|  |  |
| --- | --- |
|  Organization Name |  |
| RM Producer Name |  |
| Division / Dept. |  |
| RM Producer Representative  | Name:  | Position: |
| RM Producer Ref. No. |  |
| Team Leader Name |  |
| Reporting Assessor(s) Name(s) |  |
| RM Producer Scheme Activities |  |
| Assessment Type | [ ]  Pre-assessment | [ ]  Initial | [ ]  Assessment No. ( ) | [ ]  Follow up |
| [ ]  Re-Assessment | [ ]  Extension | [ ]  Un-Planned |
| This report covers: | [ ]  PTP self-assessment | [ ]  Document review  | [ ]  Reporting assessment visit |
| **REQUIREMENTS & COMMENTS** **Compliance = C, Non-compliance = NC**Comment below on adequacy of how requirements have been addressed, documented and/or implemented. References to**ISO 17034:2016** ~~are~~ in italics & indicated as ***Std***. The order of assessment need not follow the order of the checklist. Assessment team are expected to know & have the standard; this worksheet is designed as guidance to prompt detailed recording of the process.**REFER TO ISO 17034:2016 FOR DETAIL AND FOR CLARIFICATION NOTES.****\* Team Leader (TL) determine during the opening meeting which clauses to be covered by assessor and which to covered by TL** **\*\* Document review of TL (N/C & Cm) and PTP response will be written in this checklist specified column** |

 **Checklist for ISO 17034:2016**

| **Clause** | **Standard Requirements** | **RMP self-Assessment** | **C****NC** | **TL Document Comments** |
| --- | --- | --- | --- | --- |
| **4** | ***GENERAL REQUIREMENTS*** |
| **4.1** | ***Contractual matters*** |
| **4.1.1** | Are all requests, tenders and contracts for the production of a RM reviewed to ensure:* The requirements for the RM defined, documented and understood?
* The RMP has the capability and resources to meet the requirements?
 |  |  |  |
| **NOTE 1** | Capability means that the RMP has access to, for example, the necessary equipment, knowledge and information resources and that its personnel have the skills and expertise necessary for the production of those RMs in question. The review of capability can include an assessment of previous RM production and/or the organization of interlaboratory characterization programmes using samples of similar composition to the RMs to be produced. |
| **NOTE 2** | A contract can be any written or verbal agreement. |
| **NOTE 3** | A request to prepare a specific RM can originate from the RMP. |
| **4.1.2** | Does the review include any work that need to be subcontracted? |  |  |  |
| **4.1.3** | Does The RMP maintain the records of these reviews, including any changes, records of pertinent discussions with the customer relating to the customer’s requirements, and subcontracted work? |  |  |  |
| **4.2** | ***Impartiality*** |  |  |  |
| **4.2.1**  | Is The RMP structured and managed to safeguard impartiality? |  |  |  |
| **NOTE** | Impartiality implies, decisions based on objective criteria, and not on bias, prejudice or preference for improper reasons. |
| **4.2.2** | Does the RM producer: |  |  |  |
| **a)** | a) Have arrangements that ensure that their staff are free from any undue pressures, including commercial, financial, and any other pressure that may adversely affect their work? |  |  |  |
| **b)** | a) Identify risks to impartiality on an on-going basis, including risks from the activities, relationships of the producer and personnel? not all relationships present a risk to impartiality |  |  |  |
| **c)** | a) able to demonstrate, if a risk to impartiality is identified, how it eliminates or minimizes such risk? |  |  |  |
| **d)** | Have top management committed to impartiality? |  |  |  |
| **NOTE** | impartiality can be influenced by ownership, governance, management, personnel, shared resources, finances and contracts (other than for the sale of RMs). |
| ***4.3*** | ***Confidentiality*** |
| 4.3.1 | • Does the RMP responsible for and treat all information obtained in an appropriate manner, including confidential information?• Is information received from other individuals and bodies treated as confidential unless the information is in the public domain, or its disclosure agreed to its disclosure to others? |  |  |  |
| 4.3.2 | * When the RMP is required by law or authorized to release confidential information, is the individual or body notified? (unless prohibited by law)
 |  |  |  |
| **5** | ***Structural requirements*** |
| **5.1** | Is the RMP a legal entity, or a defined part of a legal entity, that can be held responsible for their activities?(List the legal name and registration number/s of the RMP) |  |  |  |
| **5.2** | Is the RMP organized and operated in such a way as to meet the requirements of ISO 17034? |  |  |  |
| **5.3** | Does the RMP:- |  |  |  |
| **a)** | * Have a description of its legal status?
* Define the organizational and management structure?
* Define its place in any parent organization?
* Define the relationship between management, technical operations, support services and subcontractors?
 |  |  |  |
| **b)** | Define the parts of the organization covered by the management system for RM production? |  |  |  |
| **c)** | Specify the responsibility, authority and inter-relationships of personnel whose work could affect the quality of the RM produced? |  |  |  |
| **d)** | * Have managerial personnel, supported by technical personnel, with the authority and resources required?
* Able to identify the occurrence of departures from the management system and procedures for the production of RMs?
* Able to initiate actions to prevent or minimize these departures?
 |  |  |  |
| **e)** | * Have technical management with responsibility for technical operations?
* Have the resources to ensure the required quality of each operation which form part of the RM production?

  |  |  |  |
| **f)** | * Have personnel with defined responsibility and authority to ensure that the requirements of ISO 17034 are implemented and followed?
* These personnel have access to highest management responsible for RM production?
 |  |  |  |
| **g)** | Have adequate insurance or provisions to cover liabilities? |  |  |  |
| **5.4** | Does the RMP ensured that: |  |  |  |
| **a)** | Internal & external communication mechanisms have been established? |  |  |  |
| **b)** | The effectiveness of the management system is communicated? |  |  |  |
| **c)** | The importance of meeting customer requirements and other requirements is communicated to the RMP personnel? |  |  |  |
| ***6*** | ***Resource requirements*** |
| ***6.1*** | ***Personnel*** |
| **6.1.1** | Does the RMP ensure that all personnel involved in RM production are supervised and competent and that they work in accordance with the RMP’s management system? |  |  |  |
| 6.1.2 | Are Personnel, including subcontractors, personnel of external bodies, or other individuals acting on the RMP’s behalf comply with the policies and procedures for the management of confidential information that are set by the RMP? |  |  |  |
| 6.1.3 | Does the RMP ensure:* the competence of all personnel, including technical management personnel, operating under its management system who undertake activities relating to the production of each particular type of RM.
* There are sufficient personnel having the necessary education, training, technical knowledge and experience for their assigned functions.
 |  |  |  |
| 6.1.4 | Does the RMP has procedures for identifying training needs and providing training of personnel?Is training programme relevant to the present and anticipated tasks of the RMP? |  |  |  |
| 6.1.5 | Does the RMP maintain records of job descriptions for its personnel involved in RM production activities? |  |  |  |
| 6.1.6 | Does the RMP authorize competent personnel to perform particular activities relating to RM production?Does the RMP maintain records of the authorizations, competence, educational and professional qualifications of those personnel?Does these records provide evidence that individuals havebeen adequately trained and that their competence to perform particular activities in the RM production has been assessed?Is this information available and include the date on which the authorization and/or competence has been confirmed? |  |  |  |
| 6.2 | ***Subcontracting*** |
| 6.2.1 | Does the RMP has procedures to ensure that the subcontractors’ experience and technical competence are sufficient for their assigned tasks and that they comply with the relevant clauses of ISO 17034? |  |  |  |
| NOTE 1 | It is possible that an RMP does not have its own laboratory facilities or processing facilities, or it can choose not to use its own facilities. |
| NOTE 2 | Subcontractors can be paid or unpaid. |
| 6.2.2 | Does the RMP select subcontractors on the basis of their ability to meet the requirements stipulated by the RMP? |  |  |  |
| 6.2.3 | Have any of the following processes being sub- contracted?* 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 | Does the RMP establish and maintain procedures to assess that all tasks performed by subcontractors comply with the requirements set by the RMP and with any relevant clauses of 17034? |  |  |  |
| 6.2.5 | Is evidence available of the competence of sub- contractors, including records, evaluations and audits of the sub- contractor/s?  |  |  |  |
| NOTE | Examples of evidence are assessments of tasks performed for the RMP in the past, evidence of successful participation in relevant proficiency testing, conformity assessment certificates relevant for the task contracted and acceptable results on well-characterized materials of similar or equivalent nature to that of the candidate RM. |
| 6.2.6 | In instances where Homogeneity and stability testing is not feasible can the provider demonstrate that procedures followed are sufficient for the purposes of PT Testing? |  |  |  |
| 6.2.7 | Does the RMP have results and descriptions of procedures available for technical data evaluation? |  |  |  |
| 6.2.8 | Does the RMP have personnel with sufficient knowledge of the sub-contractor’s tasks, in order to evaluate their activity? |  |  |  |
| NOTE | For testing activities, this includes knowledge of the task involved and familiarity with this International Standard and ISO/IEC 17025 for calibration and testing. |
| 6.3 | ***Provision of equipment, services and supplies*** |
| 6.3.1 | Does the RMP have procedures in place for the selection of equipment, services and supplies that affect the quality of the RMs produced? |  |  |  |
| 6.3.2 | Does the RMP use only equipment, services and supplies that comply with specified requirements to ensure the quality of the RMs it produces? |  |  |  |
| 6.3.3 | Does equipment & consumables material affecting the quality of results not used until inspected/calibrated/verified? |  |  |  |
| 6.3.4 | Does the RMP Maintain records of purchases of all equipment, services and supplies, including the selection criteria used, acceptance and commissioning data? |  |  |  |
| NOTE | 6.3 applies to all equipment including material processing and measuring equipment. 7.7 includes more provisions on operation of measuring equipment. |
| 6.4 | ***Facilities and environmental conditions*** |
| 6.4.1 | Does The RMP ensure that all laboratory facilities, calibration and testing areas (if applicable) , material handling, storage, processing and packaging areas, energy sources, lighting, humidity, temperature, pressure and ventilation are such as to facilitate proper material handling, storage, processing and packaging, as well as proper performance of calibration and testing activities (if applicable) . |  |  |  |
| 6.4.2 | Does the RMP monitor the environmental conditions that could have an adverse effect on the RM production activities with appropriately calibrated equipment? Does it controlled and recorded, such that results and processes are not adversely affected. |  |  |  |
| 6.4.3 | Does RMP protect all RM processing and calibration and testing areas, in addition to satisfying requirements forhumidity and temperature from other environmental factorssuch as incompatible activities, vibration, aerosols, airborne dust and microbiological contamination,magnetic fields, light and electromagnetic and/or ionising radiation.? |  |  |  |
| 6.4.4 | Does the RMP controlled the access and use of areas that affect the quality of the RMs. |  |  |  |
| ***7*** | ***Technical and production requirements*** |
| ***7.1*** | ***General requirements*** |
| NOTE 1 | *A CRM has at least one certified value.* |
| NOTE 2 | *7.9 applies only to certified values* |
| NOTE 3 | *7.2 to 7.18 contain requirements for certified values and other property values where necessary.**Annex A is a summary of production requirements for RMs and CRMs.* |
| ***7.2*** | ***Production planning*** |
| 7.2.1 | Does the RMP identify and plan those processes that directly affect the quality of RM production?Does this production plan documented? |  |  |  |
| NOTE  | A mechanism (e.g. a management/technical advisory group) can be established to make recommendations on part or all of the production processes, for example, assigning the property values ofinterest. |
| 7.2.2 | Does the RMP specify the technical input of subcontractors? and document it? |  |  |  |
| 7.2.3 | Does the RMP address the following, during the planning stage, the following:a)material selection (including, where appropriate, sampling);b) verification of the identity of the material;c) maintaining suitable environments for all aspects of production d) material processing e) choice of measurement procedures f)validation of measurement procedures g) verification and calibration of measuring equipment h) specification of acceptance criteria for, and assessment of, homogeneity, including sampling i) specification of acceptance criteria for, and assessment and monitoring of, stability, includingsampling j ) designing and organizing appropriate characterization, including sampling k) assessing commutability (where appropriate);NOTE Guidance on the need for commutability assessment of RMs is given in a REMCO position paper[15] .l) assigning property values m) establishing uncertainty budgets and estimating uncertainties of certified value(s) n) defining acceptance criteria for measurand levels and their uncertainties;o) establishing metrological traceability of measurement result(s) and certified value(s) p) issuing RM documents q) ensuring adequate storage facilities and conditions r) ensuring appropriate labelling and packaging of the RMs s) ensuring appropriate transport arrangementst) ensuring post-production stability monitoring, if applicableu) ensuring an adequate post-distribution service for RM users  |  |  |  |
| 7.2.4 | Where multiple batches of RMs with equivalent properties are produced by using similar startingmaterials and by applying the same procedures, verification Does the RMP ensure that information obtained from previous batches remains applicable for the new batch? |  |
| NOTE 1 | Multiple batches can be batches of the same material produced at the same time, or can be successivebatches of material produced at substantially different times. |
| NOTE 2 | Further guidance for multiple batch productions is given in ISO Guide 35. |
| NOTE 3 | Where multiple batches are produced, some tests can be omitted or simplified for some batches (see7.10.2 and 7.11.3) . |
| ***7.3*** | ***Production control*** |
|  | Does the RMP verify that the production plan has been implemented as specified? Have deviations from the plan been documented and approved? |  |  |  |
|
|
|
|
| ***7.4*** | ***Material handling and storage*** |
| 7.4.1 | Does the RMP make arrangements to ensure the integrity of its candidate RMs and RMs throughout the production process? Have precautions been taken against adverse environmental conditions and possible contamination of the candidate RM during processing? |  |  |  |
| NOTE | For example, the packaging of a cement material requires conditions of low humidity, while the processing and characterization of a material in which the content of traces of lead is to be measured requires clean room conditions to prevent contamination from dust containing lead. Clean room conditions can also berequired for other types of trace analysis. Proper choice of container material and adequate cleaning procedures are also important to avoid contamination. |
| 7.4.2 | Does the RMP identify, preserve and separate candidate RMs and RMs from chemicals and other samples, from the time of processing through to their distribution to users? |  |  |  |
| NOTE | It can be useful to uniquely identify each unit of a (candidate) RM in order to facilitate subsequent sampling, trend analysis, distribution services or complaints investigation. |
| 7.4.3 | Does the RMP ensure adequate packaging of all RMs (e.g. where appropriate, use light-shielding,air-free, moisture-free or inert-gas packaging) and provide secure storage areas/stock rooms whichprevent damage or deterioration of any item or material between characterization and distribution. ? |  |  |  |
| 7.4.4 | Does the RMP assess all conditions at appropriate intervals throughout the storage period, in order to detect possible deterioration? |  |  |  |
| 7.4.5 | Does the RMP control packaging and labeling processes to the extent necessary to ensure conformity with safety and transport requirements? Have the Procedures for transport to the customer been defined? |  |  |  |
| 7.4.6 | Does the RMP take measures to ensure that the integrity of each individual RM unit is maintained until the seal, if any, has been broken or up to the point when first used? |  |  |  |
| **7.5** | ***Material processing*** |  |  |
| 7.5.1 | Does the RMP establish procedures to ensure that the material has undergone adequate processing for its intended use? Does it address the following(at least):a) qualitative analysis for verification of material type and/or identity?b) synthesis, purification (e.g. distillation, extraction) , incubation, and transformation into the finalform (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)?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. bottling, ampouling) of the material?i) safety precautions? |  |  |  |
| 7.5.2 | Does the RMP operate the equipment used in material processing in accordance with documented procedures? |  |  |  |
| NOTE | Manufacturer’s instructions are one form of documented procedure. |
| ***7.6*** | ***Measurement procedures*** |
|  | Does the RMP ensure that the relevant requirements of ISO/IEC 17025 are met with respect to calibration and testing? Have this activities been consistent with the required accuracy of the property values of the RM, and with any standard specifications relevant to the measurement concerned? |  |  |  |
| **7.7** | ***Measuring equipment*** |
|  | Does the RMP ensure that measuring equipment used in RM production is used in compliance with the relevant requirements of ISO/IEC 17025? |  |  |  |
| NOTE | Additional information on the management of measurement systems, including information on equipment that is found to drift outside acceptable limits, can be found in ISO 10012. |
| **7.8** | ***Data integrity and evaluation*** |
| 7.8.1 |  Does the RMP ensure that all calculations and data transfers are subject to appropriate checks? |  |  |  |
| 7.8.2 | Does the RMP ensure that:1. computer software developed in-house or off-the-shelf software further developed for specific use is validated and shown to be adequate for use?

NOTE Examples of software validation can be a computer-based spreadsheet calculation that is checked by manual calculation or using test data sets with known solutions.1. 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?
2. equipment and software are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain data integrity?
3. appropriate procedures are established and implemented for the maintenance of data security, including prevention of unauthorized access and changes to records, including computer records?
 |  |  |  |
| 47.8.3 | Have the Statistical procedures used in monitoring, testing, calibration or value assignment of RMs been appropriate for their application? |  |  |  |
| NOTE 1 | Validation of statistical procedures can include evidence of a sound theoretical basis (usually by reference to appropriate literature) , known performance under the expected conditions of use and assumptions or conditions which can be shown to apply to the data sufficiently for the purpose at hand. |
| NOTE 2 | Additional information on control of data is provided in ISO/IEC 17025. |
| ***7.9*** | ***Metrological traceability of certified values*** |
| 7.9.1 | Does the RMP establish the metrological traceability of the certified values in compliance with the relevant requirements of ISO/IEC 17025?Does the RMP provide evidence of the metrological traceability of the certified value to a stated reference? |  |  |  |
| NOTE 1 | A combination of results obtained by different measurement procedures and/or laboratories all being traceable to the same reference is also traceable to that reference. |
| NOTE 2 | The evidence can be based on evaluation of the measurement process or on confirmation of metrological traceability by comparison of results with independent traceable values. |
| NOTE 3 | Clear identification of the property of interest, traceability of the numerical value and the stated reference contribute to the traceability of results. |
| NOTE 4 | ISO/TR 16476 contains additional information on establishment and expression of metrological traceability of certified values. |
| 7.9.2 | Has the stated reference been 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 | Does the RMP demonstrate that the stated reference is traceable to the International System of Units (SI) .? |  |  |  |
| 7.9.4 | Where metrological traceability to the SI units is not technically possible.Does the RMP demonstrate metrological traceability to an appropriate reference? (see traceability requirements inISO/IEC 17025) . |  |  |  |
| 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 | Secondary parameters that have a significant influence on the certified value or its uncertaintyshall have evidence of metrological traceability. |  |  |  |
| NOTE | Examples of secondary parameters are temperature and humidity |
| **7.10** | ***Assessment of homogeneity*** |  |  |  |
| **7.10.1** | Does the RMP carry out the homogeneity testing of the candidate RM in its final packaged form ? |  |  |  |
| NOTE 1 | Assessment of homogeneity can include the use of prior evidence (including prior experimental evidence) , the conduct of an experimental homogeneity study on the candidate RM or both. In most cases, an experimental study is necessary. Guidance on the need for an experimental homogeneity study is provided in ISO Guide 35. |
| NOTE 2 | In most cases, experimental homogeneity tests require measurements of a representative number of randomly chosen units. The units can be chosen for example by random selection, stratified random selection or systematic selection from a random start point. |
| **7.10.2** | When the material is produced in multiple batches, Does the RMP demonstrate the equivalence of the batches? or evaluate the homogeneity of each batch separately? |  |  |  |
| **7.10.3** | Does the RMP use validated measurement procedures for homogeneity testing?are the precision and selectivity fit for the purpose required? |  |  |  |
| **7.10.4** | Does the RMP determine the homogeneity for every property of interest?If not, Can it 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? |  |  |  |
| **NOTE** | Guidance for homogeneity testing and the establishment of minimum sample size is given in ISO Guide 35 |
| **7.10.5** | Does the RMP for all certified values, quantify the homogeneity as an uncertainty contribution, or shown as a negligible contribution to the uncertainty? |  |  |  |
| **7.11** | **Assessment and monitoring of stability** |
| 7.11.1 | *Does the RMP:**a)assess 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 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?* |  |  |  |
| NOTE 1 | *Where repeated sampling is permitted [see bullet f) above] , appropriate actions can be, for example,**provision of detailed instructions for handling and use after opening of the RM unit.* |
| NOTE 2 | *ISO Guide 35 provides detailed guidance on procedures in bullets a) to f) above.* |
| NOTE 3 | *The results of stability assessments can contribute to uncertainty evaluation* |
| 7.11.2 | *Does the RMP 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**Does the RMP verify the stability of a sufficient number of different batches experimentally? to provide**confidence in the stability of all batches.* |  |  |  |
| **NOTE 1** | Verification can be a simple test to confirm that different batches behave similarly or, for successive batches, do not change over their lifetime, while the experimental assessment of stability typically involves an extended study aimed at determining rates of change. |
| **NOTE 2** | Further guidance for multiple batch productions is given in ISO Guide 35. |
| **7.12** | **Characterization** |  |  |  |
| 7.12.1 | *Does the RMP characterize the RM when assign property values?* |  |  |  |
| 7.12.2 | *Does the RMP 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 | *Does the RMP select a characterization strategy appropriate for the intended use of the RM?* |  |  |  |
| NOTE 1 | Such characterization can include, but is not limited to, the following approaches:a)using a single reference measurement procedure (as defined in ISO/IEC Guide 99) in a single laboratory;b)characterization of a non-operationally defined measurand using two or more methods of demonstrable accuracy in one or more competent laboratories;c) characterization of an operationally-defined measurand using a network of competent laboratories;d) value transfer from an RM to a closely matched candidate RM performed using a single measurementprocedure performed by one laboratory;e) characterization based on mass or volume of ingredients used in the preparation of the RM. |
| NOTE 2 | ISO Guide 35 provides guidance on characterization. |
| 7.12.4 | *Does the RMP specify the characterization study so that the properties of interest are each characterized with appropriate traceability and sufficient reliability whether or not traceability?**and Have measurement uncertainty been reported on the RM documentation?**a)Does the RMP 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, Does the RMP 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, Does the RMP perform a technical evaluation of the data and documents involved in characterization to confirm adherence to the measurement plan?*  *in the case of deviations from the plan, Does the RMP assess whether the deviation necessitates exclusion of the data from characterization?* |  |  |  |
| ***7.13*** | **Assignment of property values and their uncertainties** |
| 7.13.1 | Does the RMP use documented procedures for the assignment of property values?  |  |  |  |
| *7.13.2* | Did These procedures 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 fromdifferent 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* | Does the RMP take due account of technical information on test methods and equipment, including reported uncertainty information, and of any evidence of laboratory performance when assigning the property values of interest? |  |  |  |
| *NOTE* | ISO Guide 35 provides guidance on valid approaches for value assignment. |
| *7.13.4* | Have the Outliers been excluded solely on statistical evidence? have they been investigated?Have the reasons for the discrepancies been identified? Have Robust statistical methods been applied? |  |  |  |
| NOTE 1 | An apparent outlier can be the only technically valid result in the data set. |
| NOTE 2 | ISO Guide 35 provides guidance on the use of robust statistical methods. |
| 7.13.5 | For certified values, Does the RMP identify the uncertainty contributions to be included in the assigned uncertainty? |  |  |  |
| NOTE | Further guidance on the estimation of uncertainties is given in ISO Guide 35 and ISO/IEC Guide 98-3. |
| 7.13.6  | For certified values, Does the RMP 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? |  |  |  |
| NOTE 1 | Other uncertainty contributions can be important such as changes of property values in use or onrepeated sampling |
| NOTE 2 | Where values other than certified values are assigned to RMs (e.g. “indicative values” or “informationvalues”) , a statement of uncertainties can be appropriate to improve the use of the material. |
| ***7.14*** | **RM documents and labels** |
| 7.14.1 | Does the RMP issue and make available an RM certificate for CRMs and product information sheet for other RMs.? |  |  |  |
| 7.14.2 | Have the contents of RM certificates and product information sheets been included 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) . |  |  |  |
| 7.14.3 | *Does the RM certificate 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?**14 International Organization for Standardization**ISO 17034:2016(E)**d) metrological traceability of the certified values?**e) name and function of RMP’s approving officer?* |  |  |  |
| NOTE1 | Further information on the content of certificates and accompanying documentation is given inISO Guide 31. |
| NOTE2 | Sector-specific requirements for RM certificates and product information sheets can exist and can beconsidered (e.g. ISO 15194 for in vitro diagnostic medical devices) . |
| 7.14.4 | Has the RM label been securely attached to the product container of an individual RM unit?Has the RM label been 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. Does the label identify the material, the RMP, its batch, and any other information necessary to enable the material to be uniquely distinguished and referenced (such as theindividual sample number) , where appropriate, to its product information sheet or RM certificate? |  |  |  |
| 7.14.5 | Where the physical size of the RM unit limits the amount of information that can be contained on the label, Has the information been included elsewhere ?(e.g. in an RM document) Has unique identifierbeen given? |  |  |  |
| NOTE | Further guidance concerning the contents of RM certificates, labels and accompanying documentationcan be found in ISO Guide 31. |
| **7.15** | **Distribution service** |
| 7.15.1 | Has the distribution process been specified including precautions needed to avoid deterioration of the RM ? Does the RMP determine the conditions of shipment and ensure that appropriate documentation is provided to allow customs clearance? |  |  |  |
| **NOTE 1** | The conditions of shipment can include for example shipping temperature, packaging, duration of transport and other precautions necessary for integrity of the material. |
| **NOTE 2** | For some RMs, additional documentation related to, for example, origin and, conformity of the material to safety requirements, might be required for customs clearance. |
| 7.15.2 | Does the RMP maintain up-to-date records of all RM sales and distribution? |  |  |  |
| *7.15.3* | Does the RMP offer to users reasonable guidance and technical support related to the RMs it produces? |  |  |  |
| *7.15.4* | Does the RMP employ best efforts to notify users of any change to the property value or uncertainty for any RM within the validity period of the RM certificate or product information sheet? |  |  |  |
| *7.15.5* | Where RMs are subject to resale through a distributor with whom the RMP has a contractualrelationship,Does the RMP pass on to the authorized distributor all necessary information?Does the RMP 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 this InternationalStandard? |  |  |  |
| **NOTE** | Where RMs are subject to resale by other organizations, the RMP has no control over these organizations’ activities after the RMs have been purchased. The requirements regarding distribution service to such resellers are limited to the first reseller. |
| **7.16** | **Control of quality and technical records** |
| 7.16.1 | Does the RMP establish and maintain procedures for identification, collection, indexing, access, storage, maintenance and disposal of quality and technical records? |  |  |  |
| NOTE | Quality records are records providing objective evidence of the extent of the fulfilment of the requirements for quality or the effectiveness of the operation of the management system. They include reports from internal audits and management reviews, and corrective action and improvement records. |
| NOTE | Technical records are accumulations of data and information which result from carrying out RM production, measurement, testing and calibration procedures and which indicate whether specified quality or process parameters are achieved. They include forms, contracts, work sheets, work books, check sheets, control charts/graphs, calibration reports/certificates, reports, certificates and other statements to users. |
| 7.16.2 | Does the RMP ensure that it has recorded such information that might be needed in a future dispute situation? |  |  |  |
| 7.16.3 | Have all records been legible and stored and retained in such a way that they are readily retrievable and in facilities that provide a suitable environment to prevent damage, deterioration or loss? Has retention time of records been established and documented in accordance with customer or other relevant requirements? |  |  |  |
|
|
| **NOTE** | Records can be in the form of any type of media, such as hard copy or electronic media. |
| 7.16.4 | When mistakes occur in records, Has each mistake been crossed out, not erased, made illegibleor deleted, and the correct information entered alongside? Have such alterations to records been signedor initialled, and dated by the person making the correction. In the case of records stored electronically?Have equivalent measures been taken to avoid the loss or change of original information? |  |  |  |
| 7.16.5 | Have all records been held securely and, where appropriate, in confidence? |  |  |  |
| 7.16.6 | Does he RMP has procedures to protect electronically held data at all times and to prevent unauthorized access to, or amendment of, such data? |  |  |  |
| 7.16.7 | Does the RMP arrange for all individual measurement observations, appropriate calculations andderived data (e.g. statistical treatments and uncertainty budgets) , calibration records and preparationreports to be retained for a defined period beyond which it is no longer probable that they will bereferred to, taking into account the period for which the RM remains valid? |  |  |  |
| 7.16.8 | Have the results of each calibration or measurement (or series of either) carried out by the RMP or bya subcontractor been reported in accordance with ISO/IEC 17025? |  |  |  |
| **7.17** | ***Management of non-conforming work*** |
| 7.17.1 | Does the RMP has and implement procedures 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 custome? |  |  |  |
| 7.17.2 | Do the procedures 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 causeanalysis 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 | Has the decision on recall of RMs been taken in a timely manner to limit the use of nonconforming RMs? |  |  |  |
| NOTE | The identification of non-conforming RMs or problems with the management system or with production activities can occur at various places within the management system, such as complaints, quality control, checking of consumable materials, staff observations or supervision, certificate and other appropriate documentation checking, management reviews and internal or external audits. |
| ***7.18*** | ***Complaints*** |
| 7.18.1 | Does the RMP have a documented process to receive, evaluate and make decisions on complaints? |  |  |  |
| 7.18.2 | Has a description of the handling process for complaints been available to any interested party on request? |  |  |  |
| 7.18.3 | Upon receipt of a complaint, Does the RMP confirm whether the complaint relates to conformity assessment activities that it is responsible for and, if so, Does the RMP deal with it? |  |  |  |
| 7.18.4 | Is the RMP responsible for all decisions at all levels of the handling process for complaints? |  |  |  |
| 7.18.5 | Does the investigation and decision on complaints result in any discriminatory actions? |  |  |  |
| 7.18.6 | Does the process for handling complaints include the following elements and methods:a) a description of the process for receiving, validating, investigating the complaint, and decidingwhat 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 | Is the RMP receiving the complaint responsible for gathering and verifying all necessary information to validate the complaint? |  |  |  |
| 7.18.8 | Does the RMP acknowledge receipt of the complaint, and provide the complainant with progress reports and the outcome? |  |  |  |
| 7.18.9 | Has the decision to be communicated to the complainant been made by, or reviewed and approvedby, individual(s) not involved in the original RM activities in question? |  |  |  |
| 7.18.10 | Does the RMP shall formal notice of the end of the complaint handling process to the complainant? |  |  |  |
| ***8*** | ***Management system requirements*** |
| ***8.1*** | ***Options*** |
| 8.1.1 | GeneralDoes the RMP establish and maintain a management system that is capable of achieving the consistentfulfilment 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*** | Does the RMP establish, implement and maintain a documented management system thataddresses the scope of its RM production activities, which covers the type, range and scale of the RM production it undertakes? |  |  |  |
| ***8.1.2.2*** | Does the RMP define and document its scope of activities? |  |  |  |
| ***8.1.2.3*** | Does the management system of the RMP address the following:— quality policy ?— general management system documentation ?— control of management system documents ?— control of records ?— management review ?— internal audit ?— actions to address risks and opportunities ?— corrective actions ?— improvement ?— feedback from customers ? |  |  |  |
| ***8.1.3*** | ***Option B*** |  |
|  | When the RMP that has established and maintains a management system, in accordance with the requirementsof ISO 9001, Does the RMP capable of supporting and demonstrating the consistent fulfilment of therequirements of Clauses 4 to 7 of this International Standard (ISO 17034)? Does the RMP fulfils the management system clause requirements in 8.2 to 8.11? |  |  |  |
| **8.2** | ***Quality policy (Option A)*** |
| 8.2.1 | Does the RMP 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 | Have the RMP’s management system policies related to quality, including a quality policy statement,been documented under the authority of the top management? |  |  |  |
| 8.2.3 | Does the quality policy 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 therequirements 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 becommitted to good professional practice and to the quality of its RMs? |  |  |  |
| 8.2.4 | Have the overall objectives been reviewed during the management review? |  |  |  |
| **8.3** | ***General management system documentation (Option A)*** |  |
|  | Does the RMP document all of its systems, programmes, procedures, instructions, findings, etc., to theextent necessary to enable the RMP to ensure the quality of the RMs produced?Has the documentation used in this management system been communicated to, understood by, available to and implemented by all personnel concerned. |  |  |  |
| **8.4** | ***Control of management system documents (Option A)*** |
| 8.4.1 | Does the RMP control the documents (internal and external) that relate to the fulfilment of this International Standard? |  |  |  |
| 8.4.2 | Does the RMP 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? |  |  |  |
| NOTE 1 | These can include documents of external origin, such as standards, guides, test and/or calibration procedures, as well as specifications, instructions and manuals related to the RM under production. |
| NOTE 2 | In this context, “document” means any information or instruction including policy statements, text books, procedures, specifications, calibration tables, charts, software, etc. These can be on various media, whether in hard copy or electronic, and they can be in digital, analogue, photographic or written form. |
| **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 thisInternational Standard. |  |  |  |
| 8.5.2 | Does the RMP establish procedures for retaining records for a period consistent with its contractual and legal obligations?Has the access to these records been consistent with the confidentiality arrangements? |  |  |  |
| 8.6 | ***Management review (Option A)*** |  |  |  |
| 8.6.1 | In accordance with a predetermined schedule and procedure, Does the RMP’s top management periodically conduct a review of its management system and production processes to ensure theircontinuing suitability and effectiveness and to introduce any necessary changes or improvements?Does the review 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 issuesrelating to the competence of the subcontractor and distributor of the RMs?k) the quality objectives? |  |  |  |
| NOTE 1 | Results can feed into the corporate planning programme, can include the goals, objectives and actionplans for the coming year and can be communicated to the staff. |
| NOTE 2 | A typical period for conducting a management review is once every year. |
| 8.6.2 | Have the findings from management reviews and the actions that arise from them been recorded?Does the management ensure that these actions are discharged within an appropriate and agreed timescale? |  |  |  |
| **8.7** | ***Internal audit (Option A)*** |
| 8.7.1 | Does the RMP, 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 this International Standard?Does the internal audit programme address all elements of the management system, including the technical and production activities leading to the finished product (RM)? Does the RMP plan and organize audits as required by the schedule and requested by management? Have this audits been 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, Does the RMP take timely corrective actions and notify, in writing, its customers whose activities may have been adversely affected? |  |  |  |
| 8.7.3 | Have All audit findings and corrective actions that arise from them been recorded.?Does the RMP’s management ensure that these actions are discharged within an appropriate and agreed timescale? |  |  |  |
| 8.7.4 | Are Follow-up activities verify and record the implementation and effectiveness of the correctiveactions taken? |  |  |  |
| **8.8** | ***Actions to address risks and opportunities (Option A)*** |
| 8.8.1 | Does the RMP 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 | Does the organization 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 | Have the actions taken to address risks and opportunitiesl been proportionate to the potential impact on the quality of the RM production and service? |  |  |  |
| NOTE 1 | Options to address risks can include avoiding risk, taking risk in order to pursue an opportunity,eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk byinformed decision. |
| NOTE 2 | Opportunities can lead to the adoption of new practices, launching new products, opening newmarkets, addressing new customers, building partnerships, using new technology and other desirable and viablepossibilities to address the organization’s or its customers’ needs. |
| ***8.9*** | ***Corrective actions (Option A)*** |
| ***8.9.1*** | ***General*** |
|  | Does the RMP establish a policy and procedure(s) and designate appropriate authorities for implementing corrective actions when non-conforming RMs, non-conforming work on the production of RMs, or departures 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 avariety of activities within the management system, such as control of non-conforming RMs, internal or externalaudits, management reviews and feedback from customers or staff observations. |
| ***8.9.2*** | ***Cause analysis*** |
|  | Are the corrective action procedures start with an investigation to identify the root causes of the problem?Has the investigation been conducted for both in-house production and, where required, any workperformed by subcontractors? |  |  |  |
| ***8.9.3*** | ***Selection and implementation of corrective actions*** |
| 8.9.3.1 | Where corrective actions are needed, Does the RMP identify potential corrective actions? Is it select and implement the action(s) most likely to eliminate the problem and to prevent recurrence? |  |  |  |
| 8.9.3.2 | Has Any corrective action taken to eliminate the causes of non-conformities or other departures been appropriate to the magnitude of the problem and commensurate with the risks encountered? |  |  |  |
| 8.9.3.3 | Does the RMP document and implement any required changes to the operational procedures resulting from corrective action investigations? |  |  |  |
| ***8.9.4*** | ***Monitoring of corrective actions*** |
|  | After having implemented the corrective actions, Does the RMP 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*** |
|  | 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 this International Standard, Does the RMP ensure that the appropriate areas of activity are audited? |  |  |  |
| ***8.10*** | ***Improvement (Option A)*** |
| ***8.10.1*** | Does the RMP 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*** | Does the RMP identify the Required improvements and potential sources of non-conformities, either technical or concerning the management system? When improvement opportunities are identifiedor if improvement is required, Does the RMP develop action plans? Have this action plans been implemented and monitored?  |  |  |  |
| ***8.10.3*** | After the implementation of the improvement, Does the RMP monitor the results to establish any reduction in deficiencies or other improvements in this operational area? Does the RMP establish the effectiveness of the preventive action? |  |  |  |
| ***8.11*** | ***Feedback from customers (Option A)*** |
|  | Does the RMP seek feedback (both positive and negative) from its customers?Does the RMP use and analys The feedback to improve the management system, RM production activities and customer service? |  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **RMP representative** (for RMP self-assessment) | **Name:** | **Sign:** | **Date:** |
| **General comments for document review** (Filled by TL) |  |
| **Recommendations for document review** (Filled by TL) |  |
| **Team Leader (TL)** | **Name:** | **Sign:** | **Date:** |