quality Assurance Standards—Part 1: Guidelines for Selection and Use
- ISO 9000–2:1993, Quality Management and Quality Assurance +s—Part 2: Generic Guidelines for the Application of ISO 9001, ISO 9002 and ISO 9003
- ISO 9000–3:1991, Quality Management and Quality Assurance Standards—Part 3: Guidelines for the Application of ISO 9001 to the Development, Supply, and Maintenance of Software
- ISO 9000–4:1993, Quality Management and Quality Assurance Standards—Part 4: Guide to Dependability Program Management
- ISO 9001:1994, Quality Systems—Model for Quality Assurance in Design, Development, Production, Installation, and Servicing
- ISO 9002:1994, Quality Systems—Model for Quality Assurance in Production, Installation and Servicing
- ISO 9003:1994, Quality Systems—Model for Quality Assurance in Final Inspection and Tests
- ISO 9004–1:1994, Quality Management and Quality System Elements—Part 7: Guidelines
- ISO 9004–2:1991, Quality Management and Quality System Elements—Part 2: Guidelines for Services
- ISO 9004–3:1993, Quality Management and Quality System Elements—Part 3: Guidelines for Processed Materials
- ISO 9004–4:1993, Quality Management and Quality System Elements—Part 4: Guidelines for Quality Improvements
- ISO 10005:1995, Quality Management—Guidelines for Quality Plans
- ISO 10007:1995, Quality Management—Guidelines for

- Configuration Management
- ISO 1001 1–1:1990, Guidelines for Auditing Quality Systems—Part 1: Auditing
- ISO 1001 1–2:1991, Guidelines for Auditing Quality Systems—Part 2: Qualification Criteria for Quality Systems Auditors
- ISO 1001 1–3:1991, Guidelines for Auditing Quality Systems—Part 3: Management of Audit Programs
- ISO 10012–1:1992, Quality Assurance Requirements for Measuring Equipment—Part 1: Metrological Confirmation System for Measuring Equipment
- ISO 10013:1995, Guidelines for Developing Quality Manuals

3. Terminology

3.1 *Definitions*—For the purposes of this guide, the relevant definition given in ISO/IEC Guide 2 and ISO 8402 and the following definitions apply:

3.1.1 *supplier, n*—the party that is responsible for the product, process, or service and is able to ensure that quality assurance is exercised. This definition may apply to manufacturers, distributors, importers, assemblers, service organizations, etc.

3.1.2 *certification/registration body, n*— a third party that assesses and certifies/registers the quality system of suppliers with respect to published quality system standards and any supplementary documentation required under the system.

3.1.3 *certificate/registration document, n*— document indicating that a supplier's quality system conforms to specified quality system standards and any supplementary documentation required under the system.

3.1.4 *certification/registration system, n*— system having its own rules of procedure and management for carrying out the assessment leading to the issuance of a certification/registration document and its subsequent maintenance.

4. Certification/Registration Body

4.1 General Provisions:

4.1.1 The policies and procedures under which the certification/registration body operates shall be nondiscriminatory, and they shall be administered in a nondiscriminatory manner. Procedures shall not be used to impede or inhibit access by applicants other than as specified in this guide.

4.1.2 The certification/registration body shall make its services accessible to all applicants. There shall not be undue financial or other conditions. Access shall not be conditional upon the size of the supplier or membership of any association or group, nor shall certification/registration be conditional upon the number of suppliers already certified/registered.

4.1.3 The criteria against which the quality system of an applicant is assessed shall be those outlined in the quality system standards or other normative documents relevant to the function performed. If an explanation is required as to the application of these documents to a specific certification/registration program, it shall be formulated by relevant and impartial committees or persons possessing the necessary technical competence and published by the certification/registration body.

² Available from American National Standards Institute, 11 W. 42nd St., 13th floor, New York, NY 10036

4.1.4 The certification/registration body shall confine its requirements, assessment, and decision on certification/registration to those matters related specifically to the scope of the certification/registration being considered.

4.2 *Organization*— The structure of the certification/registration body shall be such as to give confidence in its certifications/registrations. In particular, the certification/registration body shall do the following:

4.2.1 Be impartial;

4.2.2 Be responsible for its decisions relating to the granting, maintaining, extending, reducing, suspending, and withdrawing of certification/registration;

4.2.3 Identify the management (committee, group, or person) which will have overall responsibility for performance of assessment and certification/registration as defined in this guide, the formulation of policy matters relating to the operation of the certification/registration body, decisions on certification/registration, supervision of the implementation of its policies, supervision of the finances of the certification/registration body, and, delegation of authority to committees or individuals, as required, to undertake defined activities on its behalf.

4.2.4 Have documents, which demonstrate that it is a legal entity;

4.2.5 Have a document structure, which safeguards impartiality, including provisions to assure the impartiality of the operations of the certification/registration body; this structure shall enable the participation of all parties significantly concerned in the development of policies and principles regarding the content and functioning of the certification/registration system;

4.2.6 Ensure that each decision on certification/registration is taken by a person or persons different from those who carried out the assessment;

4.2.7 Have rights and responsibilities relevant to its certification/registration activities;

4.2.8 Have adequate arrangements to cover liabilities arising from its operations and/or activities;

4.2.9 Have the financial stability and resources required for the operation of a certification/registration system;

4.2.10 Employ a sufficient number of personnel having the necessary education, training, technical knowledge, and experience for performing certification/registration functions relating to the type, range, and volume of work performed, under a responsible senior executive;

4.2.11 Have a quality system, as outlined in 4.4, giving confidence in its ability to operate a certification/registration system for suppliers;

4.2.12 Have policies and procedures that distinguish between supplier certification/registration and any other activities in which the body is engaged;

4.2.13 Together with its senior executive and staff, be free from any commercial, financial, and other pressures, which might influence the results of the certification/registration process;

4.2.14 Have formal rules and structures for the appointment and operation of any committees, which are involved in the certification/registration process; such committees shall be free

from any commercial, financial, and other pressure that might influence decisions (see **Note 2**);

4.2.15 Ensure that activities of related bodies do not affect the confidentiality, objectivity, or impartiality of its certifications/registrations and shall not offer or provide those services that it certifies/registers others to perform, consulting services to obtain or maintain certification/registration, and services to design, implement or maintain quality systems (see **Note 3**); and,

4.2.16 Have policies and procedures for the resolution of complaints, appeals, and disputes received from suppliers or other parties about the handling of certification/registration or any other related matters.

NOTE 2—A structure where members are chosen to provide a balance of interests, where no single interest predominates, will be deemed to satisfy this provision.

NOTE 3—Other products, processes, or services may be offered, directly or indirectly, provided they do not compromise confidentiality or the objectivity or impartiality of its certification/registration process and decisions.

4.3 *Subcontracting*— When a certification/registration body decides to subcontract work related to certification/registration, for example, audits, to an external body or person, a properly document agreement covering the arrangements, including confidentiality and conflict of interests, shall be drawn up. The certification/registration body shall take full responsibility for such subcontracted work and maintain its responsibility for granting, maintaining, extending, reducing, suspending, or withdrawing certification/registration; ensure that the subcontracted body or person is competent and complies with the applicable provisions of this guide and is not involved, either directly or through its employer, with the design, implementation or maintenance of a quality system in such a way that impartiality could be compromised; and, obtain the consent of the applicant or certified/registered supplier.

NOTE 4—Requirements also are relevant, by extension, when a certification/registration body uses, for granting its own certification/registration, work provided by another certification/registration body with which it has signed an agreement.

4.4 *Quality System*— The management of the certification/registration body with executive responsibility for quality shall define and document its policy for quality, including objectives for quality and its commitment to quality. The management shall ensure that this policy is understood, implemented, and maintained at all levels of the organization. The certification/registration body shall operate a quality system in accordance with the relevant elements of this guide and appropriate to the type, range, and volume of work performed. This quality system shall be documented and the documentation shall be available for use by the staff of the certification/registration body. The certification/registration body shall ensure effective implementation of the documented quality system procedures and instructions. The certification/registration body shall designate a person with direct access to its highest executive level who, irrespective of other responsibilities, shall have defined authority to ensure that a quality system is established, implemented, and maintained in accordance with this guide; and, report on the performance of the quality system to the

management of the certification/registration body for review and as a basis for improvement of the quality system.

4.4.1 The quality system shall be documented in a quality manual and associated quality procedures, and the quality manual shall contain or refer to at least the following:

4.4.1.1 A quality policy statement;

4.4.1.2 A brief description of the legal status of the certification/registration body, including the names of its owners, if applicable, and if different, the names of the persons who control it;

4.4.1.3 The name, qualification, experience, and terms of reference of the senior executive and other certification/registration personnel influencing the quality of the certification/registration function;

4.4.1.4 An organization chart showing lines of authority, responsibility, and allocation of functions stemming from the senior executive, and in particular, the relationship between those responsible for the assessment and those taking decisions regarding certification/registration;

4.4.1.5 A description of the organization of the certification/registration body, including details of the management (committee, group, or person) identified in 4.2.3, its constitution, terms of reference and rules of procedure;

4.4.1.6 The policy and procedures for conducting management reviews;

4.4.1.7 Administrative procedures including document control;

4.4.1.8 The operational and functional duties and services pertaining to quality, so that the extent and limits of each person's responsibility are known to all concerned;

4.4.1.9 The policy and procedures for the recruitment and training of certification/registration body personnel, including auditors, and monitoring their performance;

4.4.1.10 A list of its subcontractors and details of the procedure for assessing, recording, and monitoring their competence;

4.4.1.11 Its procedures for handling nonconformities and for assuring the effectiveness of any corrective actions taken;

4.4.1.12 The policy and procedures for implementing the certification/registration process, including the conditions for issue, retention, and withdrawal of certification/registration documents, checks of the use and application of documents used in the certification/registration of quality systems, the procedures for assessing and certifying/registering suppliers' quality systems, the procedures for surveillance and reassessment of certified/registered suppliers;

4.4.1.13 The policy and procedure for dealing with appeals, complaints, and disputes; and

4.4.1.14 The procedures for conducting internal audits based on the provisions of ISO 10011-1.

4.5 *Conditions for Granting, Maintaining, Extending, Reducing, Suspending, and Withdrawing Certification/Registration :*

4.5.1 The certification/registration body shall specify the conditions for granting, maintaining, reducing, and extending certification/registration and the conditions under which certification/registration may be suspended or withdrawn, partially or in total, for all or part of the supplier's scope of

certification/registration. In particular, the certification/registration body shall require the supplier to notify it promptly of any intended changes to the quality system or other changes which may affect conformity.

4.5.2 The certification/registration body shall require the supplier to have a documented quality system which conforms to applicable quality system standards or other normative documents.

4.5.3 The certification/registration body shall have procedures to do the following:

4.5.3.1 Grant, maintain, withdraw, and, if applicable, suspend certification/registration;

4.5.3.2 Extend or reduce the scope of certification/registration; and

4.5.3.3 Conduct reassessment in the event of changes significantly affecting the activity and operation of the suppliers, such as change of ownership, changes in personnel or equipment, or if analysis of a complaint or any other information indicates that the certified/registered supplier no longer complies with the requirements of the certification/registration body,

4.5.4 The certification/registration body shall have documented procedures, which shall be made available on request for the initial assessment of a supplier's quality system, in accordance with the provisions of ISO 1001 1-1 and other relevant documents; surveillance and reassessment of supplier's quality systems in accordance with ISO 1001 1-1 on a periodic basis for continuing conformity with relevant requirements and for verifying and recording that a supplier takes corrective action on a timely basis to correct all nonconformities; and, identifying and recording nonconformities and the need for corrective action by suppliers on a timely basis for such items as incorrect references to the certification/registration or misleading use of certification/registration information.

4.6 *Internal Audits and Management Reviews:*

4.6.1 The certification/registration body shall conduct periodic internal audits covering all procedures in a planned and systematic manner, to verify that the quality system is implemented and is effective. The certification/registration body shall ensure that personnel responsible for the area audited are informed of the outcome of the audit; corrective action is taken in a timely and appropriate manner, and, the results of the audit are recorded.

4.6.2 The body's management with executive responsibility shall review its quality system at defined intervals sufficient to ensure its continuing suitability and effectiveness in satisfying the requirements of this guide and the stated quality policy and objective. Records of such reviews shall be maintained.

4.7 *Documentation:*

4.7.1 The certification/registration body shall document, update at regular intervals, and make available through publications, electronic media, or other means, on request, the following:

4.7.1.1 Information about the authority under which the certification/registration body operates;

4.7.1.2 A documented statement of its certification/registration system including its rules and procedures for