GUIDE 34

General requirements for the competence of reference material producers

Second edition 2000

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 734 10 79
E-mail copyright@iso.ch
Web www.iso.ch

Printed in Switzerland

Contents

Page

Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) form the specialized system for worldwide standardization. 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.

Guides are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

Draft Guides adopted by the responsible Committee or Group are circulated to national bodies for voting. Publication as a Guide requires approval by at least 75 % of the national bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this Guide may be the subject of patent rights. ISO and IEC shall not be held responsible for identifying any or all such patent rights.

ISO Guide 34 was prepared by the ISO Committee on Reference Materials (REMCO).

This second edition cancels and replaces the first edition (ISO Guide 34:1996), which has been technically revised.

Annex A of this Guide is for information only.

Introduction

The use of reference materials makes possible the transfer of the values of measured or assigned quantities between testing, analytical and measurement laboratories. Such materials are widely used for the calibration of measuring equipment and for the evaluation or validation of measurement procedures. In certain cases, they enable properties to be expressed conveniently in arbitrary units.

There is an increasing number of reference material producers, and a demonstration of their scientific and technical competence is now a basic requirement for ensuring the quality of reference materials. The demand for new reference materials of higher quality is increasing as a consequence of both the increased precision of measuring equipment and the requirement for more accurate and reliable data in the scientific and technological disciplines. Some previously acceptable reference materials may not meet these more stringent requirements. It is, therefore, not only necessary for reference material producers to supply information about their materials in the form of reports, certificates and statements, but also to demonstrate their competence in producing reference materials of appropriate quality.

The first edition of ISO Guide 34 set out specific guidelines on the interpretation of ISO/IEC Guide 25 and the ISO 9000 family of standards in the context of reference materials production. The more general requirements of these standards were omitted. Since the first edition of ISO Guide 34 was published in 1996, the assessment of the competence of reference material producers has gained considerable impetus. The present revision of Guide 34 now sets out all the general requirements in accordance with which a reference material producer has to demonstrate that it operates.

Pharmacopoeial standards and substances are established and distributed by pharmacopoeial authorities following the general principles of this Guide. It should be noted, however, that a different approach is used by the pharmacopoeial authorities to give the user the information provided by certificates of analysis and expiration dates. Also, the uncertainty of their assigned values is not stated since it is negligible in relation to the defined limits of the method-specific assays of the pharmacopoeias for which they are used.

General requirements for the competence of reference material producers

1 Scope

1.1 This Guide sets out the general requirements in accordance with which a reference material producer has to demonstrate that it operates, if it is to be recognized as competent to carry out the production of reference materials.

1.2 This Guide is intended for the use of reference material producers in the development and implementation of their quality system, and by accreditation bodies, certification bodies and others concerned with assessing the competence of reference material producers.

1.3 This Guide sets out the quality system requirements in accordance with which reference materials shall be produced. It is intended to be used as part of a reference material producer's general quality assurance (QA) procedures.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this Guide. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this Guide are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO/IEC Guide 2:1996, *Standardization and related activities — General vocabulary.*

ISO/IEC Guide 25:1990, *General requirements for the competence of calibration and testing laboratories.*

ISO Guide 30:1992, *Terms and definitions used in connection with reference materials.*

ISO Guide 31:1981, *Contents of certificates of reference materials.*

ISO Guide 35:1989, *Certification of reference materials — General and statistical principles.*

ISO 8402:1994, *Quality management and quality assurance — Vocabulary.*

ISO 10012-1:1992, *Quality assurance requirements for measuring equipment — Part 1: Metrological confirmation system requirements for measuring equipment.*

VIM:1993, *International vocabulary of basic and general terms in metrology* (issued by ISO, IEC, BIPM, IFCC, IUPAC, IUPAP and OIML).

3 Terms and definitions

For the purposes of this Guide, the terms and definitions given in ISO/IEC Guide 2, ISO/IEC Guide 25, ISO Guide 30, ISO 8402, VIM and the following apply.

3.1
reference material producer
technically competent body (organization or firm, public or private) that is fully responsible for assigning the certified or other property values of the reference materials it produces and supplies which have been produced in accordance with ISO Guides 31 and 35

3.2
collaborator
technically competent body (organization or firm, public or private) that undertakes aspects of the manufacture or characterization of the (certified) reference material on behalf of the reference material producer, either on a contractual (as a subcontractor) or voluntary basis

4 Organization and management requirements

4.1 Quality system requirements

4.1.1 General

The reference material producer shall establish, implement and maintain a quality system appropriate to the scope of its activities, including the type, range and magnitude of the reference material production it undertakes.

It should be recognized that a reference material needs to be characterized mainly to the level of accuracy required for its intended purpose (i.e. appropriate measurement uncertainty). The reference material producer shall describe the procedure for establishing the quality of materials as a component of the quality system.

Reference material producers shall define their scope in terms of the application, the measurement methods used in the homogeneity, stability and characterization studies, and any limitations due to the material matrix.

4.1.2 Quality policy

The reference material producer shall define and document its policy, objectives and commitment to ensuring and maintaining the quality of all aspects of reference material production, including material quality (e.g. homogeneity and stability), characterization (e.g. equipment calibration and measurement method validation), assignment of property values (e.g. use of appropriate statistical procedures) and material handling, storage and transport procedures.

The quality policy shall, when appropriate, include use of interlaboratory characterization studies employing laboratories which are active and competent in the respective field of measurement. In this context, the policy shall include a commitment to interact with the appropriate sectors of the measurement community, in order to prevent working in isolation. The policy shall also include a commitment to produce reference materials which conform to the definitions given in ISO Guide 30, characterized according to the requirements of ISO Guide 35 and whose property values are assessed using accepted statistical techniques. The policy shall, where appropriate, include a commitment to comply with ISO Guide 31 for the contents of reference material certificates and supply of associated information for users. It is important that the policy also specify the intended use of the reference materials, in order to ensure that the reference material producer fully advises the user for which types of application the materials may be used.

4.1.3 Quality system

The reference material producer shall establish, implement and maintain a documented quality system appropriate to the type, range and volume of reference material production it undertakes. The reference material producer shall document all of its policies, systems, programmes, procedures, instructions, findings, etc., to the extent necessary

to enable the producer to assure the quality of the reference materials produced. Documentation used in this quality system shall be communicated to, understood by, available to and implemented by all personnel concerned. In particular, the producer shall have a quality system that covers the following:

a) arrangements for ensuring the suitable choice (e.g. particle size range, concentration range, etc.) of the candidate reference materials;

b) preparation procedures;

c) achievement of the required degree of homogeneity of the reference material;

d) assessment of the stability of the reference material; including on-going assessment of stability where necessary;

e) procedures for undertaking characterization;

f) practical realization of traceability to national or international standards of measurement;

g) assignment of property values, including preparation of certificates or statements in accordance with ISO Guide 31 when appropriate;

h) arrangements for ensuring adequate storage facilities;

i) arrangements for suitable identification, labelling and packaging facilities, packing and delivery procedures and customer service;

j) compliance with ISO Guides 30, 31, 34 and 35.

The documented quality system should specify which activities are undertaken by the reference material producer and, where relevant, which activities are undertaken by collaborators. It shall include policies and procedures used by the producer to ensure that all activities conducted by collaborators comply with the relevant clauses of this Guide.

The documented quality system shall define the roles and responsibilities of the technical manager (however named) and quality manager, including their responsibilities for ensuring compliance with this Guide.

4.2 Organization and management

4.2.1 The reference material producer, or the organization of which it is part, shall be legally identifiable.

4.2.2 The reference material producer shall be organized and shall operate in such a way that it meets all the applicable requirements of this Guide, whether carrying out work in its permanent facilities or at sites (including associated temporary or mobile facilities) away from its permanent facilities (including work undertaken by collaborators).

4.2.3 The reference material producer shall:

a) have managerial personnel supported by technical personnel with the authority and resources needed to discharge their duties and to identify the occurrence of departures from the quality system or the procedures for the production of reference materials and to initiate actions to prevent or minimize such departures;

b) have arrangements to ensure that its management and personnel are free from any commercial, financial and other internal and external pressures that may adversely affect the quality of their work;

c) have policies and procedures to ensure the protection of its client's confidential information and proprietary rights;

d) have policies and procedures to avoid involvement in any activities that might diminish confidence in its competence, impartiality, judgement or operational integrity;

e) define, with the aid of organizational charts, the organization and management structure of the reference material producer, its place in any parent organization, and the relations between management, technical operations, support services, collaborators and the quality management system;

f) specify the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of production of reference materials;

g) have technical management, which has overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of each operation which forms part of the reference material production;

h) appoint a member of staff as quality manager (however named) who, irrespective of other duties and responsibilities, shall have defined responsibility and authority for ensuring that the requirements of this Guide are implemented and followed at all times. The quality manager shall have direct access to the highest level of management at which decisions are taken on production policy or resources;

i) where appropriate, appoint deputies for key managerial personnel such as the technical and quality managers.

4.3 Document and information control

4.3.1 General

The reference material producer shall establish and maintain procedures to control all documents (both internally generated and from external sources) and other information that form part of its quality documentation. These may include documents of external origin, such as standards, guides, test and/or calibration methods, as well as specifications, instructions and manuals related to the reference material under production.

NOTE In this context “document” means any information or instruction including policy statements, text books, procedures, specifications, calibration tables, charts, software, etc. These may be on various media, whether hard or electronic, and they may be digital, analog, photographic or written.

4.3.2 Document approval and issue

4.3.2.1 All documents (including documented procedures) issued to personnel as part of the quality system shall be suitably controlled. This shall include review and approval for use by authorized personnel prior to issue. A master list or equivalent, identifying the current revision status of documents in the quality system, shall be established and be readily available to preclude the use of invalid and/or obsolete documents.

4.3.2.2 The procedures adopted shall also ensure that:

a) authorized editions of appropriate documents are available at all locations where operations essential to the effective production of reference materials are performed;

b) documents are periodically reviewed and, where necessary, revised to ensure continuing suitability and compliance with applicable requirements;

c) invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use;

d) obsolete documents retained for either legal or information preservation purposes are suitably marked.

4.3.3 Document changes

4.3.3.1 Changes to documents (including documented procedures) shall be reviewed and approved by designated personnel performing the same function as that conducted for the original review and approval unless specifically decided otherwise. The designated personnel shall have access to pertinent background information upon which to base their review and approval.

4.3.3.2 Where practicable, the nature of the change shall be identified in the document with appropriate attachments.

4.3.3.3 If the reference material producer's documentation control system allows for the amendment of documents by hand, pending the re-issue of the documents, the procedures and authorities for such amendments shall be defined and shall ensure that amendments are initialled and dated. Documents amended by hand shall be marked, signed and dated and shall be formally re-issued as soon as practicable.

4.3.3.4 Procedures shall be established to describe how changes in documents maintained in computerized systems are made.

4.4 Request, tender and contract reviews

4.4.1 When relevant, each request, tender or contract concerning the production of a reference material shall be reviewed by the reference material producer to ensure that:

a) the requirements are adequately defined, documented and understood;

b) the reference material producer has the capability and resources to meet the requirements;

c) in the case of external contracts, any differences between the contract or order requirements and those in a tender are resolved to the satisfaction of the reference material producer and the customer or client.

The request, tender or contract review should be conducted in a practical and efficient manner and the financial, legal and time schedule aspects should be taken into account.

NOTE 1 Capability means that the reference material producer possesses the necessary equipment, intellectual and information resources and that its personnel have the skills and expertise necessary for the production of those reference materials in question. The review of the capability may include an assessment of previous reference material production and/or the organization of interlaboratory characterization programmes using samples of similar composition to the reference materials to be produced.

NOTE 2 A contract may be any written or verbal agreement to provide a customer or client with reference materials from stock or custom-produced respectively.

4.4.2 Records of such reviews, including any changes, shall be maintained. Records shall also be maintained of pertinent discussions with a customer relating to the customer's requirements or the results of the work during the period of execution of the contract or request.

4.4.3 The review shall include any work that has to be subcontracted by the reference material producer.

4.5 Use of collaborators

4.5.1 The reference material producer shall establish and maintain procedures to ensure that all tasks performed by collaborators comply with specifications set by the reference material producer for such tasks. The reference material producer shall also ensure that collaborators comply with any clauses of this Guide relevant to the tasks performed by them for the reference material producer.

4.5.2 The reference material producer shall select collaborators on the basis of their ability to meet subcontracted requirements in terms of both their technical competence and any specific quality assurance requirements relevant to their tasks. The technical requirements to be satisfied by collaborators shall be equivalent to the technical requirements specified in clause 5 of this Guide.

4.5.3 The reference material producer shall maintain a register of all collaborators used in the production process, and include a record of any assessments made of their abilities to carry out subcontracted tasks according to the requirements of this Guide.

The reference material producer is always responsible for ensuring that a collaborator is competent. The collaborator should be able to demonstrate compliance with the requirements of this Guide for all subcontracted work.

4.6 Procurement of services and supplies

4.6.1 The reference material producer shall have policies and procedures for the selection of services and supplies that affect the quality of its reference materials.

4.6.2 The reference material producer shall use only those services and supplies that are of adequate specification to ensure the quality of its reference materials.

4.6.3 When no formal approval of the quality of services and supplies is available, the reference material producer shall have procedures to ensure that purchased materials and services comply with specified requirements and records of actions taken shall be maintained.

4.6.4 The reference material producer shall ensure that purchased equipment and consumable materials are not used until they have been inspected, calibrated or otherwise verified as complying with standard specifications or requirements defined in specifications for production, characterization and certification of its reference materials.

4.6.5 The reference material producer shall maintain records of the main suppliers and collaborators from whom it obtains supplies required for the production of reference materials. These records should include any quality assurance approval the suppliers and/or collaborators hold.

4.7 Client feedback

The reference material producer shall have a policy and procedures for the resolution of complaints or other feedback received from its customers or other parties. Records shall be maintained of all complaints and of the investigations and corrective actions taken by the reference material producer.

4.8 Control of non-conforming (poor quality) reference materials

4.8.1 The reference material producer shall have a policy and procedures that shall be implemented when it establishes that any aspect of its production activities do not conform with its own specified production procedures. The policy and procedures shall ensure that:

a) responsibilities and authorities for the management of non-conforming work are designated;

b) the actions, which must be taken when any non-conforming reference materials are identified, are defined, together with a system which ensures they are implemented;

c) an evaluation of the significance of the non-conforming work is made;

d) work is halted and, if appropriate, certificates withheld as necessary;

e) remedial actions are taken within a defined timeframe;

f) where necessary, the results of non-conforming reference materials already distributed to customers are recalled;

g) the responsibility for authorization of the resumption of work is defined.

NOTE The identification of non-conforming reference materials or problems with the quality system or with certification activities can occur at various places within the quality system such as: customer complaints, quality control, checking of consumable materials, staff observations or supervision, certificate checking, management reviews and internal or external audits.