

# General guidance for the value assignment of reference materials: a proposed scope for the revision of ISO Guide 35

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## Introduction and background

The production of reference materials (RMs) is a key activity for the improvement and maintenance of a worldwide coherent measurement system. As detailed in ISO Guide 33, RMs with different characteristics are used in measurements, such as calibration, quality control and method validation, as well as for the assignment of values to other materials. Certified reference materials (CRMs) are also used to maintain or establish metrological traceability to conventional scales, such as the octane number, hardness scales and pH. Furthermore, selected pure substances are used to maintain the international temperature scale.

In order to be comparable across borders and over time, measurements need to be traceable to appropriate and stated references. CRMs play a key role in implementing the concept of traceability of measurement results in chemistry, biology and physics among other sciences dealing with materials and/or samples. Laboratories use these CRMs as readily accessible measurement standards to establish traceability of their measurement results to international standards. The property values carried by a CRM can be made traceable to SI units or other internationally agreed references during production. ISO Guide 35 explains how methods can be developed that will lead to well-established property values, which are made traceable to appropriate stated references.

For reference material producers (RMPs), there are three ISO Guides that specifically assist with the set-up of a

scheme to produce and certify RMs to ensure that the quality of the RMs meets the requirements of the end users. ISO Guide 34 outlines the requirements to be met by an RMP to demonstrate competence. ISO Guide 35 provides general guidance on property assessment issues and explains the concepts for processes such as the assessment of homogeneity, stability and value assignment for certification of RMs. ISO Guide 31 describes the format and contents of certificates for CRMs and accompanying documents for non-certified RMs, respectively.

Currently, ISO Guide 35 is in its third edition after it was revised in 2006. The Guide was developed to support best practice in the value assignment for CRMs. But a user of this type of documentation should always consider that it cannot substitute for ‘critical thinking, intellectual honesty and professional skill’ (section 3.4.8. of the Guide to the Expression of Uncertainty in Measurement (GUM), ISO Guide 98-3: 1993). Obviously, the quality of the ‘product’ RM depends as much on these aspects as on the use of general procedures and methods. Therefore, thorough knowledge of the material and its properties and of the measurement methods used during homogeneity testing, stability testing and value assignment of the material, along with a thorough knowledge of the statistical methods, are needed for correct processing and interpretation of experimental data in a typical certification project. It is the combination of these required skills that make the preparation and certification of RMs so complex. The greatest challenge in these projects is to combine these skills to allow for a smooth implementation of the project plan.

Since the release of ISO Guide 35 in 2006, ISO Guide 34 was revised and the preparation of ISO Guide 80 was started. At several occasions, ISO Guide 34 refers (also for

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non-certified RMs) to the procedures in ISO Guide 35. Therefore, the focus on ‘certification’ in the title of the current edition of ISO Guide 35 is obsolete. ISO Guide 34 became more specific in its recent revision, which allows for streamlining during the revision of Guide 35. Moreover, ISO Guide 80 will describe the preparation of non-certified in-house reference materials. As the preparation (milling, ampouling, etc.) is the same for such materials as for CRMs, a detailed section on processing in ISO Guide 35 is superfluous. Consequently, some revisions of ISO Guide 35 are required.

Therefore, Working Group 16 of ISO/REMCO, the Committee on Reference Materials of the International Organization for Standardization charged with the revision of ISO Guide 35, proposes the following scope.

### **Proposed scope**

This Guide gives general guidance and explains concepts to assist with the understanding and development of valid methods to assign values to properties of a reference material, including the evaluation of their associated measurement uncertainty and the establishment of their metrological traceability.

The Guide clearly indicates which chapters are mandatory for the production of a reference material and which chapters are optional, as well as what processes apply to

certified reference materials specifically and what chapters apply to non-certified reference materials.

This Guide complements ISO Guide 34 by providing detailed descriptions of sound approaches for the production of reference materials and by giving examples of metrologically valid approaches for the assessment of homogeneity and stability and for the characterisation of certified and non-certified reference materials, estimating uncertainties of the assigned values and by giving information on how to achieve and demonstrate the traceability of assigned values. Therefore, approaches of this Guide can be applied to demonstrate that values assigned to reference materials are traceable to the stated reference.

Where possible, this Guide will make reference to GUM (ISO Guide 98-3), as the latter describes in detail how to evaluate measurement uncertainty of a value obtained from measurement. This Guide will complement the GUM in a sense that it provides additional guidance with respect to the inclusion of the uncertainties due to the (remaining) batch heterogeneity and potential instability of the CRM in the uncertainty of the property values and the determination of these uncertainty contributions.

*Working Group 16 of ISO/REMCO welcomes comments on the proposed scope for the revision, as described above, and information on practical experience of using the present edition of ISO Guide 35. Comments should be sent to Dr. Angelique Botha (abotha@nmisa.org).*