**0. GENERAL INSTRUCTIONS**

This list has been prepared for the verification of the Reference Material Producers (RMP) by the Technical Assessor, referring to the UNI CEI EN ISO 17034 and to the ACCREDIA RG-18 and RT-34 documents.

The **Technical Assessor** shall fill in the **"DOCSG"** column to register the code and the documentation section of the RMP management system (for example technical procedures/operating instructions) in which the requirement is considered. During on-site assessment, the evidence of conformity or the shortcomings found shall be briefly recorded, with reference to the interviewed persons, to the verified equipment, to the documents examined, and so on, as foreseen by the ACCREDIA RG-18 document.

The space in the column identified with an **"R"** shall be marked with an asterisk (or other identifying sign) in the event that the examination of the requirement in question has given rise to a finding. The column refers to the single on-site assessment in progress. For the formulation and record of the findings, see the PG-09-DT procedure in force.

The "notes" field (last page of this list) can be used for further additional annotations and/or for the record of the findings to be formalized later on the DT-Mod-006 form.

Attachments (e.g. documents associated with reference material) shall be listed **in paragraph 3 of this checklist**.

**The tables in §2.1 and in §2.2 of this document refer only to the on-site assessment in progress**. The Technical Assessor shall cancel those relating to previous audits. **Information regarding the closure of previous findings** may not be indicated in this checklist but **shall in any case be reported in the appropriate section of the DT-Mod-006**.

**1. ASSESSMENTS**

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| **§** | **ASSESSMENTS** | **DOCSG** | **A\_\_S\_\_E\_\_** | **A\_\_S\_\_E\_\_** | | **A\_\_S\_\_E\_\_** | **A\_\_S\_\_E\_\_** | | **R** |
| **6.1** | **Personnel** |  |  |  | |  |  | |  |
| 6.1.1 | The technical staff involved in the verified activities shall:   1. demonstrate sufficient technical competence 2. demonstrate knowledge of the Management system within which the operating personnel shall be adequately supervised |  |  |  | |  |  | |  |
| 6.1.2 | The verified technical personnel (including subcontractors and personnel from external bodies) shall operate in accordance with company policies regarding the protection of confidential and reserved information |  |  |  | |  |  | |  |
| 6.1.3  RT-34 | The personnel involved shall be sufficient and shall have been adequately trained and educated.  Describe which procedure is implemented and which competence requirements are defined in order to guarantee the competence of the technical managers and of all the operational staff involved in the production of each RM. |  |  |  | |  |  | |  |
| 6.1.4  RT-34 | The RPM shall have procedures for qualifying and maintaining the qualification of the technical staff.  The updated and adequate staff training programme. The RPM shall provide evidence of the effectiveness of training and education activities. |  |  |  | |  |  | |  |
| 6.1.5 | Check if records are available concerning the qualification and maintenance of the qualification of the personnel involved in the production of RM. |  |  |  | |  |  | |  |
| 6.1.6 | The RMP shall have identified and authorized competent personnel to perform specific activities related to the RM production process.  Verify the presence, adequacy and updating of records related to authorizations, assessments of skills, qualifications. |  |  |  | |  |  | |  |
| 6.1.6  RT-34 | The Management shall have identified the responsible department authorized to approve the documents associated with the reference material and the authorizations shall be dated, signed by the Management and countersigned by the personnel concerned. |  |  |  | |  |  | |  |
| 6.2 | **Subcontracting** |  |  |  | |  |  | |  |
| 6.2.1  RT-34 | In the case of subcontracting of activities such as sampling, production process, handling, homogeneity and stability testing, characterization, storage and distribution of the RM check if:   * the procedures are put in place in order to guarantee the subcontractor's competence and experience for the tasks assigned. * the subcontractor's operating procedures meet the requirements of the standard and technical requirements of the sector. |  |  |  | |  |  | |  |
| 6.2.2 | RMP shall select subcontractors on the basis of their ability to meet agreed requirements. |  |  |  | |  |  | |  |
| 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  RT-34 | What procedures are put in place in order to assess that the subcontractor's work is compliant with the requirements of the RM producer and complies with the standard requirements?  Are testing or calibration activities subcontracted? |  |  |  | |  |  | |  |
| 6.2.5  RT-34 | Records concerning the subcontractor's competence with respect to the subcontracted activities shall be available.  The evidence may be, for example, previously obtained results on well-characterized reference materials with similar matrix, results obtained in the participation in interlaboratory tests, etc. |  |  |  | |  |  | |  |
| 6.2.5  RT-34 | In case of subcontracting of tests and/or calibrations, records shall be available concerning at least:  a) required measurements  b) test/calibration methods used  c) measurement uncertainty required  d) metrological traceability  e) test reports/calibration certificates  f) performance against measurement (PT/ILC). |  |  |  | |  |  | |  |
| 6.2.6  RT-34 | Alternatively, what actions have been implemented by RMP to assess the subcontractor's competence? |  |  |  | |  |  | |  |
| 6.2.7 | Results and procedures applied by subcontractors should be available at RMP |  |  |  | |  |  | |  |
| 6.2.8 | RMP staff shall be sufficiently competent to evaluate the activities performed by the subcontractor.  Check whether in the case of subcontracting of testing and calibration activities there is sufficient knowledge of the requirements of the UNI CEI EN ISO/IEC 17025 standard. |  |  |  | |  |  | |  |
| 6.3 | **Provision of equipment, services and supplies** |  |  |  | |  |  | |  |
| 6.3.1 | The RMP shall have in place and implement procedures for the selection of equipment, services and supplies that affect the production activities. |  |  |  | |  |  | |  |
| 6.3.2 | The RMP shall use only equipment, services and supplies that comply with specific requirements to ensure the quality of the product. |  |  |  | |  |  | |  |
| 6.3.3 | The RMP shall ensure that checks are carried out on equipment and consumable materials upon receipt and prior to use.  The procedures shall ensure compliance of the equipment and materials used in the production of RM. |  |  |  | |  |  | |  |
| 6.3.4 | Check if there are records related to purchases, selection criteria, acceptance and orders. |  |  |  | |  |  | |  |
| **6.4** | **Facilities and environmental conditions** |  |  |  | |  |  | |  |
| 6.4.1 | All premises used for the production process shall be such as to guarantee the quality level of RM.  The premises where the productions are carried out shall be adequately luminous, spacious and in good condition in relation to the operations to be carried out. |  |  |  | |  |  | |  |
| 6.4.2  RT-34 | For areas subject to particular constraints on environmental parameters (temperature, humidity, dust, sterility, power supply, vibrations, etc.) the environmental conditions shall be monitored with calibrated instruments and there shall be records.  These records shall be kept for at least 10 years. |  |  |  | |  |  | |  |
| 6.4.3  RT-34 | Verify:  a) if there is a system of protection/separation of the production areas for which controlled conditions are required e.g. temperature, humidity, microbiological contamination level.  b) how any maintenance and cleaning activities are handled by external personnel when applicable. |  |  |  | |  |  | |  |
| 6.4.4 | There shall be procedures governing access to the premises. |  |  |  | |  |  | |  |
| **7** | **Technical and production requirements** |  |  |  | |  |  | |  |
| **7.1** | **General requirements** |  |  |  | |  |  | |  |
| ANNEX A | Check if in the case of CRM production, the RMP applies the requirements related to  - Production planning - 7.2  - Production control - 7.3  - Material handling and storage - 7.4  - Material processing - 7.5  - Measurement procedures - 7.6  - Measuring equipment - 7.7  - Data integrity and evaluation - 7.8  - Metrological traceability of certified values - 7.9  - Assessment of homogeneity - 7.10  - Assessment and monitoring of stability - 7.11  - Characterization - 7.12  - Assignment of property values and their uncertainties - 7.13  - RM documents and labels - 7.14  - Distribution service - 7.15  - Control of quality and technical records - 7.16  - Management of non-compliant products - 7.17  - Management of complaints - 7.18 |  |  |  | |  |  | |  |
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| **7.2** | **Production planning** |  |  |  | |  |  | |  |
| 7.2.1 | The processes that affect the quality of RM production shall be identified and planned  Production planning shall be documented. |  |  |  | |  |  | |  |
| RT-34 – 7.2.1 | Check whether the production plan has been positively evaluated by ACCREDIA and whether any changes have been communicated.  Check if the production of the RM requires a Pilot Study. |  |  |  | |  |  | |  |
| 7.2.2 | If the production includes the use of subcontractors, the RMP shall provide the subcontractor with documented technical specifications.  The requested information shall be documented and periodically reviewed. |  |  |  | |  |  | |  |
| 7.2.3 | Check if in the planning of the production process RMP has included procedures and services for:  a. Material selection (including, where appropriate, sampling)  b. Verification of the identity of the material  c. maintaining suitable environments for all aspects of production - 6.4  d. Material processing - 7.5 |  |  |  | |  |  | |  |
| 7.2.3 | Check if in the planning of the production process RPM has included procedures and services for:  e. choice of measurement procedures- 7.6  f. validation of measurement procedures - 7.6  g. verification and calibration of measuring instruments - 7.7  h. definition of criteria for acceptability and assessment of homogeneity, including sampling - 7.10  i. definition of acceptability and stability assessment criteria, including sampling - 7.11 |  |  |  | |  |  | |  |
| 7.2.3 | Check if in the planning of the production process RPM has included procedures and services for:  j. design and organization of appropriate characterization activities, including sampling - 7.12  k. assessing commutability (when applicable)  l. assignment of property values ​​- 7.13  m. establishing uncertainty budgets and estimating the uncertainty of the certified values - 7.13  n. defining of the acceptability criteria for the levels of the measurands and their uncertainties. |  |  |  | |  |  | |  |
| 7.2.3 | Check if in the planning of the production process RMP has included procedures and services to:  o. establishing metrological traceability of the results of the measurements and the certified values - 7.9  p. issuing RM documents - 7.14  q. ensure adequate storage conditions - 7.4  r. ensure appropriate labelling and packaging for RM - 7.14  s. ensure appropriate transport arrangements- 7.15  t. ensure post-production stability monitoring, if applicable – 711  u. ensure an adequate post-distribution service for RM users – 7.15 |  |  | |  |  |  |  | |
| 7.2.4  RT-34 | Where multiple batches of RMs with equivalent properties are produced by using similar starting materials and by applying the same procedures, RMP shall ensure that information obtained from previous batches remains applicable for the new batch. |  |  | |  |  |  |  | |
| 7.3 | **Production control** |  |  | |  |  |  |  | |
| 7.3 | The RMP shall verify that the production plan has been implemented as specified. Any deviations from the plan shall be documented and approved. |  |  | |  |  |  |  | |
| **7.4** | **Material handling and storage** |  |  | |  |  |  |  | |
| 7.4.1 | Throughout the entire process, RMs shall be managed in order to ensure their integrity.  Suitable environmental conditions shall be ensured (6.4) and possible contamination avoided. |  |  | |  |  |  |  | |
| RT-34 – 7.4.1 | In the event that the material is transferred to a subcontractor, RMP shall provide the instructions necessary for correct storage and correct handling to the person in charge of the areas in which the material is transferred.  The environmental storage conditions shall be documented and recorded, where necessary.  The areas of storage and handling of the materials shall allow the avoidance of any contamination or confusion between the materials in the different steps of production. |  |  | |  |  |  |  | |
| 7.4.2 | Candidate RMs and RMs shall be adequately identified, protected and segregated in order to avoid mutual chemical influences between samples or between materials present in the premises for the entire duration of the production process up to distribution to users. |  |  | |  |  |  |  | |
| 7.4.3  RT-34 | The RMP shall guarantee a suitable packaging system so that RM can maintain their characteristics.  The RMP shall guarantee storage areas and warehouses that can preserve the packages from damage and deterioration between the characterization phase and the distribution. |  |  | |  |  |  |  | |
| 7.4.4  RT-34 | All stored RMs shall be verified at appropriate intervals in order to identify possible deterioration and these checks shall be recorded. |  |  | |  |  |  |  | |
| 7.4.5 | RMP shall control packaging and labelling processes to ensure compliance with safety and transport requirements.  Appropriate procedures for transporting materials to customers shall be defined. |  |  | |  |  |  |  | |
| 7.4.6 | RMP shall take measures to ensure the integrity of each RM during the entire production process until delivery to destination. |  |  | |  |  |  |  | |
| **7.5** | **Material processing** |  |  | |  |  |  |  | |
| 7.5.1 | The RMP shall establish appropriate procedures for material processing. |  |  | |  |  |  |  | |
| 7.5.1 | The procedures shall address at least:  a) qualitative analysis for the verification of the material type and/or identity  b) synthesis, purification (e.g. distillation, extraction), incubation and transformation in the final form (e.g. machining, grinding, mixing, sieving and sliding, extrusion, melting)  c) homogenization |  |  | |  |  |  |  | |
| 7.5.1 | The procedures shall provide at least:  d) appropriate handling of the material (e.g. protection against contamination and use of inert devices) - 7.4  e) measurements for process control (e.g. particle size, moisture content)  f) pre-treatment, cleaning or sterilization of equipment and tools and material sample containers. |  |  | |  |  |  |  | |
| 7.5.1 | The procedures shall address at least:  g) stabilization of the material (e.g. drying, irradiation, sterilization)  h) packaging (e.g. insertion in vials, ampoules)  i) safety precautions. |  |  | |  |  |  |  | |
| 7.5.2  RT-34 | Verify that the production equipment is used according to defined and documented operating instructions or indications provided by the user manuals.  The RMP shall implement all necessary actions in order to avoid any cross contamination between production of different materials. |  |  | |  |  |  |  | |
| **7.6** | **Measurement procedures** |  |  | |  |  |  |  | |
| RT-34 | The RMP shall comply with UNI CEI EN ISO/IEC 17025 in carrying out tests, calibrations and measurements, also for:  a) preparation of the measurement object  b) sampling  c) handling and storage  d) packaging  e) measurement uncertainty assessment  f) data analysis  These activities shall be consistent with the accuracy and property values of the material and with the defined measurement specifications, |  |  | |  |  |  |  | |
| **7.7** | **Measurement equipment** |  |  | |  |  |  |  | |
|  | The samples and the measuring instruments used shall be managed in accordance with the requirements of the UNI CEI EN/IEC 17025 standard and as specified in the ISO 10012 Standard. |  |  | |  |  |  |  | |
| 5.5.1  ISO 17025 | Check if the samples, standards, instruments and equipment supplied are all present in the laboratory and are in good condition. |  |  | |  |  |  |  | |
| 5.5.2  ISO 17025 | All samples, standards, instruments and equipment present and related software shall be adapted to the test and calibration specifications.  Check if they have been calibrated before using them. |  |  | |  |  |  |  | |
| RT-34 | Check the presence of a metrological confirmation programme (including calibration and intermediate checks) of the equipment used in the production. |  |  | |  |  |  |  | |
| 5.5.3  ISO 17025 | Check if Maintenance manuals and procedures are available to personnel authorized to use samples, instruments and equipment. |  |  | |  |  |  |  | |
| 5.5.4  ISO 17025 | Samples, standards, instruments and equipment shall be uniquely identified. |  |  | |  |  |  |  | |
| 5.5.5  ISO 17025 | For each sample, instrument, equipment and related software used by the RMP in the production, verify the presence of a document or a series of documents that report:  a) identification;  b) name of the manufacturer, model/type, serial number and/or unique identification code;  c) verification of compliance with specifications;  d) placement;  e) manufacturer's instructions;  f) date of receipt and date of commissioning  g) maintenance procedure or manual of use and maintenance of the manufacturer;  h) frequency of periodic maintenance operations;  i) chronological annotation of the inconveniences and maintenance interventions carried out;  l) responsible for calibration and metrological confirmation;  k) calibration frequency;  l) calibration procedure;  m) chronological annotation of:  • date of calibrations performing;  • date of the next calibration;   * identification of the calibration certificate; * performing of the metrological confirmation operations and of the intermediate checks; * adequacy of the instrument following each intervention. |  |  | |  |  |  |  | |
| 5.5.6  ISO 17025  RT-34 | There shall be procedures that include at least the handling, transport, storage, use and planned maintenance of the instrumentation, criteria of acceptability of the instrumentation, of the equipment and of the reference samples with respect to the requirements of the production process. |  |  | |  |  |  |  | |
| 5.5.7  ISO 17025 | Samples, standards and instruments out of calibration or faults shall be appropriately identified and possibly segregated in order to prevent their use. |  |  | |  |  |  |  | |
| 5.5.7  ISO 17025 | Appropriate measures shall be taken for equipment and instruments subjected to overload or mishandling, or giving dubious results, or appearing to be defective. |  |  | |  |  |  |  | |
| 5.5.8  ISO 17025 | Equipment subject to calibration shall be properly labelled. |  |  | |  |  |  |  | |
| 5.5.9  ISO 17025 | The RMP shall define adequate management activities for equipment that are out of control before being put back into service. |  |  | |  |  |  |  | |
| 5.5.10  ISO 17025 | Check if intermediate checks are performed when applicable and appropriate procedures are implemented. |  |  | |  |  |  |  | |
| ISO 17025  (5.5.11) | Check if any correction factors deriving from calibrations, which affect the result of the measurements, are updated (e.g. in the software) |  |  | |  |  |  |  | |
| **7.8** | **Data integrity and evaluation** |  |  | |  |  |  |  | |
| 7.8.1 | All calculations and data transfers shall be adequately checked. |  |  | |  |  |  |  | |
| 7.8.2 | The software developed internally or modified for specific use, shall be validated and appropriate for use.  Check the validation methods. |  |  | |  |  |  |  | |
| 7.8.2 | Procedures to protect the integrity of data shall be defined and implemented, including at least:  a) integrity and collection of data entered  b) storage  c) transmission  d) data processing. |  |  | |  |  |  |  | |
| 7.8.2 | The equipment and related software shall be maintained appropriately to ensure their functionality and the appropriate environmental and operational conditions to ensure data integrity. |  |  | |  |  |  |  | |
| 7.8.2 | Procedures shall be defined and implemented to  a) guarantee the maintenance of data security  b) provide activities to prevent unauthorized access or changes to data and records  c) include data management in the archiving software. |  |  | |  |  |  |  | |
| 7.8.3  RT-34 | Statistical techniques adopted in monitoring, verification, calibration, homogeneity assessment, stability assessment, characterization, assignment of property values and related uncertainties shall be adequate, scientifically founded and validated. |  |  | |  |  |  |  | |
| **7.9** | **Metrological traceability of certified values** |  |  | |  |  |  |  | |
| 7.9.1  RT-34 | In the case of CRM production, the metrological traceability of the certified values shall be guaranteed.  This traceability shall also be guaranteed if the characterization is subcontracted.  Verify that the requirements of the standard UNI CEI EN ISO/IEC 17025 - point 5.6.1 and 5.6.2.1 are applied. |  |  | |  |  |  |  | |
| ISO 17025 5.6.2.1.1 | The programme of calibration or analysis of the devices that have an effect on the metrological traceability of the measures shall guarantee this traceability. |  |  | |  |  |  |  | |
| 7.9.1  RT-34 | The RMP shall provide evidence of the traceability of CRMs to national or international standards or certified reference materials or their characterization in qualified circuits (The evidences provided shall comply with Notes 1-2-3 of the Standard and with additional information of ISO/TR 16476). |  |  | |  |  |  |  | |
| 7.9.2 | The metrological traceability shall be guaranteed through the execution of tests, application of suitable procedures or measurement standards |  |  | |  |  |  |  | |
| 7.9.3  RT-34 | Where possible, reference standards or standards effecting on the traceability of measurement results should be calibrated by:  a) Recognized organizations that ensure reference to national or international samples such as National Metrological Institutes (NMI) and Designated Institutes (DI) whose services (CMC) are eligible and covered by the International Recognition Mutual Agreement (CIPM MRA).  b) Accredited calibration laboratories whose services are suitable for the purpose and whose accreditation is issued by Accreditation Bodies (AB) signatories of the EA-MLA or ILAC-MRA agreement. |  |  | |  |  |  |  | |
| 7.9.4  RT-34  ISO 17025 (5.6.2.1.2) | In case it is not possible to assure the metrological traceability to SI:  a) the CRMs used are purchased by producers who are competent in providing reliable chemical or physical characteristics  b) the supplier shall be reliable  c) procedures or methods or samples clearly described and agreed upon between the parties are used  d) whenever possible, the RMP participates in inter-laboratory circuits. |  |  | |  |  |  |  | |
| 7.9.5 | For studies where the value requires that metrological traceability is guaranteed (e.g. in characterization studies with measurements under reproducibility conditions), the RMP shall ensure that measurements are made with instruments and reference materials whose values are metrologically traceable. |  |  | |  |  |  |  | |
| 7.9.6 | The metrological traceability shall be guaranteed for the monitoring instrumentation of secondary parameters (e.g. environmental conditions) that affect the certified values and relative uncertainty. |  |  | |  |  |  |  | |
| **7.10** | **Assessment of homogeneity** |  |  | |  |  |  |  | |
| 7.10.1 | The RMP shall evaluate the homogeneity for each candidate material to be produced under accreditation in its final packaging. |  |  | |  |  |  |  | |
| RT-34 | The homogeneity assessment shall be made both for RM and CRM. |  |  | |  |  |  |  | |
| 7.10.1 | Check if the homogeneity assessment is carried out respecting the ISO Guide 35. |  |  | |  |  |  |  | |
| 7.10.2 | In the case of production of multiple batches of the same reference material, the equivalence of the batches shall be demonstrated or the homogeneity shall be assessed individually on each batch. |  |  | |  |  |  |  | |
| 7.10.3 | Validated measurement procedures for assessing the homogeneity of the batches produced shall be prepared, such that the values of precision and selectivity are adequate for the purpose. |  |  | |  |  |  |  | |
| 7.10.4 | Verify if the experimental determination of homogeneity is performed for each property of interest. |  |  | |  |  |  |  | |
| 7.10.4 | The RPM shall provide evidence to support any alternative choices (verification on a single property representative of a group). |  |  | |  |  |  |  | |
| 7.10.4 | Check whether the minimum quantities of product on which to perform homogeneity tests are defined. |  |  | |  |  |  |  | |
| 7.10.5 | For CRMs, homogeneity shall be considered among the contributions to the uncertainty of the certified value. |  |  | |  |  |  |  | |
| **7.11** | **Assessment and monitoring of stability** |  |  | |  |  |  |  | |
| 7.11  RT-34 | Check whether the stability studies are performed according to ISO Guide 35. |  |  | |  |  |  |  | |
| RT-34 | Does RMP have to perform the stability assessment for all reference materials, both certified and non-certified? |  |  | |  |  |  |  | |
| 7.11.1 | Stability shall be assessed for all relevant properties of the RM under defined production and storage conditions. |  |  | |  |  |  |  | |
| 7.11.1 | Stability shall be assessed for all relevant properties of RM under defined transport conditions. |  |  | |  |  |  |  | |
| 7.11.1 | The RMP shall provide necessary information on the use and storage of the material in order to maintain stability in the user's warehouse. |  |  | |  |  |  |  | |
| 7.11.1 | A stability monitoring scheme for products stored in a warehouse for long periods shall be set up. |  |  | |  |  |  |  | |
| 7.11.1 | If the stability of a certified value cannot be guaranteed for the whole lifetime of the product, it shall be taken into account in the declaration of uncertainty for any changes in value before use.  When it is possible to predict the change in value over time, the RMP will have to define ways to correct the certified value and its uncertainty during the lifetime of the product.  Check whether the validity period of the indicated values is stated in the documentation. |  |  | |  |  |  |  | |
| 7.11.1 | Verify:   * how the stability of the material after opening the package is assessed, in the case in which the content is not single-dose * if there are instructions for use that take into account stability after opening * if the results of the stability assessment are considered as a contribution to the uncertainty of the certified value. |  |  | |  |  |  |  | |
| 7.11.2 | The experimental assessment of the stability of the product before the release of the product shall be foreseen |  |  | |  |  |  |  | |
| 7.11.3 | In the case of production of multiple batches of the same reference material, the stability shall be assessed on a sufficient number of different batches. |  |  | |  |  |  |  | |
| **7.12** | **Characterization** |  |  | |  |  |  |  | |
| 7.12.1 | The characterization of the reference materials shall be carried out  Check if the characterization is compliant with ISO Guide 35. |  |  | |  |  |  |  | |
| 7.12.2 | Check if it is clearly defined whether the properties to be characterized are qualitative or quantitative.  Evaluate, in the case of quantitative properties, with which modalities the measurement is defined. |  |  | |  |  |  |  | |
| 7.12.3  RT-34 | The RMP shall select a characterization approach suitable to the use of Reference Material.  The characterization can include the application of:  a) a reference measurement procedure in a single laboratory;  b) in the case of a non-operationally defined measurand, two or more methods of demonstrable accuracy in one or more laboratories;  c) in the case of an operationally-defined measurand, one or more experimental methods applied in a network of competent laboratories (collaborative study or collaborative trial);  d) transfer of the value assigned to a given property from a RM to an RM candidate, with the same chemical-physical characteristics of the matrix;  e) mass or volume assessments of the components used in the preparation of RM. |  |  | |  |  |  |  | |
| RT-34 | Check whether the competent laboratories are accredited according to the UNI CEI EN ISO/IEC 17025. |  |  | |  |  |  |  | |
| 7.12.4 | RMP shall assure the metrological traceability and the reliability of the characterization studies performed by means of:  a) preparation of a documented measurement plan that describes in detail the activities to be carried out, that will be communicated to all personnel responsible for carrying out the measures;  b) for certified values, demonstrate the competence of the laboratories involved. |  |  | |  |  |  |  | |
| 7.12.5 | The RMP shall perform a technical assessment of the data and documents related to the characterization studies. |  |  | |  |  |  |  | |
| **7.13** | **Assignment of property values and their uncertainties** |  |  | |  |  |  |  | |
| 7.13 | Check whether the methods for assigning property values and related uncertainties are performed according to ISO Guide 35. |  |  | |  |  |  |  | |
| 7.13.1 | Check for documented procedures for assigning property values. |  |  | |  |  |  |  | |
| 7.13.2 | These procedures shall include, as appropriate:  a) details of the experimental designs and statistical techniques used;  b) policies on treatment and investigation of anomalous results, including outliers;  c) whether weighting techniques are used for contributions to assigned property values derived from different procedures or laboratories with different measurement uncertainties;  d) the approach used to assign uncertainties to the property values;  e) any other significant factors that may affect the assignment of property values. |  |  | |  |  |  |  | |
| 7.13.3 | The RMP shall 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. |  |  | |  |  |  |  | |
| 7.13.4 | Check if evidence of the outliers data analysis is available and how any exclusions are handled. |  |  | |  |  |  |  | |
| 7.13.5 | Check with which approaches the measurement uncertainty to be associated with the certified values assigned by a property was estimated. |  |  | |  |  |  |  | |
| 7.13.6  RT-34 | For certified values, the RMP shall consider, at a 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;  e) any other important contribution. |  |  | |  |  |  |  | |
| **7.14** | **RM documents and labels** |  |  | |  |  |  |  | |
| 7.14.1 | The RMP shall issue and make available an RM certificate for CRMs and a product information sheet for other RMs. |  |  | |  |  |  |  | |
| 7.14.2  RT-34 | The contents of RM certificates and product information sheets shall 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) minimum 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.  The documents associated with a reference material shall be issued using letterheads bearing the ACCREDIA mark, according to a model provided for by the IO-09-DT Instruction.  The use of the ACCREDIA mark is carried out according to the provisions of RG-09. |  |  | |  |  |  |  | |
| 7.14.3  RT-34 | In addition, CRM certificates shall contain:  a) description of the CRM;  b) property of interest, property value and associated uncertainty;  c) measurement procedure for operationally defined measurands;  d) metrological traceability of the certified values;  e) name and function of the certificate approving officer;  f) any other information according to ISO Guide 31. |  |  | |  |  |  |  | |
| 7.14.4 | The RMP shall ensure that the labels are attached to each individual container so as not to be removable and remain intact and legible to the anticipated storage and handling conditions throughout the product shelf life. |  |  | |  |  |  |  | |
| 7.14.4  RT-34 | The label shall include at least the fields listed below:  a) the company name and the accreditation number of the RMP;  b) the identification of the RM;  c) the production date and the information necessary to make the material uniquely identifiable (for example serial number/batch number);  d) the univocal reference to the document associated with the reference material.  The use of the ACCREDIA mark shall comply with the provisions of the RG-09 Regulation and the RT-34 document. |  |  | |  |  |  |  | |
| 7.14.5 | Check how the label is attached and how the information is managed if the individual units are too small to be able to attach a label with all information. |  |  | |  |  |  |  | |
| **7.15** | **Distribution service** |  |  | |  |  |  |  | |
| 7.15.1 | The distribution process shall be specified including precautions needed to avoid deterioration of the RM. The RMP shall determine the conditions of shipment and ensure that appropriate documentation is provided to allow customs clearance |  |  | |  |  |  |  | |
| 7.15.2 | The RMP shall maintain up-to-date records of all RM sales and distribution. |  |  | |  |  |  |  | |
| 7.15.3 | RMP shall provide users with indications and appropriate technical support. |  |  | |  |  |  |  | |
| 7.15.4 | RMP shall notify users of any change in property values or uncertainties within the validity period of the certificate or information document. |  |  | |  |  |  |  | |
| 7.15.5 | In case of sale through an authorized distributor, RMP shall provide all the necessary information to guarantee an effective distribution service. |  |  | |  |  |  |  | |
| **7.16** | **Control of quality and technical records** |  |  | |  |  |  |  | |
| 7.16.1 | Procedures related to the management of technical and system records shall be defined and implemented. |  |  | |  |  |  |  | |
| 7.16.2 | The RMP shall guarantee the record of any information that may be necessary in the case of a dispute. |  |  | |  |  |  |  | |
| 7.16.3 | Records shall be legible, properly stored and easily retrievable. |  |  | |  |  |  |  | |
| 7.16.4 | Any corrections shall not conceal the original record, which shall not be cancelled or made illegible.  The corrections shall be initialled by the person who made them.  The rules shall also be applied in the case of electronic records. |  |  | |  |  |  |  | |
| 7.16.5 | All records shall be protected and stored securely. |  |  | |  |  |  |  | |
| 7.16.6 | The RMP shall guarantee the protection of computerized data from unauthorized access. |  |  | |  |  |  |  | |
| 7.16.7 | The RMP shall arrange for all individual measurement observations, appropriate calculations and derived data (e.g. 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. |  |  | |  |  |  |  | |
| 7.16.8 | The RMP shall manage the records related to the results of calibrations and measurements performed internally or by a subcontractor according to the UNI CEI EN ISO/IEC 17025. |  |  | |  |  |  |  | |

**2. FURTHER CHECKS**

To be completed only for the current audit.

Delete the tables relating to previous audits.

**2.1. CHECK OF CLOSURE OF FINDINGS DOCUMENT REVIEW MD-08-01-DT PROT.………… OF …………….**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **A\_S\_E** |  |  |
| **Point N°** | **EVIDENCE** | **OUTCOME** | **R** |
|  |  |  |  |

**2.2. CHECK OF CLOSURE OF FINDINGS OF PREVIOUS AUDIT DT MOD 006 OF …………..**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **A\_S\_E** |  |  |
| **Finding N°** | **EVIDENCE** | **OUTCOME** | **R** |
|  |  |  |  |

**3. ATTACHMENTS**

To be completed only for the current audit.

Delete the tables relating to previous audits**.**

**NOTES**

**TECHNICAL ASSESSOR:**

NAME, SURNAME

Signature **DATE:** ………………….