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General requirements for the competence of reference material producers

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National foreword

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General requirements for the competence of reference material producers

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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

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

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

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

This third edition cancels and replaces the second edition (ISO Guide 34:2000), which has been technically revised. It also incorporates the Technical Corrigendum ISO Guide 34:2000/Cor.1:2003.

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Introduction

The use of reference materials enables the transfer of the values of measured or assigned properties between testing and measurement laboratories. Such materials are widely used, e.g. 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.

NOTE The concept “reference material” is included in the concept “measurement standard”, both of which also include physical reference materials used for calibrating instruments in mechanical, non-destructive and construction type-testing facilities.

There are an increasing number of reference material producers, and a demonstration of their scientific and technical competence is nowadays 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 anymore. It is, therefore, not only necessary for reference material producers to provide 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 International Standards prepared by ISO/TC 176[1)] in the context of reference material production. The more general requirements of these International 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 second edition of ISO Guide 34 set out all the general requirements in accordance with which a reference material producer has to demonstrate that it operates. The present edition makes these requirements mandatory and in line with ISO/IEC 17025:2005/Cor.1:2006 in view of its use for the assessment of the competence of reference material producers applying for accreditation. For tests performed in the medical field, ISO 15189 may be used as the reference instead of ISO/IEC 17025.

1) Including ISO 9000, ISO 9001 and ISO 9004.

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General requirements for the competence of reference material producers

1 Scope

1.1 This Guide specifies 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 by reference material producers in the development and implementation of their management system for quality, administrative and technical operations. Reference material customers, regulatory authorities and accreditation bodies may also use it in confirming and recognizing the competence of reference material producers.

NOTE This Guide is not intended to be used as the basis for conformity assessment by certification bodies.

1.3 This Guide sets out the management 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.

1.4 This Guide covers the production of certified and non-certified reference materials. For non-certified reference materials, the production requirements are less stringent than for certified reference materials. The minimum requirements for the production of non-certified reference materials are specified throughout the Guide.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

ISO Guide 31, *Reference materials — Contents of certificates and labels*

ISO Guide 35, *Reference materials — General and statistical principles for certification*

ISO/IEC Guide 98-3, *Uncertainty of measurement — Part 3: Guide to the expression of uncertainty in measurement (GUM)*

ISO/IEC Guide 99, *International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*

ISO 9000, *Quality management systems — Fundamentals and vocabulary*

ISO 10012, *Measurement management systems — Requirements for measurement processes and measuring equipment*

ISO 15189, *Medical laboratories — Particular requirements for quality and competence*

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ISO/IEC 17000, *Conformity assessment — Vocabulary and general principles*

ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC 17000, ISO/IEC 17025, ISO Guides 30 and 35, ISO 9000, ISO/IEC Guide 99 and the following apply.

NOTE The definition of (certified) reference materials in this Guide is referenced to ISO Guide 30 (not ISO/IEC Guide 99).

Unless explicitly stated otherwise, the term “certification” is used for the certification of reference materials and shall not be confused with product certification or certification of management systems.

3.1
reference material producer
body (organization or company, public or private) that is fully responsible for project planning and management, assignment of and decision on property values and relevant uncertainties, authorization of property values and issue of the certificate or other statements for the reference materials it produces

3.2
subcontractor
body (organization or company, public or private) that undertakes aspects of the processing, handling, homogeneity and stability assessment, characterization, storage or distribution of the reference material on behalf of the reference material producer, on a contractual basis, either paid or non-paid (see 5.3.1)

NOTE 1 Key tasks/aspects of the reference material production process which cannot be performed by external parties are project planning, assignment and decision on property values and relevant uncertainties, authorization of property values and issuing of certificates or other statements for the reference materials.

NOTE 2 The concept “subcontractor” is equivalent to the concept “collaborator”.

NOTE 3 Advisors, who could be asked for recommendations, but who are not involved in decision making or the execution of any aspects mentioned in the definition above, are not considered as subcontractors.

3.3
production of a reference material
all necessary activities and tasks leading to a reference material (certified or non-certified) supplied to customers

NOTE Production of a reference material includes production planning, production control, material handling and storage, material processing (also referred to as “manufacturing” or “preparation”), assessment of homogeneity and stability, issue of statements and post-distribution service of the reference materials. It can include characterization, assignment of property values and their uncertainties, authorization and issue of certificates for certified reference materials.

3.4
reference material
RM
material, sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process

NOTE 1 RM is a generic term.

NOTE 2 Properties can be quantitative or qualitative (e.g. identity of substances or species).

NOTE 3 Uses may include the calibration of a measurement system, assessment of a measurement procedure, assigning values to other materials, and quality control.

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NOTE 4 A single RM cannot be used for both calibration and validation of results in the same measurement procedure.

NOTE 5 VIM has an analogous definition (ISO/IEC Guide 99:2007, 5.13), but restricts the term “measurement” to apply to quantitative values and not to qualitative properties. However, Note 3 of ISO/IEC Guide 99:2007, 5.13, specifically includes the concept of qualitative attributes, called “nominal properties”.

[ISO Guide 30:1992/Amd.1:2008, definition 2.1]

3.5
certified reference material
CRM
reference material characterized by a metrologically valid procedure for one or more specified properties, accompanied by a certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability

NOTE 1 The concept of value includes qualitative attributes such as identity or sequence. Uncertainties for such attributes may be expressed as probabilities.

NOTE 2 Metrologically valid procedures for the production and certification of reference materials are given in, among others, ISO Guides 34 and 35.

NOTE 3 ISO Guide 31 gives guidance on the contents of certificates.

NOTE 4 VIM has an analogous definition (ISO/IEC Guide 99:2007, 5.14).

[ISO Guide 30:1992/Amd.1:2008, definition 2.2]

3.6
commutability of a reference material
property of a reference material, demonstrated by the closeness of agreement between the relation among the measurement results for a stated quantity in this material, obtained according to two given measurement procedures, and the relation obtained among the measurement results for other specified materials

NOTE 1 The reference material in question is normally a calibrator and the other specified materials are usually routine samples.

NOTE 2 The measurement procedures referred to in the definition are the one preceding and the one following the reference material (calibrator) in question in a calibration hierarchy.

NOTE 3 The stability of commutable reference materials is monitored regularly.

[ISO/IEC Guide 99:2007, definition 5.15]

3.7
metrological traceability
property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty

NOTE 1 For this definition, a “reference” can be a definition of a measurement unit through its practical realization, or a measurement procedure including the measurement unit for a non-ordinal quantity, or a measurement standard.

NOTE 2 Metrological traceability requires an established calibration hierarchy.

NOTE 3 Specification of the reference must include the time at which this reference was used in establishing the calibration hierarchy, along with any other relevant metrological information about the reference, such as when the first calibration in the calibration hierarchy was performed.

NOTE 4 For measurements with more than one input quantity in the measurement model, each of the input quantity values should itself be metrologically traceable and the calibration hierarchy involved may form a branched structure or a network. The effort involved in establishing metrological traceability for each input quantity value should be commensurate with its relative contribution to the measurement result.

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NOTE 5 Metrological traceability of a measurement result does not ensure that the measurement uncertainty is adequate for a given purpose or that there is an absence of mistakes.

NOTE 6 A comparison between two measurement standards may be viewed as a calibration if the comparison is used to check and, if necessary, correct the quantity value and measurement uncertainty attributed to one of the measurement standards.

NOTE 7 The ILAC considers the elements for confirming metrological traceability to be an unbroken metrological traceability chain to an international measurement standard or a national measurement standard, a documented measurement uncertainty, a documented measurement procedure, accredited technical competence, metrological traceability to the SI, and calibration intervals (see ILAC-P10:2002[9]).

NOTE 8 The abbreviated term “traceability” is sometimes used to mean “metrological traceability” as well as other concepts, such as “sample traceability” or “document traceability” or “instrument traceability” or “material traceability”, where the history (“trace”) of an item is meant. Therefore, the full term of “metrological traceability” is preferred if there is any risk of confusion.

[ISO/IEC Guide 99:2007, definition 2.41]

3.8
measurement uncertainty
non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used

NOTE 1 Measurement uncertainty includes components arising from systematic effects, such as components associated with corrections and the assigned quantity values of measurement standards, as well as the definitional uncertainty. Sometimes estimated systematic effects are not corrected for but, instead, associated measurement uncertainty components are incorporated.

NOTE 2 The parameter may be, for example, a standard deviation called standard measurement uncertainty (or a specified multiple of it), or the half-width of an interval, having a stated coverage probability.

NOTE 3 Measurement uncertainty comprises, in general, many components. Some of these may be evaluated by Type A evaluation of measurement uncertainty from the statistical distribution of the quantity values from series of measurements and can be characterized by standard deviations. The other components, which may be evaluated by Type B evaluation of measurement uncertainty, can also be characterized by standard deviations, evaluated from probability density functions based on experience or other information.

NOTE 4 In general, for a given set of information, it is understood that the measurement uncertainty is associated with a stated quantity value attributed to the measurand. A modification of this value results in a modification of the associated uncertainty.

[ISO/IEC Guide 99:2007, definition 2.26]

4 Organization and management requirements

4.1 Management system requirements

4.1.1 General

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

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

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Reference material producers shall define their scope of activities in terms of the types of reference materials (including the sample matrices, if applicable), the properties to be certified and the ranges of assigned values (and their uncertainties) of the reference materials they produce, and their involvement in the performance of testing, calibration and measurements in relation to homogeneity, stability and characterization assessments and their use of subcontractors in these tasks.

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 with respect to specified properties), characterization (e.g. equipment calibration and measurement method validation), assignment of property values (e.g. use of appropriate statistical procedures for data evaluation) and material handling, storage and transport procedures.

The reference material producer's management system policies related to quality, including a quality policy statement, shall be documented in a quality manual (however named). It shall be issued under the authority of the top management.

The quality policy shall include but shall not be limited to the following commitments:

a) to produce reference materials which conform to the requirements of this Guide and to the definitions given in ISO Guide 30;

b) to produce, where applicable, certified reference materials according to the requirements of ISO Guide 35 and accompanied by certificates meeting the requirements of ISO Guide 31;

c) to conduct all testing and calibration in support of the production of reference materials in compliance with the requirements of ISO/IEC 17025[2)];

d) to require that all personnel concerned with the quality of any aspect of reference material production activities familiarize themselves with the quality documentation and implement the policies and procedures in their work;

e) for the management to continually improve the effectiveness of the management system and to be committed to good professional practice and to the quality of its reference materials.

The overall objectives shall be reviewed during the management review.

4.1.3 Management system

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

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

b) processing procedures;

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

d) assessment of the stability of the reference material and determination of the period of validity of the certificate or statement;

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2) For tests performed in the medical field, ISO 15189 may be used as a reference instead of ISO/IEC 17025.

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e) procedures for undertaking characterization (if applicable);

f) assessment of commutability (where appropriate);

g) practical realization of metrological traceability of measurement results to a stated reference;

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

i) arrangements for ensuring adequate storage facilities;

j) arrangements for suitable identification, labelling and packaging facilities, packing and delivery procedures in compliance with international safety regulations, and customer service;

k) assessment of post-certification stability monitoring as required for the extension of the assigned period of validity of the reference material certificate (if applicable);

l) compliance with ISO Guide 30 and with appropriate sections of ISO Guides 31 and 35.

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

The documented management system shall define the roles and responsibilities of the technical management and the quality manager (however named), 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 an entity that can be held legally responsible.

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 at its permanent facilities or at sites (including associated temporary or mobile facilities) away from its permanent facilities.

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 management 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 undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work;

c) have policies and procedures to ensure the protection of its customer'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, subcontractors 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 reference materials produced;

g) have technical management, including a technical manager, who 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) 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 management system. 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 in hard copy or electronic, and they may be in digital, analogue, photographic or written form.

4.3.2 Document approval and issue

4.3.2.1 All documents issued to personnel as part of the management 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 management 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.

4.3.2.3 Management system documents generated by the reference material producer shall be uniquely identified. Such identification shall include the date of issue and/or revision number, page numbering, the total number of pages or a mark to signify the end of the document, and the issuing authority(ies).

4.3.3 Document changes

4.3.3.1 Changes to documents 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 or appropriate attachments.

4.3.3.3 If the reference material producer's document 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. Amendments shall be clearly marked, initialled and dated. A revised document 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 and controlled.

4.4 Request, tender and contract reviews

4.4.1 Each request, tender or contract concerning the production of a reference material shall be reviewed, following documented policies and procedures, established 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 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.

NOTE 1 Capability means that the reference material producer has access to, for example, 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 can include an assessment of previous reference material productions and/or the organization of interlaboratory characterization programmes using samples of similar composition to the reference materials to be produced.

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

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 contracted by the reference material producer.

4.5 Use of subcontractors

4.5.1 The reference material producer shall have policies and use documented procedures to select competent subcontractors and shall establish and maintain procedures to ensure that all tasks performed by subcontractors comply with specifications set by the reference material producer for such tasks. The reference material producer shall also ensure that subcontractors 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 subcontractors on the basis of their ability to meet the requirements stipulated by the reference material producer in terms of both their technical competence and any specific quality management system requirements relevant to their tasks. The technical requirements that the subcontractors shall meet shall be equivalent to either all, or the applicable, technical requirements specified in Clause 5 of this Guide.

4.5.3 Work carried out by subcontractors shall be performed according to the specifications set by the reference material producer. Subcontractors can be paid or non-paid; in all cases, a protocol shall specify the requirements for executing their tasks. For subcontractors executing measurements or testing, the specifications shall include requirements as described in ISO/IEC 17025. Producers shall ensure that they are provided by the subcontractors with the information to ensure compliance with the requirements of ISO/IEC 17025.

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The reference material producer shall assess the competence of the subcontractors by appropriate means. Whilst it is encouraged that subcontractors executing measurements and testing be accredited to ISO/IEC 17025, this is not a mandatory requirement. There are other ways to assess subcontractor competence, e.g. audit, performance on quality control materials, historical performance on inter-laboratory comparisons (see also 5.3.2).

4.5.4 The reference material producer shall maintain a register of all subcontractors used and include a record of any assessments made of their abilities to carry out contracted tasks according to the requirements of this Guide. These records shall include any quality assurance approval the subcontractor holds.

4.6 Procurement of services and supplies

4.6.1 The reference material producer shall have policies and procedures in place 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 comply with specified requirements to ensure the quality of the reference materials it produces.

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 supplies 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 the specifications or requirements defined in specifications for production, characterization and certification of the reference materials it produces.

4.6.5 The reference material producer shall maintain records of the suppliers and subcontractors from whom it obtains services and supplies. These records shall include any quality assurance approval the suppliers and/or subcontractors hold.

4.7 Customer service

4.7.1 The reference material producer shall be willing to cooperate with customers or their representatives in clarifying the customer's requests and questions.

4.7.2 The reference material producer shall seek feedback, both positive and negative, from its customers. The feedback shall be used and analysed to improve the management system, reference material production activities and customer service.

4.8 Complaints

The reference material producer shall have a policy and procedure for the resolution of complaints received from customers or other parties. Records shall be maintained of all complaints and of the investigations and corrective actions taken by the reference material producer (see also 4.10).

4.9 Control of non-conforming work and/or reference materials

4.9.1 The reference material producer shall have a policy and procedures that shall be implemented when it establishes that any aspect of its production activities does not conform to its own specified production procedures or the agreed requirements of the customer.

The policy and procedures shall ensure that

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

b) the actions, which shall be taken when any non-conforming work and/or reference materials are identified, are defined, together with a system which ensures that they are effectively implemented;

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

d) where necessary, work is halted and, if appropriate, issue of the affected reference material and its certificates (and statements) withheld;

e) remedial actions are taken within a defined time-frame;

f) where necessary, the customers who, within an appropriate period, have purchased the reference material are notified of the possible effects identified and, where necessary, non-conforming reference materials and/or their certificates/statements already distributed, are recalled;

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

The decision on recall of reference materials should be taken in a timely manner to limit the use of non-conforming reference materials by customers.

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

4.9.2 Where the evaluation indicates that the non-conforming work and/or reference materials could recur or that there is doubt about the reference material producer's compliance with its own policies and procedures, the corrective action procedures in 4.10 shall be promptly followed to identify the causes of the problem and to eliminate them.

4.10 Corrective actions

4.10.1 General

The reference material producer shall establish a policy and procedures and shall designate appropriate authorities for implementing corrective actions when non-conforming reference materials, non-conforming work on the production of reference materials or departures from the policies and procedures in the management system have been identified.

NOTE A problem with the management system or with technical operations may be identified through a variety of activities within the management system, such as control of non-conforming reference materials, internal or external audits, management reviews and feedback from customers or staff observations.

4.10.2 Cause analysis

Corrective action procedures shall start with an investigation to identify the root causes of the problem. This is sometimes the most difficult, but is the key part in the corrective action procedure.

Often the root cause is not obvious and thus a careful analysis of all potential causes of the problem is required. Potential causes could include, *inter alia*, the nature of the reference material and its specifications, methods and procedures used for characterization, staff skills and training, and the materials and equipment (and/or its calibration) used in the production processes. This shall be reviewed for both in-house production and, where required, any work performed by subcontractors.

4.10.3 Selection and implementation of corrective actions

Where corrective actions are needed, the reference material producer shall identify potential corrective actions. It shall select and implement the action(s) most likely to eliminate the problem and to prevent recurrence.

Any corrective action taken to eliminate the causes of non-conformities or other departures shall be appropriate to the magnitude of the problem and commensurate with the risks encountered.

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The reference material producer shall document and implement any required changes to the operational procedures resulting from corrective action investigations.

4.10.4 Monitoring of corrective actions

After having implemented the corrective actions, the reference material producer shall monitor the results to ensure that the corrective actions taken have been effective in eliminating the root causes of the problems.

4.10.5 Additional audits

Where the identification of non-conformities or departures casts doubt on the producer's compliance with its own policies and procedures, or on its compliance with this Guide, the producer shall ensure that the appropriate areas of activity are audited in accordance with 4.14 as soon as possible.

4.11 Preventive actions

4.11.1 Required improvements and potential sources of non-conformities, either technical or concerning the management system, shall be identified. When improvement opportunities are identified or if preventive action is required, action plans shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such non-conformities and to take advantage of the opportunities for improvement.

4.11.2 After the implementation of the preventive actions, the reference material producer shall monitor the results to establish any reduction in deficiencies or other improvements in this operational area, thereby establishing the effectiveness of the preventive action.

4.12 Improvement

The reference material producer shall continually improve the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

4.13 Records

4.13.1 General

4.13.1.1 The reference material producer shall establish and maintain procedures for identification, collection, indexing, access, storage, maintenance and disposal of quality and technical records.

a) Quality records

Quality records are records providing objective evidence of the extent of the fulfilment of the requirements for quality or the effectiveness of the operation of the management system. They include reports from internal audits and management reviews, and corrective and preventive action records.

b) Technical records

Technical records are accumulations of data and information which result from carrying out testing and (if applicable) calibration procedures and which indicate whether specified quality or process parameters are achieved. They include forms, contracts, work sheets, work books, check sheets, control charts/graphs, calibration reports/certificates, reports, certificates and other statements to customers.

The reference material producer shall ensure that it has recorded such information that might be needed in a future dispute situation.

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4.13.1.2 All records shall be legible and shall be stored and retained in such a way that they are readily retrievable and in facilities that provide a suitable environment to prevent damage, deterioration or loss. Retention time of records shall be established in accordance with legal, accreditation body or customer requirements, where relevant, and shall be documented.

Records may be in the form of any type of media, such as hard copy or electronic media.

4.13.1.3 When mistakes occur in records, each mistake shall be crossed out, not erased, made illegible or deleted, and the correct information entered alongside. All such alterations to records shall be signed or initialled by the person making the correction. In the case of records stored electronically, equivalent measures shall be taken to avoid the loss or change of original information.

4.13.1.4 All records shall be held securely and, where appropriate, in confidence.

4.13.1.5 The reference material producer shall have procedures to protect electronically held data at all times and to prevent unauthorized access to, or amendment of, such data.

4.13.2 Records and reports

The reference material producer shall establish and maintain a record system to suit its particular circumstances and to comply with any applicable regulations. The reference material producer shall arrange for all individual measurement observations, appropriate calculations and derived data (e.g. statistical treatments and uncertainty budgets), calibration records and preparation reports to be retained for a defined period beyond which it is no longer probable that they will be referred to, taking into account the period for which the reference material remains valid.

The results of each calibration or measurement (or series of either) carried out by the reference material producer shall be reported in accordance with ISO/IEC 17025.

4.13.2 refers to internal reports of the reference material producer which should not be confused with a certificate of analysis or certification report which is supplied with a reference material to the customer.

4.14 Internal audits

4.14.1 The reference material producer shall, periodically and in accordance with a predetermined schedule and procedure, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the management system and the requirements of this Guide. The internal audit programme shall address all elements of the management system, including the technical and production activities leading to the finished product (reference material). It is the responsibility of the quality manager to plan and organize audits as required by the schedule and requested by management. Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited. Personnel shall not audit their own activities.

NOTE The cycle for internal auditing should normally be completed in one year.

4.14.2 When audit findings cast doubt on the effectiveness of the operations or on the integrity of the reference materials or on the correctness of their documentation, the reference material producer shall take timely corrective actions and shall notify, in writing, its customers whose activities may have been adversely affected.

4.14.3 All audit findings and corrective actions that arise from them shall be recorded. The reference material producer's management shall ensure that these actions are discharged within an appropriate and agreed timescale.

4.14.4 Follow-up activities shall verify and record the implementation and effectiveness of the corrective actions taken.

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4.15 Management reviews

4.15.1 In accordance with a predetermined schedule and procedure, the reference material producer's top management shall periodically conduct a review of its management system and production processes to ensure their continuing suitability and effectiveness and to introduce any necessary changes or improvements. The review shall take account of

— the suitability of policies and procedures;

— reports from managerial and supervisory personnel;

— the outcome of recent internal audits;

— corrective and preventive actions;

— assessments by external bodies;

— changes in volume and type of work;

— feedback from customers;

— recommendations for improvement including complaints;

— other relevant factors such as resources, staff training and, where required, technical issues relating to the competence of the subcontractor and distributor of the reference materials.

Results should feed into the corporate planning programme, should include the goals, objectives and action plans for the coming year and should be communicated to the staff.

NOTE A typical period for conducting a management review is once every year.

4.15.2 Findings from management reviews and the actions that arise from them shall be recorded. The management shall ensure that these actions are discharged within an appropriate and agreed timescale.

5 Technical and production requirements

5.1 General

This Guide covers the production of certified and non-certified reference materials. For non-certified reference materials, the production requirements are less stringent than for certified reference materials.

Homogeneity and stability assessments are always required to establish that the degree of homogeneity and stability is fit for purpose (see 5.12, 5.13, 5.14).

Where replacement batches of reference materials are produced by applying the same procedures used for previous batches to similar starting materials which lead to final products with equivalent properties, appropriate verification assessments are required to ensure that uncertainty estimations obtained on previous batches remain applicable for the new batch; see 5.4.3 n).

To fulfil the minimum requirements for a non-certified reference material, the following may not be necessary:

a) designing interlaboratory exercises, assessing commutability, assigning property values and establishing uncertainty budgets [5.4.3 j), k), l), m)];

b) providing detailed information to users on the homogeneity study; however, information on the degree of homogeneity shall be provided (5.13.1);

c) providing detailed information to users on the stability study; however, information on the degree of stability shall be provided (5.14.1);

d) characterization of the material (5.15);

e) assignment of property values and their uncertainties (5.16);

f) establishing metrological traceability of assigned values (5.12.4).

5.2 Personnel

5.2.1 The producer of reference materials shall have, where possible, competence in the production of the particular type of reference material (or related material), as well as having access to experience in the measurement of the properties being determined.

It is recognized that, for the production of novel reference materials, persons or organizations with suitable competence may not be available. In such cases, the reference material producer should be able to demonstrate the accumulation of knowledge and experience through the production records of its reference materials.

5.2.2 The reference material producer shall ensure the adequate competence of all personnel who undertake activities relating to the production of reference materials. There shall be sufficient personnel having the necessary education, training, technical knowledge and experience for their assigned functions.

5.2.3 The reference material producer shall formulate goals with respect to education, training and skills of its personnel. The reference material producer shall have a policy and procedures for identifying training needs and providing training of personnel. The training programme shall be relevant to the present and anticipated tasks of the producer. The effectiveness of training actions shall be evaluated.

The need to retrain staff periodically should be considered (e.g. the reference material producer should have in place a policy for retraining staff when a method or measurement technique is not in regular use). Staff training and retraining policies should take into account technological changes and aim at continuous upgrading of skills.

5.2.4 The reference material producer shall maintain an up-to-date record of job descriptions for the managerial, technical and support staff involved in reference material production activities.

5.2.5 The reference material producer shall use personnel who are employed by, or under contract to, the producer. Where contracted and additional technical and support personnel are used, the producer shall ensure that such personnel are supervised and competent and that they work in accordance with the producer's management system.

5.2.6 The reference material producer shall authorize specific personnel to perform particular activities relating to reference material production. The reference material producer shall maintain an up-to-date record of the authorizations, competence and educational and professional qualifications of all staff members. These records shall provide evidence that individual staff members have been adequately trained and that their competence to complete particular types of material processing and measurement has been assessed. This information shall be readily available and shall include the date on which authorization and/or competence is confirmed.

5.3 Subcontractors

5.3.1 Where a reference material producer uses subcontractors to undertake part of the procedure for the production, including processing, homogeneity and stability testing, characterization, handling, storage or distribution of a reference material, the producer shall be able to demonstrate that the subcontractor is competent to perform the concerned part of the procedure, and that the work carried out and/or the results produced are of the required quality. When assessing the competence of a subcontractor, the reference material producer shall acquire and evaluate information on the subcontractor's knowledge of the subject and details of past experience in the field and make sure that experienced staff is available as well as appropriate accommodation and environmental conditions, instrumentation and measuring equipment as required.

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Processes that shall not be carried out by subcontractors are project planning, selection of subcontractors and the assignment of and decision on property values. Also, authorization of property values and issue of certificates/statements/analysis reports/information sheets (or however named) shall be done by the reference material producer.

5.3.2 Evidence of the subcontractor's competence shall be established and records of its competence maintained. This can be done by different means. Accreditation to ISO/IEC 17025 when testing or calibration is carried out, or certification of the quality management system to ISO 9001 for other (non-testing/calibration) activities by a recognized body, is generally appropriate. In cases where accreditation is not practical, evidence of subcontractors successfully participating in a relevant proficiency testing scheme and producing acceptable results on well-characterized materials of similar or equivalent nature to that of the candidate reference material may also be considered appropriate. In cases where the competence of subcontractors cannot be ascertained via provision of documentary evidence, the reference material producer may need to assess the competence of the subcontractor on-site or may need to supervise on-site the operations carried out by the subcontractor.

The producer may consider distributing materials of a comparable matrix whose property values are well established and at appropriate concentration levels, etc., prior to or together with distributing any candidate reference material samples to help in the evaluation of the subcontractor.

5.3.3 In certain cases, the reference material producer may have no laboratory facilities or processing facilities, or may choose not to use its own facilities. It shall ensure that all work carried out by subcontractors who may contribute to the assignment of the property values of interest is fit for that purpose and in compliance with this Guide and ISO/IEC 17025 for measurement, calibration and testing.

Under these circumstances the reference material producer shall

— employ personnel having knowledge to ensure that subcontracted activities are executed in compliance with this Guide and ISO/IEC 17025 for measurement and testing, and

— evaluate the results of all subcontracted activities (e.g. analytical and statistical aspects).

5.3.4 The reference material producer shall ensure that all details of the methodology, results and the descriptions of procedures of any subcontractor are available. Suitable details of methodology shall be maintained by the reference material producer to allow the technical evaluation of data. If required, it shall ensure that a register/database of all subcontractors and the accreditation for testing, calibration and measurement activities, certification of the management system or other forms of competence status are maintained.

5.4 Production planning

5.4.1 The reference material producer shall identify and plan those processes which directly affect the quality of reference material production and shall ensure that they are carried out in accordance with specified procedures. Where available, procedures given in technical standards for the production of specific reference materials shall be used.

5.4.2 Technical input of the different subcontractors involved shall be identified and the necessary information documented and regularly reviewed. A mechanism (e.g. a management/technical advisory group) may be established to make recommendations on how to plan the production processes.

NOTE These could include recommendations for production, setting up a monitoring system (to ensure timeliness and quality for each production phase) and having an evaluation procedure to assess the production processes retrospectively.

5.4.3 In planning the production processes, the reference material producer shall have procedures and service facilities, for

a) definition of storage conditions;

b) material selection (including, where appropriate, sampling);

c) maintaining suitable environments for all aspects of production (5.6);

d) material processing (5.8);

e) measuring/testing (5.9, 5.10);

f) validation of measurement methods (5.9);

g) verification and calibration of equipment (5.10);

h) assessing material homogeneity (5.13);

i) assessing material stability (5.14);

j) designing and organizing appropriate interlaboratory exercises for the purpose of assigning property values, if applicable (5.15);

k) assessing commutability (where appropriate) (Annex B);

l) assigning property values based on the results of measurements, if applicable (5.16);

m) establishing uncertainty budgets and estimating uncertainties of the assigned property values, if applicable (5.16);

n) defining acceptance criteria for verifying that uncertainty estimates are applicable for replacement batches of reference materials produced under conditions described in 5.1;

o) establishing metrological traceability of the measurement result(s) (5.12);

p) issuing certificates and/or other documentation (5.17);

q) ensuring adequate storage facilities and conditions (5.7);

r) ensuring appropriate labelling and packaging of the samples meeting safety regulations (5.7);

s) ensuring appropriate transport arrangements which comply with shipping regulations (5.18);

t) ensuring post-certification stability monitoring, if applicable (5.14);

u) ensuring an adequate post-distribution service for reference material customers (5.18).

5.5 Production control

The reference material producer shall identify the verification procedures necessary to ensure the quality of each stage of reference material production, and shall assign adequate resources and personnel for such activities. These activities shall include inspection, testing and monitoring of all stages of production.

5.6 Accommodation and environmental conditions

5.6.1 The reference material producer shall ensure that all laboratory accommodation, calibration and measurement areas (if applicable), material processing and packaging areas, energy sources, lighting, humidity, temperature, pressure and ventilation are such as to facilitate proper material processing and packaging, as well as proper performance of calibration and measurements (if applicable).

Precautions shall be taken against possible contamination of the reference material during its processing and characterization. All reference material processing and testing areas, in addition to satisfying requirements for humidity and temperature, shall be protected from vibration, airborne dust and microbiological contamination, magnetic fields and electromagnetic radiation (as appropriate). The technical requirements for

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accommodation and environmental conditions that can affect the results and processes of the production of reference materials shall be documented.

NOTE For example, the packaging of a cement material requires conditions of low humidity, while the processing and characterization of a material in which the content of traces of lead is to be measured requires clean room conditions to prevent contamination from dust containing lead. Clean room conditions may also be required for other types of trace analysis. Proper choice of container material and adequate cleaning procedures are also important to avoid contamination. Processing of reference materials of genetically modified organisms requires measures to prevent DNA/protein cross-contamination.

5.6.2 Where appropriate, the environment in which the reference material production activities are undertaken shall be monitored with appropriately calibrated equipment, controlled and recorded, such that results and processes are not adversely affected.

5.6.3 Appropriate health, safety and environmental protection precautions shall also be implemented where necessary (e.g. when handling pesticides or serum).

5.7 Material handling and storage

5.7.1 In order to avoid any contamination, the reference material producer shall identify, preserve and separate (i.e. from other chemicals and samples) all candidate materials and reference materials, from the time of processing through to their distribution to users.

5.7.2 The reference material producer shall ensure adequate packaging of all reference materials (e.g. where appropriate, use light shielding, air-free, moisture-free or inert-gas packaging) and provide secure storage areas/stock rooms which prevent damage or deterioration of any item or material between characterization and distribution. Appropriate procedures for dispatch shall be stipulated.

5.7.3 The condition of all stored/stocked items and materials shall be assessed at appropriate intervals throughout the storage period, in order to detect possible deterioration.

5.7.4 The reference material producer shall control packing and labelling processes to the extent necessary to ensure conformity with safety and transport requirements.

NOTE The proper distribution of samples can present a severe problem for some types of material which require uninterrupted storage in a freezer, or which should not be exposed to X-rays, shocks or vibrations. Most types of chemical material benefit from air-tight packaging to avoid oxidation by atmospheric oxygen and/or contamination by atmospheric contaminants (e.g. fuel vapours or engine exhaust gases) which may be encountered during transport.

The reference material producer shall ensure that the integrity of each individual reference material unit is maintained until the seal has been broken or up to the point when presented for analysis. The producer cannot be held responsible for the material once its seal has been broken. This may require, in some cases, that the reference material is packaged in unit quantities sufficient for a single use.

5.7.5 The reference material label shall be securely attached to the product container of an individual reference material unit, and shall be designed to remain legible and intact under the defined storage and handling conditions within the lifetime of the reference material, i.e. the period during which the reference material is available from the reference material producer extended by the period of validity of its certificate. The label shall identify the material, the producer, its batch and catalogue numbers, and any other information necessary to enable the material to be uniquely distinguished and referenced (such as the individual sample number), where appropriate, to its statement or certificate. The labels shall also, where appropriate, comply with requirements related to safety and risk regulations, e.g. show toxicity symbols, risk and safety phrases.

Where the physical size of the reference material unit limits the amount of information that can be contained on the label, the information shall be included elsewhere (e.g. in a certificate) and the user shall be directed to this information from the label. At a minimum, a unique identity number should be given.

5.7.6 The reference material producer shall make arrangements to ensure the integrity of each reference material throughout the entire production process. Where contractually specified, this protection shall be extended to include delivery to destination.

5.8 Material processing

The reference material producer shall establish procedures to ensure that the item or material has undergone adequate processing for its intended use. Procedures for material processing shall include, where appropriate,

a) qualitative analysis for verification of material type and/or identity;

b) synthesis, purification (e.g. distillation, extraction), transformation into the final form (e.g. machining, grinding, blending, sieving and riffling, extrusion, melting);

c) homogenization;

d) proper handling (e.g. protection from contamination and use of inert equipment);

e) measurements for processing control (e.g. particle size distribution, moisture content);

f) cleaning of sample containers;

g) stabilization of material (e.g. drying, irradiation, sterilization);

h) packaging (e.g. bottling, ampouling) of the batch.

5.9 Measurement methods

5.9.1 The reference material producer shall meet the requirements of ISO/IEC 17025[3)] with respect to tests, calibrations and measurements under their responsibility (including preparation of items, sampling, handling, preservation, storage, packaging, transport to subcontractors, estimation of measurement uncertainty and analysis of measurement data). These activities shall be consistent with the required accuracy, where appropriate, of the assigned values of the reference material, and with any standard specifications relevant to the measurement concerned.

5.9.2 Measurement methods developed in-house by the reference material producer shall be validated and authorized before use. Such methods shall be thoroughly investigated, and shall clearly and exactly describe the necessary conditions and procedures for which the measurement of the property values of interest is valid at the level of accuracy commensurate with the intended use of the reference material. Records of the method of validation shall be retained. Validation shall meet the requirements of ISO/IEC 17025.

5.9.3 Where sampling is carried out as part of the measurement method (e.g. sub-sampling a representative quantity from a batch of material), the reference material producer shall use documented procedures and appropriate statistical techniques to take test portions.

5.10 Measuring equipment

5.10.1 Measuring equipment used in reference material production shall be used in compliance with ISO/IEC 17025. It shall be properly calibrated, verified and maintained, with all procedures being documented and the results recorded. Where appropriate, periodic performance checks shall be carried out and recorded (e.g. to check the response, stability, linearity, resolution, alignment, repeatability) to ensure that the measurement equipment is performing adequately. The frequency of such performance checks shall be determined by experience and based on the type and previous performance of the equipment. Intervals between checks shall be shorter than the defined time within which the equipment has been found to drift outside acceptable limits, in accordance with the requirements of ISO 10012.

5.10.2 Any item of equipment that has been subjected to overloading or mishandling, shown to provide suspect results, or shown by verification or otherwise to be defective, shall be clearly identified, withdrawn from service and, wherever possible, stored at a specified location until repaired and shown by calibration,

3) For tests performed in the medical field, ISO 15189 may be used as reference instead of ISO/IEC 17025.

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verification or testing to perform satisfactorily. The reference material producer shall review the implications for results obtained using such equipment, with particular regard to the extent of the calibration deviation, the results involved and the allowable tolerance on the results. Where results have been significantly in error, the reference material producer shall have the results checked and shall take appropriate remedial action. Records of the review and any checks/remedial action shall be maintained.

5.10.3 Each item of equipment, including any measurement standard, that is used in the calibration/validation of equipment/measurement methods used for reference material production shall, where appropriate, be labelled, marked or otherwise identified to indicate its calibration status and expiry date. This shall also include reference materials, standard solutions and chemical reagents used in chemical analysis, microbiological testing, etc.

5.10.4 All measuring and testing equipment having an effect on the traceability and accuracy of the measurement results shall be calibrated and/or verified before being commissioned into service. The reference material producer shall have an established programme for the calibration and verification of measuring and testing equipment.

5.10.5 The overall programme of calibration and/or verification of equipment shall be designed and operated so as to ensure that, wherever applicable, measurement results obtained by the reference material producer are traceable to a stated reference through an unbroken chain of calibrations with stated uncertainties. Calibration certificates of measurement instruments shall, wherever appropriate, indicate the metrological traceability to this stated reference.

5.11 Data evaluation

5.11.1 The reference material producer shall ensure that calculations and data transfers are subject to appropriate checks, including those from its own sources.

5.11.2 Where computers or computer-controlled systems are used for the capture, processing, evaluation, recording, reporting, storage or retrieval of calibration or testing data, the reference material producer shall ensure that

a) computer software developed in-house or off-the-shelf software further developed for specific use, which affects the characterization or the properties of the reference material, shall be validated and shown to be adequate for use;

b) procedures are established and implemented for protecting the integrity of data; such procedures shall include, but are not limited to, integrity of data entry and capture, data storage, data transmission and data processing;

c) equipment is maintained to ensure proper functioning and is provided with the environmental and operating conditions necessary to maintain data integrity;

d) appropriate procedures are established and implemented for the maintenance of data security, including prevention of unauthorized access to, and amendment of, computer records.

5.11.3 All technical data relating to the production of reference materials shall be retained in accordance with the requirements of 4.13.2.

5.12 Metrological traceability

5.12.1 The reference material producer shall provide documentary evidence on the metrological traceability, of the measurement results to a stated reference (see also 3.7).

NOTE The concept of “metrological traceability” includes identification of the property of interest of the reference material, the numerical value and the stated reference.

5.12.2 The stated reference shall be a definition of a measurement unit through its practical realization, a measurement procedure including the measurement unit, or a measurement standard. Wherever possible,

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metrological traceability shall be achieved through an unbroken chain of calibrations, all having stated uncertainties. Where this cannot be achieved, the reference material producer shall provide satisfactory evidence of the correlation of results with other stated values, either by exhaustive evaluation of the measurement process or by comparison with known and accepted certified reference materials, which have certified values preferably with comparatively small uncertainty and which are higher in the metrological traceability hierarchy with few steps of comparison.

The concept of "metrological traceability" applies to the measurement results for the assessment of homogeneity and stability as well as to the assignment of values as the result of the characterization process.

The definition of reference material as "sufficiently homogeneous and stable *with respect to one or more specified properties*" inherently requires a clear definition of these properties. Metrological traceability of measurement results to the chosen reference shall be ensured to make relevant statements on the degree of homogeneity and stability.

5.12.3 Different requirements apply for relative assessments and absolute assessments.

5.12.3.1 For studies in which results are compared relative to each other (e.g. homogeneity studies, stability studies with measurements performed under repeatability conditions in isochronous schemes), it shall be ensured that

a) the measurand in the study is the same as the one for which the value is assigned (i.e. the chosen method is selective);

b) the calibration function for the measurement procedure is valid in the range of the measurement results;

c) the measurement procedure is sufficiently precise to make meaningful statements about the variation of the measurement results of the measurand.

In this case, no traceability to a higher order reference system is required.

ISO Guide 35:2006, 7.4, allows homogeneity testing only on a subset of the assigned values. In this case, documentary evidence shall be provided that the measurand quantified indeed correlates with the measurand for which the value is assigned in the material in question.

NOTE 1 In principle, no trueness of measurement results has to be established for this kind of study.

NOTE 2 These requirements are met if appropriate selectivity, working range and precision of a method have been established.

5.12.3.2 For studies in which the absolute values are compared (e.g. characterization studies, stability studies with measurements under reproducibility conditions), it shall be ensured that

a) the measurand in the study is the same as the one for which the value is assigned (i.e. the chosen method is selective);

b) the calibration function for the measurement procedure is valid in the working range of the measurement results;

c) the measurement procedure has an appropriate limit of quantification;

d) the measurement procedure is sufficiently precise to make meaningful statements about the variation of the measurement results;

e) the measurement procedure is calibrated with standards traceable to the same reference as the assigned value (refer to Annex A for more information);

f) all other relevant input quantities have been appropriately calibrated.

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NOTE These requirements are met if appropriate selectivity, limit of quantification, working range, precision and trueness of a method have been established.

5.12.4 To ensure the metrological traceability of the assigned values, the reference material producer shall provide documentary evidence that all measurement results used for value assignment are traceable to the same reference as the assigned value.

NOTE A combination of results obtained by different methods and/or laboratories – all being traceable to the same reference – is also traceable to this reference.

An additional discussion on the concept and requirements of metrological traceability is given in Annex A.

5.13 Assessment of homogeneity

5.13.1 Assessment of homogeneity is always required to establish that the degree of homogeneity of the reference material with respect to the property(ies) of interest is fit for purpose.

The definition of reference material as "*sufficiently* homogeneous" inherently requires quantification or limits for heterogeneity to demonstrate fitness for purpose. Therefore, the provisions of ISO Guide 35 for homogeneity testing also apply for the production of non-certified reference materials.

5.13.2 The reference material producer shall carry out an assessment of the homogeneity of any candidate reference material. In most cases, this involves analysing a representative number of randomly, systematically or stratified randomly chosen units. Testing, calibration, measurement, sampling or other activities performed for the assessment of homogeneity shall be carried out in compliance with ISO/IEC 17025. Measurement procedures shall be selected so that the repeatability is fit for the purpose required. The homogeneity studies shall be designed and performed in accordance with ISO Guide 35. Although the measurement values do not have to be communicated to customers, the degree of homogeneity (e.g. expressed as maximum between-bottle variation) shall be indicated in the documentation accompanying the reference material.

If the material is produced in several batches, it is necessary to test the equivalence of the batches (or to assign property values to each batch separately).

The assessment shall be performed after the material has been packaged in its final form unless stability studies indicate that storage should be maintained in bulk form. In some cases, intermediate homogeneity checks may be necessary (e.g. prior to bottling/ampouling).

NOTE 1 For reference materials that are expected to be homogeneous on physical grounds, the main purpose of homogeneity testing is to detect unforeseen problems, for example point contamination during packaging into individual units, or incomplete dissolution or equilibration of an analyte in a solvent (which could lead to steadily changing concentrations). For these types of examples, systematic sampling (e.g. one from every 50 samples produced in a continuous process; sampling at regular intervals for each sub-batch in those cases where the sub-batch can be defined) may be a better way to detect inhomogeneity than random sampling. A statistical trend analysis may also be helpful in detecting inhomogeneity.

NOTE 2 A relatively inhomogeneous material may be the best available, and may therefore still be useful as a reference material, provided the uncertainties of the assigned property values take due account of this.

5.13.3 The amount of tested material on which the homogeneity of the reference material has been established shall be specified in the documentation supplied by the reference material producer. This documentation shall also state the minimum sample size for use (see ISO Guide 31).

NOTE Although ISO Guide 31 is strictly speaking established for certified reference materials, the requirement for indicating the minimum sample size is also valid for non-certified reference materials.

5.14 Assessment of stability

5.14.1 Assessment of stability is always required to establish that the degree of stability of the reference material is fit for purpose.

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The definition of reference material as "*sufficiently* stable" inherently requires quantification or limits for degradation to demonstrate fitness for purpose. Therefore, the provisions of ISO Guide 35 for stability testing also apply for the production of non-certified reference materials.

5.14.2 The stability of the reference material shall be assessed. Testing, calibration, measurement, sampling and other activities performed for the assessment of stability shall be carried out in compliance with ISO/IEC 17025. Stability testing can be performed only if sufficient homogeneity is demonstrated. The stability studies shall be designed and performed in accordance to ISO Guide 35.

The evaluation of measurement data as described in ISO Guide 35 covers only apparently stable materials. In case of detectable degradation, both the degradation and its uncertainty shall be included in the assessment.

The properties of interest of the candidate reference material shall be evaluated for the adopted storage conditions. Effects of, for example, light, moisture and temperature shall be evaluated in function of time for estimating a lifetime of the reference material and hence establishing a period of validity of the certificate.

Although the measurement values do not have to be communicated to customers, the degree of stability shall be indicated in the documentation accompanying the reference material.

5.14.3 The stability of the material under transport conditions shall be assessed.

5.14.4 Where appropriate, an assessment of the stability of the reference material shall be performed at periodic intervals after characterization, to confirm that all values are maintained from production until the expiry date. The reference material producer shall provide a period of validity of the certificate which is stated in the documentation accompanying the material. It shall be made clear on the documentation on which starting date the period of validity is based (e.g. the date of certification, the date of shipment of the reference material or the date of opening the packaging).

5.14.5 The reference material producer shall inform its customers about shelf-life changes of the reference material including possible consequences for its use.

5.15 Characterization

For certified reference materials, the producer shall use and document technically valid procedures to characterize its reference materials. The characterization shall comply with the requirements of ISO Guide 35 and ISO/IEC 17025 for testing, calibration and related activities.

There are several technically valid approaches for characterizing a reference material. These include carrying out measurements using

a) a single (primary) method in a single laboratory;

b) two or more independent reference methods in one or several laboratories;

c) one or more methods of demonstrable accuracy, performed by a network of competent laboratories;

d) an approach providing method-specific, operationally defined property values, using a network of competent laboratories.

Depending on the type of reference material, its intended use, the competence of the laboratories involved and the quality of methods employed, one approach may be chosen as appropriate.

Results obtained from proficiency testing can be used only if the competence of the laboratories involved has been checked and it has been ensured that the measurements done comply with ISO/IEC 17025 (see also 5.3).

The single (primary) method approach a) shall be carried out only when the procedure and expertise enable it to ensure metrological traceability. More usually, a property value can be reliably assessed when its value is confirmed by several laboratories working independently and using more than one method, for each of which the accuracy has been well established.

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5.16 Assignment of property values and their uncertainties

5.16.1 The reference material producer shall use documented procedures, as outlined in ISO Guide 35, for the assignment of property values.

These procedures shall include, as appropriate:

a) details of the experimental designs and statistical techniques used;

b) policies on treatment and investigation of statistical outliers and/or the use of robust statistics;

c) whether weighting techniques are used for contributions to assigned property values derived from different methods with different measurement uncertainties;

d) the approach used to assign uncertainties to the property values;

e) any other significant factors which may affect the assignment of property values.

The reference material producer shall never rely entirely on only a statistical analysis of the characterization data when assessing the property values of interest. Outliers shall not be excluded on statistical evidence until they have been thoroughly investigated and, where possible, the reasons for the discrepancies identified. Alternatively, the use of robust statistics may be appropriate in some cases.

When several methods have been used to characterize a reference material, difficulty may arise when the results show significant differences, in which case a property value based on the mean is inappropriate. It is essential in such cases that the reference material producer and its subcontractors have considerable experience of the different methods and are able to give more or less weight to the results from the use of a particular measurement method. In some cases, the results may be weighted according to the inverse of the variance of each method. In some cases, measurement methods will produce irreconcilable results and it may be necessary to assign separate property values according to the methods used (i.e. a method-specific approach).

In assigning the property values of interest, the reference material producer shall consider establishing a group of independent experts whose responsibility is to check that all work, data and documents are fit for their purpose.

5.16.2 An important aspect of establishing the property values of the reference material being produced is an assessment of their uncertainties. The reference material producer shall carry out an assessment of the measurement uncertainties to be included in the assignment of the property values in accordance with the requirements of the GUM (ISO/IEC Guide 98-3). In the process of estimating uncertainties of the property values of interest, any uncertainties resulting from between-unit variations and/or from possible doubts on stability (both during storage and during transportation) shall be assessed in accordance with ISO Guide 35 and shall be included in the assigned uncertainty.

A statement of the measurement uncertainty is mandatory for certified values. In case values are assigned to non-certified reference materials (e.g. “indicative values” or “information values”), a statement of uncertainties is highly recommended to improve the use of the material.

5.17 Certificates or documentation for users

The reference material producer shall issue a certificate for certified reference materials and provide appropriate documentation for non-certified reference materials in the form of a statement, analysis report, or information sheet howsoever named.

The contents of certificates for certified reference materials shall comply with the requirements of ISO Guide 31. If the certificate also contains non-certified values, a clear distinction shall be made between certified and non-certified values.

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The documentation for non-certified reference materials shall include information on homogeneity and stability and on the period of validity of the stated information. It shall also contain information for the user on the proper application and storage conditions of the reference material.

NOTE In some cases which are covered by specific legislation (e.g. most pharmacopoeia assay standards), the uncertainties of the assigned values are not stated since they are considered to be negligible in relation to the defined limits of the method-specific assays for which they are used.

5.18 Distribution service

5.18.1 The distribution process shall be carefully studied to avoid deterioration of the reference material (see 5.14.3). The producer shall determine the conditions of shipment, the maximal time the shipment may endure under the conditions chosen and what documentation is required to allow customs clearance.

NOTE For some reference materials, additional documentation related to, for example, origin, conformity of the material to safety requirements, might be required for customs clearance.

5.18.2 The reference material producer shall maintain an up-to-date record of all reference material sales or distribution.

5.18.3 The reference material producer shall offer to customers reasonable guidance and technical support related to the reference materials it produces.

5.18.4 The reference material producer shall employ best efforts to notify customers of any change to the assigned value or uncertainty for any products not expired.

5.18.5 Where goods are subject to resale through an authorized distributor, with whom the producer has a contractual relationship, the reference material producer shall pass on to its authorized distributor all necessary information to ensure that an effective post-distribution service is maintained and make arrangements with the distributor to ensure that its activities are executed in accordance to the relevant parts of this Guide.

5.18.6 Where goods are subject to resale by other organisations, the producer has no control over these organisations' activities after they have purchased. Therefore, the requirements regarding distribution service to such resellers are limited to the first reseller as with any direct customer.

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Annex A
(informative)

Metrological traceability of certified property values of reference materials

A.1 Concept of metrological traceability

Metrological traceability is defined in the VIM (ISO/IEC Guide 99:2007, 2.41) as the "property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty". In other words, when the result of a measurement is described as traceable, it is essential to specify to which reference metrological traceability has been established. It can be to a base quantity of the International System of Units (SI) (such as the ampere), to a derived quantity (such as mass fraction), to a defined scale (such as pH or hardness), to a value represented by a reference material or to a value resulting from the use of a method described in a national or international standard.

In the case of reference materials for physical properties, it is usually possible to establish metrological traceability via a series of instrument calibrations to the appropriate base quantities of the SI. For example, the certification of a reference material for specific heat capacity is based on measurements of electrical energy, temperature and mass. All those values are readily traceable to the SI units by means of instruments calibrated by or traceable to measurement standards maintained at national metrology laboratories.

In the case of reference materials for chemical composition, establishing metrological traceability of the assigned values often involves more steps. For example, the amount of the analyte of interest is usually determined by the physical response of an analytical instrument only after carrying out a number of processes such as sampling, dissolution or extraction, separation by chromatography or more traditional wet-chemical methods. Any or all of these processes may constitute links in the metrological traceability chain of the final result, each contributing to the uncertainty of the final result. The analytical chemist shall therefore assess the influence of the entire measurement process on the quantity value. This includes e.g. how efficient each process has been in completely retaining the analyte, either unchanged or stoichiometrically converted to another chemical species and how it separated the analyte from substances which interfere in the final instrumental measurement and which contribution each step has made to the uncertainty of the final result.

Care shall be taken that the measured quantity is sufficiently defined. For example, the measurand may be defined as the mass of lead in a given volume of blood and expressed in units of grams per litre, or as amount-of-substance of DDT per mass of animal tissue, expressed in units of moles per kilogram.

A.2 Assignment of property values to reference materials

As noted in the main text in 5.15, this Guide recognizes four main procedures for the characterization leading to the assignment of property values of reference materials.

A single (primary) method is considered to be one where the property "is either directly measured in terms of the base units of measurement or indirectly related to the base units through physical or chemical theory expressed in exact mathematical equations". Even where such a so-called primary method is available, it is desirable that two or more analysts make independent determinations, preferably with different experimental facilities.

Value assignment by interlaboratory comparison presupposes the existence of a number of equally capable laboratories employing methods which have been independently validated, and implies that differences between individual results are statistical in nature and can therefore be treated by purely statistical procedures. This approach to certification has to include sufficient assessment based on technical knowledge and

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judgement. Statistical treatment of data should not predominate. A subset of this procedure is when the analysis is method-specific.

The metrological traceability of the property values assigned to reference materials can therefore range from a rigorous chain of instrumental calibrations back to the base units of the SI to the use of a well-defined reference method. In each case, the reference material producer needs to consider how to apply the relevant principle. What is essential is that the certificate contains a statement of metrological traceability indicating the principles and procedures on which the property values (together with their uncertainties) are based. A certified value without this additional information is generally considered unacceptable for a certified reference material.

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Annex B
(informative)

Commutability of reference materials

B.1 Concept of commutability

A material is said to be commutable when equivalent mathematical ratios are observed for the results for a stated measurand obtained from the application of different measurement procedures both to the material and to a set of routine test samples containing the measurand.

In the particular case of a reference material, the assessment of commutability requires a comparison of the relationship between the property values assigned to a reference material and to standard test samples using both a “higher-order” reference measurement procedure and one or more “lower-order” routine measurement procedures. If the ratio between the results obtained for the reference material by the reference procedure and each of the routine measurement procedures is the same as the ratio of the results for representative test samples analysed by the same set of measurement procedures, the reference material is said to be commutable and can be used for establishment of metrological traceability.

If a “higher order” reference measurement procedure is not available, at least harmonization can be achieved if commutability has been established through comparison of the relationship between the property value assigned to a reference material and to representative routine test samples using the two measurement procedures to be harmonized.

In other words, a reference material is commutable if the behaviour of the target analyte towards a given measurement procedure is equivalent in the reference material and in routine test samples. This implies that the application of the procedure to the reference material would produce the same quantitative response as a normal test sample containing the same amount/activity/concentration of the analyte. It is important to note that there is no *a priori* requirement that the application of different procedures nominally for determination of the same measurand to a commutable reference material will necessarily produce quantitative results for the measurand that are in close absolute agreement. The only constraint for the establishment of commutability is that the ratio of the results obtained with the different procedures be equivalent both for the reference material and for the routine samples.

Statements about the commutability of a reference material always require specification of the measurement procedures for which it is found to be commutable. Likewise, commutability of the reference material may be demonstrated relative to some routine procedures but not towards others. In cases where the reference material is commutable with all methods investigated, it does not imply that it is commutable with any method.

There are a number of definitions of commutability given in various standard or guidance documents. They all agree on the basic principles of the concept and the process for the establishment of commutability, but differ in wording and details of the nature of the materials used in the assessment of commutability and the description of how the relationship between measurement procedures is to be established.

In this Guide, the VIM (ISO/IEC Guide 99:2007, 5.15) definition of commutability is used (see 3.6).

The desirability of determining the commutability of reference materials was first established in clinical chemistry, where a range of measurement procedures are used for the routine clinical testing of particular measurands in patient samples. These procedures rely on a number of different physicochemical or biochemical principles or are based on the detection and measurement of various sub-components of a complex biomolecular species that are assumed to relate directly to the level of the clinically significant forms of the molecule present in the sample. The procedures are sensitive to varying degrees to interferences arising from differences between the matrix of a reference material and that of clinical samples, or to differences in response due to alterations of the analyte (such as denaturation, changes in aggregation,

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oligomeric state, metal binding) and the matrix in the course of the production of the reference material. Consequently, it is not possible to attribute discrepancies observed among measurement procedures that have been calibrated or validated by reference materials of unknown commutability to genuine problems with the measurement procedure(s) or to a bias introduced by differences in response of the reference materials towards the various procedures under test.

Calibration or trueness control using reference materials of demonstrated commutability produces test results that are in principle comparable, traceable to the reference measurement system used to assign the reference material property values and without a calibration bias among the assessed procedures.

The need for the establishment of the commutability of reference materials is not limited to clinical chemistry. It is desirable in any field where the measurement procedures in routine use are based on different physical or chemical principles in comparison to the reference method used to assign the property values of a reference material. It is particularly important to assess commutability where differences between the matrix of the reference material or changes to the secondary/tertiary structure of the analyte in the reference material relative to normal test samples could potentially introduce a bias between results obtained with one measurement procedure relative to the results obtained with (an)other procedure(s) when used on representative test samples. In the particular case of clinical chemistry, it is desirable that the commutability of reference materials be assessed relative to representative clinical samples from healthy individuals and if necessary also from diseased individuals.

B.2 Assessment of the commutability of reference materials

There are various approaches reported for assessing commutability of reference materials and leading references are provided in the accompanying bibliography. In particular, the Clinical and Laboratory Standards Institute (CLSI) produces guidelines relevant to the establishment of commutability for reference materials for use in clinical chemistry.

The simplest case is the establishment of the commutability of a reference material relative to two measurement procedures, one of them preferably being a measurement procedure of higher metrological order. The mathematical relationship between the results obtained using routine test samples is determined using both measurement procedures. Regression analysis can be used to establish the relation between the results obtained with the two procedures and typically a 95 % prediction interval is calculated to describe the distribution of the result ratio expected for routine samples. If the result ratio obtained for the reference material using the two methods is consistent with the confidence interval calculated for representative test samples, the reference material is commutable with respect to the routine measurement procedure. The 95 % prediction interval should be consistent with the precision level allowable for given applications of the measurement procedures. Therefore, a large scatter in the correlation plot should trigger either a refinement of the measurement procedures to make them detect the same analyte or different analytes in a constant concentration ratio in typical routine samples or should lead to a redefinition of the analyte and eventually existing reference measurement procedures. Only then can comparability between results of different measurements procedures on typical routine samples be achieved.

Examples of references to more complex approaches using multivariate statistical assessments that can be used to establish the commutability of a reference material to multiple test procedures are given in the Bibliography (see References [2], [3], [4], [16]).

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Annex C
(informative)

ISO/IEC 17025/ISO Guide 34 cross-reference table

Only closely corresponding subclauses are listed in the same row. Cells are left empty if the respective document has no closely corresponding subclause.

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