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## New definitions on reference materials

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**Abstract** The new definitions for reference material and certified reference material as approved by ISO REMCO are provided and further explained.

**Keywords** Reference material · Certified reference material · Terminology · Harmonization

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### Introduction

Definitions for the terms “Reference Material” (RM) and “Certified Reference Material” (CRM) given in the ISO Guide 30 [1] and the International Vocabulary of Metrology (VIM) [2] have been developed in the eighties of the past century based on the needs and experience of the main RM user communities at that time. With the rising awareness for analytical quality assurance (AQA) and the increasing number of standardization, accreditation and regulatory bodies dealing with AQA it became obvious that some additional aspects for explanation and clarification of these terms are necessary to avoid confusion about underlying concepts and terminological systematic. Moreover, the currently ongoing revision of the VIM has stimulated a reflection on RM terminology.

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### The ISO REMCO approach

As a result of discussions within ISO REMCO (the Committee on Reference Materials of the International Organization for Standardization) and with many stakeholders of the RM community, the committee has finally approved the new following definitions on its Annual Meeting 2005:

1. 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.

Note 4: An RM can only be used for a single purpose in a given measurement.

The new definition points to the fact that ‘Reference Material’ should be understood as a “family name”. This takes note of existing confusion among users, some producers, standardisation and accreditation bodies and their auditors, where the term RM is used both for the whole range of RMs (including CRMs) as well as for the subgroup comprising only the non-certified RMs. Another term will be recommended in the future to identify the latter, but it should be understood that the requirements of homogeneity and stability as laid down in the definition above are fundamental prerequisites for any reference material, certified or non-certified.

The second note in the definition takes into account that qualitative analysis plays an increasing role in many analytical laboratories and that proper QA/QC tools have to be provided also for this area of testing. The identity of, e.g., a chemical compound, namely its molecular structure, is indeed the target of many analytical problems. Consequently, validation and verification of such methods are also supported by reference materials.

Note 3 elaborates further on typical uses for reference materials. In contrast to the old definition, it clarifies that a particular reference material may be qualified for one or more applications, but not particularly qualified for others. For example, a specific reference material may be perfectly suitable for quality control but not for calibration. This note underpins further the generic nature of the term ‘RM’, as certified and non-certified RMs usually have distinguishable characteristics and the latter ones are more restricted in their applicability for QA/QC.

Note 4 has to be understood as a clear warning with respect to common practice in several laboratories and analytical communities. A single reference material cannot be used in the same measurement for two different purposes at the same time, e.g., both as calibrator and as the quality control material. On the other hand, a single reference material can be used to assess the reliability of a measurement procedure during its development and validation. Afterwards the same material may be used for quality control of subsequent measurements applying the validated measurement procedure.

A special subgroup of RMs, called “certified reference materials” possesses additional characteristics. This subgroup is now defined as.

## 2. 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.

This new definition takes into account that the term ‘traceability’ is now-a-days also used for identifying the source and chain of custody of a product, for example in tracing foodstuff. Consequently, the adjective ‘metrological’ has been incorporated to make the definition unambiguous in this respect. This terminology is consistent with the current draft for the revision of the VIM, which is still under discussion.

Note 1 recognizes again the increasing importance of qualitative analysis. Appropriate CRMs have to serve the AQA needs for such measurements. The problem of estimating uncertainties for results of qualitative analysis has still to be solved in many cases. Obviously, the present “Guide to the Expression of Uncertainty in Measurement” (GUM) [3] does not cover such aspects and new concepts are required.

Notes 2 and 3 are cross-referencing relevant ISO Guides. However, they are not intended to be exhaustive. Other descriptions and specific guides for the production and certification of reference materials may be fully compliant with the requirements on RMs as defined above.

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## Outlook

The long lasting discussions in RM expert groups such as ISO REMCO have demonstrated again that a precise wording is important for the common understanding of scientific concepts and classifications. However, the wider acceptance and application of such terminology depends also on the use of a reasonable level of sophistication in the chosen language. ISO REMCO will promote the new definitions in cooperation with other RM stakeholders as widely as possible and hopes that they will penetrate quickly into the scientific literature, standardisation documents, and eventually into legal texts.

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**References**

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2. BIPM, IEC, IFCC, ISO, IUPAC, IUPAP, OIML (1993) International vocabulary of basic and general terms in metrology. 2nd edn., ISO, Geneva
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