General requirements for the competence of Reference Material Producer as per ISO 17034:2016

Management System Requirements

8.1 Options

8.1.1 General

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 Options

8.1.2.3 The management system of the RMP shall address the following:

— quality policy (see 8.2);
— general management system documentation (see 8.3);
— control of management system documents (see 8.4);
— control of records (see 8.5);
— management review (see 8.6);
— internal audit (see 8.7);
— actions to address risks and opportunities (see 8.8);
— corrective actions (see 8.9);
— improvement (see 8.10) ;
— feedback from customers (see 8.11).

8.1 Options

8.1.3 Option B

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.

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 Quality policy (Option A)

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 Quality policy (Option A)

8.2.4 The overall objectives shall be reviewed during the management review.

8.3 General management system documentation (Option A)

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 this 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

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;

8.6 Management review (Option A)

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).

✓Results can feed into the corporate planning programme, can include the goals, objectives and action plans for the coming year and can be communicated to the staff.

✓A typical period for conducting a management review is once every year.

8.6 Management review (Option A)

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 this 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 Internal audit (Option A)

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 Actions to address risks and opportunities (Option A)

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 Actions to address risks and opportunities (Option A)

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.

✓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 by informed decision.

✓Opportunities can lead to the adoption of new practices, launching new products, opening new markets, addressing new customers, building partnerships, using new technology and other desirable and viable possibilities to address the organization's or its customers' needs.

8.9 Corrective actions (Option A)

8.9.1 General

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 departures from the policies and procedures in the management system have been identified.

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.

8.9 Corrective actions (Option A)

8.9.2 Cause analysis

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.

The root cause is often not obvious and a careful analysis of all potential causes of the problem is required. Potential causes could include the nature of the RM and its specifications, general procedures and procedures used for characterization, staff skills and training, and the materials and equipment (and/or its calibration) used in the production processes.

8.9 Corrective actions (Option A)

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 Corrective actions (Option A)

8.9.4 Monitoring of corrective actions

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

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, 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 following:

- ✓**quality policy,**
- ✓**quality objectives,**
- ✓**audit results,**
- ✓**analysis of data,**
- ✓**corrective and preventive actions and**
- ✓ **management review.**

8.10 Improvement (Option A)

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)

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