Guidelines

Central Administration of Drug Control
Accreditation Programs Unit

Guidance on the Egyptian Drug Authority Reference Materials Certification program For the year 2021

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1- Introduction

Within the scope of the Egyptian Drug Authority's keenness to support the pharmaceutical industry and the continuous update of quality control standards in line with the latest international quality standards and to contribute to providing the pharmaceutical companies' needs for reference materials, the Egyptian Drug Authority's accreditation program for reference materials aims to provide a mechanism for certifying and continuously provide the reference materials required for quality control laboratories. to ensure rapid fulfillment of analysis requirements and thus the arrival of safe and effective drugs to Egyptian patient in the shortest possible time without wasting the foreign currency resources for the pharmaceutical companies in Egypt.

2- Scope

- The Egyptian Drug Authority qualifies the reference materials required for the analysis of control samples (Active Pharmaceutical Ingredients and impurities) such that qualification and analysis of these reference materials are carried out in EDA's laboratories, as well as the continuous verification of their quality, which could be provided by:

- Suppliers of reference materials or their agents.
- Local and international pharmaceutical companies.
- Service laboratories affiliated with governmental and private agencies.

3- Abbreviations

None

4- Definitions

None

5- The main topic

5.1. Program Privileges

- Granting an accreditation certificate for the qualified reference materials, valid for three years.
- Logging the qualified reference materials into the list of approved reference materials.

5.2. Time schedule for phased implementation

Phase	Period	State	Type
One	Starting from the program launching	▪ Certification of the reference materials required for analyzing pharmaceutical products.	Optional
Two	3 months after the program launching	▪ Certification of the reference materials required for registering pharmaceutical products	Mandatory
Three	6 months after the program launching	▪ Certification of the reference materials required for the registration of pharmaceutical products ▪ Certification of the reference materials required for the analysis of registered pharmaceutical products (having variation approval)	Mandatory
Four	9 months after the program launching	▪ Certification of the reference materials required for the registration of pharmaceutical products ▪ Certification of the reference materials required for the analysis of registered pharmaceutical preparations (having variation approval) ▪ Certification of the reference materials required for the analysis of registered pharmaceutical products (random withdrawal) ▪ Certification of the reference materials required for the analysis of active pharmaceutical ingredients (API)	Mandatory

5.3. Groups of reference materials included in the Program

The accreditation mechanism is implemented according to the time schedule of implementation for the certification of reference materials, which are categorized into the following groups:

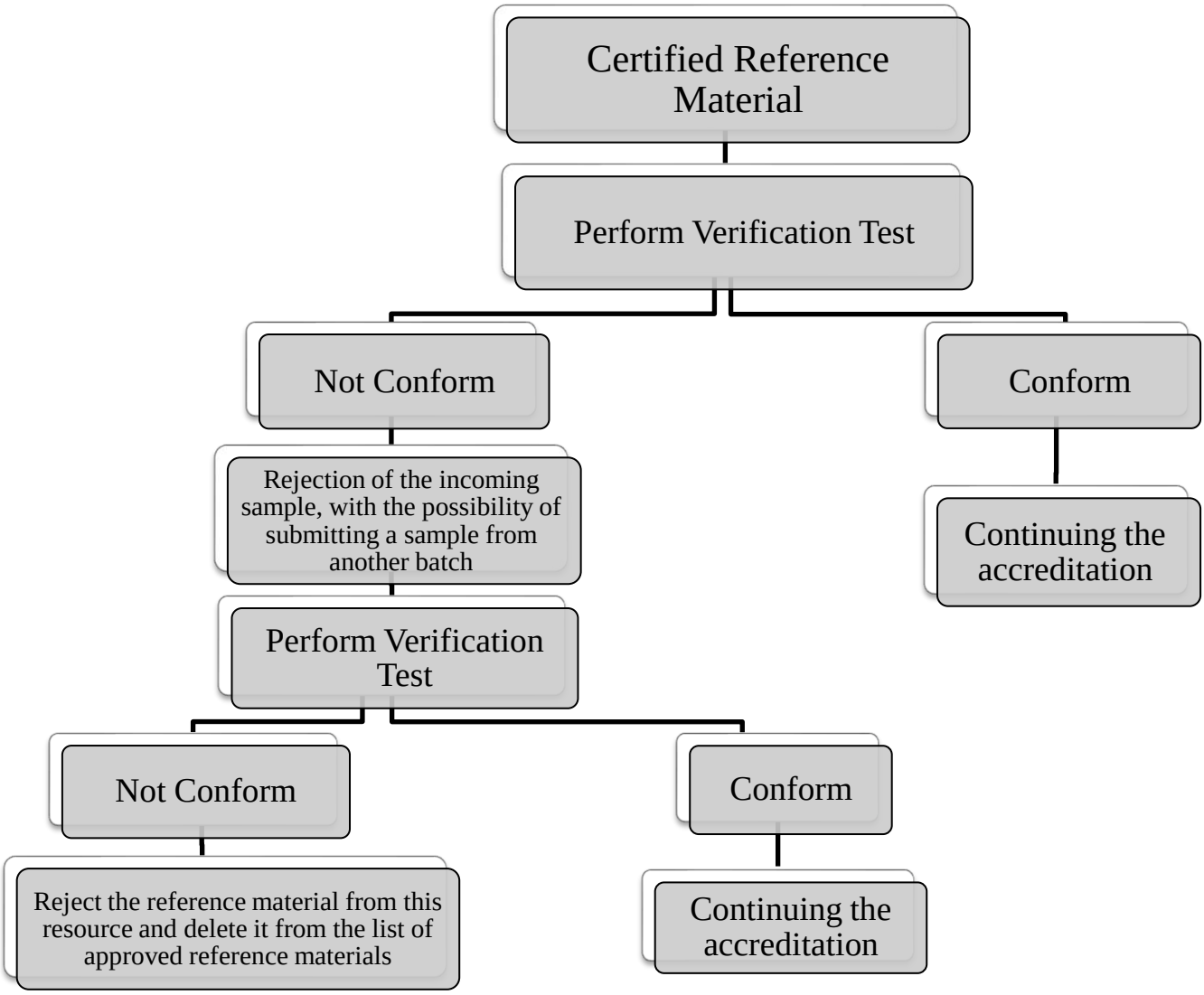
Group 1	- The first group includes official reference standards, standards from the national institutes of measurement, and internationally recognized bodies and organizations e.g. Pharmacopoeia Reference standards, and internationally recognized national metrological institutes or agencies. -The reference materials of this group are not subjected to any evaluation or verification procedure and are not included in the list of approved reference materials.
Group 2	**Reference standards Group 2A** Reference standards are supplied by a body that is accredited with ISO 17034, this group is accredited by reviewing the attached documents and conducting verification if necessary. **Reference standards Group 2B** Reference standards are supplied by a party that meets the requirements of ISO 17034, this group is approved by reviewing the attached documents and performing verification.
Group 3	Reference materials from other sources (Working / Secondary Reference Standards) Tests for certification and verification are performed for this group

5.4. Implementation mechanism

5.4.1 .Pre-accreditation procedures

Responsible	Action
The Applicant	Send an email requesting certification
Central Administration of Drug Control	Send the application form to be filled out electronically
The Applicant	Pay of the service fees for the certification of a reference material , fulfill and send the application form electronically Send the required documents electronically (Annex 1)
Central Administration of Drug Control	Study and review the documents, respond to the applicant, determine the quantity required to be sent of each reference material and any analysis requirements if necessary, and determine the service fees for the reference materials under evaluation (ten days)
The Applicant	Pay the analysis service fees and deliver the samples (Annex 2), accompanied by the reference materials from the first group, any analysis requirements if present, and the required documents (Annex 3) Within five days
EDA Laboratories	Analysis within a period not exceeding 5 working days for each reference material
Central Administration of Drug Control	Issue a an accreditation certificate and logging the reference material into the list of approved reference materials and issue a schedule sincluding the approved reference materials.

5.4.2. Post-accreditation procedures.



- Reference materials belonging to group 2 are verified by reviewing the document and analysis if necessary
- Verification testing for reference materials belonging to group 3 is performed when each sample is submitted for regulatory analysis or once a year, whichever comes first.

5.5 . General Terms and Conditions

1. The company must adhere to the regulatory rules and technical controls issued by the Egyptian Drug Authority.
2. When a sample is submitted for verification testing to be used for quality control analysis, the samples whose conformity has been confirmed to the applicant for the verification test are returned with the (EDA) logo attached to them to be delivered to the laboratory concerned with the analysis of the final product during the submission the product to the lab for analysis.
3. In case the company does not adhere to the time frames specified for payment of a certain service and for delivering the samples and analysis requirements, the application will be considered as if it did not exist, and the company has the right to submit an appeal to the Head of the Central Administration of drug Control to grant an additional period, and in case of refusal, the company will submit a new application if it desires to gain the accreditation.
4. The company is committed to notifying the Central Administration of Drug Control as soon as any changes occur in the submitted documents, and the accreditation programs unit will respond within a period not exceeding ten days by accepting or suspending the accreditation until the changes are completed.
5. If the accreditation application is rejected, the company has the right to resubmit a new application after changing the source of the reference material required to be approved and paying the required fees.
6. If the company wishes to renew the accreditation, the application must be submitted within a period not less than three months from the date of renewal.
7. The applicant is committed to providing any requirements for analysis, if necessary.
8. The Central Administration of Drug Control may conduct an observed or virtual audit if necessary, with the applicant’s obligation to provide all requirements for the virtual audit.
9. Verification tests are conducted randomly for materials approved by EDA.
10. If a working reference material is approved for a pharmaceutical company, only the company applying can use it.
11. If the verification of a sample does not conform during the accreditation period, the approval of the substance will be stopped.

5.6. Official communication channels

The official email of EDA Reference Materials Accreditation Program
dc.crmlabaccredit@edaegypt.gov.eg

- Electronic links for the accreditation program:
- To book a payment appointment for the accreditation application
https://form.jotform.com/212552933971056

- To book a payment appointment to pay the analysis fees + deliver the analysis requirements
https://form.jotform.com/212553322378050

Link of Annex 1 Submission -
https://forms.office.com/r/VSkb5CLpqS

6. References

1- ISO 17034: 2016 E “General requirements for the competence of reference material producers”
2- Handling and Use of Non-Compendial Reference Standards in the OMCL Network PA/PH/OMCL (11) 204 R9.
3- https://www.sigmaaldrich.com/EG/en/technical-documents/technical-article/analytical-chemistry/calibration-qualification-and-validation/how-to-choose-the-correct-reference-material-quality-grade.
4- United states pharmacopeia USP <11>.

7. Attachments and Annexes

7.1. Attachments:
None
7.2. Annexes:
7.2.1. **Annex 1:** Documents required to be sent electronically
7.2.2. **Annex 2:** Sample requirements
7.2.3. **Annex 3:** Documents required to be delivered as hard copies .
7.2.4. **Annex 4:** Assessment checklist for the reference materials producers (RMP).

Annex 1

Documents to be sent electronically

Documents needed for Group 2:

• A copy of the ISO 17034:2016 certificate attached with the scope of accreditation, or a copy of an accreditation equivalent to the ISO 17034.
• Legal representation is needed when dealing with official agents of international companies or suppliers of reference materials.
• Analysis certificates or reports including the data required according to ISO guide 31:

- Title of the Document
- Unique identifier of the RM
- Name and Description of the RM
- Name and Contact Details of the RM Producer
- Intended Use
- Minimum Sample Size/Homogeneity
- Period of Validity
- Storage and Handling Information
- Document Version and Page Numbers
- Property of interest, property value and associated uncertainty(CRM)
- Measurement Methods.
- Meteorological traceability
- Name and function of the RM producer's approving officer.

•Safety material data sheet

Documents needed for Group 3:

- **Certificate of Analysis (CoA) includes:**
  - -Standard name
  - -Unique identifier (batch no, code no etc.)
  - -Reference monographs.
  - -Retest date /Expiry date
  - -Results of all required tests according to the reference monographs.
  - -Storage conditions.
  - -Instructions of use when necessary
  - -Intended use when necessary
  - -Name and function of approving officer.
  - -Date of certification

-Safety data sheet.

In case of In-house (non-official) reference materials

- Testing Monographs
- Validation studies for methods described in the relevant testing monographs.
- Evidence of characterization of submitted reference materials (e.g. IR, UV spectra, LC/MS, etc…).

Annex 2

Number of vials

- **Vials needed for the accreditation procedure: (Certification)**

When a reference material for API and Impurities (Group 3): 12 vials

- **Vials needed for verification (Verification):**

  - When verifying the standardized material API or Impurity (Group 3): 12 vials
  - When conducting verification for a Reference material (RM) or Certified Reference material (CRM) for API or Impurities (group 2B) : 2 vials

- **Identification label information on the package**
  - Standard name.
  - Name of manufacturer.
  - Identification code i.e. Batch no., Lot no.
  - Expiry/Retest date
  - Potency (if applicable)
  - Water content
  - Storage condition
  - Weight
  - Safety instructions

Conditions for sealing containers for standard materials and impurities (sealing):

- Materials must be sent in containers that suit the storage conditions of the material, and the containers must be tightly sealed with a lid that matches the specifications of each material.

Annex 3

Documents to be delivered as hard copies

- An original application form signed by the legal or authorized person.
- Delegation letter of authorization
- Original receipts for payment for the service

Annex 4

Assessment checklist for the reference materials producers (RMP)

Requirement	Yes /No
1-Contractual requirements	
Is any request, tender or contract verbal or written; concerning the production of an RM reviewed, following documented policies and procedures established by the RMP?	
Do these policies and procedure ensure the requirements for RMs and their production are adequately defined, documented and understood?	
Do these policies ensure that the RMP has the capability and resources to meet the requirements?	
Does the review include any work that needs to be subcontracted by the RMP?	
Does the RMP maintain records of these reviews, including any changes, records of pertinent discussions with the customer relating to the customer's requirements, and subcontracted work?	
2-Impartiality	
Is the RMP structured and managed so as to safeguard impartiality?	
Does the lab have arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work?	
Does the lab identify risks to its impartiality on an on-going basis, which shall include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel?	
Does the lab have the ability to demonstrate, if a risk to impartiality is identified, and how it eliminates or minimizes such risk?	
Does the lab have top management commitment to impartiality?	
3- Confidentiality	

Is the RMP responsible for and does it treats in an appropriate manner all information obtained, including confidential information unless this information is placed in the public domain or agreed to its disclosure to others or required by law?
In case the confidential information is required to be disclosed is the individual or the body concerned notified unless prohibited by the law?
4- Structural requirements - Is the RMP a legal entity, or a defined part of a legal entity, that can be held responsible for all its activities related to the production of RMs and does it have a description of its legal status? - Does the RMP define its organizational and management structure of, its place in any parent organization and the relations between management, technical operations, support services and subcontractors using organization charts? c) Does the RMP define the parts of the organization covered by the management system for the production of RM s? d) Does the RMP specify the responsibility, authority and interrelationships of all personnel who manage perform or verify work affecting the quality of RMs produced? e) Does the RMP 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 management system or the procedures for the production of RMs and to initiate actions to prevent or minimize such departures? d) Does the RMP have technical management with 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? e) Does the RMP appoint personnel that have defined responsibility and authority for ensuring that the requirements for the competence of the lab to produce RMs are met and have direct access to the highest level of management at which decisions are taken on RM production policy or resources? - Does the RMP management ensure communication internal and external to ensure the effectiveness of the management system and that meeting the customer and other requirements are well communicated?
5-Resources requirements **5 .1 Personnel** -Does the RMP ensure that all personnel involved in RM production are supervised and competent and that they work in accordance with the RMP's management system? -Do personnel, including subcontractors, personnel of external bodies, or other individuals acting on the RMP's behalf; comply with the policies and procedures for management of confidential information that are set by the RMP?

-Does the RMP 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? -Are there sufficient personnel having the necessary education, training, technical knowledge, and experience for their assigned functions? -Does the RMP have procedures for identifying training needs and providing training of personnel? Is there a training program in place that is relevant to the present and anticipated tasks of the RMP? Does The RMP maintain records of job descriptions for its personnel involved in RM production activities? Does the RMP authorize competent personnel to perform particular activities relating to RM production where records of these authorizations, competence, educational and professional qualifications of those personnel shall be kept and provide the evidence of adequate training and competence and include the date on which the authorization and/or competence has been confirmed?
5.2. Subcontracting - Does the RMP have procedures to ensure: a) The subcontractors' experience and technical competence are sufficient for their assigned tasks? b) Selection of subcontractors based on their ability to meet the requirements stipulated by the RMP? c) Is an assessment done by the RMP that all tasks performed by subcontractors comply with the requirements set by the RMP? - Has the RMP ensured not to subcontract: ➢ 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? -Does the RMP establish and maintain the evidence of the subcontractor's competence, including records of evaluations and any audits made or supervision of the operations carried out by the subcontractor to ensure their capabilities of performing the subcontracted tasks? - Does the RMP have personnel operating under its management system having sufficient knowledge of the subcontractor's task to evaluate the subcontractor's activity?
5.3. Provision of equipment, services and supplies

- does the RMP have procedures in place for the selection of equipment, services, and supplies that affect the quality of the RMs produced? -does the RMP use only equipment, services, and supplies that comply with specified requirements to ensure the quality of the RMs it produces? - Does the RMP 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? - Does the RMP maintain records of purchases of equipment, services, and supplies, including records of the selection criteria used in confirmation of acceptance?
5.4. Facilities and environmental conditions Does the RMP 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 suitable for performing the required activities? -Are environmental conditions in which the RM production activities are undertaken monitored controlled and recorded when the environmental conditions could have an adverse effect on the RM? - Are all RM processing and calibration and testing areas, protected, where appropriate, from other environmental factors such as incompatible activities? - Is access to and use of areas controlled as appropriate?
6-Technical and production requirements **6.1. Production planning** Does the RMP identify and plan those processes that directly affect the quality of RM production, and is this production plan documented and does it address: a) Material l selection including, where appropriate, sampling? b) Verification of the identity of the material? c) Maintaining suitable environments for all aspects of production? d) Material processing? e) Choice of measurement procedures? f) Validation of measurement procedures? g) Verification and calibration of measuring equipment? h) Specification of acceptance criteria for, and assessment of, homogeneity, including sampling? i) Specification of acceptance criteria for, and assessment and monitoring of, stability including sampling? j) Designing and organizing appropriate characterization, including sampling? k) Assessing commutability (where appropriate)?

l) Assigning property values? m) Establishing uncertainty budgets and estimating uncertainties of certified value(s) n) defining acceptance criteria for measurand levels and their uncertainties? o) Establishing metrological traceability of measurement result(s) and certified value(s)? p) Issuing RM documents? q) Ensuring adequate storage facilities and conditions? r) Ensuring appropriate label ling and packaging of the RM s? s) Ensuring appropriate transport arrangements? t) Ensuring post-production stability monitoring?
6.3. Production control Does the RMP verify that the production plan has been implemented as specified? Are deviations from the plan documented and approved?
6 .4 Material handling and storage - Does the RMP identify, preserve and separate candidate RMs and RMs from chemicals and other samples, from the time of processing through to their distribution? - Does the RMP ensure adequate packaging of all RMs and provide secure storage areas /stock rooms which prevent damage or deterioration of any item or material between characterization and distribution? Is the condition of all RMs monitored at appropriate intervals throughout the storage period, in order to detect possible deterioration? Does the RMP control packaging and labeling processes to the extent necessary to ensure conformity with safety and transport requirements? - Does the RMP take measures to ensure that the integrity of each individual RM unit is maintained until the point when first used?
6 .5 Material processing Does the RMP establish procedures to ensure that the material has undergone adequate processing for its intended use and address: a) Qualitative analysis for verification of material type and/or identity? b) Synthesis, purification, incubation, and transformation into the final form? c) Homogenization? d) proper handling e) Measurements for control of material processing? f) Pre -treatment, cleaning or sterilization of processing equipment and sample containers? g) Stabilization of material? h) Packaging of the material?

i) Safety precautions? Is equipment used in material processing operated in accordance with documented procedures?
6.6 Measurement procedures Are testing and calibration activities consistent with the required accuracy of the property values of the RM, and with any standard specifications relevant to the measurement concerned?
6.7 Measurement equipment -Does the RMP have a procedure for handling, transport, storage, use and planned maintenance of equipment in order to ensure proper functioning and to prevent contamination or deterioration? - Does the laboratory verify that equipment conforms to specified requirements before being placed or returned into service? - Is the equipment used for measurement capable of achieving the measurement accuracy and/or measurement uncertainty required to provide a valid result? -Is the measuring equipment calibrated when? -Does the laboratory establish a calibration program? -Is the calibration program reviewed and adjusted as necessary to maintain confidence in the status of calibration? - Is all equipment labeled for their calibration status? - Is equipment that is out of use shall be isolated and clearly labeled to be out of service until service return and verified for proper use. -Are intermediate checks shall be carried out according to a procedure when necessary? -Are records retained for equipment which can influence laboratory activities?
6.8 Data integrity and evaluation Does the RMP ensure that: a) Computer software developed software is validated and shown to be adequate for use? b) Procedures are established and implemented for protecting the integrity of data? c) Equipment and software are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain data integrity? d) Appropriate procedures are established and implemented for the prevention of unauthorized access and changes to records, including computer records? Are statistical procedures used verified for their appropriate application?

6 .9 Metrological traceability of certified values -When producing CRMs, Is the metrological traceability of the certified values established using a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference? When metrological traceability to the SI units is not technically possible, -Does the laboratory demonstrate metrological traceability to an appropriate reference? - Is the evidence of meteorological traceability established when secondary parameters have a significant influence on the certified value or its uncertainty?
6 .10 Assessment of homogeneity -Does the RMP carry out an assessment of the homogeneity of any candidate RM in its final packaged form to ensure its fitness for purpose? -When the material is produced in multiple batches, is the equivalence of the batches demonstrated or the homogeneity of each batch evaluated separately? -Are validated measurement procedures selected so that the precision and selectivity are fit for the purpose required? - For certified values, is homogeneity quantified as an uncertainty contribution to the certified value or shall be shown to be a negligible contribution to the uncertainty of the certified value?
6.11. Assessment and monitoring of stability Does The RMP: a) Assess, by experimentation, if necessary, the stability of all relevant properties of an RM under proposed storage conditions and choose pre-treatment, packaging, and storage conditions in accordance with the results of the assessment. b) Assess, by experimentation, if necessary, the stability of all relevant properties of an RM under proposed conditions of transport, and choose transport conditions to maintain stability during transport.? c) Establish any necessary advice on storage and use of the material to maintain stability at the user‘s premises. d) Select a scheme for monitoring the stability of materials held in long-term storage that permits prompt detection of change, taking into account the possible rate of change?
6.12. Characterization Where the RMP assigns property values, is there characterization of the RM?
Does the RMP clearly define whether a quantitative or a qualitative property will be characterized?

Does the RMP select a characterization strategy appropriate for the intended use of the RM?
Does the RMP specify the characterization study so that the properties of interest are each characterized with appropriate traceability and sufficient reliability?
Does the lab document a measurement plan that clearly describes the tasks to be performed and communicate this to all personnel responsible for measurements used in characterization?
Does the lab perform technical evaluation of characterization data and documents to ensure - The implementation of the measurement plan? - Evaluation of the impact of any deviation if present on the characterization data?
6.13. Assignment of property values and their uncertainties Does the RMP use documented procedures for the assignment of property values?
Do these procedures include, as appropriate? a) Details of statistical techniques and policies on treatment and investigation of anomalous results, including outliers? b)) The approach used to assign uncertainties to the property values? c) Any other significant factors that may affect the assignment of property values?
Does the RMP take due account of technical information on test methods and equipment, including reported uncertainty information, and of any evidence of laboratory performance when assigning the property values of interest?
For Certified Reference Materials "CRM", does the RMP identify the uncertainty contributions to be included in the assigned uncertainty and considers at minimum uncertainty contributions of each of the following: a) Characterization, including any difference between multiple procedures used for characterization? b) between-unit and within-unit inhomogeneity? c) Changes of property values during storage? d) Changes of property values during transport?
6.14.RM documents and Labels Does the RMP issue and make available an RM certificate for CRMs and a product information sheet for other RMs? Does the content of RM certificates and product information sheets include the following? a) Title of the document? b) Unique identifier of the RM? c) The name of the RM?

d) Name and contact details of the RMP? e) Intended use? f) Sample size (whenever applicable)? g) Period of validity? h) Storage information? i) Instructions for handling and use that are sufficient to ensure the integrity of the material? j) Page number and the total number of pages? k) Document version? l) Information on commutability of the material (where appropriate)? And the following additional information a) Description of the CRM? b) Property of interest, property value, and associated uncertainty? c) Measurement procedure for operationally defined measurand(s)? d) Metrological traceability of the certified values? e) Name and function of RMP's approving officer?
Is the RM label securely attached to the product container of an individual RM unit, and designed to remain legible and intact under the defined storage and handling conditions within the lifetime of the RM?
Does the label identify the material, all information necessary to enable the material to be uniquely distinguished and referenced where appropriate, to its product information sheet or RM certificate?
Where the physical size of the RM unit limits the amount of information that can be contained on the label, is the information included elsewhere (e.g., in an RM document)? Is a unique identifier given?
6.15. Distribution services Does the RMP determine the conditions of shipment and ensure that appropriate documentation is provided to allow customs clearance?
Does the RMP maintain up-to-date records of all RM sales and distribution?
Does the RMP offer users reasonable guidance and technical support related to the RMs it produces?
Does the RMP employ best efforts to notify users of any change to the property value or uncertainty for any RM within the validity period of the RM certificate or product information sheet?
Where RMs is subject to resale through a distributor with whom the RMP has a contractual relationship, does the RMP pass on to the authorized distributor all

necessary information to ensure that an effective post-distribution service is maintained?
6.16. Control of quality and technical records Does the RMP establish and maintain procedures for the identification, collection, indexing, access, storage, maintenance, and disposal of quality and technical records?
Does the RMP ensure that it has recorded such information that might be needed in a future dispute situation?
Are all records legible and 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?
Do all records have retention time of records been established in accordance with customer or other relevant requirements, and documented?
When mistakes occur in records, is each mistake be crossed out, not erased, made illegible or deleted, and the correct information entered alongside
Are all such alterations to records signed or initialed, and dated by the person correcting? In the case of records stored electronically, have equivalent measures been taken to avoid the loss or change of original information?
Are all records held securely and, where appropriate, in confidence?
Does the RMP have procedures to protect electronically held data at all times and to prevent unauthorized access to, or amendment of, such data?
Does the RMP arrange for all individual measurement observations, appropriate calculations and derived data, 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?
Have the results of each calibration or measurement (or series of either) carried out by the RMP or by a subcontractor reported in accordance with ISO/IEC 17025?
6.17. Management of non-conforming work Does the RMP have procedures that are implemented when it establishes that any aspect of its production activities does not conform to its own specified production procedures or the agreed requirements of the customer?
Do the procedures ensure that? a) Responsibilities and authorities for the management of nonconforming work are designated? b) Are there actions to be taken when any non-conforming work and/or RMs are identified including root cause analysis and a system that ensures that they are effectively implemented?

c) Is there an evaluation of the significance of the non-conforming work made and identification and implementation of correction and corrective action? d) Is the work halted , if appropriate, issue of the affected RM and its certificates and other appropriate documentation is withheld.? e) Are remedial actions such as customer notifications taken within a defined time-frame.? f) Where necessary, are best efforts employed to notify the users of the possible effects, within an appropriate period and, where necessary, non-conforming RMs and/or their certificates and other appropriate documentation already distributed, are recalled? g) Is the responsibility for authorization of the resumption of work defined? h) Is an internal audit conducted to verify the closure and effectiveness of the corrective actions taken?
Is the decision on the recall of RMs taken promptly to limit the use of nonconforming RMs?
6.18. Complaints Does the RMP have a documented process to receive, evaluate, and make decisions on complaints?
Is a description of the handling process for complaints available to any interested party on request?
Upon receipt of a complaint, does the RMP confirm whether the complaint relates to conformity assessment activities that it is responsible for and, if so, shall deal with it?
Is the RMP responsible for all decisions at all levels of the handling process for complaints?
Are investigations and decisions on complaints not result in any discriminatory actions? Does the process for handling complaints include at least the following elements and methods? a) A description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it? b) Tracking and recording complaints, including actions undertaken to resolve them? c) Ensuring that any appropriate action is taken?
Is the RMP receiving the complaint responsible for gathering and verifying all necessary information to validate the complaint?
Whenever possible, does the RMP acknowledge receipt of the complaint, and provide the complainant with progress reports and the outcome?
Is the decision to be communicated to the complainant made by, or reviewed and approved by, individual(s) not involved in the original RM activities in question?

Whenever possible, does the RMP give formal notice of the end of the complaint handling process to the complainant?
7.Management system requirements Does the RMP define and document its scope of and address the following: ➢ Quality policy? ➢ General management system documentation ➢ control of management system documents ➢ Control of records? ➢ Management review? ➢ Internal audit? ➢ Actions to address risks and opportunities? ➢ Corrective actions? ➢ Improvement? ➢ Feedback from customers?