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IQAS-034

SUPPLEMENTARY CRITERIA FOR REFERENCE MATERIAL PRODUCER ACCREDITATION

(AS PER ISO 17034:2016)

AMENDMENT SHEET

Sr. No.	Page No.	Clause No.	Date of Amendment	Reasons of amendment	Amendment details	Remark	Approved by
1.	10	4	02.12.2025	Outcome of internal audit	Accreditation process flow chart corrected	-	R. S. Rana
2.							
3.							

CONTENTS

1. Introduction

Reference Material Producer (RMP) accreditation activities are administered under the direction of the International Quality and Accreditation Services (IQAS), involving Assessment Team and Accreditation Committee as recommending bodies. The Reference Material Producers are required to comply with all the requirements listed in the international standard ISO 17034: 2016 'General Requirements for the competence of Reference Material Producer', APAC TEC 1 – 008 'APAC Guidance on Reference Material Use and Production', ILAC P9 'ILAC Policy for Participation in Proficiency Testing Activities' and ILAC P10 'ILAC Policy on Traceability of Measurement Results'.

Requirements specified in ILAC P9:06/2014 and ILAC P10:01/2013 have been reproduced in respective IQAS documents i.e. **IQAS-009** 'Policy for Participation in Proficiency Testing Activities' & **IQAS-008** 'Policy on Traceability of Measurements'. The Supplementary Criteria document i.e. **IQAS-034** must be used in conjunction with ISO 17034: 2016. It provides an interpretation of the later document and describes specific requirements for those clauses of ISO 17034: 2016 which are general in nature. Further, the RMP shall follow the national, regional and local laws and regulations as applicable

2. TERMS & DEFINITIONS

(Key definitions from ISO Guide 30: 2015 (E) & ISO 17034: 2016)

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 to entry: RM is a generic term.

Note 2 to entry: Properties can be quantitative or qualitative, e.g. identity of substances or species.

Note 3 to entry: Uses may include the calibration of a measurement system, assessment of a measurement procedure, assigning values to other materials, and quality control.

Note 4 to entry: ISO/IEC Guide 99:2007 has an analogous definition (5.13), but restricts the term “measurement” to apply to quantitative values. However, Note 3 of ISO/IEC Guide 99:2007, 5.13 (VIM), specifically includes qualitative properties, called “nominal properties”.

Certified reference material (CRM)

reference material (RM) characterized by a metrologically valid procedure for one or more specified properties, accompanied by an RM certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability

Note 1 to entry: The concept of value includes a nominal property or a qualitative attribute such as identity or sequence. Uncertainties for such attributes may be expressed as probabilities or levels of confidence Note 2 to entry: Metrologically valid procedures for the production and certification of RMs are given in, among others, ISO Guides 35.

Note 3 to entry: ISO Guide 31 gives guidance on the contents of RM certificates. Note 4 to entry: ISO/IEC Guide 99:2007 has an analogous definition.

Candidate reference material

Material, intended to be produced as a reference material (RM)

Note 1 to entry: A candidate material has yet to be characterized and tested to ensure that it is fit for use in a measurement process. To become an RM, a candidate material needs to be investigated to determine if it is sufficiently homogeneous and stable with respect to one

or more specified properties, and is fit for its intended use in the development of measurement and test methods that target those properties.

Note 2 to entry: A candidate reference material may be an RM for other properties, and a candidate reference material for the target property.

Matrix reference material

Reference material that is characteristic of a real sample EXAMPLE Soil, drinking water, metal alloys, and blood.

Note 1 to entry: Matrix reference materials may be obtained directly from biological, environmental or industrial sources.

Note 2 to entry: Matrix reference materials may also be prepared by spiking the component(s) of interest into an existing material.

Note 3 to entry: A chemical substance dissolved in a pure solvent is not a matrix material.

Note 4 to entry: Matrix materials are intended to be used in conjunction with the analysis of real samples of the same or a similar matrix.

Reference material certificate

Document containing the essential information for the use of a CRM, confirming that the necessary procedures have been carried out to ensure the validity and metrological traceability of the stated property values

Note 1 to entry: The required and recommended content of a reference material certificate is described in ISO Guide 31.

Categories, sub-categories and sub–sub categories of reference materials are given IQAS-026 and this documents can serve as good guidance to describe the specific types of RMs that a RMP is accredited to produce.

Certificates or documentation for a certified reference material or non-certified reference material should contain a unique identification of its production process. This identification may take the form of a reference number, the name of the process or in other suitable information.

A summary of the requirements is given in Table 1.

Content	Product Information Sheet	RM Certificate
Title of the document	Mandatory	Mandatory
Unique identifier of the RM	Mandatory	Mandatory
Name of the RM	Mandatory	Mandatory
Name and contact details of the RM producer	Mandatory	Mandatory
Intended Use	Mandatory	Mandatory
Minimum Sample Size	Mandatory whenever applicable	Mandatory whenever applicable
Period of Validity	Mandatory	Mandatory
Commutability	Mandatory whenever applicable	Mandatory whenever applicable
Storage information	Mandatory	Mandatory
Instructions for handling and use	Mandatory	Mandatory
Page number and the total number of pages	Mandatory	Mandatory
Document version	Mandatory	Mandatory
Description of the material Recommended	Recommended	Mandatory
Property of interest, property value and associated uncertainty	Optional	Mandatory
Metrological traceability	Optional	Mandatory
Measurement methods for method dependent measurands	Recommended	Mandatory whenever applicable
Name and function of the RM producer's approving officer	Optional	Mandatory
Measurement methods for method-independent measurands	Recommended	Recommended
Health and safety information	Recommended	Recommended
Subcontractors	Optional	Optional
Indicative values	Optional	Optional
Legal notice	Optional	Optional
Reference to a certification report	Optional	Optional

3. SAMPLE SCOPE

S. No	Types of reference materials (Certified Reference Materials, Reference Materials or both) Category & Subcategory	Reference Material Matrix or Artefact	Property / Properties Characterized	Range of property	Assigned value, uncertainty and best reference value capability (as relevant)	Approach used to assign property values/ Characterization Technique	Activities being subcontracted (e.g. assessment of homogeneity, stability, characterization, testing, calibration, measurements etc. if any)
1	Category: Chemical Composition Subcategory: Metals	Ferrous (Steels)	Carbon	0.08% - 1.10%	Assigned value-0.09% (MU-0.0001%) (Best reference value capability – 0.0001%)	Inter-laboratory comparison	Testing activity subcontracted to M/s ABC laboratory
2	Category: Biological and Clinical Properties Subcategory: Bacteriology & Mycology	Reference cultures	E. Coli	-	Qualitative	Primary method	Sub-contracting not done

4. Accreditation process