General requirements for the competence of Reference Material Producer as per ISO 17034:2016

Definitions

Standards and Guides for RMP

There is an International Standard and three ISO Guides that support the production, characterization and certification of RMs to ensure that the quality of the RMs meets the requirements of the end users. They are:

— ISO 17034 outlines the general requirements to be met by an RMP to demonstrate competence.

— ISO Guide 35 provides more specific guidance on technical issues and explains the concepts for processes such as the assessment of homogeneity, stability and characterization for the certification of RMs.

— ISO Guide 31 describes the contents of certificates for CRMs, and of accompanying documents for other RMs.

— ISO Guide 30 contains the terms and definitions related to reference materials.

Standards and Guides for RMP

— ISO Guide 33 describes good practice in using reference materials (RMs), and certified reference materials (CRMs) in particular, in measurement processes. These uses include the assessment of precision and trueness of measurement methods, quality control, assigning values to materials, calibration, and the establishment of conventional scales. It relates key characteristics of various types of RMs to the different applications.

— ISO/TR 16476 :2016 Reference materials — Establishing and expressing metrological traceability of quantity values assigned to reference materials - This Technical Report investigates, discusses, and specifies further, the general principles of establishing traceability of measurement results laid down in the Joint BIPM, OIML, ILAC and ISO Declaration on Metrological Traceability, in particular for values assigned to (certified) reference materials.

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

- ✓RM is a generic term
- ✓Properties can be quantitative or qualitative, e.g. identity of substances or species
- ✓Uses may include the calibration of a measurement system, assessment of a measurement procedure, assigning values to other materials, and quality control.

Certified Reference Material (CRM)

Reference material (RM) characterized by a metrologically valid procedure for one or more specified properties, accompanied by an RM certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability

- ✓The concept of value includes a nominal property or a qualitative attribute such as identity or sequence.
- ✓Uncertainties for such attributes may be expressed as probabilities or levels of confidence.

Reference Material Producer(RMP)

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,
- ✓issuance of a reference material certificate or other statements for the reference materials it produces

RM Document

Document containing all the information that is essential for using any RM

Reference Material Certificate

Document containing the essential information for the use of a CRM, confirming that the necessary procedures have been carried out to ensure the validity and metrological traceability of the stated property values

Product Information Sheet

Document containing all the information that is essential for using an RM other than a CRM

Certified Value

Value, assigned to a property of a reference material that is accompanied by

an uncertainty statement and

a statement of metrological traceability,

identified as such in the reference material certificate

✓A CRM shall have at least once certified Value

Operationally defined measurand

Measurand that is defined by reference to a documented and widely accepted measurement procedure to which only results obtained by the same procedure can be compared

Examples include crude fibre in foods, impact toughness, enzyme activities and extractable lead in soils.

Property Value (of a reference material, RM)

Value corresponding to a quantity representing a physical, chemical or biological property of an RM

Production (of a reference material, RM)

All necessary activities and tasks leading to the release and maintenance of an RM (certified or non-certified)

Activities include, for example,

- ✓Planning!
- ✓ (production) control,
- ✓material handling and storage,
- ✓material processing,
- ✓assessment of homogeneity and stability,
- ✓characterization,
- ✓assignment of property values and their uncertainties!!
- ✓Authorization!!! and
- ✓issue of RM certificates or other statements!!!!.

Candidate Reference Material

Material, intended to be produced as a reference material (RM)

A candidate material has yet to be characterized and tested to ensure that it is fit for use in a measurement process. To become an RM, a candidate material needs to be investigated to determine if it is sufficiently homogeneous and stable with respect to one or more specified properties, and is fit for its intended use in the development of measurement and test methods that target those properties.

A candidate reference material may be an RM for other properties, and a candidate reference material for the target property.

Matrix Reference Material

Reference material that is characteristic of a real sample. EXAMPLE: Soil, drinking water, metal alloys, blood. (naturally contaminated)

Matrix reference materials may be obtained directly from biological, environmental or industrial sources.

✓Matrix reference materials may also be prepared by spiking the component(s) of interest into an existing material.

✓A chemical substance dissolved in a pure solvent is not a matrix material.

✓Matrix materials are intended to be used in conjunction with the analysis of real samples of the same or a similar matrix.

Primary measurement standard

Measurement standard that is designated or widely acknowledged as having the highest metrological qualities and whose property value is accepted without reference to other standards of the same property or quantity, within a specified context

Secondary measurement standard

Measurement standard whose property value is assigned by comparison with a primary measurement standard of the same property or quantity

Sample

Portion (amount) of material taken from a batch

- ✓The sample should be representative of the batch with respect to the property or properties being investigated.
- ✓The term may be used to cover either a unit of supply or a portion for analysis.
- ✓The portion taken may consist of one or more sampling units (such as subsamples or units) and the batch may be considered to be the population from which the sample is taken.

Minimum sample size (minimum sample intake)

Lower limit of the amount of an RM, usually expressed as a mass quantity, that can be used in a measurement process such that the values or attributes expressed in the corresponding RM documentation are valid

Characterization (of a reference material)

Determination of the property values or attributes of a reference material, as part of the production process

Value assignment

Process by which reference material (RM) property values or attributes obtained by characterization are combined and expressed in accompanying RM documentation

Homogeneity

Uniformity of a specified property value throughout a defined portion of a reference material (RM)

✓Tests for homogeneity are described in ISO Guide 35.

✓The 'defined portion' may be, for example, an RM batch or a single unit within the batch.

Between-unit homogeneity

Uniformity of a specified property value among units of a reference material

The term "between-unit homogeneity" applies to any type of package (e.g. vial) and other physical shapes and test pieces.

Within-unit homogeneity

Uniformity of a specified property value within each unit of a reference material

Stability

Characteristic of a reference material, when stored under specified conditions, to maintain a specified property value within specified limits for a specified period of time

- ✓ Long term stability – Stability under specified storage conditions
- ✓ Short term term stability – Stability under specified transport conditions.

Long term stability

Stability of a reference material property over an extended period of time

- ✓At the shelves of the RMP
- ✓At the specified storage conditions

Short term stability

Stability of a reference material (RM) property for the time period and conditions encountered in transportation to the user of the RM

Transportation stability has often been referred to as "short term stability".

Life time (of an RM)

Time interval during which RM properties retain their assigned values within their associated uncertainties

The lifetime is often determined retrospectively, i.e. after RM properties no longer retain assigned values or attributes

Time interval during which the RM can be used

Period of validity (of a RM)

Time interval during which the producer of the RM warrants its stability

- ✓ The period of validity may be expressed as a specific date or an otherwise defined period of time.
- ✓ The period of validity is designed to be within the lifetime of an RM.

Commutability

Property of a reference material (RM), demonstrated by the equivalence of the mathematical relationships among the results of different measurement procedures for an RM and for representative samples of the type intended to be measured

✓Mainly applicable to clinical RMs

Calibrant

Reference material used for calibration of (an) equipment or a measurement procedure

Quality control material

Reference material used for quality control of a measurement

Indicative Value

Also referred as Information Value

Value of a quantity or property, of a reference material, which is provided for information only

- ✓ **An indicative value cannot be used as a reference in a metrological traceability chain**

Reference method (Reference procedure)

Measurement method, that has been shown to have the appropriate trueness and precision for its intended use and has been officially defined as reference method by a competent body

(RM) Certification report

Document giving detailed information, in addition to that contained in a reference material certificate, (e.g)

- ✓the preparation of the material,
- ✓methods of measurement,
- ✓factors affecting accuracy,
- ✓statistical treatment of results, and
- ✓the way in which metrological traceability was established

Subcontractors

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 under its own management system on behalf of the RMP

Key tasks/aspects of the RM 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 reference material certificates or other statements for the RMs + selection of subcontractors

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.

Simple random sampling

Sampling, where a sample of *n* sampling units is taken from a batch in such a way that all the possible combinations of *n* sampling units have the same probability of being taken

Stratified sampling

Sampling such that portions of the sample are drawn from the different strata and each stratum is sampled with at least one sampling unit

Stratified simple random sampling

Simple random sampling from each stratum

If the proportions of items drawn from the differing strata are equal to the proportions of population items in the strata, it is called proportional stratified simple random sampling

Target Value

Property value of an RM specified on the basis of its intended use

The target value of an RM property is usually specified in the design phase of RM production (e.g) Soil CRM for series of trace level elements.

Target measurement uncertainty (Target uncertainty)

Measurement uncertainty specified as an upper limit and decided on the basis of the intended use of measurement results

For the production of RMs, the term target uncertainty may be used to describe the intended uncertainty for the assigned property value

Which organization can be called as an RMP

- ✓ RMP only shall do the following activities and the same can't be subcontracted:
  1) Production planning,
  2) Selection of Subcontractors
  3) Assignment of Property Values & their uncertainties,
  4) Authorization of property values & their uncertainties.
  5) Authorization of RM documents
- ✓ Although RMP accreditation conveys competence as a producer (not as a laboratory), testing and/or calibration are integral components of RM production.
- ✓ Where an organization only provides services such as the provision of reference values to a Candidate RM, it shall not be considered as a RMP.

Scope of accreditation of RMP

Scope of RMP should include – matrix, meausrand, and concentration.

- ✓ If the measurand is <u>quantitative,</u> the range of values in which RMP has competence + Measurement Uncertainty are to be specified for a CRM.
- ✓ This can be at percent level, ppm level or ppb level.
- ✓ RMP producing RMs with identification value (such as species identification) or where the property value is an ordinal number (such as a colour fastness chart) do not require an uncertainty value to be stated in the scope of accreditation.

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SYMBOLS USED IN RMP STATISTICS

y_{char} – Certified property value
S_{bb} – Between unit SD
S_w - Within unit SD
S_r – Repeatability SD and S_R – Reproducibility SD
u_{char} – Standard uncertainty due to characterization
u_{bb} – Between unit (standard) uncertainty
u_{wb} – within unit (standard) uncertainty
u_{hom} - Homogeneity (standard) uncertainty
u_{lts} – Uncertainty (standard) due to long term stability (storage) -
u_{sts}- Uncertainty (standard) due to short term stability (transport)
u_{trg}- Target standard uncertainty
u_{CRM} – Standard uncertainty of the certified Value
U_{CRM}- Expanded uncertainty of the certified Value

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