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Reference materials — Establishing and expressing metrological traceability of quantity values assigned to reference materials

Matériaux de référence — Etablissement et expression de la traçabilité métrologique de valeurs assignées à des matériaux de référence

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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ISO/TR 16476 was prepared by the ISO Committee on Reference Materials (ISO/REMCO).

Introduction

Reference materials (RM), in particular when certified (CRM), are a major tool for assuring the quality and reliability of results obtained in measurement and testing. CRM property values, in particular used for assessing the trueness of a measurement procedure as implemented in a laboratory, also establish traceability of the measurement result. Which reference the property values assigned to (C)RM should be traceable to, and how this traceability should be established, demonstrated, and reported on certificates is, therefore, a question of primary importance, mainly for RM producers. However, users of (C)RMs should also know what the endpoint of their traceability chain is, in particular for all purposes of cross-border acceptance of measurement results.

It was therefore considered necessary to conduct a study into existing principles for, and requirements to, the traceability of (C)RM, in particular with a specific view to the current definition of metrological traceability given by the Vocabulary of International Metrology (VIM), edition 3, 2007.

Reference materials — Establishing and expressing metrological traceability of quantity values assigned to reference materials

1 Scope

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 [1], in particular for values assigned to (certified) reference materials. The document covers the following topics:

a) a study into existing principles for, and requirements to, the traceability of the value assigned to the property of a (C)RM, with a specific view to the current definition of metrological traceability given by the 2007 edition of the VIM (published also as JCGM 200:2008[2] and ISO/IEC Guide 99:2007[21]);

b) the development of a sensible, widely applicable approach to the understanding of the traceability of a value assigned to (C)RM property;

c) recommendations on how traceability should be established, demonstrated, and reported on certificates and other documents accompanying (C)RM.

The developed approach is exemplified for measurement procedures not covered earlier by other guidance documents on the topic.

2 The VIM definition of metrological traceability

The recent edition of the VIM[2],[21] defines *metrological traceability* (term 2.41) as

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.
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 P-10:2002).
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.

NOTE 7 makes clear that the measurement method/procedure is a part of the traceability statement, but insufficient if taken alone. This implies that a measurement result or the assigned value of a (C)RM can be traceable to a method or a series of methods used, but not to the method alone, although such statements can still be found on CRM certificates. Without any doubt, the measurement procedure used will mostly be reflected in the definition of the measurand, but additionally, the value assigned to the measurand has to be made traceable to stated references given the procedure applied, thus, the latter cannot be the endpoint of the traceability chain for the assigned value. Recent presentations on the topic (e.g. Reference [3]) support this viewpoint.

As expressed in NOTE 2, the definition as given above is governed by the (assumed) existence of a straightforward, single-route top-down reference standard hierarchy. Reference [4], as a guidance to implement the above VIM definition in chemistry, almost always assumes the existence of higher-order reference materials, conveniently certified at the highest level by using allegedly primary methods. This Technical Report does not go into further details of these situations since References [4] to [6] provide sufficient guidance. Considerations and guidance on traceability hierarchies together with graphs visualizing and illustrating traceability chains, including branched ones, can also be found in Reference [7].

The described philosophy works fine for all levels which still have a "higher-order" level above, or fields where primary methods exist and can readily be used for a valid and reliable value assignment to the measurand. However, at some point, the top with no "higher-order" is reached. It may also be stated that for a huge amount of certified reference materials at this level, no primary method is available for assigning values to the measurands. This causes the general problem of traceability for property values of (C)RMs allocated at prominent places in the hierarchy. More critical points will be discussed under Clause 3.

NOTE An annotation document is being developed. Its aim is to give further explanations to the VIM definitions; it will also provide advice regarding the application of these definitions.

3 Challenges arising from the definition of metrological traceability

3.1 Conventions

For the purposes of this Technical Report, the following conventions apply.

— "Traceability of an RM"

  is in common and daily use, it is understood throughout as the traceability of the quantity value assigned to a (certified) reference material.

— "(Analytical) method"

  is used in the sense of defining the instrumental implementation of the (most often physical) principle of obtaining, from an appropriately pre-processed and/or transformed object under

investigation, a signal (subject to further processing) reflecting the sought-after property. Such implementations are, for example, ToF-IDMS, GC-FID, LC-MS/MS, HPLC-DAD, FT-IR, etc.

— "Measurement protocol"

is used to refer to measurement procedures prescribed or standardized to an extent that the value(s) assigned to the material becomes senseless without direct reference to these prescriptions, i.e. where not only the *conditions* under which measurements have to be taken but *also form, structure, shape, size* and/or *composition* of the specimen are prescribed.

— "RM document", sometimes also called "property value sheet" or "product information sheet" (see ISO Guide 31)

is used as an analogue to, and distinction from, the term "certificate" as defined in ISO Guide 31. Certificates refer to CRM, while an RM document provides the necessary information on the properties of a (non-certified) RM.

— "Matrix (C)RM"

an RM made out of natural-born substance(s) or synthetically re-constituted ingredients, characterised for composition.

— "Property (C)RM"

an RM characterized for a property other than the content of main components and/or impurities as e.g. tensile strength or Charpy impact for an alloyed steel.

NOTE This Technical Report refers to the requirements of ISO Guide 34, in force at the time of publication of this Technical Report. For traceability issues, the future ISO 17034 will also follow the principles of the named ISO Guide 34.

3.2 (C)RM as the carrier of traceable values

In the context of (C)RM production, a basic problem of the definition of metrological traceability (see Clause 2) is that it refers to traceability of a result of a measurement. (C)RMs are normally considered as artefacts providing traceability of a measurement result.

NOTE An RM which comes without a (measured) value attributed to its properties, e.g. in cases where the material has an intended purpose not requiring such attributed value, does not experience the need of establishing traceability.

The value and uncertainty carried by an (C)RM are, in virtually almost all cases, combinations of results of various measurements. These results may refer to the different steps of RM production, namely homogeneity and stability estimation, and to measurements taken in the characterization step based upon independent implementations of the same measurement procedure, or implementations of different independent measurement procedures.

Even in cases when all of the single results obtained in an RM certification are traceable, it remains unclear to which extent and endpoint of the traceability chain a combined result is traceable. This problem increases considerably if the results to be combined are traceable to different endpoints, or at least via different pathways all having different lengths and reliabilities.

EXAMPLE Karl Fischer titration and the oven (drying) method have different endpoints of their traceability chains. It might be sensible to include the method in the definition of the measurand which solves the problem of the traceability endpoint.

However, for the seemingly clear specification "water in a matrix", the above mentioned problem arises. A sensible traceability statement for the value combined from results of both methods might be based upon the more direct oven method (see also 5.3.2).

3.3 Implicit traceability to the unit of the measurement scale

The measurement procedure is a convention, it most often also includes transformation(s) of the measurand. This holds for most areas in chemistry, biology, or life sciences. Different conventions (i.e. different measurement procedures) for the same measurand may lead to different results, i.e. they turn out to be incompatible. This is reflected in NOTE 5 to the definition saying that traceability is a necessary condition for *comparability* of measurement results, but insufficient for their *compatibility*.

Generally speaking, the measurement procedure has a non-negligible influence on the value assigned. The principal approach is that traceability can only be established "given the specified measurement procedure used". The specification of this procedure in a written standard, an SOP, etc., is a nominal prescription. Any implementation in a specific place, by a specific operator using specific equipment will cause inevitable deviations from the prescription, no matter whether these are negligibly small or introduce a real contribution to the total uncertainty. The deviations should be assessed in specific investigations virtually considered as calibrations against the nominal prescription.

EXAMPLE ISO 148-3 describes the production of samples for Charpy impact tests. ISO 148-3 provides nominal values for the size of the sample and the location and shape of the V notch. Despite the fact that the instrument measuring the size (e.g. a calliper) should duly be calibrated and introduces a measurement uncertainty, the machining tool also has a certain variability. Both should be considered.

NOTE In chemical analysis, a ruggedness test as part of a thorough method validation assesses most of the deviations occurring from implementation of a method under real, and varying within specified limits, laboratory conditions.

All of these calibrations will normally not introduce real corrections to the measured value but contribute to the overall uncertainty which makes the approach compatible with the VIM definition.

It is commonly accepted that the combination of metrological traceability and proper measurement uncertainty is the only way how measurement results can legitimately be compared.[8] Moreover, measurement uncertainty estimation of the calibration steps is a mandatory prerequisite for the establishment of traceability. The concept of calibration against a nominal requirement closes the gap in cases where the routes to measurement scales (SI and others) are considered "indirect". Demonstration of compliance with nominal requirements has to be carried out using measuring instruments which are, for the measurand they tackle, traceable to the corresponding unit of the scale (callipers, balances, volumetric flasks, etc.). This concept is formalised as approach B under Clause 4.

The significance and influence of indirect pathways to measurement scales is also recognized in the Joint Declaration on Metrological Traceability[1] stating that "*In general, … references are the International System of Units (SI), but where such traceability is not yet feasible, measurement results should be traceable to other internationally agreed references…*"

It might seem viable to attribute all the peculiarities of the measurement method or procedure to the definition of the measurand as proposed in Reference [9]. In general, one should remember that the VIM defines the measurand as the "quantity intended to be measured", not as the procedures necessary for accomplishing the intention. At the same time, the faults that might happen when the quantity is measured are not considered.

Two other points have to be considered.

— Firstly, the approach of Reference [9] will work only with one single method of determination which then (according to the requirements of ISO Guide 34) should be a primary method, a restriction limiting the applicability of the approach to special cases.

— Secondly, it will limit the field of application of the material or its commutability and, thus, considerably reduce its technical and commercial value.

A sensible and balanced distribution of method impact on the measurement result between the definition of the measurand and the traceability chain(s) to units of scale is therefore crucial (see also 5.4).

3.4 Traceability networks

NOTE 4 in the definition of *metrological traceability* (Clause 2) suggests that for measurements with more than one input quantity in the measurement model (a situation which is daily practice in chemical analysis and virtually all fields of testing), 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.

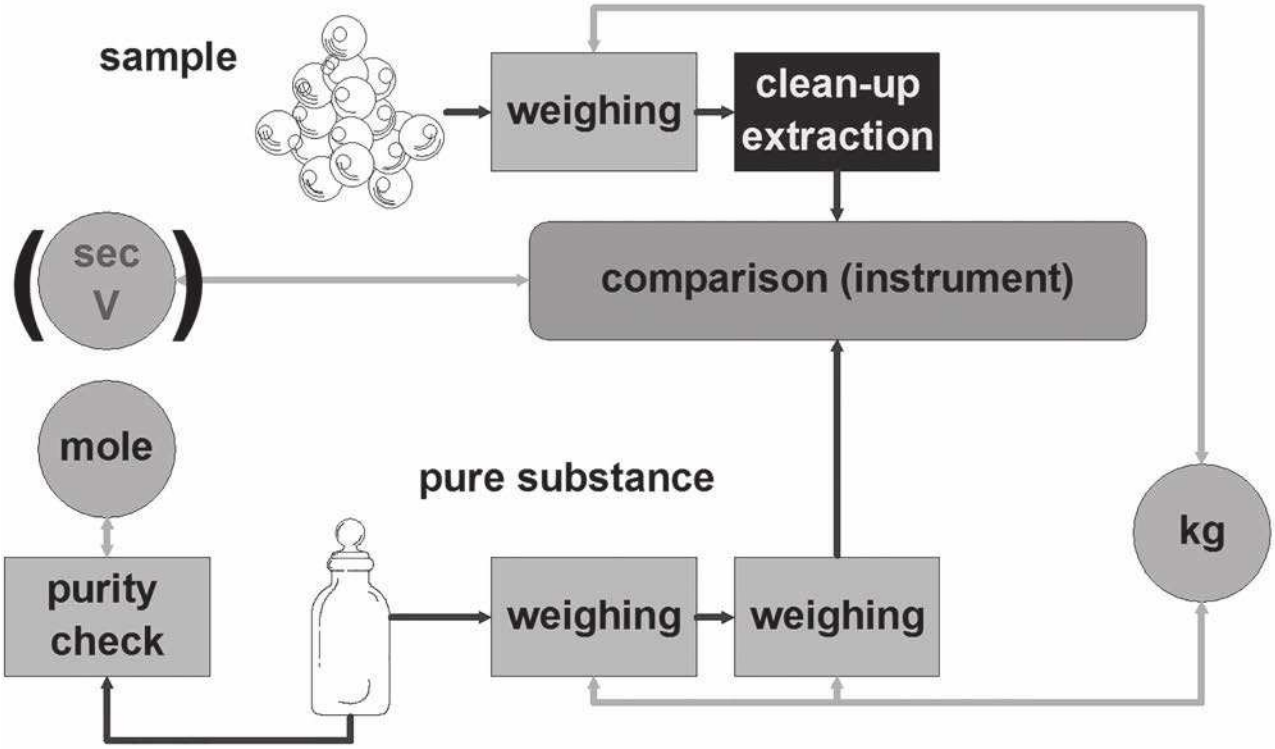


Figure 1 — "Horizontal" traceability network relating the measured quantities in a measurement procedure model to a set of SI units

It is assumed that this explicitly allows a "horizontal" networked strategy for establishing the traceability of a particular implementation of a measurement procedure as visualized in Figure 1. The concept formalized under approach B of Clause 4 is a consequence of NOTE 4 to the definition of metrological traceability and implements this "horizontal" strategy. It is the only feasible approach when no higher-order reference is available in the vertical direction.

3.5 Properties expressed in units of measurement scales other than the SI

Most of the scales other than the SI have nevertheless similarities with the latter, namely that they are realised by a single or a set of materialisations/artefacts with assigned values expressed predominantly in real numbers (e.g. pH scale). Furthermore, fractions or multiples of the basic unit exist. Some scales use ordinal numbers which express a cardinal "smaller-larger" relationship between the realizations of the points on the scale (e.g. Mohs hardness, see Reference [10]) rather than an explicit proportionality or a counting result. Here, specific problems with the resolution of the scale may arise. However, for establishment of traceability to these scales the same rules and recommendations may be applied as given in this Technical Report for traceability to the endpoint SI.

A prominent, widely used non-SI measurement scale is the series of natural numbers. It is the basic measurement scale in all areas of measurement where counting is involved, e.g. of specified objects (pollen in a certain amount of air, *E.coli* bacteria in a specified volume of a food product, etc.). The

peculiarity of this scale is that no materialization of the unit exists to which traceability might be established by direct comparison (calibration).

On the other hand, the unit "unity" can hardly be misinterpreted, and an interpretation of the unit in one implementation will exactly match the interpretation in any other. The problems are rather object-specific (misidentification of objects, double-counting, object overlap, etc.), and the resolution of the scale always has to be taken into account. Furthermore, depending on the kind of the objects and the background of the measurement, statistics different from those commonly accepted for continuous-scale measurements may apply. Thus, the procedure and its specifications gain even more importance for measurement results expressed in the unit of this scale, and the impacts of deviations from the specified procedure has to be thoroughly evaluated. However, also with these peculiarities, the principles of Clauses 4 and 5 also apply here.

3.6 Properties other than quantitative

It is assumed that this is covered by NOTE 1 in the definition of *metrological traceability* (Clause 2) which uses the term "non-ordinal quantity" meaning that these measurement results are traceable to the measurement procedure alone. However, more guidance is needed for the distinction of ordinal and non-ordinal quantities, in particular with a specific view to the fact that modern measurement procedures virtually always involve measurements of fully quantifiable (and, thus, not non-ordinal) quantities and some nominal-valued decisions on the set of quantified measurement results.

Examples are identity of a substance which materializes through measurement, and the sequence of objects which involves identity and a series of ordinal numbers.

This Technical Report solely deals with quantitative results.

3.7 Summary of an ISO/REMCO event on metrological traceability

In June 2012, ISO/REMCO held a brainstorming session on recent views and approaches to (C)RM traceability in Vienna/Austria, in connection with its 35th General Assembly. The session could be joined by interested parties world-wide via on-line (video and telephone) connections.

Issues covered during the session included the role of (C)RM in establishing traceability and traceability statements in certificates. Three major perspectives have been considered in presentations, namely those of users of (C)RM, the accreditation bodies, and the reference material producers (RMP). The presentations and a summary are available on the ISO/REMCO webpage.

The user's perspective referred to the field of geoanalysis (in particular XRF analysis of minerals) and emphasized a) the use of (C)RM specifically tailored for use in the area and b) the impact of calibration pathways (standard solutions versus matrix (C)RM), in particular unresolved inconsistent results when using different calibrants.

Accreditation bodies (AB) identify increased and evolving expectations to RMP (accredited under ISO Guide 34), statements of traceability (required under ISO Guide 34), additional information on the certification procedure (certification report), and the intended use of the (C)RM. Users (accredited under ISO/IEC 17025) are required to describe the role of (C)RM in establishing the traceability of their results. (C)RM are critical consumables requiring a specific traceability evaluation if not sourced from accredited RMP or a material included in KCDB Appendix C or the JCTLM RM database. It was also stated that the AB implementation policy needs to be consistent with respect to traceability.

An RMP scrutinized the role of (C)RM in the delivery of traceability, providing examples of how (C) RM can be used to validate results including measurement uncertainty assignments, demonstrate the equivalence of measurements, establish comparability (in the VIM sense) to a measurement scale, and evaluate and correct for bias.

Fully consistent with this Technical Report, participants of the event concluded that traceability

— cannot be established to an institution,

— establishes comparability, not necessarily trueness of results, and

— is defined by, and potentially limited to, the certification method (for method-defined measurands).

Full information from the RMP on the certification procedure and the intended use is critical and should be required by the users (e.g. in the form of a certification report). The challenge of propagating a quantity through a traceability chain when the measurand changes is generally underestimated (see 3.3), implying a need to check with care for inconsistencies between "claimed" and "actual" quantity measured.

The following conclusions have been drawn.

— Current practice of reporting traceability on CRM certificates is very often not consistent or sufficient.

— A need for evaluation (by RMP and accreditors) of traceability statements to "higher-order" references (including but not limited to SI) exists.

— Traceability statements should avoid generic claims, and a concise summary of the technical basis/certification procedure used to obtain the property values should be available (at least on request of users or accreditors).

— Intended-use statements are a critical component for appropriate use by end users.

— Further work is needed on minimum requirements for the content of certificates and supplementary information. For possible approaches, see Clause 6.

4 Approaches to metrological traceability of (C)RM

4.1 General

Given the definition and the considerations made in Clauses 3 and 4, two approaches to (C)RM traceability seem feasible in principle. Note that their citation (as A and B) should in no way be confused with preferences given, or hierarchies attributed to, the approaches.

4.2 Approach A

According to NOTE 2 in the definition of *metrological traceability* (Clause 2), metrological traceability requires an established calibration hierarchy. One might be tempted to define (C)RM as being endpoints of the traceability chain which do not need further traceability "upwards". In particular, one might look at (C)RM as being artefacts which establish their own measurement scales.

NOTE A small number of recent CCQM Key Comparisons might be interpreted into this direction although basically covering other aims. CRM from different NMI representing different amounts of substance of the same analyte in the same matrix have been compared for equivalence, thus, establishing a "scale" of this specified analyte in the specified matrix, say NO in N_2, or amounts of ethanol in water.

The approach has a number of undoubted advantages and is used for the reference standards produced and issued by the World Health Organization (WHO). Both the measurement uncertainty calculation and the traceability chain start from the internationally accepted reference standard. The validity of the standard is assured by a series of technical and assessment procedures,[11] namely:

— The need is recognized by scientific and medical community worldwide and a case formally made by the WHO Secretariat to the Expert Committee on Biological Standardization (ECBS) on the basis of public health impact.

— Working groups of experts are involved in setting the priorities and characteristics for selection of the candidate reference preparations.

— An international collaborative study has to be carried out before any candidate reference preparation can be considered for establishment by the WHO ECBS.

— The goal of such a study is to determine which candidate material is suitable to serve as a WHO reference material for the standardization of a biological product or of an in vitro diagnostic tests.

— An internationally agreed unit is attributed to the first WHO Biological Reference Material for biological activity characterization. The continuity of such a unit is ensured by replacement with a new batch of reference material which is calibrated against the first or previous reference material.

— A requirement to be met by any batch of a WHO Biological Reference Material is that the content in every ampoule in the batch should be identical in terms of composition, quantity, potency and stability.

— The Biological Standardization document which reports the international multi-method collaborative study is peer-reviewed before being submitted to the WHO ECBS. It has to be approved by the ECBS for final release of the material.

An overview[12] of the fields of analytes and measurement areas covered by WHO standards is given in Annex C, and an example of accompanying documentation for a primary standard shown. The WHO creates as many scales as is needed in reality.

Propagating and multiplying this fit for the specific purposes approach to the full spectrum of measurement and testing activities would create a very large (at least infinite) number of scales, one for each feasible analyte-matrix (in chemistry) or property-of-substance combination (in testing). Although this treatment of the requirement for calibration hierarchies does also not fully coincide with the network idea of NOTE 4 in the definition of *metrological traceability* (Clause 2), where calibrations may be at the same level but go into different "horizontal" directions, there are situations (in particular for qualitative-property RM) which will make approach A mandatory. This might be covered by format D in 6.2. However, this is not further elaborated in this Technical Report (see also 3.6).

4.3 Approach B

This approach is fully in line with the principles of the ISO Guide 35[20] and described by the options given under ISO Guide 35:2006, 9.2. Traceability is stated "given the specified measurement procedure used", i.e. the pathway and the endpoint of the traceability chain have to be specified. The specification of the procedure is nominal. Any implementation in a specific place will cause deviations from the nominal prescription. These need to be assessed in specific investigations virtually considered as calibrations against the nominal (written) standard. For more detailed considerations, see the example in Annex A.

The complete model formula describing the measurement procedure, at least for the majority of measurement procedures commonly used in chemical analysis, but also in testing, takes the form (see, for example, Reference [13]):

$$x_{\text{meas}} = \frac{\prod_{i=1}^{k} p_i}{\prod_{i=k+1}^{m} p_i} \cdot \prod_{i=m+1}^{n} F_i \quad \text{with} \quad 1 \le k \le m \le n \tag{1}$$

where the p_i represent the directly measured/determined (explicit) parameters, and the F_i the influences from grouped/combined sources, both with and without corrective influence (i.e. values differing from unity or not), and all with uncertainty contributions. Special cases, where model formulae include additive terms or are non-linear, have to be considered separately. However, the division into directly observed and indirect influential parameters equally applies.

The F_i influences may, for example, represent the (used for correction or not) bias term from a calibration, or the degree of compliance with a nominal prescription. As compliance is normally assumed, the value assigned to the corresponding F term would be unity, but the uncertainty connected with this term

would be assessed in a virtual "calibration" procedure by deliberately deviating from the prescription and evaluating the influence on the measured value. In method validation, this is normally called robustness or ruggedness test. Note that the model equation as above can be treated as a consequence of NOTE 4 in the definition of *metrological traceability* (Clause 2).

With the model formula above, the relative uncertainty attributed to the measurement result would be

$$u_r^2(x_{\text{meas}}) = \sum_{i=1}^{m} u_r^2(p_i) + \sum_{i=m+1}^{n} u_r^2(F_i) \tag{2}$$

except possible correlation terms which have to be accounted for if the influential parameters are not, or not fully, independent of each other.

NOTE For RM coming without a (measured) value, see 3.2.

5 Establishing traceability of (C)RM property values (Approach B)

5.1 Principles

Under approach B, the traceability of a (C)RM can be established within a framework of reasonable interpretations of the basic VIM definition, namely:

— Traceability of the assigned value of a (C)RM is a property of this value whereby the single or a consolidated set of measurement results obtained for the (C)RM can be related to a single or a set of references through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty.

— A reference can be an established and well-understood method/procedure, a written description and specification of an operational procedure, or an artefact/artefacts realizing a point or a range on the measurement scale of the quantity under consideration. Explicit reference has to be made to the measurement procedures applied by citing the standard, protocol (e.g. AOAC Peer Reviewed Method), publication or text book.

— Members of a set of references may refer to the same quantity (when defining a measurement scale) or of different but essential in the measurement process quantities (realizing a traceability network). This is particularly important for more-dimensional measurands (e.g. spectra).

— A consolidated set of measurement results is a measurement result combined from several measurement results using appropriate procedures which assure full compatibility between the results combined and the result consolidated from the former, all within an appropriately assessed uncertainty. The establishment of the total measurement uncertainty budget of the consolidated value follows the commonly accepted rules and includes allowances for the "procedure impact" according to Clause 4.

Compatibility between the results combined may arise *per se* or may have to be established by introducing uncertainty components which account for data discrepancies. Decision on the level of admissible discrepancy is case-sensitive and subject to expert judgment, meaning that starting from a certain level of discrepancy, the measurement results may seem non-commensurable (and thus no longer traceable to the same or the same set of references).

Establishment and statement of traceability of a CRM is mandatory; it is not for an RM fulfilling the basic requirements only (i.e. coming without an assigned value). However, if any values are assigned to an RM, their traceability should be assured as well (see ISO Guide 33:2015, 6.4.2).

5.2 Traceability pathways

ISO Guide 34 and ISO Guide 35 in their current editions accept four general approaches for the characterization of reference materials, namely

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

b) measurement by two or more independent reference methods in one laboratory;

c) measurement by a network of laboratories using one or more methods of demonstrable accuracy;

d) a method-specific approach giving only method-specific assessed property values, using a network of laboratories.

Traceability pathways may have different targets, namely

1) (direct) traceability to the unit of the measurement scale,

2) traceability to the unit of the measurement scale via, and given by, a measurement method or procedure, and

3) traceability to a protocol.

As a rule, pathways and certification schemes combine as shown in Table 1.

Table 1 — Certification/characterization schemes and pathways of traceability

Scheme	Pathway		
	1)	2)	3)
a)	X	—	X
b)	X	X	-
c)	—	X	-
d)	—	X	X

5.3 Steps in establishing traceability

5.3.1 General

General steps to be taken, and provisions to be made are described in ISO Guide 35[20] and should be followed strictly. Major points are as follows:

— *Transformation (of the measurand)*: Although the determination of the property value itself can be made traceable to appropriate units through, for example, calibration of the measurement equipment used, steps like the transformation of the sample from one physical (chemical) state to another cannot. Such transformations may only be compared with a reference (when available), or among themselves. For some transformations, reference methods have been defined and may be used in certification projects to evaluate the uncertainty associated with such a transformation. In other cases, only a comparison among different laboratories using the same method is possible. In this case, certification takes place on the basis of agreement among independent measurement results (see ISO Guide 35:2006, Clause 10[20]).

— *Calibration* should take place against measurement standards that are traceable to appropriate references. CRMs may be used for this purpose, as long as they are suited for this purpose. The calibration should be appropriate for accurate measurements, thus, not introducing any unnecessary extra uncertainty. The reference chosen may be an SI unit (e.g. for composition measurements and many physical quantities), or a conventional scale (e.g. for method-defined characteristics).

— *All* aspects of the measurement procedure need to be under control, including sample weighing, purity of reagents, solvents, “pure materials”, calibration status of common laboratory

equipment and glassware, interferences in the measurement signal, appropriate and validated statistical/mathematical techniques for doing calculations (e.g. calibration curves, interpolations), and contaminations, losses, flaws in the measurement process.

— *Method validation* is a suitable tool for bringing aspects under proper control.

5.3.2 Combining results

This clause does not make reference to accumulation and consolidation, for statistical reasons, of a number of measurement results from a single measurement procedure, a situation which will occur, in the context of (C)RM certification, only for primary methods and direct comparison. In both cases, traceability pathways are straightforward. The Clause deals with combination of results obtained using either one measurement procedure in several implementations, or several measurement procedures in several implementations.

It is assumed that the general steps of 5.3.1 are followed for all measurement procedures and/or all implementations of measurement procedures participating in the certification process. It is also assumed that the "procedure impact", i.e. the influences of an implementation deviating from the nominal description, have properly been assessed following the principles of Clause 4 for all methods and implementations involved.

General principles, approaches and tools for combining measurement results are given in Reference [14]. From the point of view of establishing traceability, the major problem is at which point and/or by whom traceability to a materialization of the unit concerned has to be established. Theoretically, all procedures in all implementations should provide results which are a) traceable and b) traceable to the same artefact or c) have the same endpoint of the traceability chain. While requirement a) is mandatory, requirement b) will apply only in a limited number of cases. The alternative requirement c) is normally quite difficult to fulfil, in particular in interlaboratory comparisons with external participants. They are normally not in the position to verify the full traceability chain of the calibrators they use and/or demonstrate the validity and correctness of the values assigned to their calibrators.

A feasible approach (illustrated in Figure 2) would be a single traceability strand originating from a reference laboratory capable to cope with the requirement of being able to demonstrate traceability of the calibrator(s) used.

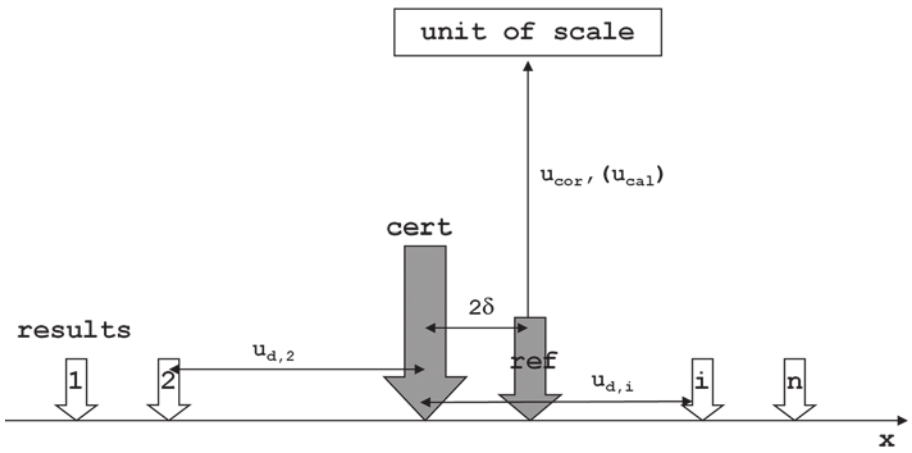


Figure 2 — Single-strand traceability to a common endpoint (unit of a measurement scale)

All measurement results provided by the participants are combined into an appropriate estimator serving as the assigned value (in Figure 2: *cert*). Each contribution is considered a calibration introducing an uncertainty, normally assessed as an average u_d of the deviations of all single values from the assigned value. The reference laboratory establishes traceability of the calibrator(s) used, thus, defining a single endpoint of the traceability chain. It determines correction factors which may apply when using the calibrator(s) (e.g. for purity), and applies it to the assigned value. The uncertainty

cumulated in the traceability chain will normally be expressed as the uncertainty of the correction factor u_{cor} (even if the factor is unity), if not, both uncertainties should be taken on board. Finally, an allowance δ for the remaining misfit between the assigned value and the result of the reference laboratory should be included in the final uncertainty budget, assessed as half of the difference between both values. Thus, the uncertainty of the characterization is (expressed as relative uncertainties)

$$u_{\text{char,r}}^2 = u_{\text{d,r}}^2 + u_{\text{cor,r}}^2 + \delta_{\text{r}}^2 + \ldots \quad (3)$$

where "…" indicates uncertainty sources other than those originating from calibration.

An alternative way of dealing with these ILC-like situations is certification based on characterization of the material using only the results from the procedure for which the traceability of the calibrator(s) used can fully be demonstrated. The ILC is considered as supporting both the assigned value and the commutability of the (C)RM. A specific "commutability" term, namely δ, can be included in the total uncertainty budget of the material making all measured values compatible.

5.4 Summary

The basic requirements to establishing traceability may be summarized in the sense that metrological traceability always consists of two parts:

— a clear definition of the measurand that defines what is supposed to be traceable;

— the traceability of the property values themselves to the appropriate stated references.

Traceability of measurement results is assured through proper calibration of all relevant input quantities against appropriate standards [revision of Reference [13]; in progress], and in most cases can only be established in a networked approach. This is, however, fully in line with the requirements of ISO/IEC 17025:2005, 5.6.

6 Reporting traceability

6.1 Inquiry

An inquiry was carried out in April 2012 into the status of traceability statements in certificates of recently released reference materials. Around 200 certified reference materials from the data base COMAR were screened following a selection criterion enabling a coverage of different types of materials and application areas as wide as possible, as well as coverage of different locations of the issuing institutes around the world (America, Asia, Australia, and Europe). Furthermore, different types of issuing institutes were considered including National Metrology Institutes (NMI), designated and other institutes, commercial associations and single commercial producers. Fifty six certificates were selected for further analysis following the above principles. The scope of materials included purity CRM, physic-chemical CRM as e.g. pH standards, CRM certified for different analyte contents and applications in environmental or food analysis, and CRM for other (i.e. mechanical) properties.

6.2 Results of the inquiry

An important observation from the inquiry is that in 28 out of the 56 investigated certificates, no traceability statement is given. These cases relate to the more complicated situations where the measurand is method-related and/or model-dependent. Furthermore, sum parameters like proximates in food and feed may constitute a certain problem. Nevertheless, traceability may be established given an adequately defined measurand.

Some institutes follow Approach B as described herein under Clauses 5 also for matrix CRM and distinguish between the measurand definition involving possible method dependence, and the traceability of the eventually measured value to analyte realizations of known purity.

Interestingly enough, the (high-)purity materials used for such purposes normally come without a (further) traceability statement.

Most often, traceability statements are given in cases where primary methods are used, traceability is taken from, and established to, the certified property value of another certified reference material, or where the measurement has been done on, or could directly be traced back to, a National Measurement Standard.

Some institutes tend to follow Approach A (see Clause 4) when omitting a statement for the traceability of the CRM itself, but stating on its use: "This RM is used… to demonstrate the chemical traceability in classical and instrumental analysis."

Finally, some institutes are probably unsure about endpoints of traceability chains. A statement like "The value is traceable to units of the SI (*S* and *m*) using conductivity cell calibrated by the CRM." circles in itself and does not provide added value to the potential user.

General conclusions from the inquiry can be drawn as follows:

— Regardless of the kind of the institute, issuers of certified reference materials (still) experience problems in establishing value traceability, and expressing it in certificates and accompanying documentation.

— Particular problems constitute (high-) purity materials, method-related/-defined measurands, sum parameters, and property CRMs.

— Guidance beyond the limits of this report might be necessary, including technical guidance for specific kinds of materials, in particular in the abovementioned areas.

Since then, some reference material producers may have changed their policies with regard to traceability statements. A new inquiry should reasonably be undertaken a certain period of time after the publication of this Technical Report.

6.3 Requirements

Traceability statements for the certified or stated property values of a (C)RM are required

— on the certificate provided with the CRM

  This statement should be as compact as possible but still reflect the different pathways of traceability. Short but comprehensive reflection of the traceability structure of a material may be complicated, in particular in network situations. Suggestions for the different cases are given below. Admittedly, special cases may require explanatory notes to the traceability statement. Instead of notes, explicit reference to a publicly available standard, document (e.g. the report), or publication is acceptable.

  Traceability statements are not required, but may nevertheless be provided on the RM document, if applicable.

— in the certification or characterization report of the (C)RM

  In the summary part of a certification report, usually the statement used for the certificate will be reproduced. The report shall contain a section on establishing traceability of the material describing the traceability pathway within the particular certification/characterization layout, the single-strand chain or network of traceability, and the contributing uncertainties of the chain. Special cases may be dealt with in detail since no space limitations apply.

NOTE 1 Fitness for the intended purpose of a (C)RM implies traceability of the property values stated for the material (if applicable).

NOTE 2 ISO Guide 34 requires recording, archiving, and full retrieval of all information related to the production of an RM/certification of a CRM, i.e. a "report" in the above sense, regardless of whether this report is of internal use only or available to the customer. However, CRM normally should have a certification report available.

NOTE 3 The requirement of a traceability statement on the certificate or RM document applies regardless of whether this documentation refers to a single object or a batch of objects. For policies involving generic certificates providing only specifications (ranges) for the property values and individual value sheets for every single item produced (and certified) under the specification, the traceability statement may be included in the specification provided the chain is properly described. The individual value sheets shall bear a reference.

Traceability statements are not required in other documentation accompanying (C)RM whatever the kind of this documentation is.

NOTE 4 Documentation other than the certificate and report normally includes handling instructions, safety warnings, safety sheets, and shipment documentation. It is obvious that these documents are not required to refer to the specific issue of traceability.

6.4 Formats

Traceability statements recommended for the use on reference material certificates depend on the certification approach used. Four cases are described below.

Case A) Measurands for which values may be assigned by using a primary method (also called method-independent measurands), where the on-site implementation of the method is well understood, and all sources of uncertainty have been investigated and are accounted for. One would state

"The certified value… is traceable to the unit of the measurement scale."

The latter may not necessarily be the SI, although this will be the case in a large number of cases.

EXAMPLE Determination of the mass fraction of ^{10}B in an aqueous boric acid solution using IDMS.

Case B) Measurands for which values may be assigned by direct comparison with a higher-order CRM, using a well-documented method in a well-understood on-site implementation, and all sources of uncertainty have been investigated and are accounted for.

B1: One would state

"The certified value… is traceable to the property value assigned to CRM XYZ."

B2: Depending on the endpoint which the higher-order CRM is traceable to, this might include that also the derived material is traceable to the unit of the measurement scale, justifying a case A statement:

"The certified value… is traceable to the unit of the measurement scale."

Such a statement requires that appropriate information on the traceability of the higher-order CRM to the measurement scale is available, documented, and can be proved in case of necessity. However, statements referring to the unit of scale and based upon long chains of comparisons between different-hierarchy-level CRMs are not encouraged here.

Note also that the certified value is not traceable to the institute issuing the CRM and the RM certificate, but to the unit of scale. In some cases, the value may be traceable to the realization of a measurement unit as maintained by a certain institution. Again, the anchor point is the realization of the unit, not the institute.

Case C) Measurands which include the definition of a specified measurement procedure.

C1: One measurement procedure in several implementations, all uncertainty sources for the measured quantities combined, plus the biases arising from differences between the implementations, plus uncertainties arising from non-compliance with the specifications of the measurement procedure. One would state

"The certified value of the measurand defined by the measurement method/procedure (ABC) as specified (in standard…), … is traceable to the unit of the measurement scale."

— The wording after "defined by…" may be adjusted according to the specific case. It may be "measurement method" only, "measurement method" plus "after pre-processing, digestion or transformation using XYZ procedure" or a generic term for the full procedure including the (analytical) method.

— However, traceability statements should be kept as short as possible. Mentioning the measurement method (if decisive) in a traceability statement is, at least partially, a repetition of the specification of the measurand. It is supported for enhancing clarity but should not be misused. If the certificate *unavoidably* states a method-defined measurand, the wording starting with "defined by…" might be omitted.

C2: Several independent measurement procedures in several implementations, all uncertainty sources for the measured quantities combined, plus the biases arising from differences between the implementations, plus uncertainties arising from non-compliance with the specifications of the methods, plus the biases between measurement procedures (arising from different measurand definitions). One would state

"The certified value of the measurand defined by either of the set of measurement procedures (ABC) as specified (in standard(s)…)… is traceable to the unit of the measurement scale."

— *As in case C1,* the wording after "defined by…" may be adjusted according to the specific case. It may be "measurement method" only, "measurement method" plus "after pre-processing, digestion or transformation using XYZ procedure" or a generic term for the full procedure including the (analytical) method.

— *As in case C1,* traceability statements should be kept as short as possible. Mentioning the measurement method (if decisive) in a traceability statement is, at least partially, a repetition of the specification of the measurand. It is supported for enhancing clarity but should not be misused. If the certificate *unavoidably* states a method-defined measurand, the wording starting with "defined by…" might be omitted.

Case C2 describes the quite often implemented approach of certification in an inter-laboratory comparison (ILC). Depending on the selection of the methods used by the participants, in particular when they comply with the mentioned under C2 criteria and all preparatory steps are traceable, the measurement scale can be the SI.

EXAMPLE An example for a CRM certified in an ILC and traceable to the SI is given in Annex C.

Case D) Measurands solely defined by a protocol. One would state

"The certified value… is traceable to the unit of the measurement scale (defined by procedure ABC)."

"The certified value… is a reference point on the measurement scale defined by procedure ABC".

The latter format reflects VIM[2],[21] definition 2.43 for *metrological traceability to a measurement unit*. If the measurement procedure defined by the protocol is a primary procedure, alternatively a Case A statement may be used. An example for an artefact-defined scale of Mohs hardness is given, and described in detail in Reference [10].

The formats align with the certification/characterization layouts and the traceability pathways in the following form:

Table 2 — Schemes, pathways and formats

Scheme	Pathway		
	1)	2)	3)
a)	A, B2	—	D
b)	A	B1, C2	—
c)	—	B1, C1, C2	—
d)	—	C1, C2	D

A considerable part of measurements can only be made and/or evaluated under the assumptions of a particular model. In these cases, it is suggested to extend the statements (especially in format C) by

"… and the evaluation on the basis of the … model."

6.5 Further recommendations

Technical needs will, in some cases, require even more comprehensive explanations than those given in the statements above. These should be included in the report for the (C)RM, and appropriately referenced to on the certificate (e.g. through notes). Issuing a technical report for a (C)RM is thus recommended and particularly considered helpful for demonstrating traceability of the assigned value(s).

Annex A
(informative)

Worked-out example

A.1 Testing procedure: Breaking strength of textiles

This is an example where the measured result is seemingly directly traceable to the SI via a well-established route of hierarchical calibrations. However, the result is meaningless for the measurand without the specified procedure. The measurand is the combination of a certain set of measured quantities and the method used. In special investigations, compliance with the procedure, i.e. the stated reference which in this case is a written standard, has to be established.

A.2 Flow chart of the method

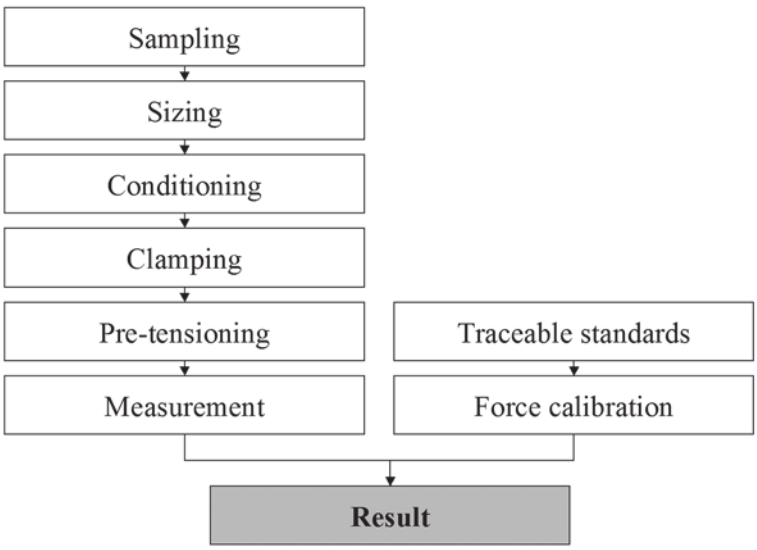


Figure A.1 — Flow chart of the method

A.3 Model equation and uncertainty budget

The model formula consists of a term related to direct, and directly traceable, measurement of the breaking force f_{br} (here as a mean value of a number of replicate force measurements), and a compliance term describing the influences of variation in the implementation of the prescribed method:

$$f_{\mathrm{br}} = \frac{\sum_{h=1}^{k} f_{\mathrm{br},h}}{k} \cdot F_{\mathrm{c}} \qquad \text{(A.1)}$$

The compliance term F_{c} consists of several terms describing compliance with the prescriptions (tolerances) set for patch width and fabrics conditioning, as well as estimates for sample skew, slip

avoidance, maximum-force determination, machine drift, and measurement repeatability (best: long-term or intermediate precision).

$$F_c = F_{pw} \cdot F_{skew} \cdot F_{slip} \cdot F_{cond} \cdot F_{d\,max} \cdot F_{drift} \cdot F_{rep} \quad \text{(A.2)}$$

The full uncertainty budget is:

Quantity	Value	Uncertainty	Relative uncertainty
mean f_{br} (A-type estimate)	as per run	—	0,041
$f_{br,h}$	—	—	0,009
F_{pw}	1	0,01	0,013*
F_{slip}	1	0,01	0,01**
F_{skew}	1	0,034	0,034***
F_{cond} (A-type estimate)	1	0,015	0,015
F_{dmax}	1	0,01	0,01****
F_{rep} (A-type estimate)	1	0,028	0,028
F_{drift}	1	0,023	0,023
f_{br} according to specs	as per analysis	—	0,069 5
* - from the specification for width (50 mm ± 1 mm) assuming a rectangular distribution			
** - undetected slip/nominal patch length			
*** - reduction in effective width from skewing, max skew angle 2°, estimated from 1/(1 + tan *a*)			
**** - worst-case estimate			

Provided measurement results are reported together with the total uncertainty estimated from the above budget, these results are traceable to the SI given the prescribed measurement procedure is used. Certification of a breaking-strength reference material seems possible in an inter-laboratory comparison scheme. All participating laboratories should provide traceable values in order to establish comparability of the data accepted for certification. However, the assigned value itself should be made traceable using the network approach as described in 5.3.2.

It should be noted that the method exemplified here includes dimensional measurements, meaning that at least a second chain of calibrations (i.e. of the dimensional measurements) is involved. Without this calibration, the compliance with the nominal prescriptions and also uncertainties of most of the *F* terms cannot be established. Its uncertainty is, however, at a level which allows neglecting it in the above budget.

Annex B
(informative)

Catalogue of analytes and measurement areas covered by WHO

The catalogue of International Reference Preparations is updated following the Expert Committee on Biological Standardization meetings (dated March 2014, web link http://www.who.int/bloodproducts/ref_materials/en/). The listings are in alphabetical order and by subject as well as for the distribution.

— Allergens

— Animal Sera

— Antibiotics

— Blood Products

— Blood Safety

— Coagulation Factors

— Cytokines and Growth Factors

— Endocrines

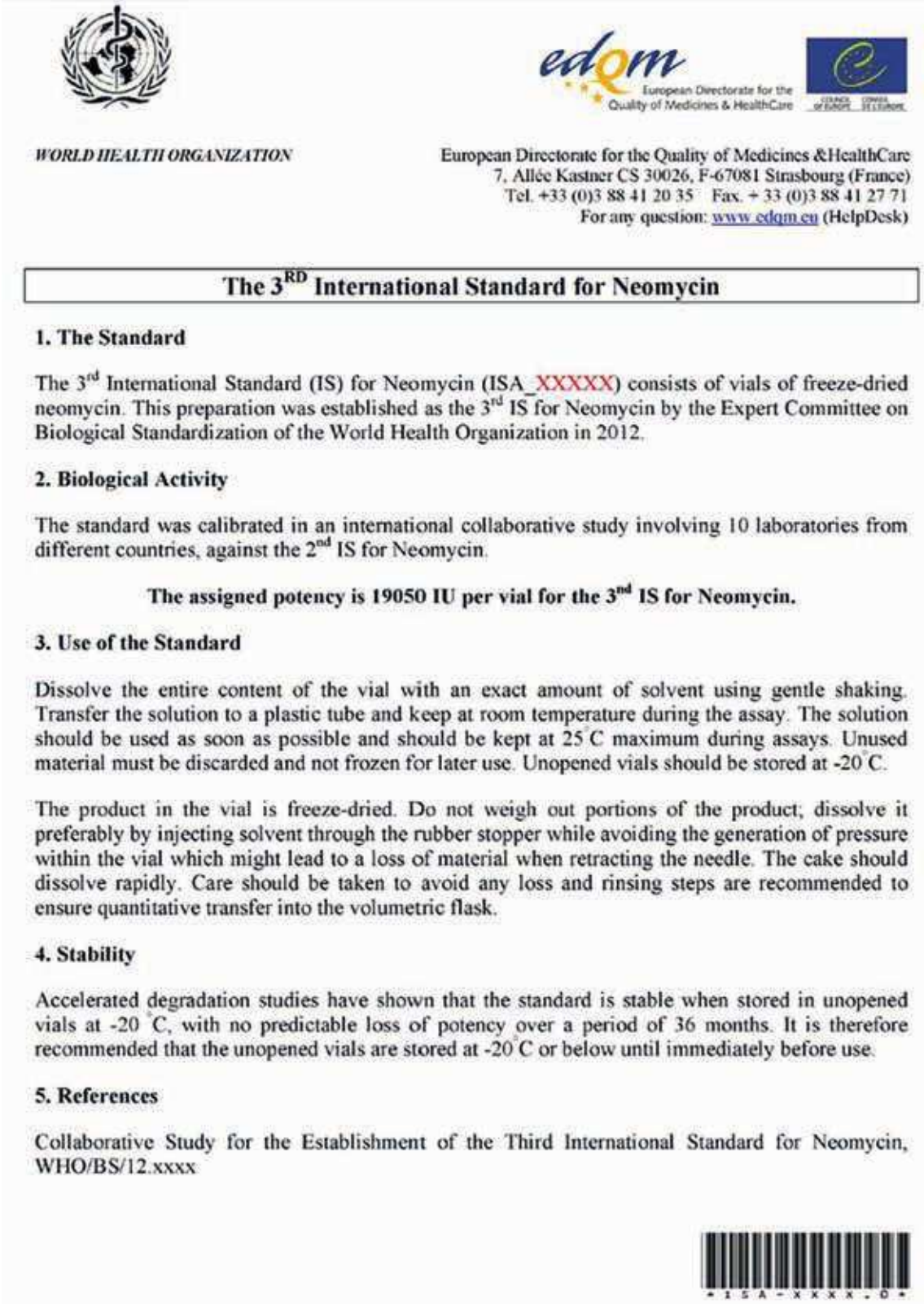
— Fibrinolytic Agents, Protease Inhibitors, Anticoagulant Substances

— Immunoglobulins and Human Sera

— Platelets

— Vaccines/Toxoids/Toxins

— Miscellaneous (including CJD specimens)



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The 3RD International Standard for Neomycin

1. The Standard

The 3rd International Standard (IS) for Neomycin (ISA_XXXXX) consists of vials of freeze-dried neomycin. This preparation was established as the 3rd IS for Neomycin by the Expert Committee on Biological Standardization of the World Health Organization in 2012.

2. Biological Activity

The standard was calibrated in an international collaborative study involving 10 laboratories from different countries, against the 2nd IS for Neomycin.

The assigned potency is 19050 IU per vial for the 3nd IS for Neomycin.

3. Use of the Standard

Dissolve the entire content of the vial with an exact amount of solvent using gentle shaking. Transfer the solution to a plastic tube and keep at room temperature during the assay. The solution should be used as soon as possible and should be kept at 25 °C maximum during assays. Unused material must be discarded and not frozen for later use. Unopened vials should be stored at -20 °C.

The product in the vial is freeze-dried. Do not weigh out portions of the product; dissolve it preferably by injecting solvent through the rubber stopper while avoiding the generation of pressure within the vial which might lead to a loss of material when retracting the needle. The cake should dissolve rapidly. Care should be taken to avoid any loss and rinsing steps are recommended to ensure quantitative transfer into the volumetric flask.

4. Stability

Accelerated degradation studies have shown that the standard is stable when stored in unopened vials at -20 °C, with no predictable loss of potency over a period of 36 months. It is therefore recommended that the unopened vials are stored at -20 °C or below until immediately before use.

5. References

Collaborative Study for the Establishment of the Third International Standard for Neomycin, WHO/BS/12.xxxx

1SA-XXXX.0

Figure B.1 — Example of an accompanying document for a primary realization of a standard

A typical example of an accompanying document for a primary realization of a standard is given in Figure B.1 (from the category "Antibiotics", compound Neomycin, 3rd issue). The documentation is part of the certification report. Traceability and uncertainty statements are omitted.

Annex C
(informative)

Example for method-independent, SI traceable values obtained by inter-laboratory comparison

Figure C.1 provides the main page of the certificate of ERM®CD200.

European Commission

ERM
European Reference Materials

JOINT RESEARCH CENTRE
Institute for Reference Materials and Measurements

CERTIFICATE OF ANALYSIS

ERM®- CD200

SEAWEED

	Mass Fraction	
	Certified value [1,2] [mg/kg]	Uncertainty [3] [mg/kg]
As	55	4
Cd	0.95	0.06
Cu	1.71	0.18
Hg	0.0186	0.0016
Pb	0.51	0.06
Se	0.088	0.010
Zn	25.3	1.7

1) Unweighted mean value of the means of accepted sets of data, each set being obtained in a different laboratory and/or with a different method of determination. The certified value and its uncertainty are traceable to the International System of Units (SI).

2) Certified mass fractions are corrected for the water content of the material (and expressed as dry mass), determined as described in the section "Instructions for use and intended use".

3) The uncertainty is expanded with a coverage factor $k = 2$ corresponding to a level of confidence of about 95 % estimated in accordance with ISO/IEC Guide 98-3, Guide to the Expression of Uncertainty in Measurement (GUM:1995), ISO, 2008.

Figure C.1 — Main page of the certificate

Methods involved in the inter-laboratory comparison included CV-, ET-, F-, Pyrolysis and Hydride-Generation AAS, ICP-OES, ICP-QuadMS, ICP-Sector-Field-MS, ID-ICP-MS, and NAA. It is supposed that under these conditions, method-specific biases are largely reduced or completely cancelled out. With due calibration, i.e. traceability of all other handling equipment, the values assigned are directly traceable to the unit of kilogram of the SI.

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[22] ISO/IEC 17025:2005, *General requirements for the competence of testing and calibration laboratories*

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