HOKLAS Supplementary Criteria No. 1

Acceptability of Chemical Reference Materials and Commercial Chemicals Used for the Calibration of Equipment

1 INTRODUCTION

1.1 This document is applicable to tests involving the use of chemical reference materials for the calibration of equipment. It covers all test categories except for medical testing.

1.2 ISO/IEC Guide 99:2007 defines reference material (RM) as material, sufficiently homogeneous and stable with reference to specified properties, which has been established to be fit for its intended use in measurement or in examination of nominal properties. It further explains that examination of a nominal property provides a nominal property value and associated uncertainty. This uncertainty is not a measurement uncertainty. RM with or without assigned quantity values can be used for measurement precision control whereas only reference materials with assigned quantity values can be used for calibration or measurement trueness control. RMs comprise materials embodying quantities as well as nominal properties. A RM is sometimes incorporated into a specially fabricated device. Some RMs have assigned quantity values that are metrologically traceable to a measurement unit outside a system of units. Such materials include vaccines to which International Units (IU) have been assigned by the World Health Organisation. In a given measurement, a given RM can only be used for either calibration or quality control. The specifications of a RM should include its material traceability, indicating its origin and processing.

1.3 ISO/IEC Guide 99:2007 defines certified reference material (CRM) as RM, accompanied by documentation issued by an authoritative body and providing one or more specified property values with associated uncertainties and traceabilities, using valid procedures. It explains that documentation is given in the form of a ‘certificate’. Requirements for the production and certification of CRMs are given in ISO 17034:2016. In this definition, ‘uncertainty’ covers both ‘measurement uncertainty’ and ‘uncertainty associated with the value of a nominal property’, such as for identity and sequence. ‘Traceability’ covers both ‘metrological traceability of a quantity value’ and ‘traceability of a nominal property value’. Specified quantity values of CRMs require metrological traceability with associated measurement uncertainty.

1.4 In establishment of traceability of reported results, ISO/IEC 17025:2017 requires that, measuring equipment be calibrated with traceability to the International System of Units (SI units), and if this is not technically possible, to, for example, certified values of CRMs provided by a competent producer, results of reference measurement procedures, specified methods or consensus standards that are clearly described and accepted as providing measurement results fit for their intended use and ensured by suitable comparison, unless it has been established that the associated contribution from calibration contributes little to the total uncertainty of the test results. RMs provided by a competent producer shall be used to give a reliable physical or chemical characterization of a material. RMs shall, where possible, be traceable to SI units of measurement, or to CRMs. RMs produced in-house shall be checked as far as technically and economically practicable.

2 HOKLAS REQUIREMENTS FOR THE USE OF REFERENCE MATERIALS FOR CALIBRATION OF EQUIPMENT

2.1 Where test standards call for the use of certain RMs, laboratories shall use those specified materials.

2.2 In cases where RMs to be used for calibration of equipment are not specified, suitable CRMs supplied by appropriate National Metrology Institutes or Designated Institutes with assigned values covered by the International Bureau of Weights and Measures (BIPM) Key Comparison Database, if available, may be used without further verification.

2.3 CRMs produced by an accredited reference material producer (RMP) under its scope of accreditation to ISO 17034:2016 are considered to have met the metrological traceability requirement of ISO/IEC 17025:2017 and may be used for calibration without further verification.

2.4 Non-certified RMs, and RMs supplied by producers other than those given in clauses 2.2 and 2.3, shall be verified before use. The purpose of verification is to demonstrate that the assigned values are reliable and that the materials are sufficiently homogenous and stable for use as RMs. The extent of verification depends on the information supplied by the producers as well as the nature and properties of the RMs. Laboratories shall have a defined procedure for the verification of these materials, according to the provisions as follow:

2.4.1 Laboratories should verify non-certified RMs or RMs from non-accredited RM producers against those CRMs given in clause 2.2

and 2.3, whenever possible.

2.4.2 Otherwise, laboratories should verify two independently sourced RMs from different producers against each other to ascertain that the values agree with each other within specified limits that are suitable for the application.

2.4.3 If another independent source is not available, a less preferred method is to compare RMs from the same supplier but a different batch.

2.4.4 If neither clause 2.4.1, 2.4.2 nor 2.4.3 is possible, the laboratory should consider using appropriate methods based on physical or chemical properties of the RMs, such as melting point, boiling point, mass spectrum, infra-red spectrum, etc. to confirm their identity and purity.

2.5 Laboratories shall also demonstrate that, for all CRMs and non-certified RMs used,

(a) full records are kept of the identity and source of each material;

(b) the documentation of certified values includes details of the mode of verification of the assigned values by the producers and/or laboratories, uncertainties of the assigned values, instructions for storage and use, and homogeneity and stability data, and expiration dates;

(c) the matrices of the RMs used match those of the laboratory's test samples and the effect of any non-matching of matrices are determined and accounted for; and

(d) uncertainties of the assigned values and of the verifications of RMs are appropriate for the test methods concerned, and that their contributions, where significant, are included in the evaluation of the total measurement uncertainties of the test results.

2.6 Laboratories should particularly note that RMPs certified to ISO 9001 or other management system standards are not considered as ‘competent’ suppliers of RMs. RMs produced by these producers shall be verified before use, following the provisions given herein. By the same token, RMs supplied by the manufacturer of equipment or proprietary test kits shall be verified before use unless the RMs meet the requirements given in clauses 2.2 or 2.3.

2.7 RMs produced in-house shall also be subject to appropriate verifications and relevant provisions given herein apply.

2.8 RMs shall be uniquely identified and bear an expiration date. Laboratories shall record the unique identity of the RMs used in worksheets.

2.9 When using RMs for calibration, the principles described in ISO Guide 33:2015 ‘Reference materials - Good practice in using reference materials’ should be followed where appropriate.

3 REQUIREMENTS FOR THE USE OF COMMERCIAL CHEMICALS

3.1 Laboratories sometimes use commercial chemicals to prepare ‘standard’ mixtures for calibration of analytical instruments. These ‘standard’ mixtures are prepared by, for example, mixing known amounts of chemicals or dissolving the chemicals in a solvent. Sometimes ‘standard solutions’ available commercially are also used for calibration. These mixtures or solutions however are often not CRMs and thus measurement traceability is not provided by these solutions.

3.2 Laboratories should determine the need to strictly follow the metrological traceability requirement of ISO/IEC 17025:2017 by evaluating the contribution of calibration uncertainty to the total uncertainty. If the contribution is significant, the standard mixtures or standard solutions used for calibration of equipment as mentioned in clause 3.1 are functioning as RMs. Laboratories should have a defined system and procedure for verification of these calibration mixtures or standard solutions, and relevant requirements given in ISO/IEC 17025:2017 and Section 2 of this document apply. Records of such verification shall be maintained. If such mixtures or solutions are to be stored for an extended period, their stability throughout the intended storage period shall also be verified and records shall be kept.

Annex (Informative)

The following is a list of references which contain useful information on RMs and CRMs.

1. ISO Guide 30:2015 *Reference materials - Selected terms and definitions*

2. ISO Guide 31:2015 *Reference Materials – Contents of certificates, labels and accompanying documentation*

3. ISO Guide 33:2015 *Reference materials - Good practice in using reference materials*

4. ISO 17034:2016 *General requirements for the competence of reference material producers*

5. ISO Guide 35:2017 *Reference materials – Guidance for characterization and assessment of homogeneity and stability*

6. ISO Guide 99:2007 *International vocabulary of metrology - Basic and general concepts and associated terms (VIM)*

7. ILAC P10:07/2020 *Policy on traceability of measurement results*