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

Resource Requirements

6.1 Personnel

6.1.1 The RMP shall ensure that all personnel involved in RM production are supervised and competent and that they work in accordance with the RMP's management system.

6.1.2 Personnel, including subcontractors, personnel of external bodies, or other individuals acting on the RMP's behalf, shall comply with the policies and PROCEDURES for management of confidential information that are set by the RMP.

6.1.3 The RMP shall ENSURE the competence of all personnel, including technical management personnel, operating under its management system who undertake activities relating to the production of each particular type of RM. There shall be sufficient personnel having the necessary education, training, technical knowledge and experience for their assigned functions.

6.1 Personnel

6.1.4 The RMP shall have PROCEDURES for identifying training needs and providing training of personnel. The training programme shall be relevant to the present and anticipated tasks of the RMP.

6.1.5 The RMP shall maintain RECORDS of job descriptions for its personnel involved in RM production activities.

6.1.6 The RMP shall authorize competent personnel to perform particular activities relating to RM production. The RMP shall maintain RECORDS of the authorizations, competence, educational and professional qualifications of those personnel. These records shall provide evidence that individuals have been adequately trained and that their competence to perform particular activities in the RM production has been assessed. This information shall be readily available and shall include the date on which the authorization and/or competence has been confirmed.

Personnel

The designated personnel (howsoever named), responsible for implementation, maintenance and improvement of the management system of RMP should be familiar with and fully aware of the requirements of ISO 17034:2016, and principles applicable to the organization's field of accreditation / compliance. The competence shall be verified by the assessment team.

Accredited / applicant RMP is required to select and appoint a person (however named) responsible for Quality management system, Technical management system and RMs approving officer. A person can perform more than one of these functions as long as he / she satisfies minimum requirements of qualification and experience subject to the conditions that the work load is adequately justified in relevance to scope and with deputies in each field in place.

Personnel

Individuals who issue RM documents shall assume responsibility for the technical validity and accuracy of all information contained in the certificate. Those personnel shall have and demonstrate a sound knowledge of:

- ✓ ISO 17034:2016, Guide 30, Guide 31 & Guide 35, AB Policy & Procedures and this document;
- ✓ the principles of the calibrations, measurements, analysis and/or tests they perform or supervise;
- ✓ the scope for which accreditation is sought;
- ✓ the facility's management system;
- ✓ sound understanding of quality control data including homogeneity / stability, characterization of property values, assignment of property value etc;
- ✓ knowledge of statistics, preparation of RM, etc
- ✓ measurement ranges and the estimation of the uncertainties of measurement associated with the test or calibration results for which the facility is accredited or seeking accreditation.

Personnel

RMP should have an official who is conversant with the subcontractor activities in order to verify the activities performed by subcontractors.

6.2 Subcontracting

6.2.1 Where an RMP uses subcontractors to undertake part of the production, including sampling, processing, handling, homogeneity and stability testing, characterization, storage or distribution of an RM, the RMP shall have PROCEDURES to ensure that the subcontractors' experience and technical competence are sufficient for their assigned tasks and that they comply with the relevant clauses of this International Standard and other appropriate standards.

✓It is possible that an RMP does not have its own laboratory facilities or processing facilities, or it can choose not to use its own facilities.

✓Subcontractors can be paid or unpaid.

6.2.2 The RMP shall select subcontractors on the basis of their ability to meet the requirements stipulated by the RMP.

6.2 Subcontracting

6.2.3 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.

6.2.4 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.

6.2 Subcontracting

6.2.5 Evidence of the subcontractor's competence shall be established and maintained, including RECORDS of evaluations and any audits made of their capability to carry out contracted tasks.

Examples of evidence are

- ✓ assessments of tasks performed for the RMP in the past,
- ✓ evidence of successful participation in relevant proficiency testing,
- ✓ conformity assessment certificates relevant for the task contracted and
- ✓ acceptable results on well-characterized materials of similar or equivalent nature to that of the candidate RM.

6.2 Subcontracting

6.2.6 Where the competence of subcontractors cannot be ascertained via provision of documentary evidence, the RMP shall evaluate the competence of the subcontractor or supervise the operations carried out by the subcontractor.

6.2.7 The RMP shall ensure that results and the descriptions of procedures used by subcontractors are available to allow the technical evaluation of data.

6.2.8 When working with subcontractors, the RMP shall have personnel operating under its management system having sufficient knowledge of the subcontractor's task to evaluate the subcontractor's activity.

For testing activities, this includes knowledge of the task involved and familiarity with this International Standard and ISO/IEC 17025 for calibration and testing.

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

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

6.3 Provision of equipment, services and supplies

6.3.1 The RMP shall have PROCEDURES in place for the selection of equipment, services and supplies that affect the quality of the RMs produced.

6.3.2 The RMP shall use only equipment, services and supplies that comply with specified requirements to ensure the quality of the RMs it produces.

6.3 Provision of equipment, services and supplies

6.3.3 The RMP shall ENSURE that equipment and consumable materials are not used until they have been inspected, calibrated or otherwise verified as complying with the specifications or requirements defined for the RM production activities.

6.3.4 The RMP shall maintain RECORDS of purchases of equipment, services and supplies, including records of the selection criteria used, confirmation of acceptance, and any commissioning data.

6.3 applies to all equipment including material processing and measuring equipment. 7.7 includes more provisions on operation of measuring equipment.

6.4 Facilities and environmental conditions

6.4.1 The RMP shall ensure that all laboratory facilities, calibration and testing areas (if applicable), material handling, storage, processing and packaging areas, energy sources, lighting, humidity, temperature, pressure and ventilation are such as to facilitate proper material handling, storage, processing and packaging, as well as proper performance of calibration and testing activities (if applicable).

6.4.2 When the environmental conditions could have an adverse effect on the RM, the environmental conditions in which the RM production activities are undertaken shall be monitored with appropriately calibrated equipment, and shall be controlled and RECORDED, such that results and processes are not adversely affected.

6.4 Facilities and environmental conditions

6.4.3 All RM processing and calibration and testing areas, in addition to satisfying requirements for humidity and temperature, shall be protected, where appropriate, from other environmental factors such as incompatible activities, vibration, aerosols, airborne dust and microbiological contamination, magnetic fields, light and electromagnetic and/or ionising radiation.

6.4.4 Access to and use of areas shall be controlled as appropriate to maintain the quality of the RMs.