



# National Accreditation Board for Testing and Calibration Laboratories (NABL)

## Specific Criteria for Reference Material Producer Accreditation

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## AMENDMENT SHEET

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## 1. INTRODUCTION

Reference Material Producer (RMP) accreditation activities are administered under the direction of the National Accreditation Board for Testing and Calibration Laboratories (NABL), involving Assessment Team and Accreditation Committee as recommending bodies. The Reference Material Producers are required to comply with all the requirements listed in the international standard ISO 17034: 2016 'General Requirements for the competence of Reference Material Producer', APAC TEC 1 – 008 'APAC Guidance on Reference Material Use and Production', ILAC P9 'ILAC Policy for Participation in Proficiency Testing Activities' and ILAC P10 'ILAC Policy on Traceability of Measurement Results'.

Requirements specified in ILAC P9:06/2014 and ILAC P10:01/2013 have been reproduced in respective NABL documents i.e. NABL163 'Policy for Participation in Proficiency Testing Activities' & NABL142 'Policy on Traceability of Measurements'. The Specific Criteria document i.e. NABL 191 must be used in conjunction with ISO 17034: 2016. It provides an interpretation of the later document and describes specific requirements for those clauses of ISO 17034: 2016 which are general in nature. Further, the RMP shall follow the national, regional and local laws and regulations as applicable.

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## 2. SCOPE OF ACCREDITATION FOR A REFERENCE MATERIAL PRODUCER

NABL shall provide a scope of accreditation that describes the specific types of Reference Material (RM) that the RMP is competent to produce. Although RMP accreditation conveys competence as a producer (not as a laboratory), testing and/or calibration are integral components of RM production.

It is also recognized that the property values and the associated uncertainties for certain RMs may vary between batches/lots of RMs although they are produced by the same accredited production procedures. These variations should however be within the accredited ranges and uncertainties in order for them to be considered for coverage under the scope of accreditation.

RM produced shall be fit for purpose or its intended use. The production of RMs involves some activities that are not normally considered the activities of a laboratory. The term “production” is defined under clause 7 of this document). When used in this document, it includes all necessary activities and tasks leading to a RM supplied to customers. Where an organization only provides services such as the provision of reference values to a Candidate RM, it shall not be considered as a RMP.

For some types of RMs as well as for certain property values, a RMP may only be competent to produce a particular range and within a certain uncertainty of the property value. The scope of accreditation for all CRMs with numerical property values, except for those with identity and ordinal property values shall include both range and the uncertainty of the assigned values. CRMs with identification value (such as species identification) or where the property value is an ordinal number (such as a colour fastness chart) do not require an uncertainty value to be stated in the scope of accreditation.

Reference material producers shall define their scope of activities in terms of the types of reference materials (including the sample matrices, if applicable), the properties to be certified and the ranges of Assigned value, uncertainty and best reference value capability (as relevant) of the reference materials they produce, and their involvement in activities like testing, calibration and measurements in relation to homogeneity, stability and characterization assessments and their use of subcontractors in these tasks.

An example of a typical RMP scope of accreditation is shown in **Annexure I**.

Best reference value capability is the capability of the RMP to produce lowest uncertainty for the concerned RM within the said range in the scope of accreditation.

Categories, sub-categories and sub-sub categories of reference materials are given below and this appendix can serve as good guidance to describe the specific types of RMs that a RMP is accredited to produce.

RMP Accreditation Procedure is shown in **Annexure II**.

## **CATEGORIES OF REFERENCE MATERIAL**

### **CATEGORY A: CHEMICAL COMPOSITION**

Reference materials, being either pure chemical compounds or representative sample matrices, either natural or with added analytes (e.g. animal fats spiked with pesticides for residues analysis), characterized for one or more chemical or physicochemical property values.

#### **A1: METALS**

##### **A1.1 Ferrous**

Steels  
Carbon steels  
Low alloy steels  
High alloy steels  
Cast steels  
Speciality steels  
Irons  
White cast irons  
Ductile irons  
Gases in metals

##### **A1.2 Nonferrous**

Aluminium alloys  
Copper base alloys  
Lead base alloys  
Tin base alloys  
Brasses  
Bearing alloys  
Titanium base alloys  
Zirconium base alloys  
Gases in metals

##### **A1.3 Special Alloys**

##### **A1.4 Refractory Metals and Alloys**

##### **A1.5 Rare Earth Metals**

##### **A1.6 High Purity Metals**

Solid forms  
Spectrochemical materials  
Spectrochemical solutions

#### **A2: INORGANIC REFERENCE MATERIALS**

##### **A2.1 Ores and Minerals**

##### **A2.2 Cements, Clays and Related Products**

##### **A2.3 Ceramics, Glasses and Refractory Oxides**

Carbides  
Glasses

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**A2.4 Agricultural Chemicals and Fertilizers****A2.5 Solid Fuels**

Coal and coke  
Mineral content  
Major elements  
Trace elements

**A2.6 Pure Chemicals**

Stoichiometry standards (primary standards, secondary standards, working standards)  
Chromatography standards  
Pharmaceutical materials  
Cosmetic materials

**A2.7 Stable Isotope Materials****A3: ORGANIC REFERENCE MATERIALS****A3.1 Pure Organic Compounds**

Compounds for elemental analysis  
Compounds for molecular weight  
Chromatography standards  
Illicit drugs and their metabolites - (See also A8 Forensic Reference Materials)  
Illicit drugs  
    Delta-9-THC and other cannabinoids  
    Amphetamine  
    Methylamphetamine  
    3,4-methylenedioxamphetamine  
    3,4-methylenedioxymethylamphetamine  
    3,4-methylenedioxyethylamphetamine  
    Diacetylmorphine  
    Morphine  
    Cocaine  
    Lysergic acid diethylamide and isomers  
Therapeutic drugs  
Veterinary drugs  
Steroids  
Pesticides, herbicides, acaricides, etc  
Metabolites of any of the above  
Priority pollutants  
    PCBs, PAHs, etc  
Fine chemicals  
Pharmaceutical materials  
Impurities in drugs & Pharmaceuticals  
Ayush Products  
Herbal extract / Phytochemical reference standards  
Cosmetic materials  
Isotopically labelled compounds

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**A3.2 Agricultural Materials, Fertilizers**

**A3.3 Foodstuffs**

Proximate analysis  
Nutritional properties  
Vitamins  
Other food additives  
    Antioxidants  
    Emulsifiers  
Toxins  
    Animal origin  
    Plant origin  
    Other biological origin  
Trace elements  
Trace organics  
    Pesticide residues  
    Antibiotic residues  
    Other organic contaminants

**A3.4 Plastics and Rubbers**

Hardness  
Natural rubber content  
Identity  
    Copolymers  
    Plasticisers  
    Vulcanising agents  
    Blowing agents  
    Antioxidants  
    Fillers

**A3.5 Petroleum Products**

Fuels and lubricants  
    Metals (Lead, Vanadium, Nickel etc)  
    Non-Metals  
    Physical Properties  
    Chemical Properties  
Transformer oils  
    Moisture  
    PCBs  
Heat exchange fluids  
    Moisture  
    PCBs

**A3.6 Vegetable Oils and Fats**

Fatty acid profile  
Triglyceride composition

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**A4: ENVIRONMENTAL REFERENCE MATERIALS****A4.1 Soils and Sludges**

Trace elements  
Mineral content  
Trace organics  
TCLP leachate

**A4.2 Ashes**

Fly ash from coal and coke  
Incinerator ash

**A4.3 Waters**

Potable water  
    Routine analytes  
    Trace elements  
    Organic pollutants  
    Other analytes  
Fresh water  
    Major elements  
    Trace elements  
    Other analytes  
Sea water  
    Major elements  
    Trace elements  
    Other analytes  
Industrial waste water  
    Routine analytes  
    Trace elements  
    Organic pollutants  
    Other analytes  
Treated sewage  
    Routine analytes

**A4.4 Plant Material**

Trace elements  
Mineral content

**A4.5 Marine**

Fish - trace elements  
Molluscs - mineral content  
Plankton - organics

**A4.6 BOD Reference Compounds****A4.7 Miscellaneous Biological Materials** (e.g. Human hair)**A5: HEALTH AND INDUSTRIAL HYGIENE****A5.1 Clinical Laboratory Materials****A5.2 Ethanol Solutions****A5.3 Toxic Substances in Urine**

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Toxic metals

Fluoride

Mercury

**A5.4 Drugs of Abuse in Urine**

**A5.5 Drugs of Abuse in Hair**

**A5.6 Materials on Filter Media**

**A5.7 Trace Elements in Blank Filters**

**A5.8 Lead in Paint (Powder and Sheet forms)**

**A5.9 Respirable Silica**

**A6: ENGINE WEAR MATERIALS**

**A6.1 Metallo-Organic Compounds**

**A6.2 Wear Metals in Oil**

**A7: Analysed Gases / Gas Reference Material**

**A7.1 Gas Mixtures (and High Purity Gases)**

**A7.2 Trace Volatile Organic Compounds**

**A8: FORENSIC REFERENCE MATERIALS**

**A8.1 Ethanol Reference Standards**

Ethanol

Ethanol, aqueous solutions containing 0.050, 0.150, 0.250 g/100mL

**A8.2 Drugs (individually named) and Metabolites\***

In whole human blood and urine (\*metabolites to include glucuronides).

See also A3.1 Pure Organic Compounds.

**A8.3 Glasses**

Bottle

Window

Automotive

Spectacle

**A8.4 Paints**

Automotive

Architectural

**A8.5 Accelerants**

Flammable liquids and residues thereof

**A8.6 Explosives and Primers**

**A8.7 Gunshot Residues**

**A8.8 Noxious Substances**

Crowd control agents

capsaicin

o-chlorobenzalmalononitrile (CS)

chloroacetophenone (CN)

**A8.9 Examination Documents**

- A9: ION ACTIVITY**
- A9.1 pH Standards**
- A9.2 Ion Selective Electrode Calibrants**
- A9.3 Conductivity Standards**
- A9.4 Buffer Systems**

## **CATEGORY B: BIOLOGICAL AND CLINICAL PROPERTIES**

Materials similar to Category A, but characterised for one or more biochemical or clinical property values.

- B1 GENERAL MEDICINE**
  - B1.1 Human Serum Materials (powder and solution forms)**
- B2 CLINICAL CHEMISTRY**
  - B2.1 Proteins**
  - B2.2 Apolipoproteins**
  - B2.3 Enzymes**
  - B2.4 Hormones**
  - B2.5 Trace Elements**
    - Lead and cadmium
  - B2.6 Routine Blood Analytes like urea, uric acid, glucose etc.**
- B3 TISSUE PATHOLOGY AND CYTOLOGY**
- B4 HAEMATOLOGY**
  - B4.1 Blood**
- B5 IMMUNOHAEMATOLOGY**
- B6 IMMUNOLOGY**
- B7 PARASITOLOGY**
- B8 BACTERIOLOGY AND MYCOLOGY**
  - B8.1 Reference cultures**
  - B8.2 Antibiotics**
- B9 VIROLOGY**
- B10 OTHER BIOLOGICAL AND CLINICAL REFERENCE MATERIALS**
- B11 FORENSIC REFERENCE MATERIALS**
  - Purified DNA of known and continuing genetic composition
  - Human, primate and animal blood
  - Animal hairs
  - Fibres

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## CATEGORY C: PHYSICAL PROPERTIES

Materials characterised for one or more physical property values, e.g. melting point, viscosity, density.

### C1 REFERENCE MATERIALS WITH OPTICAL PROPERTIES

#### C1.1 Optical Rotation

#### C1.2 Refractive Index

#### C1.3 Spectral Absorbance

Visible

Ultraviolet

Infrared

#### C1.4 Specular Reflectance

#### C1.5 Colour

White reference material (opal glass)

Ceramic tiles

### C2 REFERENCE MATERIALS WITH ELECTRICAL AND MAGNETIC PROPERTIES

#### C2.1 Dielectric strength

#### C2.2 Resistivity

#### C2.3 Magnetic susceptibility

### C3 REFERENCE MATERIALS FOR FREQUENCY MEASUREMENTS

### C4 REFERENCE MATERIALS FOR RADIOACTIVITY

#### C4.1 Radiation Dosimetry

#### C4.2 Radiopharmaceuticals

#### C4.3 Labelled Compounds

#### C4.4 Natural Matrix Materials

#### C4.5 Carbon-14 Dating

### C5 REFERENCE MATERIALS FOR THERMODYNAMIC PROPERTIES

#### C5.1 Calorimetry

#### C5.2 Thermal Conductivity

Metals

Pyrex glass

Resin-bonded fibre board

#### C5.3 Vapour Pressure

#### C5.4 Thermal Expansion

#### C5.5 Thermal Resistance

#### C5.6 ITS-90 Temperature Fixed Point

#### C5.7 Curie Point

#### C5.8 Boiling Point

#### C5.9 Melting Point

#### C5.10 Thermal Analysis Standards

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**C6 REFERENCE MATERIALS FOR PHYSICOCHEMICAL PROPERTIES**

**C6.1 Density**

**C6.2 Viscosity**

**C6.3 Surface Tension**

**C6.4 Molecular Weight**

**C7 REFERENCE MATERIALS FOR FIBRE IDENTIFICATION**

**C7.1 Natural Fibres**

Animal hairs

Plant fibres

**C7.2 Synthetic Fibres**

Organic polymers

Inorganic fibres

**C7.3 Asbestos Fibres**

Crude fibres

Mounted specimens for fibre counting

**C8 REFERENCE MATERIALS FOR OTHER PROPERTIES**

**C8.1 Shear Testing of Powders**

**C8.2 Minerals for X-ray Diffraction**

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## CATEGORY D: ENGINEERING PROPERTIES

Materials characterised for one or more engineering property values (e.g. hardness, tensile strength, surface characteristics, etc).

### D1 SURFACE FINISH

#### D1.1 Surface Roughness

#### D1.2 Corrosion

#### D1.3 Abrasive Wear

#### D1.4 Properties of Films and Surfaces

Nominal thickness

- X-Ray fluorescence
- Beta particle backscattering
- Ion beam sputtering

### D2 SIZING

#### D2.1 Particle Size

Particulate materials

Latex sphere suspensions

#### D2.2 Surface Area

### D3 NON DESTRUCTIVE TESTING

#### D3.1 Dye Penetrant Test Blocks

#### D3.2 Artificial Flaw for Eddy Current

#### D3.3 Magnetic Particle Inspection

### D4 HARDNESS

#### D4.1 Hardness Standardised Block (Rockwell/ Vickers/ Brinell)

#### D4.2 Microhardness

### D5 IMPACT TOUGHNESS

#### D5.1 Charpy Impact Standardised Blocks (Notches U/V/ Keyhole)

#### D5.2 Izod Impact Standardised Block

### D6 TENSILE STRENGTH

### D7 ELASTICITY

### D8 CREEP

### D9 FIRE RESEARCH

#### D9.1 Surface Flammability

#### D9.2 Smoke Density

## CATEGORY E: MISCELLANEOUS

### E1: OTHERS

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### 3. TERMS & DEFINITIONS (Key definitions from ISO Guide 30: 2015 (E) & ISO 17034: 2016)

#### Reference material (RM)

Material, sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process

Note 1 to entry: RM is a generic term.

Note 2 to entry: Properties can be quantitative or qualitative, e.g. identity of substances or species.

Note 3 to entry: Uses may include the calibration of a measurement system, assessment of a measurement procedure, assigning values to other materials, and quality control.

Note 4 to entry: ISO/IEC Guide 99:2007 has an analogous definition (5.13), but restricts the term “measurement” to apply to quantitative values. However, Note 3 of ISO/IEC Guide 99:2007, 5.13 (VIM), specifically includes qualitative properties, called “nominal properties”.

#### Certified reference material (CRM)

reference material (RM) characterized by a metrologically valid procedure for one or more specified properties, accompanied by an RM certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability

Note 1 to entry: The concept of value includes a nominal property or a qualitative attribute such as identity or sequence. Uncertainties for such attributes may be expressed as probabilities or levels of confidence

Note 2 to entry: Metrologically valid procedures for the production and certification of RMs are given in, among others, ISO Guides 35.

Note 3 to entry: ISO Guide 31 gives guidance on the contents of RM certificates.

Note 4 to entry: ISO/IEC Guide 99:2007 has an analogous definition.

#### Candidate reference material

Material, intended to be produced as a reference material (RM)

Note 1 to entry: A candidate material has yet to be characterized and tested to ensure that it is fit for use in a measurement process. To become an RM, a candidate material needs to be investigated to determine if it is sufficiently homogeneous and stable with respect to one or more specified properties, and is fit for its intended use in the development of measurement and test methods that target those properties.

Note 2 to entry: A candidate reference material may be an RM for other properties, and a candidate reference material for the target property.

### Matrix reference material

Reference material that is characteristic of a real sample EXAMPLE Soil, drinking water, metal alloys, blood.

Note 1 to entry: Matrix reference materials may be obtained directly from biological, environmental or industrial sources.

Note 2 to entry: Matrix reference materials may also be prepared by spiking the component(s) of interest into an existing material.

Note 3 to entry: A chemical substance dissolved in a pure solvent is not a matrix material.

Note 4 to entry: Matrix materials are intended to be used in conjunction with the analysis of real samples of the same or a similar matrix.

### Commutability

Property of a reference material (RM), demonstrated by the equivalence of the mathematical relationships among the results of different measurement procedures for an RM and for representative samples of the type intended to be measured.

Note 1 to entry: See also ISO/IEC Guide 99:2007,[1] ISO 17511:2003.[7]

### Reference material certificate

Document containing the essential information for the use of a CRM, confirming that the necessary procedures have been carried out to ensure the validity and metrological traceability of the stated property values

Note 1 to entry: The required and recommended content of a reference material certificate is described in ISO Guide 31.

### Product information sheet

Document containing all the information that is essential for using an RM other than a CRM

### Reference material producer

Body (organization or company, public or private) that is fully responsible for project planning and management; assignment of, and decision on property values and relevant uncertainties; authorization of property values; and issuance of a reference material certificate or other statements for the reference materials it produces

### Subcontractor

Body (organization or company, public or private) that undertakes aspects of the processing, handling, homogeneity and stability assessment, characterization, storage or distribution of the reference material under its own management system on behalf of the reference material producer

Note 1 to entry: According to ISO 17034 key tasks/aspects of the RM production process, which cannot be performed by external parties are project planning, assignment and decision on property values and relevant uncertainties, authorization of property values and issuing of reference material certificates or other statements for the RMs.

Note 2 to entry: The concept “subcontractor” is equivalent to the concept “collaborator”.

Note 3 to entry: Advisors, who could be asked for recommendations, but who are not involved in decision making or the execution of any aspects mentioned in the definition above, are not considered as subcontractors.

### Impartiality

Presence of objectivity

Note 1 to entry: Objectivity means that conflicts of interest do not exist, or are resolved so as not to adversely influence the activities of the reference material producer.

Note 2 to entry: Other terms that are useful in conveying the element of impartiality include “independence”, “freedom from conflict of interests”, “freedom from bias”, “lack of prejudice”, “neutrality”, “fairness”, “open-mindedness”, “even-handedness”, “detachment”, “balance”.

[SOURCE: ISO/IEC 17021-1:2015, 3.2, modified — In Note 1 to entry, “certification body” has been replaced by “reference material producer”.]

### Operationally defined measurand

Measurand that is defined by reference to a documented and widely accepted measurement procedure to which only results obtained by the same procedure can be compared

Note 1 to entry: Examples include crude fibre in foods, impact toughness, enzyme activities and extractable lead in soils.

## 4. GENERAL REQUIREMENTS

### 4.1 Contractual Matters

When reviewing requests, tenders and 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.

*Note 1: Capability means that the reference material producer 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 reference materials in question. The review of capability can include an assessment of previous reference material productions and/or the organization of inter laboratory characterization programmes using samples of similar composition to the reference materials 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 itself.*

### 4.2 Impartiality

RMP activities shall be undertaken impartially and structured so as to safeguard impartiality.

The organizational structure shall be such that there is no conflict of interest with other activities, defining the responsibilities: this may be seen where organization defines the structure particularly in case of In-house reference material producers or where the RMP is the part of larger organization. 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.

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.

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

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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

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.

#### 4.3 Confidentiality

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

## 5. STRUCTURAL REQUIREMENTS

RMP shall provide one of the following documents in support of its legal status claimed:

| Type of Legal Identity        | Document(s) to be submitted                                                                                        |
|-------------------------------|--------------------------------------------------------------------------------------------------------------------|
| Proprietorship                | Bank passbook/ Account statement and PAN of the laboratory                                                         |
| Limited Liability Partnership | Registration certificate under The Limited Liability Partnership Act, 2008                                         |
| Company                       | Registration certificate under The Companies Act, 1956 or 2013                                                     |
| Societies/ Trust              | Registration certificate under Societies Registration Act, 1860/<br>Registration under The Indian Trusts Act, 1882 |
| Government                    | Gazette or Government Notification or self-Declaration on Letter head by Head of the organization                  |

If the RMP is part of an organization which has laboratory/ inspection body, the roles of key personnel shall be clearly defined identifying any potential conflict of interest. In addition, the organization chart shall clearly define the position and relationship of RMP with other activities.

The designated personnel (howsoever named), responsible for implementation, maintenance and improvement of the management system of RMP should be familiar with and fully aware of the requirements of ISO 17034:2016, and principles applicable to the organization's field of accreditation / compliance. The competence shall be verified by NABL assessment team.

## 6. RESOURCE REQUIREMENTS

### 6.1 Personnel

Accredited / applicant RMP is required to select and appoint a person (however named) responsible for Quality management system, Technical management system and RMs approving officer. A person can perform more than one of these functions as long as he / she satisfies minimum requirements of qualification and experience subject to the conditions that the work load is adequately justified in relevance to scope and with deputies in each field in place.

The minimum qualification for the technical personnel shall be Graduate in Science/ Diploma in Engineering.

For a person to be approved as authorised signatory personal evaluation shall be done during assessment. The minimum qualification for the authorized signatory shall be Graduate in relevant field of science or Engineering & Technology with minimum 10 years experience (Out of which 5 years particularly in the manufacturing / testing of the material in the applied category). The relevant academic qualifications, experience and demonstration of technical competence to the assessment team shall be the basis for acceptance of authorised signatories.

Individuals who issue reference material / certified reference material certificate shall assume responsibility for the technical validity and accuracy of all information contained in the certificate. Those personnel shall have and demonstrate a sound knowledge of:

- ISO 17034:2016, Guide 30, Guide 31 & Guide 35, NABL Policy & Procedures and this document (NABL 191);
- the principles of the calibrations, measurements, analysis and/or tests they perform or supervise;
- the scope for which accreditation is sought;
- the facility's management system;
- sound understanding of quality control data including homogeneity / stability, characterization of property values, assignment of property value etc;
- knowledge of statistics, preparation of RM, etc
- measurement ranges and the estimation of the uncertainties of measurement associated with the test or calibration results for which the facility is accredited or seeking accreditation.

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RMP official who releases results shall hold a position within the organisation which provides authority over the accredited activities and, where necessary, results to be rejected when they consider them to be inadequate.

RMP should have an official who is conversant with the subcontractor activities in order to verify the activities performed by subcontractors.

Where a RMP's approval process for assigning staff to critical tasks including the release of reference material results is found not to satisfy the requirements for accreditation, the RMP will be required to review all reports issued since the time non compliance to the standard requirement is determined and, if necessary, withdraw and/or issue replacement reports. The accreditation status of the RMP may also be reviewed.

## 6.2 Subcontracting

RMPs shall document, in the management system document howsoever named (e.g. quality manual) or related documents, their policy and procedures for sub-contracting.

A task which is originally performed by a competent subcontractor at the time of initial accreditation/assessment of competence cannot be subsequently carried out by the RMP itself unless its competence in that task has been demonstrated to NABL. For example, characterization of a RM by a single (primary) method may be carried out by a competent laboratory but may not be by the RMP itself if it does not have the expertise to enable it to ensure metrological traceability (see clause 7.12 of ISO 17034:2016). It may also be possible that the RMP may lack the necessary equipment for the tasks (e.g. homogenizer for homogenizing the candidate material, measuring equipment for characterization, etc.). In other words, if the characterization of a RM by a single (primary) method was initially carried out by a laboratory as per the RMP's system for subcontracting and the same was assessed as competent during initial assessment then this arrangement may not be suddenly changed without information to NABL. In all such cases a fresh assessment may be carried out by NABL for assessing competence as per the revised sub-contracting arrangement of the RMP.

NABL does not permit serial Sub-contracting (i.e. Subcontracting of Sub- contracted work).

There are some processes that are not allowed to be subcontracted. Such processes are:

- 1) Production planning,
- 2) Selection of Subcontractors
- 3) Assignment of Property Values & their uncertainties,
- 4) Authorization of property values & their uncertainties.
- 5) Authorization of RM documents

RMP may subcontract activities other than above to a competent subcontractor. However, the RMP shall ensure that such services are subcontracted to competent laboratories / agencies / organizations conforming to relevant requirements of ISO 17034:2016 and the relevant ISO standards as given below:

- A competent subcontractor is one which is accredited by an ILAC / IAF signatory accreditation body for the specific scope as per ISO/IEC 17025/ ISO 15189 for testing, calibration and measurement activities. RMP to ensure that subcontractor is complying with ILAC P9 for same or closely similar materials wherever available.

Note: Assessor may decide the extent of specific scope in cases where accredited labs as per ISO/IEC 17025 or ISO 15189 are not available for specific equipment (e.g. NMR) / tests"

- For other activities like Material preparation, Material Handling and storage (including post certification testing) and Material Distribution & post distribution services, NABL accepts ISO 9001 Certification issued by certification bodies which are accredited by an IAF signatory accreditation body and whose certification scopes cover activities sub-contracted.

RMP shall cover the sub-contractor's activities in its internal audit schedule. (See clause 8.7 also). The Internal Audit of such subcontracted activities should preferably be carried out during actual execution of the job at the subcontractor site.

Subcontractor activities may also be assessed by NABL during RMP assessment.

Activities that can be subcontracted cover a part of the procedure for production including the following:

- 1) Processing
- 2) Homogeneity and stability testing
- 3) Characterization
- 4) Handling
- 5) Storage
- 6) Distribution

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Primarily it is the responsibility of the RMP to demonstrate that the sub-contractor is competent to perform the concerned part of the procedure and the work is carried out and the results produced are of required quality. RMP shall also ensure that the subcontractor complies with all the relevant requirements as specified in clauses 6.1 (Personal), 7.2, 7.3 (Production planning and control), 6.4 (Facilities and environmental conditions), 7.4 (Material handling and storage), 7.5 (Material processing), 7.6 (Measurement procedures), 7.7 (Measuring equipment), 7.8 (Data integrity and evaluation), 7.9 (Metrological traceability), 7.10 (Assessment of homogeneity), 7.11 (Assessment of stability), 7.12 (Characterization).

The appropriate evidences, records, etc. shall be maintained and available with the RMP to demonstrate the above as well as the records of evaluation and re-evaluation of the sub-contractor as per defined frequency.

NABL shall invariably confirm the competence of sub-contractor through an assessment of the sub-contractor as relevant, however this does not absolve the RMP of its primary responsibility as stated above.

### **6.3 Provision of equipment, services and supplies**

Same as per the standard ISO 17034:2016.

### **6.4 Facilities and environmental conditions**

Suitability of the accommodation and environmental conditions for the production of a specific reference material should be assessed based on their effect on the quality and validity of the reference material being produced, including how they affect the:

- a. Integrity of the reference materials;
- b. Performance of laboratory equipment and compliance to the test/measurement methods and procedures;
- c. Competent performance of laboratory staff;
- d. Compliance with the conditions specified in the production plan.

Consideration of environmental effects on reference materials includes precautions necessary to prevent contamination and degradation (refer to 7.4.3 of ISO 17034:2016. The areas for the material preparation, preconditioning, testing or calibration and storage should be of adequate size, free from dust, fumes and other factors (such as excessive temperature, humidity and direct sunlight) which may affect the integrity of the reference materials. If the reference materials produced require refrigeration, refrigerators / freezers

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of adequate capacity and capable of maintaining the required temperatures shall be available and temperature of these shall be monitored.

The potential effects of environment on equipment performance include corrosion, temperature, humidity, vibration, electrical power stability, dust, magnetic influence and electromagnetic influences. The operation of the equipment should be ensured such that the effect of such influences does not exist.

Accommodation and environmental conditions should also be assessed based on their effects on staff competence in performing specific activities. There should be sufficient space available for staff to perform their duties comfortably, with adequate provision of lighting and with precautions taken to minimize noise.

## 7. TECHNICAL AND PRODUCTION REQUIREMENTS

### 7.1 General requirements

The RMP shall address the requirements of this clause for the production of RMs, including CRMs.

- A CRM has at least one certified value
- 7.9 applies only to certified values
- 7.2 to 7.18 contain requirements for certified values and other property values where necessary.

### 7.2 Production planning

It is critical that, before the start of the production of reference material, a detailed production plan is available. It is understood that pilot studies may sometimes need to be carried out but the need of any pilot study should be considered at the planning stage. The production plan should be fully documented. There are requirements for each step of the production process given in ISO 17034:2016 and the RMP is required to provide evidence that, at the planning stage, these requirements are given full consideration, and if necessary, recommendations from advisory groups have been sought.

*Note 1: Advisory group shall have the expertise to carry out the functions as required in clause 7.2.3 of ISO 17034:2016. Technical experts may be used on an ad-hoc basis either in-house or external (– eliminating conflict of interest). The terms of reference and membership criteria of the advisory group shall be documented. Records of the competence of advisory group shall be maintained. Also records of their participation in the planning process shall be maintained, if used.*

The production plan may need to be reviewed regularly during the production process. If it is necessary to make any change to the plan, the effects of the change on the conformity with the requirements of ISO 17034:2016 should be evaluated. Changes should be approved by the person authorized (in accordance with clause 6.1.6 of ISO 17034:2016), to perform production planning of the reference material. Changes should be fully documented, and should include the reasons and justifications for the changes. If the changes can affect the contract with the customer, the customer should be consulted. Customer's agreement with the changes should be obtained and records maintained as required by clause 4.1.3 of ISO 17034:2016.

Production and purchasing of starting material largely depend on the type of CRM. Therefore, when planning to produce matrix CRM, starting material with suitable properties must be obtained in sufficient quantity. The starting material must be checked whether they are suitable for the production of the planned CRM.

When RM is produced in multiple batches, verification shall ensure the equivalence of the properties.