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Standard Practice for Competency Requirements of Reference Material Producers for Water Analysis[1]

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1. Scope

1.1 This practice establishes the general requirements with which a reference materials (RM) producer has to demonstrate that it operates, if it is to be recognized as competent to produce RMs used for water analysis.

1.2 This practice establishes the quality system requirements in accordance with which waters RMs shall be produced. It is intended to be used as part of a RM producer's general QA procedures. RM producers shall define their scope in terms of the application, the measurement methods used in the homogeneity, stability and characterization studies.

1.3 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

D1129 Terminology Relating to Water

D6362 Practice for Certificates of Reference Materials for Water Analysis

2.2 *ISO Documents:*[3]

ISO/IEC 17025:1999 General Requirements for the Competence of Calibration and Testing Laboratories

ISO 8402:1994 Quality Management and Quality Assurance—Vocabulary

ISO 10012-1:1992 Quality Assurance Requirements for Measuring Equipment—Part 1: Metrological Confirmation Systems for Measuring Equipment

ISO/IEC Guide 2:1996 Standardization and Related Activities—General Vocabulary

ISO Guide 30:1992 Terms and Definitions used in Connection with Reference Materials

ISO Guide 31:2000 Contents of Certificates and Labels of Reference Materials

ISO/IEC Guide 32:1997 Calibration in Analytical Chemistry and Use of Certified Reference Materials

ISO Guide 34:2000 General Requirements for the Competency of Reference Material Producers

ISO Guide 35:1989 Certification of Reference Materials—General and Statistical Principles

ISO 3534 Series: 1993 Statistics—Vocabulary and Symbols

VIM: 1993 International Vocabulary of Basic and General Terms in Metrology (issued by ISO, IEC, BIPM, IFCC, IUPAC, IUPAP and OIML)

ISO Guide to the Expression of Uncertainty in Measurement: 1995 (issued by ISO, IEC, BIPM, IFCC, IUPAC, IUPAP and OIML)

3. Terminology

3.1 *Definitions:*

3.1.1 For the purposes of this practice, the definitions given in Terminology D1129, ISO/IEC Guide 2, ISO/IEC 17025, ISO Guide 30, ISO 8402, ISO 3534, VIM and the following definitions apply.

3.1.2 *collaborator*—technically competent body (organization or firm, public or private) that undertakes aspects of the manufacture, or characterization, of the (certified) RM on behalf of the RM producer, either on a contractual (as a sub-contractor) or voluntary basis.

3.1.3 *reference material producer*—technically competent body (organization or firm, public or private) that is fully responsible for assigning the certified or other property values of the RMs it produces and supplies, which have been produced in accordance with ISO Guide 35, Practice D6362, and ISO Guide 31.

4. Significance and Use

4.1 This practice is for the use by RM producers in the development and implementation of their quality system and by those concerned with assessing the competence of RM

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[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

producers. It should be recognized that a RM needs to be characterized mainly to the level of accuracy required for its intended purpose (that is, appropriate measurement uncertainty). The RM producer shall describe the procedure for establishing the quality of materials as a component of the quality system.

4.2 This practice is for the use of RM users in the establishment if a RM producer has a quality system adequate to produce high quality RMs. It can be used by users to determine if the scientific and technical competence of a RMs producer is adequate to ensure the quality of RMs. This practice is consistent with the requirements for RM producers established in ISO Guide 34.

4.3 This practice does not specify specific protocols for the contents of RMs certificates of analysis, for calibration in analytical chemistry and use of certified RMs and for certification of RMs. For this information, users are referred to Practice D6362, ISO Guide 32, and ISO Guide 35.

5. Organization and Management Requirements

5.1 *Quality System Requirements:*

5.1.1 The RM producer shall establish, implement and maintain a quality system appropriate to the scope of its activities including the type, range and magnitude of the RM production it undertakes.

5.1.2 *Quality Policy:*

5.1.2.1 The RM producer shall define and document its policy, objectives and commitment to ensuring and maintaining the quality of all aspects of RM production, including material quality (that is, homogeneity and stability), characterization (that is, equipment calibration and measurement method validation), assignment of property values (that is, use of appropriate statistical procedures) and material handling, storage and transport procedures.

5.1.2.2 The quality policy shall, when appropriate, include use of interlaboratory characterization studies employing laboratories that are active and competent in the respective field of measurement in this context. The policy shall include a commitment to interact with the appropriate sectors of the measurement community in order to prevent working in isolation. The policy shall also include a commitment to produce RMs which conform to the definitions given in ISO Guide 30, characterized according to the requirements of ISO Guide 35 and whose property values are assessed using accepted statistical techniques. The policy shall, where appropriate, include a commitment to comply with Practice D6362 for the contents of RM certificates and supply of associated information for users. It is important that the policy also specifies the intended use of the RMs in order to ensure that the RM producer fully advises the user which types of application the materials may be used.

5.1.3 *Quality System:*

5.1.3.1 The RM producer shall establish, implement and maintain a documented quality system appropriate to the type, range and volume of RM production it undertakes. The RM producer shall document all of its policies, systems, programs, procedures, instructions, findings, etc., to the extent necessary to enable the producer to assure the quality of the RMs produced. Documentation used in this quality system shall be communicated to, understood by, available to and implemented by all personnel concerned. In particular, the producer shall have a quality system that covers the following:

(a) Arrangements for ensuring the suitable choice (for example, particle size range, concentration range, etc.) of the candidate RMs;

(b) Preparation procedures;

(c) Achievement of the required degree of homogeneity of the RM;

(d) Assessment of the stability of the RM; including on-going assessment of stability where necessary;

(e) Procedures for undertaking characterization;

(f) Practical realization of traceability to national or international standards of measurement;

(g) Assignment of property values, including preparation of certificates or statements in accordance with Practice D6362 when appropriate;

(h) Arrangements for ensuring adequate storage facilities;

(i) Arrangements for suitable identification, labeling and packaging facilities, packing and delivery procedures and customer service; and

(j) Compliance with ISO Guides 30, 34 and 35 and Practice D6362.

It is encouraged that the documented quality system specify which activities are undertaken by the RM producer and, where relevant, which activities are undertaken by collaborators and shall include policies and procedures used by the producer to ensure that all activities conducted by collaborators comply with the relevant clauses of this practice.

5.1.3.2 The documented quality system shall define the roles and responsibilities of the technical manager (however named) and quality manager including their responsibilities for ensuring compliance with this practice.

5.2 *Organization and Management:*

5.2.1 The RM producer, or the organization of which it is part, shall be legally identifiable.

5.2.2 The RM producer shall be organized and shall operate in such a way that it meets all the applicable requirements of this practice whether carrying out work in its permanent facilities or at sites (including associated temporary or mobile facilities) away from its permanent facilities (including work undertaken by collaborators).

5.2.3 The RM producer shall:

(a) Have managerial personnel supported by technical personnel with the authority and resources needed to discharge their duties and to identify the occurrence of departures from the quality system or the procedures for the production of RMs and to initiate actions to prevent or minimize such departures.

(b) Have arrangements to ensure that its management and personnel are free from any commercial, financial and other internal and external pressures that may adversely affect the quality of their work;

(c) Have policies and procedures to ensure the protection of its client's confidential information and proprietary rights;

(d) Have policies and procedures to avoid involvement in activities that might diminish confidence in its competence, impartiality, judgement or operational integrity;

(e) Define, with the aid of organizational charts, the organization and management structure of the RM producer, its place in any parent organization, and the relations between management, technical operations, support services, collaborators and the quality management system;

(f) Specify the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of production of RMs;

(g) Have technical management, which has overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of each operation which forms part of the RM production;

(h) Appoint a member of staff as quality manager (however named) who, irrespective of other duties and responsibilities, shall have defined responsibility and authority for ensuring that the requirements of this practice are implemented and followed at all times. The quality manager shall have direct access to the highest level of management at which decisions are taken on production policy or resources; and

(i) Where appropriate, appoint deputies for key managerial personnel such as the technical and quality managers.

5.3 *Document and Information Control:*

5.3.1 *General:*

5.3.1.1 The RM producer shall establish and maintain procedures to control all documents (both internally generated and from external sources) and other information that forms part of its quality documentation. These may include documents of external origin such as standards, guides, test and/or calibration methods as well as specifications, instructions and manuals related to the RM under production (see Note 1).

NOTE 1—In this context "document" means any information or instruction including policy statements, text books, procedures, specifications, calibration tables, charts, software, etc. These may be on various media whether hard or electronic and they may be digital, analogue, photographic or written.

5.3.2 *Document Approval and Issue:*

5.3.2.1 All documents (including documented procedures) issued to personnel as part of the quality system shall be suitably controlled. This shall include review and approval for use by authorized personnel prior to issue. A master list or equivalent identifying the current revision status of documents in the quality system shall be established and be readily available to preclude the use of invalid and/or obsolete documents.

5.3.2.2 The procedures adopted shall also ensure that:

(a) Authorized editions of appropriate documents are available at all locations where operations essential to the effective production of RMs are performed;

(b) Documents are periodically reviewed and, where necessary, revised to ensure continuing suitability and compliance with applicable requirements;

(c) Invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use; and

(d) Obsolete documents retained for legal or informational purposes are suitably marked.

5.3.3 *Document Changes:*

5.3.3.1 Changes to documents (including documented procedures) shall be reviewed and approved by designated personnel performing the same function as that conducted for the original review and approval unless specifically decided otherwise. The designated personnel shall have access to pertinent background information to base their review and approval.

5.3.3.2 Where practicable, the nature of the change shall be identified in the document with appropriate attachments.

5.3.3.3 If the RM producer's documentation control system allows for the amendment of documents by hand, pending the re-issue of the documents, the procedures and authorities for such amendments shall be defined and shall ensure that amendments are initialed and dated. Documents amended by hand shall be marked, signed and dated and shall be formally re-issued as soon as practicable.

5.3.3.4 Procedures shall be established to describe how changes in documents maintained in computerized systems are made.

5.4 *Request, Tender and Contract Reviews:*

5.4.1 When relevant, each request, tender or contract (see Note 2) concerning the production of a RM shall be reviewed by the RM producer to ensure that:

(a) The requirements are adequately defined, documented and understood;

(b) The RM producer has the capability (see Note 3) and resources to meet the requirements;

(c) In the case of external contracts (see Note 4) any differences between the contract or order requirements and those in a tender are resolved to the satisfaction of the RM producer and the customer or client.

NOTE 2—The request, tender or contract review should be conducted in a practical and efficient manner and the financial, legal and time schedule aspects be taken into account.

NOTE 3—Capability means that the RM producer possesses the necessary equipment, intellectual and information resources and that its personnel have the skills and expertise necessary for the production of those RMs in question. The review of the capability may include an assessment of previous RM production and/or the organization of interlaboratory characterization programs using samples of similar composition to the RMs to be produced.

NOTE 4—A contract may be any written or verbal agreement to provide a customer or client with RMs from stock or custom-produced respectively.

5.4.2 Records of such reviews including any changes shall be maintained. Records shall also be maintained of pertinent discussions with a customer relating to the customer's requirements or the results of the work during the period of execution of the contract or request.

5.4.3 The review shall include any work that has to be sub-contracted by the RM producer.

5.5 *Use of Collaborators:*

5.5.1 The RM producer shall establish and maintain procedures to ensure that all tasks performed by collaborators comply with specifications set by the RM producer for such tasks. The RM producer shall ensure also that collaborators comply with any clauses of this practice relevant to the tasks performed by them for the RM producer.

5.5.2 The RM producer shall select collaborators based on their ability to meet sub-contracted requirements in terms of both their technical competence and any specific quality assurance requirements relevant to their tasks. The technical requirements to be satisfied by collaborators shall be equivalent to the technical requirements specified in Section 5 of this practice.

5.5.3 The RM producer shall maintain a register of all collaborators used in the production process, and include a record of any assessments made of their abilities to carry out sub-contracted tasks according to the requirements of this practice (see Note 5).

NOTE 5—The RM producer is always responsible for ensuring that a collaborator is competent. The collaborator should be able to demonstrate compliance with the requirements of this practice for all sub-contracted work.

5.6 *Procurement of Services and Supplies:*

5.6.1 The RM producer shall have policies and procedures for the selection of services and supplies that affect the quality of its RMs.

5.6.2 The RM producer shall use only those services and supplies that are of adequate specification to ensure the quality of its RMs.

5.6.3 When no formal approval of the quality of services and supplies is available, the RM producer shall have procedures to ensure that purchased materials and services comply with specified requirements and records of actions taken shall be maintained.

5.6.4 The RM producer shall ensure that purchased equipment and consumable materials are not used until they have been inspected, calibrated or otherwise verified as complying with standard specifications or requirements defined in specifications for production, characterization and certification of its RMs.

5.6.5 The RM producer shall maintain records of the main suppliers and collaborators from whom it obtains supplies required for the production of RMs. These records should include any quality assurance approval the suppliers and/or collaborators hold.

5.7 *Client Feedback:*

5.7.1 The RM producer shall have a policy and procedures for the resolution of complaints or other feedback received from its customers or other parties. Records shall be maintained of all complaints and of the investigations and corrective actions taken by the RM producer.

5.8 *Control of Nonconforming (Poor Quality) RMs:*

5.8.1 The RM producer shall have a policy and procedures that shall be implemented when it establishes that any aspect of its production activities do not conform with its own specified production procedures (see Note 6). The policy and procedures shall ensure that:

(a) Responsibilities and authorities for the management of non-conforming work are designated;

(b) The actions which must be taken when any non-conforming RMs are identified are defined, together with a system which ensures they are implemented;

(c) An evaluation of the significance of the non-conforming work is made;

(d) Work is halted and, if appropriate, certificates withheld as necessary;

(e) Remedial actions are taken within a defined timeframe;

(f) Where necessary, the results of non-conforming RMs already distributed to customers are recalled; and

(g) The responsibility for authorization of the resumption of work is defined.

NOTE 6—The identification of non-conforming RMs or problems with the quality system or with certification activities can occur at various places within the Quality System such as: customer complaints, quality control, checking of consumable materials, staff observations or supervision, certificate checking, management reviews, and internal or external audits.

5.8.2 Where the evaluation indicates that the supply of non-conforming RMs could recur or that there is doubt about the RM producer's compliance with its own policies and procedures, the corrective action procedures in 5.9 shall be promptly followed to identify the causes of the problem and to eliminate them.

5.9 *Corrective Action:*

5.9.1 *General:*

5.9.1.1 The RM producer shall establish a policy and procedures and shall designate appropriate authorities for implementing corrective action when non-conforming RMs or departures from the policies and procedures in the quality system have been identified (see Note 7).

NOTE 7—A problem with the quality system or with technical operations may be identified through a variety of activities within the quality system such as control of non-conforming RMs, internal or external audits, management reviews, feedback from clients, or staff observations.

5.9.1.2 Any corrective action taken to eliminate the causes of non-conformances or other departures shall be to a degree appropriate to the magnitude of the problems and commensurate with the risks encountered.

5.9.1.3 The RM producer shall document and implement any required changes to the operational procedures resulting from corrective action investigations as described in this section.

5.9.2 *Cause Analysis:*

5.9.2.1 Corrective action procedures shall include an investigation process to determine the causes of the problem (see Note 8).

NOTE 8—This is sometimes the most difficult, but the key part in the corrective action procedure. Often the root cause is not obvious and thus a careful analysis of all potential causes of the problem is required. Potential causes could include, inter alia, the nature of the RM and its specification, methods and procedures used for characterization, staff skills and training, and the materials and equipment (and/or its calibration) used in the production processes.

5.9.3 *Corrective Actions:*

5.9.3.1 The RM producer shall identify possible causes and potential corrective actions. It shall select the actions most likely to eliminate the problem and to prevent it recurring.

5.9.4 *Monitoring of Corrective Actions:*

5.9.4.1 After having implemented the action plans, the RM producer shall monitor the results to ensure that the actions taken have been effective in overcoming the problems originally identified.

5.9.5 *Management Review:*

5.9.5.1 The results of corrective action shall be submitted for management review.

5.10 *Preventative Action:*

5.10.1 All operational procedures shall be systematically reviewed at regular intervals to identify any potential sources of non-conformances and any opportunities for improvement, either technical or with the quality system. Action plans shall be developed, implemented and monitored, to reduce the likelihood of occurrence of such non-conformances and to take advantage of the improvement opportunities (see Note 9).

NOTE 9—Preventative action is a pro-active process to identify improvement opportunities, rather than a reaction to the identification of problems or complaints. TQM tools such as brainstorming, flowcharting, mind-mapping and parieto charts will assist this process.

5.10.2 After the implementation of the preventative actions, the RM producer shall monitor the results to establish any reduction in deficiencies or other improvements in this operational area, thereby establishing the effectiveness of the preventative action.

5.10.3 The results of preventative actions shall be submitted for management review.

5.11 *Records:*

5.11.1 *General:*

5.11.1.1 The RM producer shall establish and maintain procedures for identification, collection, indexing, access, storage, maintenance and disposal of quality (see Note 10) and technical records (see Note 11).

NOTE 10—Quality records are records providing objective evidence of the extent of the fulfillment of the requirements for quality or the effectiveness of the operation of the quality system. For example, they include reports from internal audits and management reviews and corrective and preventative action records.

NOTE 11—Technical records are accumulations of data and information which result from carrying out testing and calibration procedures and which indicate whether specified quality or process parameters are achieved. They include forms, contracts, work sheets, work books, check sheets, control charts/graphs, calibration reports/certificates and papers, reports and certificates to customers and clients.

5.11.1.2 All records shall be legible and shall be stored and retained in such a way that they are readily retrievable, and in facilities that provide a suitable environment to prevent damage, deterioration or loss (see Note 12). Retention times of records shall be established and recorded.

NOTE 12—Records may be in the form of any type of media, such as hard copy or electronic media.

5.11.1.3 All records shall be held secure and, where appropriate, in confidence to the client.

5.11.1.4 The RM producer shall have procedures to protect electronically-held data at all times and to prevent unauthorized access to, or amendment of, such data.

5.11.2 *Records and Reports:*

5.11.2.1 The RM producer shall establish and maintain a record system to suit its particular circumstances and to comply with any applicable regulations. The RM producer shall arrange for all individual measurement observations, appropriate calculations and derived data (for example, statistical treatments and uncertainty budgets), calibration records and preparation reports to be retained for a defined period beyond which it is no longer probable that they will be referred to, taking into account the period for which the RM remains valid.

5.11.2.2 The results of each calibration or measurement (or series of either) carried out by the RM producer and, where appropriate, its collaborators, shall be reported unambiguously and objectively, in accordance with any instructions in the calibration or measurement methods. The results shall normally be reported in a calibration or measurement report and shall include all information necessary for interpretation of the calibration or measurement results and a summary of the method employed (see Note 13).

NOTE 13—This is for internal reports of the RM producer and should not be confused with a certificate of analysis or certification report which is supplied with a RM to the customer or client.

5.12 *Internal Audits:*

5.12.1 The RM producer shall, periodically and in accordance with a predetermined schedule and procedure (see Note 14), conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the quality system and the requirements of this practice. The internal audit program shall address all elements of the quality system, including the technical and production activities leading to the finished product (RM). It is the responsibility of the quality manager to plan and organize audits as required by the schedule and requested by management. Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited. Personnel shall not audit their own activities except where it is necessary and it can be demonstrated that an effective audit has been carried out.

NOTE 14—The schedule for internal auditing should normally be completed in one year.

5.12.2 When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of its RMs, the RM producer shall take timely corrective action and shall notify, in writing, its customers whose activities may have been adversely affected.

5.12.3 All audit findings and corrective actions that arise from them shall be recorded. The RM producer's management shall ensure that these actions are discharged within an appropriate and agreed timescale.

5.13 *Management Reviews:*

5.13.1 The RM producer's senior management shall periodically (see Note 15) conduct a review of it's quality system and production processes to ensure their continuing suitability and effectiveness and to introduce any necessary changes or improvements. The review shall take account of reports from managerial and supervisory personnel, the outcome of recent

internal audits, assessments by external bodies, feedback from customers, including complaints and other relevant factors.

NOTE 15—A typical period for conducting a management review is once every year. Results should feed into the corporate planning program and should include the goals, objectives and action plans for the coming year.

5.13.2 Findings from management reviews and the actions that arise from them shall be recorded. The management shall ensure that these actions are discharged within an appropriate and agreed timescale.

6. Technical and Production Requirements

6.1 *Management, Staffing and Training:*

6.1.1 The production of RMs should, where possible, only be undertaken by organizations having experience in the production of the particular type of RM (or related material), as well as having experience in the measurement of the properties being determined. The RM producer and any associated collaborators shall have managerial staff with the necessary authority, resources and technical competence required to discharge their duties. Measurement of the property of interest shall be completed by, or under the supervision of a technically competent manager qualified either in terms of suitable academic qualifications or relevant work experience. The RM producer's management shall define the minimum levels of qualification and experience necessary for the key posts within its body.

6.1.2 The RM producer shall have sufficient personnel having the necessary education, training, technical knowledge and experience for their assigned functions (see Note 16).

NOTE 16—For example, a staff member undertaking thermal expansion measurements should have a degree or appropriate level qualification, together with adequate experience in the field working with a more senior scientist making measurements at an equivalent level of accuracy.

6.1.3 The RM producer shall also ensure that staff receive additional training, when necessary, to ensure competent performance of measurements, operation of equipment and any other activities which affect quality (see Note 17). Where possible, objective measures should be used to assess the attainment of competence during training.

NOTE 17—The need to retrain staff periodically should be considered (for example, the RM producer should have in place a policy for retraining staff when a method or measurement technique is not in regular use). Staff training and retraining policies should take account of technological change and aim at continuous skill upgrading.

6.1.4 The RM producer shall maintain an up-to-date record of the training that each staff member has received. These records shall provide evidence that individual staff members have been adequately trained and that their competence to complete particular types of material preparation and measurement has been assessed.

6.2 *Collaborators:*

6.2.1 Where a RM producer undertakes any part of the procedure for the production or characterization of a RM on an interlaboratory basis, the producer shall be able to demonstrate that the experience of any collaborators is sufficient, and that the results produced are of the required quality. In assessing the competence of a collaborator, the RM producer shall require information on the collaborator's knowledge of the subject and details of past experience in the field (for example, valid results for comparable measurements). In the latter context, the producer may consider distributing materials of a comparable matrix whose property values are well established and at appropriate concentration levels, ranges, etc., prior to distributing any candidate RM samples. Evidence of collaborators being accredited to ISO/IEC 17025 when testing is carried out, or registered to the ISO 9000 series for other activities, will generally be appropriate. Evidence of collaborators participating in a relevant proficiency testing scheme and producing acceptable results on well-characterized materials of similar or equivalent nature to that of the RM would also be considered appropriate. In the limit, the RM producer may have no laboratories facilities, but shall ensure that all scientific work carried out by collaborators which may contribute to the assignment of the property values of interest is fit for that purpose and in compliance with the above requirements.

6.2.2 The RM producer shall ensure that all details of the methodology, results and all the performance procedures of any collaborators are available, if required, and that a register/database of all collaborators and their accreditation/quality system/other forms of competence status is maintained.

6.3 *Production Planning:*

6.3.1 The RM producer shall identify and plan those processes which directly affect the quality of RM production and shall ensure that they are carried out in accordance with prescribed procedures.

6.3.2 Organizational and technical input of the different collaborators involved shall be identified and the necessary information documented and regularly reviewed (see Note 18). A mechanism (for example, a management/technical advisory group) shall be established to make recommendations on how to plan the production processes.

NOTE 18—These could include recommendations for production, setting up a monitoring system (to ensure timeliness and quality for each production phase) and having an evaluation procedure to assess the production processes retrospectively.

6.3.3 In planning the production processes, the RM producer will need to have procedures and service facilities, where appropriate, for:

(a) Material selection (including, where appropriate, sampling);

(b) Maintaining suitable environments for all aspects of production;

(c) Material preparation;

(d) Measuring/testing;

(e) Calibration/validation of equipment/measurement methods;

(f) Assessing material homogeneity;

(g) Assessing material stability;

(h) Organizing interlaboratory studies with its collaborators;

(i) Assigning property values based on the results of measurements;

(j) Producing uncertainty budgets and uncertainty intervals to the assigned property values;

(k) Ensuring adequate storage facilities and conditions;