General requirements for the competence of Reference Material Producer as per ISO 17034:2016

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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

- ✓RM is a generic term
- ✓Properties can be quantitative or qualitative, e.g. identity of substances or species
- ✓Uses may include the calibration of a measurement system, assessment of a measurement procedure, assigning values to other materials, and quality control.

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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

- ✓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.

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Reference Material Producer(RMP)

Body (organization or company, public or private) that is fully responsible for

- ✓project planning and management;
- ✓assignment of, and decision on property values and relevant uncertainties;
- ✓authorization of property values; and,
- ✓issuance of a reference material certificate or other statements for the reference materials it produces

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Characterization (of a reference material)

Determination of the property values or attributes of a reference material, as part of the production process

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Standards and Guides for RMP

There is an International Standard and three ISO Guides that support the production, characterization and certification of RMs to ensure that the quality of the RMs meets the requirements of the end users. They are:

— ISO 17034 outlines the general requirements to be met by an RMP to demonstrate competence.

— ISO Guide 35 provides more specific guidance on technical issues and explains the concepts for processes such as the assessment of homogeneity, stability and characterization for the certification of RMs.

— ISO Guide 31 describes the contents of certificates for CRMs, and of accompanying documents for other RMs.

— ISO Guide 30 contains the terms and definitions related to reference materials.

Standards and Guides for RMP

— ISO Guide 33 describes good practice in using reference materials (RMs), and certified reference materials (CRMs) in particular, in measurement processes. These uses include the assessment of precision and trueness of measurement methods, quality control, assigning values to materials, calibration, and the establishment of conventional scales. It relates key characteristics of various types of RMs to the different applications.

— ISO/TR 16476 :2016 Reference materials — Establishing and expressing metrological traceability of quantity values assigned to reference materials - This Technical Report investigates, discusses, and specifies further, the general principles of establishing traceability of measurement results laid down in the Joint BIPM, OIML, ILAC and ISO Declaration on Metrological Traceability, in particular for values assigned to (certified) reference materials.

ISO 17034:2016

1. SCOPE
2. NORMATIVE REFERENCE
3. TERMS AND DEFINITIONS
4. GENERAL REQUIREMENTS
5. STRUCTURAL REQUIREMENTS
6. RESOURCE REQUIREMENTS
7. TECHNICAL AND PRODUCTION REQUIREMENTS
8. MANAGEMENT SYSTEM REQUIREMENTS

4. General requirements

4.1 Contractual matters

4.2 Impartiality

4.3 Confidentiality

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5. Structural requirements

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6. Resource requirements

6.1 Personnel

6.2 Subcontractors

6.3 Provision of equipment, services and supplies

6.4 Facilities and Environmental conditions

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TECHNICAL & PRODUCTION REQUIREMENTS

7.1 General requirements
7.2 Production planning
7.3 Production control
7.4 Material handling and storage
7.5 Material processing
7.6 Measurement procedures
7.7 Measuring equipment
7.8 Data integrity and evaluation
7.9 Metrological traceability of certified values

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TECHNICAL & PRODUCTION REQUIREMENTS

- **7.10 Assessment of homogeneity**
- **7.11 Assessment and monitoring of stability**
- **7.12 Characterization**
- **7.13 Assignment of property values & their uncertainties**
- **7.14 RM documents and label**
- **7.15 Distribution service**
- **7.16 Control of quality and technical records**
- **7.17 Management of non-conforming work**
- **7.18 Complaints**

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MANAGEMENT SYATEM REQUIREMENTS

- **8.1 Options**
- **8.2 Quality Policy**
- **8.3 General management system documentation**
- **8.4 Control of management system documents**
- **8.5 Control of records**
- **8.6 Management review**
- **8.7 Internal audit**
- **8.8 Action to address risks and opportunities**
- **8.9 Corrective actions**
- **8.10 Improvement**
- **8.11 Feedback from customers**

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Production (of a reference material, RM)

All necessary activities and tasks leading to the release and maintenance of an RM (certified or non-certified)

Activities include, for example,

- ✓**Planning!**
- ✓ **(production) control,**
- ✓**material handling and storage,**
- ✓**material processing,**
- ✓**assessment of homogeneity and stability,**
- ✓**characterization,**
- ✓**assignment of property values and their uncertainties!!**
- ✓**Authorization!!! and**
- ✓**issue of RM certificates or other statements!!!!.**

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Which organization can be called as an RMP

- ✓ RMP only shall do the following activities and the same can't be subcontracted:
  1) Production planning,
  2) Selection of Subcontractors
  3) Assignment of Property Values & their uncertainties,
  4) Authorization of property values & their uncertainties.
  5) Authorization of RM documents
- ✓ Although RMP accreditation conveys competence as a producer (not as a laboratory), testing and/or calibration are integral components of RM production.
- ✓ Where an organization only provides services such as the provision of reference values to a Candidate RM, it shall not be considered as a RMP.

Subcontracting

RMPs shall document their policy and procedures for sub-contracting.

If the characterization of a RM by a single (primary) method was initially carried out by a laboratory as per the RMP's system for subcontracting and the same was assessed as competent during initial assessment then this arrangement may not be suddenly changed without information to AB. In all such cases a fresh assessment may be carried out by AB for assessing competence as per the revised sub-contracting arrangement of the RMP.

AB shall not permit serial Sub-contracting (i.e. Subcontracting of Sub- contracted work).

Subcontracting

A competent subcontractor is one which is accredited by an ILAC / IAF signatory accreditation body for the specific scope as per ISO/IEC 17025/ ISO 15189 for testing, calibration and measurement activities. RMP to ensure that subcontractor has participated in a PT program for same or closely similar materials wherever available.

For other activities like Material preparation, Material Handling and storage (including post certification testing) and Material Distribution & post distribution services, AB can accept ISO 9001 Certification issued by certification bodies which are accredited by an IAF signatory accreditation body and whose certification scopes cover activities sub-contracted.

Subcontracting

RMPs shall not subcontract the following processes:

— the production planning;

— the selection of subcontractors;

— the assignment of property values and their uncertainties;

— the authorization of property values and their uncertainties;

— the authorization of RM documents.

The RMP shall establish and maintain PROCEDURES to assess that all tasks performed by subcontractors comply with the requirements set by the RMP and with any relevant clauses of this International Standard.

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Subcontracting

RMP shall cover the sub-contractor's activities in its internal audit schedule. The Internal Audit of such subcontracted activities should preferably be carried out during actual execution of the job at the subcontractor site.

Subcontractor activities may also be assessed by AB during RMP assessment.

Activities that can be subcontracted cover a part of the procedure for production including the following:

- ✓Processing
- ✓Homogeneity and stability testing
- ✓Characterization
- ✓Handling
- ✓Storage & Distribution

ISO 17034:2016

1) What is a Reference Material?
2) What is a CRM?
3) What is the difference between an ordinary RM and a CRM??
4) What is characterization?
5) What is reference Value or true value of an RM?

ISO 17034:2016

6) Which standard specifies the Quality Management System to be implemented for a Reference Material Producer?

7) Which are the relevant ISO guides to be referred by the RMP and what do they specify?

8) In which document NABL specific criteria for RMP is available?

9) What are the 3 main stages while manufacturing a Certified Reference Material?

10) What is Homogeneity of RM and what are the 2 different types of homogeneity of RM?

ISO 17034:2016

11) What is Stability of RM and what are the 2 different types of stability of RM?

12) What is measurement uncertainty?

13) What is the difference between stability assessment and stability monitoring?

14) Give 10 critical points to be considered while preparing a plan for producing a CRM?

15) Which activities can't be subcontracted by an RMP?

ISO 17034:2016

16) What are the purposes of "Pilot study" or "Feasibility study" for an RM production?

17) Write the sequence of activities to be done by an RMP while producing a CRM for the first time?

18) What are the different strategies/ methodologies by which a CRM can be characterized?

19) Which critical activities can be subcontracted?

20) Which are the major components to be considered while evaluating measurement uncertainty of a CRM?

ISO 17034:2016

21) Which ISO Guide specifies the different statistics to be adopted while producing a CRM?

22) Who can be called as an RMP?

23) What is the difference between an operationally defined measurand and a non operationally defined measurand? Explain with an example.

24) Which additional information has to be given in the certificate for a CRM when compared with that of an ordinary RM?

25) What are the contents of a CRM label?

ACTION PLAN FOR RM PRODUCTION

1) Identify the matirx (product), measurand (test/ property) and level of measurand of RM to be produced
2) Define acceptance level of measurands and MU for the RM
3) Prepare plan as per cl. 7.2.3 of ISO 17034 – (a to u)
4) Pilot study / Feasibility study :
   - Identify specs of raw material to be procured
   - Identify source of raw material supply
   - Identify subcontractors (processing/ production etc.,)
   - Determine processing conditions & equipment required
   - Determine testing procedure for Homo, Stab and characterization
   - Identify labs to be used for ILC

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ACTION PLAN FOR RM PRODUCTION

5) Conduct preliminary ILC
6) Conduct preliminary homogeneity study
7) Produce RM on large scale
8) Conduct homogeneity study
9) Calculate U_{bb} and U_{wb}
10) Commence stability study – immediately, after 1 month, 3 months, 6 months etc.,
11) Characterization by ILC/ Single Lab approach
12) Assign property values and MU
13) Continue with STABILITY MONITORING

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