1. **GENERAL INSTRUCTIONS**

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

The Assessor shall fill in the **"DOCSG"** column to register the code and the documentation section of the management system of the organization in which the requirement in question is considered. In the course of the on-site assessment, the evidence of conformity or the shortcomings found shall be briefly recorded (with the support, where possible, **for paragraph 7 of the standard**, of the Technical Assessor) and reporting on the checklist any reference to the interviewed persons, documents examined, etc. as set out in 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 registration 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 notes and/or for the recording of the findings to be formalized later on the DT-Mod-006.

Attachments (e.g. documents associated with reference material) shall be listed in **paragraph 6 of this checklist**.

**The tables in §5.1 and §5.2 refer only to the assessment in progress.** The System Assessor shall delete 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**.

| **OPENING OF THE ON-SITE ASSESSMENT** | **CLOSING OF THE ON-SITE ASSESSMENT** |
| --- | --- |
| **Internal meeting of assessors preliminary to the opening of the audit**   * Summary to the assessors of the general criteria of the assessment conduction * Development of methods for evaluating and distributing tasks. | **Internal meeting of assessors preliminary to the closing of the audit**   * Joint review of any findings made by the assessors, their classification and compilation of the DT-Mod-006. |
| **Initial meeting with the RMP**   * Present the assessment team with the related tasks and clarify the roles and responsibilities of possible ACCREDIA-DT (EVA) assessors, FT, guides, trainee assessors and observers; * Explain the purposes of the on-site assessment, which shall be carried out respecting the safety conditions; * Explain the on-site assessment plan, clarify any points not included and agree any changes to it; * Define the possible production process of reference material, or a part of it, to be carried out in the presence of the Assessor; * Define the details of any calibration to be carried out in the presence of the Assessor; * Expose possible subdivisions of the team into subgroups and identifying the verification phases to be assigned to the subgroups, in order to optimize the performing time of the on-site assessment; * Agree the timing and methods for the assessment of any off-site activities; * Agree on any changes to the on-site assessment plan; * Explain the assessment procedure and the possibility of the RMP to present reservations; * Recall the commitment of each member of the team to the confidentiality of information; * Declare that confidential meetings of the assessors may be necessary in the course of the assessment; * Request confirmation of the presence of the RMP Management of one of its Representatives at least at the final meeting and complete and sign the list of persons taking part in the on-site assessment; * Offer the RMP the opportunity to ask for further clarifications; * Formalize security requirements as required in the notification document and on-site assessment plan. | **Final meeting with the RMP**   * Submit a summary of the activities carried out; * Present the opinion on the RMP formulated by the assessment team; * Remind that the results of the on-site assessment are the result of a sampling and that therefore other problems, in addition to those detected, could be present and be identified in the subsequent on-site assessments of both ACCREDIA-DT and internal audits; * Present any findings identified, explaining their contents and motivations trying to obtain understanding and sharing of the same findings by the RMP, specifying that the part related to the corrective actions proposed by the RMP shall be completed only after the request for corrective actions by ACCREDIA-DT. * Collect any reservations submitted by the RMP; alternatively, the RMP can express reservations by completing the relative form (DT-Mod-007) within 3 working days; the acceptance or otherwise of the reservations formulated by the RMP is delegated to the Director of the Department. * Request to the RMP the signature for acceptance of the report containing the findings and the feedback section of the on-site assessment; this report is also signed by the members of the assessment team, each for their own relevant competence. * Release to the RMP copy of the report containing both the list of findings and the summary, specifying that ACCREDIA-DT reserves the right to confirm or not the contents. |

**1. GENERAL INFORMATION**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **A\_S\_E\_R** | **A\_S\_E\_R** | **A\_S\_E\_R** | **A\_S\_E\_R** |
| **Date of on-site assessment** |  |  |  |  |
| **RMP assessed** |  |  |  |  |
| **Subcontracted work** |  |  |  |  |
| **Subcontracted activities verified at the subcontractor's premises** |  |  |  |  |
| **Assessing team** |  |  |  |  |
| **Internal calibrations** |  |  |  |  |
| **Calibrations at customer’s premises** |  |  |  |  |
| **Observers** |  |  |  |  |
| **Initial meeting:**  **Date, time, RMP personnel present** |  |  |  |  |
| **Final meeting:**  **Date, time, RMP personnel present** |  |  |  |  |

**2. ASSESSMENT PLAN** (indicate the date and, if necessary, the scheduled time for the requirements check)

| **Work** | **corporate function interviewed** | **A\_S\_E\_R\_** | **A\_S\_E\_R\_** | **A\_S\_E\_R\_** | **A\_S\_E\_R\_** |
| --- | --- | --- | --- | --- | --- |
| Meeting preliminary to the opening |  |  |  |  |  |
| Initial meeting with RMP |  |  |  |  |  |
| **4. General requirements** |  |  |  |  |  |
| 4.1 Contractual matters |  |  |  |  |  |
| 4.2 Impartiality |  |  |  |  |  |
| 4.3 Confidentiality |  |  |  |  |  |
| **5. Structural requirements** |  |  |  |  |  |
| **6. Resource requirements** |  |  |  |  |  |
| 6.1 Personnel |  |  |  |  |  |
| 6.2 Subcontracting |  |  |  |  |  |
| 6.3 Provision of equipment, services and supplies |  |  |  |  |  |
| 6.4 Facilities and environmental conditions |  |  |  |  |  |
| **7. Technical and production requirements** |  |  |  |  |  |
| 7.1 General requirements |  |  |  |  |  |
| 7.2 Production planning |  |  |  |  |  |
| 7.3 Production Control |  |  |  |  |  |
| 7.4 Material handling and storage |  |  |  |  |  |
| 7.5 Material processing |  |  |  |  |  |
| 7.6 Measurement procedures |  |  |  |  |  |
| 7.7 Measurement equipment |  |  |  |  |  |
| 7.8 Data integrity and evaluation |  |  |  |  |  |
| 7.9 Metrological traceability of certified values |  |  |  |  |  |
| 7.10 Assessment of homogeneity |  |  |  |  |  |
| 7.11 Assessment and monitoring of stability |  |  |  |  |  |
| 7.12 Characterization |  |  |  |  |  |
| 7.13 Assignment of property values and their uncertainties |  |  |  |  |  |
| 7.14 RM documents and labels |  |  |  |  |  |
| 7.15 Distribution service |  |  |  |  |  |
| 7.16 Control of quality and technical records |  |  |  |  |  |
| 7.17 Management of non-conforming work |  |  |  |  |  |
| 7.18 Complaints |  |  |  |  |  |
| **8. Management system requirements** |  |  |  |  |  |
| 8.1 Options |  |  |  |  |  |
| 8.2 Quality policy (Option A) |  |  |  |  |  |
| 8.3 General management system documentation (Option A) |  |  |  |  |  |
| 8.4 Control of management system documents (Option A) |  |  |  |  |  |
| 8.5 Control of records (Option A) |  |  |  |  |  |
| 8.6 Management review (Option A) |  |  |  |  |  |
| 8.7 Internal Audit (Option A) |  |  |  |  |  |
| 8.8 Actions to address risks and opportunities (Option A) |  |  |  |  |  |
| 8.9 Corrective actions (Option A) |  |  |  |  |  |
| 8.10 Improvement (Option A) |  |  |  |  |  |
| 8.11 Feedback from customers (Option A) |  |  |  |  |  |
| Meeting preliminary to the closing |  |  |  |  |  |
| Final meeting with RMP |  |  |  |  |  |

# 3. PRELIMINARY VERIFICATIONS AND ACCREDIA REQUIREMENTS

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| § | REQUIREMENTS | A\_\_\_S\_\_\_E | A\_\_\_S\_\_\_E | A\_\_\_S\_\_\_E | A\_\_\_S\_\_\_E | R |
| .1 | Indicate the acronym, date and revision index of the management system documentation examined during the audit. |  |  |  |  |  |
| .2 | Indicate in which document/format RMP reports the production plan with the acronyms, date and revision index. |  |  |  |  |  |
| .3 | Indicate date and revision index of the Accreditation Application submitted by the RMP (if applicable). |  |  |  |  |  |
| .4  RG-18 | Indicate how many system findings to the documentation required by the accredited SGQ and to the production plan (Md 08-01-DT) have not been treated satisfactorily [Report the details in section 5.1] |  |  |  |  |  |
| .5 | Indicate how many treatments following the findings of the last audit have been implemented effectively. [Report the details in section 5.2 and report the assessment in the specific section of the DT-Mod-006] |  |  |  |  |  |
| .6 | Indicate how many certificates (CRM) under accreditation have been issued in the last year. |  |  |  |  |  |
| .7 | Indicate how many product information sheets (RM) under accreditation have been issued in the last year. |  |  |  |  |  |
| .8 | Indicate the number and motivation to issue documents without the accreditation mark but with presentation of the results within the accredited field if applicable). |  |  |  |  |  |
| .9 | Check whether the accreditation table is correctly expressed. [with the help of the Technical Assessor] |  |  |  |  |  |
| .10  RG18 | In the event of a change in its structure that could influence the maintenance of compliance with the requirements prescribed by ACCREDIA, has the Organization promptly informed ACCREDIA? |  |  |  |  |  |
| .11 | Indicate if the RMP is accredited for a flexible scope. |  |  |  |  |  |
| .12 | Indicate whether the RMP has been suspended in the period prior to the assessment. |  |  |  |  |  |
| .13 | Indicate if in the period prior to the audit ACCREDIA received complaints against the RMP. |  |  |  |  |  |
| .14 | Indicate whether the RMP has provided the ACCREDIA assessors with all the necessary cooperation to check that the requirements of UNI CEI EN ISO 17034 and ACCREDIA have been complied with. |  |  |  |  |  |
| .15 | Indicate whether the RMP has an internal laboratory and if so indicate:  - If and which test/calibration activities are performed  - If and which activities are under accreditation  - If it participates in PT/ILC. |  |  |  |  |  |

# 4. Requirements

| § | ASSESSMENTS | | DOC  SG | | A\_\_S\_\_E\_\_ | A\_\_S\_\_E\_\_ | | A\_\_S\_\_E\_\_ | A\_\_S\_\_E\_\_ | | R |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **4** | General Requirements | |  | |  |  | |  |  | |  |
| **4.1** | Contractual matters | |  | |  |  | |  |  | |  |
| 4.1.1  RT 34 | It is guaranteed that the client's request is :  - complete [with what serves to identify the customer, the RM to be provided, the type of service requested and is understandable by all the parties involved]  - correct [there are no errors in the indication of customer, object, performance, ...]  - achievable [the RMP can meet the customer’s requirement also in terms of times, methods, equipment, knowledge ...] - understood;  - re-examined (even if modified)   * maintain record of the information exchange in the contract acquisition process   - met with the information concerning stability  - clarified, when applicable, on the difference between the activities covered by accreditation and not. | |  | |  |  | |  |  | |  |
| 4.1.2  RT 34 | The review also includes any activities that will be subcontracted. Since accreditation is granted to the RMP and does not affect its potential subcontractors, a written agreement is required with them. | |  | |  |  | |  |  | |  |
| 4.1.3 | Records of reviews including changes and correspondence with customers - including subcontracted work - shall be retained. | |  | |  |  | |  |  | |  |
| RG-09 | The RMP shall consider in its contractual documentation the correct use of the ACCREDIA mark as required by RG-09. | |  | |  |  | |  |  | |  |
| **4.2** | Impartiality | |  | |  |  | |  |  | |  |
| 4.2.1  4.2.2 | The RMP provides policies and procedures that prevent involvement in activities that may diminish trust in competence, impartiality and in operational and judgmental integrity. | |  | |  |  | |  |  | |  |
| 4.2.2  RT 34 | Impartiality risks shall be assessed on the basis of objective and possibly measurable parameters. | |  | |  |  | |  |  | |  |
| **4.3** | **Confidentiality** | |  | |  |  | |  |  | |  |
| 4.3.1 RT 34 | The implementation of any element that may affect the accredited production shall take into account the requirement of confidentiality, unless explicitly requested by the client or in presence of applicable binding requirement that requires it to be disclosed through external channels.  Appropriate countermeasures shall be defined. | |  | |  |  | |  |  | |  |
| 4.3.2 | Where provided for by contractual or legal arrangements, the RMP shall provide the information involved in a confidential manner. | |  | |  |  | |  |  | |  |
| **5** | **Structural requirements** | |  | |  |  | |  |  | |  |
| 5.1 RT 34 | The RMP shall be legally identifiable. [C.C.I.A.A. Certificate, company structure, any professional qualification] | |  | |  |  | |  |  | |  |
| 5.2 | If applicable, a list of temporary and/or mobile operating units shall be available. | |  | |  |  | |  |  | |  |
| 5.3  RT 34 | a) the RMP shall define an organizational and management structure coherent with the overall corporate organization, the relationships with those supporting and subcontracted, the name of personnel who works both in the overall organization and within the RMP, covering different roles in the two areas.  b) the activities other than those concerning the accreditation field of the Producer shall be defined and identified, if provided for within the Management System. c) the organization charts or equivalent documents in relation to the established organization chart shall be defined.  d) the RMP shall have management staff, supported by technical staff, with the authority and resources necessary to perform their duties and to identify any deviations from the Management System or RM production procedures and take actions to prevent or reduce these deviations to the minimum  e) assignments or equivalent documents for the functions of technical responsibility shall be defined; they shall be formalized and contain the exact indication of the proxies, in particular for what regards the signing of the documents concerning the RM.  f) if there are responsibilities for personnel outside the Producer (for example, external consultant), the exact definition of the role that this appointment entails and the time limits of the appointment shall be formalized under contract.  g) protections shall be provided (e.g. insurance) in order to guarantee the coverage of the responsibilities regarding the activities carried out under accreditation. | |  | |  |  | |  |  | |  |
| 5.4  RT 34 | Suitable internal and external communication processes shall be ensured for the RMP, including the effectiveness of the management system. [acknowledgement sheets, intranets]  The communication to the staff regarding the importance of meeting the customer's requirements, those relating to accreditation and applicable regulations shall be provided. | |  | |  |  | |  |  | |  |
| **6** | **Resource requirements** | |  | |  |  | |  |  | |  |
| **6.1** | **Personnel** | |  | |  |  | |  |  | |  |
| 6.1.1 | The personnel assigned to the production activities shall be qualified (competent and supervised).  Data shall be collected and managed. | |  | |  |  | |  |  | |  |
| 6.1.2 | The competence and awareness of the RMP staff shall be verified, including any subcontractors involved, in order to ensure proper compliance with the RMP policies and confidentiality procedures defined in the management system applied. | |  | |  |  | |  |  | |  |
| 6.1.3 RT 34 | The names of the RMP staff (Technical Management, Management System Manager, and Technical Operators) shall be subject of competence assessment. | |  | |  |  | |  |  | |  |
| 6.1.4  RT 34 | The RMP shall have procedures in order to identify the needs of competence and the necessary training actions.  A training programme shall be available. | |  | |  |  | |  |  | |  |
| 6.1.5 | The job descriptions of the personnel involved in RM activities shall be defined and updated. | |  | |  |  | |  |  | |  |
| 6.1.6  RT 34 | Records of authorizations, skills, educational and professional qualifications and experience relating to all technical personnel shall be defined.  The RMP identifies the Responsible authorized by the Management to approve documents associated with a reference material.  Authorizations shall be dated, signed by the Management and countersigned by the personnel concerned. | |  | |  |  | |  |  | |  |
| **6.2** | **Subcontracting** | |  | |  |  | |  |  | |  |
| 6.2.1  RT 34 | a) Procedures and requirements shall be defined to ensure that the experience and technical expertise of subcontractors is sufficient for the tasks assigned and that the subcontracted activities are carried out in accordance with relevant points of ISO 17034 and other international standards, when applicable.  b) The RMP shall demonstrate that it is responsible for the planning and management phases of the project, the assignment and the decision concerning the property values and uncertainties associated with them, the authorization of property values and the issuance of documents associated with the reference materials. | |  | |  |  | |  |  | |  |
| 6.2.2 | The RMP shall demonstrate that the criteria for the qualification of skills and competences are oriented to the assessment of their abilities in meeting the established contractual requirements. | |  | |  |  | |  |  | |  |
| 6.2.2  RT 34 | Variations related to the subcontracted activities are managed in compliance with the requirements defined in the RT 34 regulation. | |  | |  |  | |  |  | |  |
| 6.2.3  RT 34 | The scope of subcontracting, prohibits subcontracting for the following processes:  - production plan,  - selection of contractors,  - assignment of property values and uncertainty,  - authorization of property values and uncertainty,  - authorization of documents related to RM   * serial subcontracting | |  | |  |  | |  |  | |  |
| 6.2.4  RT 34 | If measures, calibrations or tests are subcontracted, the subcontractor shall comply with the provisions attesting the traceability of the metrology according to ILAC P10 - Ref. Par. 9 RT 34. | |  | |  |  | |  |  | |  |
| 6.2.5  RT 34 | The RMP shall keep records of the assessment of the subcontractor's competence with respect to the subcontracted activities, to ensure compliance with the contractual, regulatory requirements. | |  | |  |  | |  |  | |  |
| 6.2.6 RT 34 | The evaluation of the supplier by the RMP regarding subcontracted activities deemed critical shall be done through a second part audit. | |  | |  |  | |  |  | |  |
| 6.2.7 | Procedures and records relating to subcontracting activities used by the subcontractor shall be made available for technical assessment by the subcontractor. | |  | |  |  | |  |  | |  |
| 6.2.8 | The competence of the personnel who assess the compliance of the subcontracted activities shall be evaluated periodically. | |  | |  |  | |  |  | |  |
| **6.3** | **Provision of equipment, services and supplies** | |  | |  |  | |  |  | |  |
| 6.3.1  RT 34 | The activities for the selection, purchase and acceptance of the following are regulated:  1. RM/equipment/instruments;  2. significant consumables for RM production activity;  3. services (maintenance, cleaning ...) | |  | |  |  | |  |  | |  |
| 6.3.2 | The RMP shall use only RM/equipment/instrument/services that comply with the specifications to ensure the quality of the RM produced. | |  | |  |  | |  |  | |  |
| 6.3.3 | The RMP shall ensure that equipment and consumables are not used prior to the successful outcome of acceptance checks, calibration and any other type of verification necessary to demonstrate compliance with the specifications or requirements defined in the RM preparation activities. | |  | |  |  | |  |  | |  |
| 6.3.4 | The RMP shall keep records of the procurement of equipment, services and supplies with regard to the criteria used for the selection, to the results of the checks in acceptance and the related commissioning data. | |  | |  |  | |  |  | |  |
| **6.4** | **Facilities and environmental conditions** | |  | |  |  | |  |  | |  |
| 6.4.1 | Premises and equipment shall ensure the quality level of RM and the uncertainty defined in the accreditation scope, if applicable. |  | | |  | |  |  |  |  | |
| 6.4.2  RT 34 | For areas subject to particular constraints on environmental parameters (temperature, humidity, dust, sterility, power supply, vibrations, etc.) the traceability of the monitoring instruments and the correct preservation of the relative records shall be guaranteed. |  | | |  | |  |  |  |  | |
| 6.4.4  RT 34 | Procedures that regulate the access to the premises shall be defined in order to guarantee the maintenance of the quality requirements of the RM, also in case of external personnel (e.g. maintenance personnel). |  | | |  | |  |  |  |  | |
| **7** | **Technical and production requirements** |  | | |  | |  |  |  |  | |
| **7.2** | **Production planning** |  | | |  | |  |  |  |  | |
| 7.2.1  RT 34 | The Production Plan shall be identified, documented and evaluated by ACCREDIA, also considering the processes of technical and operational change. |  | |  | | |  |  |  |  | |
| 7.2.2 | In planning, the RMP shall take into account the possible influence that the subcontractors might have in the course of RM production. |  | |  | | |  |  |  |  | |
| **7.3** | **Production Control** |  | |  | | |  |  |  |  | |
| 7.3 | The RMP shall verify that the production plan has been implemented as specified and that deviations from the plan are documented and approved. |  | |  | | |  |  |  |  | |
| **7.4** | **Material handling and storage** |  | |  | | |  |  |  |  | |
| 7.4.1 RT 34 | Control of storage and handling shall be guaranteed even if the material is transferred to a subcontractor. |  | |  | | |  |  |  |  | |
| 7.4.2 | The RMP shall identify, store and separate candidate RMs and RMs from chemicals and other samples, from the time of production to their distribution to users. |  | |  | | |  |  |  |  | |
| 7.4.3 RT 34 | The risks and countermeasures relating to packaging safety problems shall be identified, in order to avoid any damage and deterioration between the characterization and distribution. The RMP shall ensure that the packaging and labelling of the materials are carried out in accordance with legal requirements. |  | |  | | |  |  |  |  | |
| 7.4.4 RT 34 | The condition of all RMs shall be assessed at appropriate intervals throughout the storage period, in order to identify any possible deterioration. |  | |  | | |  |  |  |  | |
| 7.4.5 | The RMP shall monitor the packaging and labelling processes to the extent necessary to ensure compliance with the safety and transport requirements.  The procedures for transport to the customer shall be defined. |  | |  | | |  |  |  |  | |
| 7.4.6 | The RMP shall take steps to ensure that the integrity of each single unit of RM is maintained until the seal, if any, is broken or until the time of first use. |  | |  | | |  |  |  |  | |
| ***7.5*** | **Material processing** |  | |  | | |  |  |  |  | |
| *7.5.1* | The RMP shall establish procedures to ensure that the material has undergone adequate processing for its intended use. Procedures for material processing shall address at least the following:  a) qualitative analysis for verification of material type and/or identity;  b) synthesis, purification (e.g. distillation, extraction), incubation and transformation into the final form (e.g. machining, grinding, blending, sieving and riffling, extrusion, melting);  c) homogenization;  d) proper handling (e.g. protection from contamination and use of inert equipment) (see 7.4);  e) measurements for control of material processing (e.g. particle size distribution, moisture content);  f) pre-treatment, cleaning or sterilization of processing equipment and sample containers;  g) stabilization of material (e.g. drying, irradiation, sterilization);  h) packaging (e.g. bottles, ampoules) of the material;  i) safety precautions. |  | |  | | |  |  |  |  | |
| *7.5.2*  *RT 34* | Equipment used in material processing shall be operated in accordance with documented procedures.  *When the same equipment is used for different materials, the RMP shall verify, if applicable, that no contamination occurs.* |  | |  | | |  |  |  |  | |
| ***7.6*** | **Measurement procedures** |  | |  | | |  |  |  |  | |
| *7.6*  *RT 34* | The RMP shall ensure that the relevant requirements of ISO/IEC 17025, with respect to calibration and testing, are met. These activities shall, where appropriate, be consistent with the required accuracy of the property values of the RM, and with any standard specifications relevant to the measurement concerned.  *If the measurement, test or calibration process is used under accreditation, in accordance with the UN CEI EN ISO/IEC 17025, this attestation is sufficient to demonstrate the fulfilment of the requirement.* |  | |  | | |  |  |  |  | |
| **7.7** | **Measuring equipment** |  | |  | | |  |  |  |  | |
| *7.7*  *RT 34* | The RMP shall ensure that measuring equipment used in RM production is utilized in compliance with the relevant requirements of ISO/IEC 17025.  *ACCREDIA considers among the relevant requisites to be met also the one related to the metrological traceability required by the UN CEI EN ISO/IEC 17025. The use of equipment also used for activities other than those accredited shall not affect in any way the metrological characteristics and the reliability. The RMP shall prepare a metrological confirmation programme (including calibration and intermediate checks) of the equipment used in production. It is required to indicate in the procedures the criteria of acceptability of the instrumentation, the equipment and the reference samples with respect to the requirements of the production process.*  *For equipment used also under accreditation, in accordance with the UNI CEI EN ISO/IEC 17025 standard, such certification is sufficient to demonstrate the fulfilment of the requirement. On the other hand, the RMP shall apply or ensure that its subcontractor applies the traceability policy described in Chapter 9 of the RT Regulation 34.* |  | |  | | |  |  |  |  | |
| **7.8** | **Data integrity and evaluation** |  | |  | | |  |  |  |  | |
| 7.8.1 | The RMP shall ensure that all calculations and data transfers are subject to appropriate checks. |  | |  | | |  |  |  |  | |
| 7.8.2 | The RMP shall ensure that:  a) computer software developed in-house or off-the-shelf software further developed for specific use is validated and shown to be adequate for use;  b) procedures are established and implemented for protecting the integrity of data; such procedures shall include, but are not limited to, integrity of data entry and capture, data storage, data transmission and data processing;  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 maintenance of data security, including prevention of unauthorized access and changes to records, including computer records. |  | |  | | |  |  |  |  | |
| 7.8.3  RT 34 | Statistical procedures used in monitoring, testing, calibration or value assignment of RMs shall be appropriate for their application.  *Evaluation of homogeneity, stability, characterization, assignment of values ​​to properties and related uncertainties require data evaluation. For these evaluations the RMP shall use appropriate and scientifically sound statistical techniques.* |  | |  | | |  |  |  |  | |
| **7.9** | **Metrological traceability of certified values** |  | |  | | |  |  |  |  | |
| 7.9.1  RT 34 | When producing CRMs, the metrological traceability of the certified values shall be established in compliance with the relevant requirements of ISO/IEC 17025. The RMP shall provide evidence of the metrological traceability of the certified value to a stated reference.  *The RMPs that produce CRM shall ensure the metrological traceability of the certified values, as defined in UNI CEI 70099, in accordance with the applicable requirements of the UNI CEI EN ISO/IEC 17025, both when the characterization is carried out internally and in case of subcontracting.*  *If the attribution of the certified value takes place through a measurement process, performed under accreditation, and therefore in accordance with the UNI CEI EN ISO/IEC 17025, this attestation is sufficient to demonstrate the fulfilment of the requirement. On the other hand, the RMP shall comply with or guarantee that its subcontractor complies with the applicable requirements of the UNI CEI EN ISO/IEC 17025 and the traceability policy described in chapter 9 of the Regulation RT 34.*  *ACCREDIA considers the application of the methods reported in the notes of ISO 17034 as evidence of traceability of the certified value.*  *ISO/TR 16476 contains further information on how to establish and how to express the metrological traceability of the certified values.* |  | |  | | |  |  |  |  | |
| 7.9.2 | The stated reference shall be a definition of a measurement unit through its practical realization, or a measurement procedure including the measurement unit, or a measurement standard. |  | |  | | |  |  |  |  | |
| *7.9.3* | Where it is technically possible, the RMP shall demonstrate that the stated reference is traceable to the International System of Units (SI). |  | |  | | |  |  |  |  | |
| 7.9.4  RT 34 | Where metrological traceability to the SI units is not technically possible, the RMP shall demonstrate metrological traceability to an appropriate reference (see traceability requirements in ISO/IEC 17025).  *If a CRM is used to guarantee the metrological traceability of the certified value, the uncertainty associated with the certified value of the CRM used shall be smaller than that of the CRM produced.*  *The RMP shall determine the competence of the CRM manufacturer that he uses as evidence of metrological traceability. The policy implemented by ACCREDIA in this sense is reported in chapter 9 of the document RT 34.* |  | |  | | |  |  |  |  | |
| 7.9.5 | For studies in which the values need to be traceable to a higher order reference system (e.g. characterization studies with measurements under reproducibility conditions), it shall be ensured that the measurements are calibrated with standards with metrologically traceable values. |  | |  | | |  |  |  |  | |
| *7.9.6*  *RT 34* | Secondary parameters that have a significant influence on the certified value or its uncertainty shall have evidence of metrological traceability.  *In the event that the RMP performs the ACCREDIA calibrations internally, it evaluates the metrological traceability and the uncertainty report in compliance with the requirements set out in chapter 10 of the Regulation RT 34.* |  | |  | | |  |  |  |  | |
| **7.10** | **Assessment of homogeneity** |  | |  | | |  |  |  |  | |
| 7.10.1 | The RMP shall carry out an assessment of the homogeneity of any candidate RM in its final packaged form to ensure its fitness for purpose. |  | |  | | |  |  |  |  | |
| 7.10.2 | When the material is produced in multiple batches, the equivalence of the batches shall be demonstrated or the homogeneity of each batch shall be evaluated separately. |  | |  | | |  |  |  |  | |
| 7.10.3 | Validated measurement procedures shall be selected so that the precision and selectivity are fit for the purpose required. |  | |  | | |  |  |  |  | |
| 7.10.4 | Where homogeneity needs to be determined experimentally, the RMP shall determine the homogeneity for every property of interest unless it can be shown, using scientific evidence or previous experience, that particular groups of properties are sufficiently closely associated that measurement of  one property in such a group furnishes evidence of homogeneity for other properties in the same group. |  | |  | | |  |  |  |  | |
| 7.10.5 | For certified values, homogeneity shall be 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. |  | |  | | |  |  |  |  | |
| **7.11** | **Assessment and monitoring of stability** |  | |  | | |  |  |  |  | |
| 7.11.1 | The RMP shall:  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;  e) where the stability of a certified value cannot be ensured, make due allowance in the stated uncertainty for possible change in the value prior to use or, where the change with time can be predicted, provide a means of correcting the certified value and its uncertainty for the expected change over time;  f) where repeated sampling from an RM unit or repeated use of an entire RM unit is permitted by the instructions for use, assess the possible effects on the stability of the material and take appropriate action. |  | |  | | |  |  |  |  | |
| 7.11.2 | The RMP shall conduct an experimental assessment of stability before release unless the RMP has evidence of stability or prior experience of stability from closely similar materials held for an extended period under the same planned storage conditions.  Note “Closely similar” materials are materials characterized for the same properties, which share the same matrix composition, processing conditions, similar or less effective packaging, etc. |  | |  | | |  |  |  |  | |
| 7.11.3 | Where an RM is produced in multiple batches that are not individually tested for stability, the RMP shall verify the stability of a sufficient number of different batches experimentally to provide confidence in the stability of all batches. |  | |  | | |  |  |  |  | |
| **7.12** | **Characterization** |  | |  | | |  |  |  |  | |
| 7.12.1 | Where the RMP assigns property values, characterization of the RM is required. |  | |  | | |  |  |  |  | |
| 7.12.2 | The RMP shall clearly define whether a quantitative or a qualitative property will be characterized and, if quantitative, whether the measurand is operationally defined or is defined independently of any  specific procedure. |  | |  | | |  |  |  |  | |
| *7.12.3*  *RT 34* | The RMP shall select a characterization strategy appropriate for the intended use of the RM.  *ACCREDIA considers the UNI CEI EN ISO/IEC 17025 accredited laboratories as competent laboratories and considers a network of competent laboratories to be the circuit organized by an accredited PT provider.* |  | |  | | |  |  |  |  | |
| 7.12.4 | The RMP shall specify the characterization study so that the properties of interest are each characterized with appropriate traceability and sufficient reliability whether or not traceability and measurement uncertainty are reported on the RM documentation. To this end, the RMP shall:  a) document a measurement plan that clearly describes the tasks to be performed and communicate this to all personnel responsible for measurements used in characterization;  b) for certified values, demonstrate the competence of each involved laboratory by using data from each laboratory that was not obtained on the material to be characterized. |  | |  | | |  |  |  |  | |
| 7.12.5 | When evaluating the characterization data, the RMP shall perform a technical evaluation of the data and documents involved in characterization to confirm adherence to the measurement plan as defined in 7.12.4, bullet a), and, in the case of deviations from the plan, assess whether the deviation necessitates exclusion of the data from characterization. |  | |  | | |  |  |  |  | |
| **7.13** | **Assignment of property values and their uncertainties** |  | |  | | |  |  |  |  | |
| 7.13.1 | The RMP shall use documented procedures for the assignment of 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 | Outliers shall not be excluded solely on statistical evidence until they have been investigated and, where possible, the reasons for the discrepancies identified. Robust statistical methods may be applied  where appropriate. |  | |  | | |  |  |  |  | |
| *7.13.5*  *RT 34* | For certified values, the RMP shall identify the uncertainty contributions to be included in the assigned uncertainty.  *Since the certified values assigned to a property of a CRM ensure metrological traceability, their uncertainty shall be calculated, taking into account, among others, the characterization contributions to the homogeneity and stability in the short and long term. Where the RMP considers these contributions to be negligible, it shall be demonstrated.*  *At this point we refer to the uncertainties of measurement of a quantity and the uncertainty associated with a classification property (sequence of DNA, colour, etc.).* |  | |  | | |  |  |  |  | |
| 7.13.6 | 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. |  | |  | | |  |  |  |  | |
| **7.14** | **RM documents and labels** |  | |  | | |  |  |  |  | |
| 7.14.1 | The RMP shall issue and make available an RM certificate for CRMs and 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 (where appropriate).  *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. It is not permitted to report on these documents information relating to reference materials not included in the scope of accreditation. It is permissible to report in the Certificates of Reference Materials also non-certified values provided they are clearly identified with an asterisk and accompanied by the declaration that such data cannot and shall not be used for the dissemination of metrological traceability (for example they cannot be used for the purposes of calibration of an instrument).*  *The use of the ACCREDIA mark is carried out according to the provisions of RG-09.* |  | |  | | |  |  |  |  | |
| 7.14.3 | In addition to the minimum requirements given in 7.14.2, RM certificates shall contain the following additional information:  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 RMP’s approving officer. |  | |  | | |  |  |  |  | |
| *7.14.4*  *RT 34* | The RM label shall be securely attached to the product container of an individual RM unit, and shall be designed to remain legible and intact under the defined storage and handling conditions within the lifetime of the RM, i.e. the period during which the RM is available from the RMP extended by the period of validity of its certificate. The label shall identify the material, the RMP, its batch, and any other information necessary to enable the material to be uniquely distinguished and referenced (such as the individual sample number), where appropriate, to its product information sheet or RM certificate.  *The use of labels with the ACCREDIA mark is allowed directly on the reference material, provided that these labels are put only on the production lots of materials included in the scope of accreditation. The ACCREDIA mark shall not be used/glued on the material independently of the label that identifies it. This label shall include at least the fields listed below:*  *• The company name and the accreditation number of the RMP;*  *• The identification of the RM;*  *• The production date and the information necessary to make the material uniquely identifiable (for example serial number/lot number);*  *• 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. These requirements are necessary to ensure that the production and characterization of the specific material are performed by an accredited organization in accordance with ISO 17034. The presence of the ACCREDIA label on a material does not imply that such material is approved by ACCREDIA.* |  | |  | | |  |  |  |  | |
| 7.14.5 | Where the physical size of the RM unit limits the amount of information that can be contained on the label, the information shall be included elsewhere (e.g. in an RM document). A unique identifier shall be given [see 7.14.2, letter b)]. |  | |  | | |  |  |  |  | |
| **7.15** | **Distribution service** |  | |  | | |  |  |  |  | |
| 7.15.1 | The distribution process shall be specified including precautions needed to avoid deterioration of the RM (see 7.11.1). 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 | The RMP shall offer to users reasonable guidance and technical support related to the RMs it produces. |  | |  | | |  |  |  |  | |
| 7.15.4 | The RMP shall 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. |  | |  | | |  |  |  |  | |
| 7.15.5 | Where RMs are subject to resale through a distributor with whom the RMP has a contractual relationship, the RMP shall pass on to the authorized distributor all necessary information to ensure that an effective post-distribution service is maintained and make arrangements with the distributor to ensure that its activities are executed in accordance with the relevant clauses of the International Standard. |  | |  | | |  |  |  |  | |
| **7.16** | **Control of quality and technical records** |  | |  | | |  |  |  |  | |
| *7.16.1*  *RT 34* | The RMP shall establish and maintain procedures for identification, collection, indexing, access, storage, maintenance and disposal of quality and technical records.  *The RMP shall also process data for the statistical study of the properties of the materials produced and the instruments used in production in accordance with the requirement.* |  | |  | | |  |  |  |  | |
| 7.16.2 | The RMP shall ensure that it has recorded such information that might be needed in a future dispute situation. |  | |  | | |  |  |  |  | |
| 7.16.3 | 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. Retention time of records shall be established in accordance with customer or other relevant requirements, and shall be documented.. |  | |  | | |  |  |  |  | |
| 7.16.4 | When mistakes occur in records, each mistake shall be crossed out, not erased, made illegible or deleted, and the correct information entered alongside. All such alterations to records shall be signed or initialled, and dated by the person making the correction. In the case of records stored electronically, equivalent measures shall be taken to avoid the loss or change of original information. |  | |  | | |  |  |  |  | |
| 7.16.5 | All records shall be held securely and, where appropriate, in confidence. |  | |  | | |  |  |  |  | |
| 7.16.6 | The RMP shall have procedures to protect electronically held data at all times and to prevent unauthorized access to, or amendment of, such data. |  | |  | | |  |  |  |  | |
| 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*  *RT 34* | The results of each calibration or measurement (or series of either) carried out by the RMP or by a subcontractor shall be reported in accordance with ISO/IEC 17025.  *If the calibration and/or measurement activity is part of the accreditation issued in compliance with the UNI CEI EN ISO/IEC 17025 standard or is performed by an NMI, this attestation is sufficient to demonstrate the fulfilment of the requirement. On the other hand, the RMP shall apply or guarantee that its subcontractor complies with the applicable requirements of Chapter 9 of the RT 34 Regulation.* |  | |  | | |  |  |  |  | |
| **7.17** | **Management of non-conforming work** |  | |  | | |  |  |  |  | |
| *7.17.1*  *RT 34*  *RG 18* | The RMP shall have procedures that shall be 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.  *In the event that non-compliant activities are identified that could jeopardize the execution of accredited productions, the RMP - in addition to the provisions of its quality management system in application of the standard requirements - shall promptly inform ACCREDIA and, if necessary, proceed to the request for self-suspension according to the provisions of the RG-18 Regulations.* |  | |  | | |  |  |  |  | |
| 7.17.2 | The procedures shall ensure that:  a) responsibilities and authorities for the management of non-conforming work are designated;  b) the 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) an evaluation of the significance of the non-conforming work is made and identification and implementation of correction and corrective action;  d) where necessary, work is halted and, if appropriate, issue of the affected RM and its certificates and other appropriate documentation is withheld;  e) remedial actions such as customer notifications are taken within a defined time-frame;  f) where necessary, best efforts are 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) the responsibility for authorization of the resumption of work is defined;  h) where necessary, an internal audit is conducted to verify the closure and effectiveness of the corrective actions taken. |  | |  | | |  |  |  |  | |
| 7.17.3 | The decision on recall of RMs shall be taken in a timely manner to limit the use of nonconforming RMs. |  | |  | | |  |  |  |  | |
| **7.18** | **Complaints** |  | |  | | |  |  |  |  | |
| 7.18.1 | The RMP shall have a documented process to receive, evaluate and make decisions on complaints. |  | |  | | |  |  |  |  | |
| 7.18.2 | A description of the handling process for complaints shall be available to any interested party on request. |  | |  | | |  |  |  |  | |
| 7.18.3 | Upon receipt of a complaint, the RMP shall confirm whether the complaint relates to conformity assessment activities that it is responsible for and, if so, shall deal with it. |  | |  | | |  |  |  |  | |
| 7.18.4 | The RMP shall be responsible for all decisions at all levels of the handling process for complaints. |  | |  | | |  |  |  |  | |
| 7.18.5 | Investigation and decision on complaints shall not result in any discriminatory actions. |  | |  | | |  |  |  |  | |
| 7.18.6 | The process for handling complaints shall 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. |  | |  | | |  |  |  |  | |
| 7.18.7 | The RMP receiving the complaint shall be responsible for gathering and verifying all necessary information to validate the complaint. |  | |  | | |  |  |  |  | |
| 7.18.8 | Whenever possible, the RMP shall acknowledge receipt of the complaint, and provide the complainant with progress reports and the outcome. |  | |  | | |  |  |  |  | |
| 7.18.9 | The decision to be communicated to the complainant shall be made by, or reviewed and approved by, individual(s) not involved in the original RM activities in question. |  | |  | | |  |  |  |  | |
| 7.18.10 | Whenever possible, the RMP shall give formal notice of the end of the complaint handling process to the complainant. |  | |  | | |  |  |  |  | |
| **8** | **MANAGEMENT SYSTEM REQUIREMENTS** |  | |  | | |  |  |  |  | |
| **8.1** | **Options** |  | |  | | |  |  |  |  | |
| **8.1.1** | **General** |  | |  | | |  |  |  |  | |
| 8.1.1 | The RMP shall establish and maintain a management system that is capable of achieving the consistent fulfilment of the requirements of this International Standard in accordance with either Option A or Option B. |  | |  | | |  |  |  |  | |
| **8.1.2** | **Option A** |  | |  | | |  |  |  |  | |
| 8.1.2.1 | The RMP shall establish, implement and maintain a documented management system that addresses the scope of its RM production activities, which covers the type, range and scale of the RM production it undertakes. |  | |  | | |  |  |  |  | |
| 8.1.2.2 | The RMP shall define and document its scope of activities. |  | |  | | |  |  |  |  | |
| 8.1.2.3 | The management system of the RMP shall address the following:  a) quality policy (see 8.2);  b) general management system documentation (see 8.3);  c) control of management system documents (see 8.4);  d) control of records (see 8.5);  e) management review (see 8.6);  f) internal audit (see 8.7);  g) actions to address risks and opportunities (see 8.8);  h) corrective actions (see 8.9);  i) improvement (see 8.10);  l) feedback from customers (see 8.11). |  | |  | | |  |  |  |  | |
| **8.1.3** | **Option B** |  | |  | | |  |  |  |  | |
| *8.1.3*  *RT 34* | An RMP that has established and maintains a management system, in accordance with the requirements of ISO 9001, and that is capable of supporting and demonstrating the consistent fulfilment of the requirements of Clauses 4 to 7 of this International Standard (ISO 17034), fulfils the management system clause requirements in 8.2 to 8.11.  *ACCREDIA, when assessing the management system of an RMP, applies the resolution number 22 of the EA of May 2015 (reference EA Resolution 2015 (35) 22 published at http://www.european-accreditation.org), recognizing that a RMP, which operates with a management system that complies with ISO 9001, is able to obtain the same results as would have directly implementing the requirements set out in paragraphs 8.2.28.11 of ISO 17034. ACCREDIA's evaluation therefore extends to this correspondence.*  *ACCREDIA does not evaluate the certified system in compliance with the requirements of ISO 9001, but assesses its coverage with respect to all the requirements of ISO 17034. This means that the management system contains the necessary references to describe completely how the production of reference materials complies with all the paragraphs of ISO 17034. As evidence of coverage of the field of activity ACCREDIA evaluates the presence of references to the RMP in all the records provided by the management system.* |  | |  | | |  |  |  |  | |
| **8.2** | **Quality policy (Option A)** |  | |  | | |  |  |  |  | |
| 8.2.1 | The RMP shall define and document its policy, objectives and commitment to ensure and maintain the quality of all aspects of RM production, storage and distribution procedures. |  | |  | | |  |  |  |  | |
| 8.2.2 | The RMP’s management system policies related to quality, including a quality policy statement, shall be documented under the authority of the top management. |  | |  | | |  |  |  |  | |
| 8.2.3 | The quality policy shall include the following commitments:  a) to produce RMs which conform to the requirements of this International Standard;  b) to conduct all testing and calibration in support of the production of RMs in compliance with the requirements of ISO/IEC 17025;  c) to require that all personnel concerned with the quality of any aspect of RM production activities familiarize themselves with the quality documentation and implement the policies and procedures in their work;  d) for the management to continually improve the effectiveness of the management system and to be committed to good professional practice and to the quality of its RMs. |  | |  | | |  |  |  |  | |
| 8.2.4 | The overall objectives shall be reviewed during the management review. |  | |  | | |  |  |  |  | |
| **8.3** | **General management system documentation (Option A)** |  | |  | | |  |  |  |  | |
| 8.3 | The RMP shall document all of its systems, programmes, procedures, instructions, findings, etc., to the extent necessary to enable the RMP to ensure the quality of the RMs produced. Documentation used in this management system shall be communicated to, understood by, available to and implemented by all personnel concerned. |  | |  | | |  |  |  |  | |
| **8.4** | **Control of management system documents (Option A)** |  | |  | | |  |  |  |  | |
| 8.4.1 | The RMP shall control the documents (internal and external) that relate to the fulfilment of the International Standard. |  | |  | | |  |  |  |  | |
| 8.4.2 | The RMP shall ensure that:  a) documents are approved for adequacy prior to issue by authorized personnel;  b) documents are periodically reviewed and updated (as necessary);  c) changes and the current revision status of documents are identified;  d) relevant versions of applicable documents are available at points of use;  e) documents are uniquely identified and where necessary their distribution controlled;  f) the unintended use of obsolete documents is prevented, and suitable identification applied to them if they are retained for any purpose. |  | |  | | |  |  |  |  | |
| **8.5** | **Control of records (Option A)** |  | |  | | |  |  |  |  | |
| 8.5.1 | The RMP shall establish procedures to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of its records related to the fulfilment of this  International Standard. |  | |  | | |  |  |  |  | |
| 8.5.2 | The RMP shall establish procedures for retaining records for a period consistent with its contractual and legal obligations. Access to these records shall be consistent with the confidentiality arrangements. |  | |  | | |  |  |  |  | |
| **8.6** | **Management review (Option A)** |  | |  | | |  |  |  |  | |
| 8.6.1 | In accordance with a predetermined schedule and procedure, the RMP’s top management shall periodically conduct a review of its management 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, but not be limited to:  a) the suitability of policies and procedures;  b) reports from managerial and supervisory personnel;  c) the outcome of internal audits;  d) corrective actions;  e) result of risk identification;  f) assessments by external bodies;  g) changes in scale and type of work;  h) feedback from customers;  i) recommendations for improvement including complaints;  j) other relevant factors such as resources, staff training and, where required, technical issues relating to the competence of the subcontractor and distributor of the RMs;  k) the quality objectives (see 8.2) |  | |  | | |  |  |  |  | |
| 8.6.2 | 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. |  | |  | | |  |  |  |  | |
| **8.7** | **Internal audit (Option A)** |  | |  | | |  |  |  |  | |
| 8.7.1 | The RMP shall, periodically and in accordance with a predetermined schedule and procedure, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the management system and the requirements of the International Standard. The internal audit programme shall address all elements of the management system, including the technical and production activities leading to the finished product (RM). It is the responsibility of the RMP 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. |  | |  | | |  |  |  |  | |
| 8.7.2 | When audit findings cast doubt on the effectiveness of the operations, or on the integrity of the RMs, or on the correctness of their documentation, the RMP shall take timely corrective actions and shall notify, in writing, its customers whose activities may have been adversely affected. |  | |  | | |  |  |  |  | |
| 8.7.3 | All audit findings and corrective actions that arise from them shall be recorded. The RMP’s management shall ensure that these actions are discharged within an appropriate and agreed timescale. |  | |  | | |  |  |  |  | |
| 8.7.4 | Follow-up activities shall verify and record the implementation and effectiveness of the corrective actions taken. |  | |  | | |  |  |  |  | |
| **8.8** | **Actions to address risks and opportunities (Option A)** |  | |  | | |  |  |  |  | |
| 8.8.1 | The RMP shall consider the risks and opportunities to:  a) give assurance that the management system can achieve its intended result(s);  b) enhance desirable effects;  c) prevent, or reduce, undesired effects;  d) achieve improvement. |  | |  | | |  |  |  |  | |
| 8.8.2 | The organization shall take actions to:  a) address these risks and opportunities;  b) integrate and implement the actions into its management system processes;  c) evaluate the effectiveness of these actions. |  | |  | | |  |  |  |  | |
| 8.8.3 | Actions taken to address risks and opportunities shall be proportionate to the potential impact on the quality of the RM production and service. |  | |  | | |  |  |  |  | |
| **8.9** | **Corrective actions (Option A)** |  | |  | | |  |  |  |  | |
| **8.9.1** | **General** |  | |  | | |  |  |  |  | |
| *8.9.1*  *RT 34*  *RG 18* | The RMP shall establish a policy and procedure(s) and shall designate appropriate authorities for implementing corrective actions when non-conforming RMs, non-conforming work on the production of RMs, or deviations from the policies and procedures in the management system have been identified.  NOTE A problem with the management system or with technical operations can be identified through a variety of activities within the management system, such as control of non-conforming RMs, internal or external audits, management reviews and feedback from customers or staff observations.  *In the event that non-compliant activities are identified that could jeopardize the execution of accredited productions, the RMP - in addition to the provisions of its quality management system in application of the standard requirements - shall promptly inform ACCREDIA and, if necessary, proceed to the request for self-suspension according to the provisions of the RG-18 Regulations.* |  | |  | | |  |  |  |  | |
| **8.9.2** | **Cause analysis** |  | |  | | |  |  |  |  | |
| 8.9.2 | Corrective action procedures shall start with an investigation to identify the root causes of the problem. Corrective action procedures shall start with an investigation to identify the root causes of the problem.  The investigation shall be conducted for both in-house production and, where required, any work performed by subcontractors. |  | |  | | |  |  |  |  | |
| **8.9.3** | **Selection and implementation of corrective actions** |  | |  | | |  |  |  |  | |
| 8.9.3.1 | Where corrective actions are needed, the RMP shall identify potential corrective actions. It shall select and implement the action(s) most likely to eliminate the problem and to prevent recurrence. |  | |  | | |  |  |  |  | |
| 8.9.3.2 | Any corrective action taken to eliminate the causes of non-conformities or other departures shall be appropriate to the magnitude of the problem and commensurate with the risks encountered. |  | |  | | |  |  |  |  | |
| 8.9.3.3 | The RMP shall document and implement any required changes to the operational procedures resulting from corrective action investigations. |  | |  | | |  |  |  |  | |
| **8.9.4** | **Monitoring of corrective actions** |  | |  | | |  |  |  |  | |
| 8.9.4 | After having implemented the corrective actions, the RMP shall monitor the results to ensure that the corrective actions taken have been effective in eliminating the root causes of the problems. |  | |  | | |  |  |  |  | |
| **8.9.5** | **Additional audits** |  | |  | | |  |  |  |  | |
| 8.9.5 | Where the identification of non-conformities or departures casts doubt on the RMP’s compliance with its own policies and procedures, or on its compliance with the International Standard, the RMP shall  ensure that the appropriate areas of activity are audited in accordance with 7.17, as soon as possible. |  | |  | | |  |  |  |  | |
| **8.10** | **Improvement (Option A)** |  | |  | | |  |  |  |  | |
| 8.10.1 | The RMP shall continually improve the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions  and management review. |  | |  | | |  |  |  |  | |
| 8.10.2 | Required improvements and potential sources of non-conformities, either technical or concerning the management system, shall be identified. When improvement opportunities are identified  or if improvement is required, action plans shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such non-conformities and to take advantage of the opportunities for improvement. |  | |  | | |  |  |  |  | |
| 8.10.3 | After the implementation of the improvement, the RMP shall monitor the results to establish any reduction in deficiencies or other improvements in this operational area, thereby establishing the  effectiveness of the preventive action. |  | |  | | |  |  |  |  | |
| **8.11** | **Feedback from customers (Option A)** |  | |  | | |  |  |  |  | |
| 8.11 | The RMP shall seek feedback, both positive and negative, from its customers. The feedback shall be used and analysed to improve the management system, RM production activities and customer service. |  | |  | | |  |  |  |  | |

**5. ADDITIONAL CHECKS**

To be completed only for the current audit.

Delete the tables relating to previous audits.

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

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

# 5.2. CHECK OF CLOSURE OF FINDINGS OF PREVIOUS AUDIT DT MOD 006 OF …………..

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

**6. ANNEXES**

To be completed only for the current audit.

Delete the tables relating to previous audits.

**NOTES**

**SYSTEM ASSESSSOR:**

NAME, SURNAME

Signature DATE: ………………….