

## General & Structural Requirements

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### 4.1 Contractual matters

4.1.1 Any request, tender or contract concerning the production of an RM shall be reviewed, following documented policies and PROCEDURES established by the RMP, to ensure:

- a) the requirements for RMs and their production are adequately defined, documented and understood;
- b) the RMP has the capability and resources to meet the requirements.

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.

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### 4.1 Contractual matters

✓ A contract can be any written or verbal agreement.

✓ A request to prepare a specific RM can originate from the RMP.

4.1.2 The review shall include any work that needs to be subcontracted by the RMP.

4.1.3 The RMP shall maintain RECORDS of these reviews, including any changes, records of pertinent discussions with the customer relating to the customer's requirements, and subcontracted work.

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### Aspects to be covered during contract review

- ✓ When reviewing requests, tenders & contracts, RMPs shall ensure that the requested matrix, property values and their metrological traceability and measurement uncertainty meet the need of the customer.
- ✓ In some cases, the stability time required should also be included in the review.
- ✓ If necessary, the RMP should give advice to the customers and help them to determine their needs.
- ✓ If the requirement is Market driven or through survey then formal contract agreement may not be needed for those cases. However, the RMP shall ensure its capability before starting up the activity.

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## 4.2 Impartiality

4.2.1 The RMP shall be structured and managed so as to safeguard impartiality.

Impartiality implies that decisions are based on objective criteria and not on the basis of bias, prejudice, or preferring the benefit of one person over another for improper reasons.

4.2.2 The RMP shall:

- a) have arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work;

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## 4.2 Impartiality

- b) identify risks to its impartiality on an on-going basis, which shall include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel; however, such relationships do not necessarily present an RMP with a risk to impartiality;

- c) be able to demonstrate, if a risk to impartiality is identified, how it eliminates or minimizes such risk;

- d) have top management commitment to impartiality.

A relationship that threatens the impartiality of the RMP can be based on ownership, governance, management, personnel, shared resources, finances or contracts for purposes other than the sale or production of RMs.

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### Impartiality

The organizational structure shall be such that there is no conflict of interest with other activities,

To safeguard the impartiality in an organization wherein there are other activities in addition to the RM production, RMP shall clearly define the segregation of the other activities in its organization which may be vulnerable to risks to impartiality.

For being impartial, RMP shall conduct its activities without any bias.

Results of the RMP activities should not be compromised due to being influenced by any relationships of the personnel involved in the activities of the RM producer, with its customer.

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### Impartiality

Risks to impartiality may also arise within the RMP itself by means of creating undue pressure on the technicians to skip the procedural steps for faster production of batches or to overlook the adverse results which will distress a customer. Further undue pressure may also include offering monetary incentives to the employees for faster production of RM material. It is suggested that the identification of risks to impartiality should be carried out on an on-going basis or at a regular interval.

Also, looking at the external risks to impartiality, there are following possibilities as given below which may cause the bias:

- ✓ Business relationships between the RMP and the customer;
- ✓ Family or personal relationships between persons of the RMP who are involved in production activities and the customer

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### Impartiality

It is worth mentioning that simply by having a relationship with a customer does not necessarily lead to a risk to impartiality. However, the RM Producer is required to identify the potential risk and thereafter demonstrate that the risk has been eliminated or mitigated.

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### 4.3 Confidentiality

4.3.1 The RMP shall be responsible for and shall treat in an appropriate manner all information obtained, including confidential information. Where information is received from another individual or body, such information shall be regarded as confidential unless the individual or body concerned places the information in the public domain or agrees to its disclosure to others.

4.3.2 When the RMP is required by law or authorized by contractual arrangements to release confidential information, the individual or the body concerned shall, unless prohibited by law, be notified of the information provided.

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### Confidentiality

Legally enforceable commitments may be in the form of contract / agreement / work order between the RMP and its customer.

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### 5. Structural requirements

5.1 The RMP shall be a **legal** entity, or a defined part of a legal entity, that can be held responsible for all its activities related to the production of RMs.

5.2 The RMP shall be organized and shall operate in such a way that it meets all the applicable **requirements** of this International Standard, whether carrying out work at its permanent facilities or at other sites (including associated temporary or mobile facilities).

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## 5. Structural requirements

### 5.3 The RMP shall:

- a) have a description of its legal status, **define the organizational and management structure of the RMP**, its place in any parent organization and the relations between management, technical operations, support services and subcontractors;
- b) define the parts of the organization covered by the management system for the production of RMs;
- c) **specify the responsibility, authority** and interrelationships of all personnel who manage, perform or verify work affecting the quality of RMs produced;

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## 5. Structural requirements

- d) have **managerial personnel**, supported by technical personnel, with the authority and resources needed to discharge their duties and to identify the occurrence of departures from the management system or the procedures for the production of RMs and to initiate actions to prevent or minimize such departures;
- e) have **technical management** with overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of each operation which forms part of the RM production;

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## 5. Structural requirements

- f) appoint personnel (however named) who, irrespective of other duties and responsibilities, shall have defined responsibility and authority for ensuring that the **requirements of this International Standard are implemented** and followed at all times – these appointed personnel shall have direct access to the highest level of management at which decisions are taken on RM production policy or resources;
- g) **have adequate provision (e.g. insurance or reserves) to cover liabilities arising from its activities.**

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## 5. Structural requirements

5.4 The RMP management shall ensure that:

- a) internal and external communication mechanisms are established;
- b) communication takes place regarding the effectiveness of the management system;
- c) the importance of meeting customer and other requirements is communicated to the RMP personnel.

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