Certified Reference Material criteria for stating a Reference Value Capability in the scope of accreditation

For Certified Reference Material Producers, the scope of accreditation must identify materials produced and reported as a Certified Reference Material.

For Certified Reference Materials, the scope of accreditation is to be expressed in terms of a best Reference Value Capability which will include the facility's estimate of their least uncertainty of measurement (U_{CRM}) for each property value's range they report. The 'Reference Value' in this sense being the provision of a property value and its uncertainty of measurement, which is then used as a Reference Standard by the material consumer. Producers are required to maintain detailed records for these estimates and to review them periodically for currency.

CRMs that are an 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 of measurement to be stated in the scope of accreditation.

As a minimum a Reference Value Capability is to be stated for each subcategory type as listed in ILAC G12 Appendix B and for each property value type (chemical, physiochemical, biochemical, clinical or physical) reported for the materials in said subcategory.

For each property value it may be necessary to further subdivided into a separate Reference Value Capability for each major technique and/or characterization method as defined by the measurement model used to evaluate the measurement uncertainty. The measurement model should include all quantities that might contribute significantly to the uncertainty of the property value. Where producers incorporate several techniques and/or methods within the one material category, the accreditation body will determine which of these are considered the major techniques and/or methods to be included in the scope of accreditation in order to suitably inform the users of the CRM as to the best capability of the producer.

コメント **[ptm1]:** The more detailed the reference value capability in the scope leads to a shorter assessment of the producer. More open scopes often require more discussion during assessment. This comment could form part of a note.

Note For the definition of a measurement model and definitions of U_{CRM}, u_{sts}, u_{its}, & u_{bb}, refer to Section 6.1 of ISO Guide 35.

Where practicable the measurement model will include contributions applicable to a best typical batch production and include contributions from short term stability (as dispatched to the customer u_{sts}), long term stability (at the time of sale u_{its}) and homogeneity (between bottle variation u_{bb}). These batch dependent contributions maybe based on ideal conditions as applicable for each material type.

The uncertainty of property values from single-artefact CRMs that are certified based on a single calibration may be carried out using the normal procedures as outlined in the GUM. It should be noted, however, that the uncertainty calculation of this type of CRM should also include long term stability effects.

Note An example of this type of CRM would be a hardness block.

In instances where subcontractors report major contributions to the uncertainty budget (u_{sts}, u_{its} and u_{bb}) the producer will provide evidence of their assessment of the subcontractors' technical competence including the subcontractors' claimed traceability and evaluation of the measurement uncertainty of these contributions. Where a subcontractor provides a reference value determination/characterisation or provides testing as part of material preparation, the requirements for measurement traceability for a calibration and test as applicable in ILAC P10 must be applied with records kept by the producer and assessed by the accreditation body.

Producers will be expected to be able to provide evidence that they can provide property values to customers with measurement uncertainties equal to those covered by the Reference Value Capability. Such evidence would typically include performance in proficiency testing, measurement audits or rigorous evaluation of the U_{CRM} during assessment.

There shall be no ambiguity on the expression of the Reference Value Capability on the scopes of accreditation and, consequently, on the smallest uncertainty of property value that can be expected to be achieved by a producer. Particular care should be taken when the property value covers a range of values. This is generally achieved through employing one or more of the following methods for expression of the uncertainty:

- A single value, which is valid throughout the value range.
- A range. In this case a producer should state proper assumption for the interpolation to find the uncertainty at intermediate values.
- An explicit function of the property value.
- Open intervals (e.g., "$U < x$") are not allowed in the specification of uncertainties.
- A matrix of measurement points where the values of the uncertainty depend on the property value and additional parameters.
- A graphical form, providing there is sufficient resolution on each axis to obtain at least two significant figures for the uncertainty.

コメント **[ptm2]:** Matrix effects maybe defined through the use of two or more ranges. Examples maybe provided in a note?

コメント **[ptm3]:** A two dimensional table is a good method for describing matrix effects. Examples maybe provided in a note?

When the property value is dependent on associated values such as a range of temperature, hydration, or dilution, the associated value range must also be stated. In this instance a matrix of measurement points is a useful form of expressing the Reference Value Capability.

コメント **[ptm4]:** Add examples of matrix effects here?

The uncertainty covered by the Reference Value Capability shall be expressed as the expanded uncertainty having a specific coverage probability (often 95 %). The unit of the uncertainty shall always be the same as that of the property value or in a term relative to the property value, for example a percentage or ratio of the property value.

A producer is not permitted to report on a reference material certificate an uncertainty of property value which is less than or better than that stated in their scope of accreditation.

Producers shall have a system for reviewing and, where necessary, updating their uncertainty calculations following recalibration of reference equipment, a change of subcontractors, a change of material suppliers or other changes

that would significantly affect the magnitude of relevant uncertainty components.