NABL 191

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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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 Guide 34: 2009 (General Requirements for the competence of Reference Material Producer), APLAC TC008:2015/03 (Requirements and guidance on the accreditation of a Reference Material Producer), ILAC P9:06/2014 (ILAC Policy for Participation in Proficiency Testing Activities), ILAC P10:01/2013 (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 Guide 34:2009, ISO Guide 31:2015, ISO Guide 35:2006. It provides an interpretation of the later document and describes specific requirements for those clauses of ISO Guide 34 which are general in nature. Further, the RMP shall follow the national, regional and local laws and regulations as applicable.

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.

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 testing scope of accreditation is shown in **Annexure I**.

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.

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), characterised 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

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-methylenedioxyamphetamine
- 3,4-methylenedioxy-methylamphetamine
- 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
Cosmetic materials
Isotopically labelled compounds

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
Lead
Vanadium
Nickel
Transformer oils
Moisture
PCBs
Heat exchange fluids
Moisture
PCBs

A3.6 Vegetable Oils and Fats

Fatty acid profile
Triglyceride composition

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

A5.3Toxic Substances in Urine

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
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

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

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

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

3 DEFINITIONS (As per ISO Guide 34: 2009)

1. Reference Material Producer (RMP)

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 issue of the certificate or other statements for the reference materials it produces.

2. 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 on behalf of the reference material producer, on a contractual basis, either paid or non-paid (see 5.3.1)

NOTE 1: *Key tasks/aspects of the reference material 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 certificates or other statements for the reference materials.*

NOTE 2: *The concept "subcontractor" is equivalent to the concept "collaborator".*

NOTE 3: *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.*

3. Production of a Reference Material

All necessary activities and tasks leading to a reference material (certified or non-certified) supplied to customers

NOTE: *Production of a reference material includes production planning, production control, material handling and storage, material processing (also referred to as "manufacturing" or "preparation"), assessment of homogeneity and stability, issue of statements and post-distribution service of the reference materials. It can include characterization, assignment of property values and their uncertainties, authorization and issue of certificates for certified reference materials.*

4. 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: *RM is a generic term.*

NOTE 2: *Properties can be quantitative or qualitative (e.g. identity of substances or species).*

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

NOTE 4: *A single RM cannot be used for both calibration and validation of results in the same measurement procedure.*

NOTE 5: *VIM has an analogous definition (ISO/IEC Guide 99:2007, 5.13), but restricts the term "measurement" to apply to quantitative values and not to qualitative properties. However, Note 3 of ISO/IEC Guide 99:2007, 5.13, specifically includes the concept of qualitative attributes, called "nominal properties". [ISO Guide 30:1992/Amd.1:2008, definition 2.1]*

5. Certified Reference Material (CRM)

Reference material characterized by a metrological valid procedure for one or more specified properties, accompanied by a certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability.

NOTE 1: *The concept of value includes qualitative attributes such as identity or sequence. Uncertainties for such attributes may be expressed as probabilities.*

NOTE 2: *Metrologically valid procedures for the production and certification of reference materials are given in, among others, ISO Guides 34 and 35.*

NOTE 3: *ISO Guide 31 gives guidance on the contents of certificates.*

NOTE 4: *VIM has an analogous definition (ISO/IEC Guide 99:2007, 5.14).*
[ISO Guide 30:1992/Amd.1:2008, definition 2.2]

6. Commutability of a Reference Material

Property of a reference material, demonstrated by the closeness of agreement between the relation among the measurement results for a stated quantity in this material, obtained according to two given measurement procedures, and the relation obtained among the measurement results for other specified materials.

NOTE 1: *The reference material in question is normally a calibrator and the other specified materials are usually routine samples.*

NOTE 2: *The measurement procedures referred to in the definition are the one preceding and the one following the reference material (calibrator) in question in a calibration hierarchy.*

NOTE 3: *The stability of commutable reference materials is monitored regularly.*
[ISO/IEC Guide 99:2007, definition 5.15]

7. Metrological Traceability

Property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty.

NOTE 1: *For this definition, a "reference" can be a definition of a measurement unit through its practical realization, or a measurement procedure including the measurement unit for a non-ordinal quantity, or a measurement standard.*

NOTE 2: *Metrological traceability requires an established calibration hierarchy.*

NOTE 3: *Specification of the reference must include the time at which this reference was used in establishing the calibration hierarchy, along with any other relevant metrological information about the reference, such as when the first calibration in the calibration hierarchy was performed.*

NOTE 4: *For measurements with more than one input quantity in the measurement model, each of the input quantity values should itself be metrological traceable and the calibration hierarchy involved may form a branched structure or a network. The effort involved in establishing metrological traceability for each input quantity value should be commensurate with its relative contribution to the measurement result.*

NOTE 5: *Metrological traceability of a measurement result does not ensure that the measurement uncertainty is adequate for a given purpose or that there is an absence of mistakes.*

NOTE 6: *A comparison between two measurement standards may be viewed as a calibration if the comparison is used to check and, if necessary, correct the quantity value and measurement uncertainty attributed to one of the measurement standards.*

NOTE 7: *ILAC considers the elements for confirming metrological traceability to be an unbroken metrological traceability chain to an international measurement standard or a national measurement standard, a documented measurement uncertainty, a documented measurement procedure, accredited technical competence, metrological traceability to the SI, and calibration intervals (see ILAC-P10)*

NOTE 8: *The abbreviated term "traceability" is sometimes used to mean "metrological traceability" as well as other concepts, such as "sample traceability" or "document traceability" or "instrument traceability" or "material traceability", where the history ("trace") of an item is meant. Therefore, the full term of "metrological traceability" is preferred if there is any risk of confusion. [ISO/IEC Guide 99:2007, definition 2.41]*

8. Measurement Uncertainty

Non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used.

NOTE 1: *Measurement uncertainty includes components arising from systematic effects, such as components associated with corrections and the assigned quantity values of measurement standards, as well as the definitional uncertainty. Sometimes estimated systematic effects are not corrected for but, instead, associated measurement uncertainty components are incorporated.*

NOTE 2: *The parameter may be, for example, a standard deviation called standard measurement uncertainty (or a specified multiple of it), or the half-width of an interval, having a stated coverage probability.*

NOTE 3: *Measurement uncertainty comprises, in general, many components. Some of these may be evaluated by Type A evaluation of measurement uncertainty from the statistical distribution of the quantity values from series of measurements and can be characterized by standard deviations. The other components, which may be evaluated by Type B evaluation of measurement uncertainty, can also be characterized by standard deviations, evaluated from probability density functions based on experience or other information.*

NOTE 4: *In general, for a given set of information, it is understood that the measurement uncertainty is associated with a stated quantity value attributed to the measurand. A modification of this value results in a modification of the associated uncertainty.*
[ISO/IEC Guide 99:2007, definition 2.26]

4 CRITERIA FOR SECTION 4 OF ISO GUIDE 34:2009 (Clause 4: Organization and Management Requirements)

General: The principles to the assessment and accreditation of RMPs:

At a minimum, the RMP is the organization responsible for the project Planning and management, assignment of and decision on property values and relevant uncertainties, authorization of property values and issue of the certificate or other statements for the reference materials (RM). It is the recognized legal entity that can be accredited. The RMP can be considered a “producer” but cannot be considered solely a “laboratory”.

The production of RMs involves some activities that are not normally considered the activities of a laboratory. The term “production” is defined under clause 3 (refer page 14 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.

The RMP shall be assessed for the purpose of accreditation in accordance with ISO Guide 34. As there are many different approaches a RMP can use to generate and assign values to its reference materials, the relevance of a requirement should be assessed in the context of the tasks performed. Tasks that may be critical for one RMP may not be as important or may even be insignificant for another. RMs can range from the fairly simple e.g. calibration solution, to the very complex e.g. DNA sequence. The assessment team should perform an analysis of the RMP operation and determine how the accreditation criteria documents should be applied based on the principles, guidance and requirements given in this document.

The following table provides examples, numbered 1 to 8, of how tasks of RM production (identified below in Table 1) may be shared between the RMP and their subcontractors (where applicable). This table is offered for the purpose of description and should not be considered to provide an exhaustive coverage or to be all inclusive of every possible or probable RMP/subcontractor arrangement.

Table 1

Stages/ Tasks of RM production	ISO Documents	Example Scenarios and organisations responsible for the activity							
		1	2	3	4	5	6	7	8
Production planning	**ISO Guide 34 + ISO/IEC 17025**	***R***	***R***	***R***	***R***	***R***	***R***	***R***	***R***
# Material processing **	ISO Guide 34 + ISO/IEC 17025	R	S*	S*	S*	S*	R	S*	R
# Homogeneity/ Stability testing	ISO Guide 34 + ISO/IEC 17025	R	R	R	S*	S*	S*	S*	R
# Characterization of Property Values**	ISO Guide 34 + ISO/IEC 17025	R	R	R	S*	S*	S*	R	S*
Assignment of and decision on Property Values	**ISO Guide 34 + ISO/IEC 17025**	***R***	***R***	***R***	***R***	***R***	***R***	***R***	***R***
Authorization of property values and issue of certificate	**ISO Guide 34**	***R***	***R***	***R***	***R***	***R***	***R***	***R***	***R***
# Handling and storage (including post certification testing)	ISO Guide 34 + ISO/IEC 17025	R	R	S*	R	S*	S*	S*	R
#Distribution & post distribution service	ISO Guide 34	R	R	S	R	S	R	S	R

Tasks denoted in *italics & Bold* shall be performed by the RMP

R = Tasks performed by the RMP.

S = Task performed by subcontractor.

If performed by a subcontractor, the RMP shall ensure the technical competence of that subcontractor.

* Any conclusions in regards to these tasks shall be made by the RMP.

** Testing, calibration, measurement, sampling and other activities involved in material assessment and production shall, as cross-referenced in ISO Guide 34, comply with the relevant parts of ISO/IEC 17025/ISO 15189.

Some existing modes of operation of an RMP are as mentioned below:

a) A single organisation produces the candidate RM and assigns the property values based on its own measurement results (example 1 as given in the above table).

b) An organisation produces the candidate RM and assigns the property values based on the measurement results from other (subcontractor) laboratories. Handling and storage of the RM are performed by the subcontractor. The certificate is issued by the producer (example 6).

c) An organisation produces the candidate RM and is responsible, as an example, for the homogeneity and stability studies. The property values are characterized by an external accredited or non-accredited laboratory. The producer makes a decision on the values, issues certificate and sells the RM (example 8).

d) An organisation subcontracts the preparation of a candidate RM and then assigns the property values based on measurement results from its own laboratories. The organization that issues the certificate sells the RM (example 2).

e) An organisation subcontracts the production of a candidate RM and all laboratory work necessary to assign the RM property values. The certificate is issued by the RMP and the RM is distributed by the RMP or an external party (example 5)\

4.1 Management System Requirements

The management system of a RMP need not be complex and its format will depend on a number of factors including the size of the RMP, number of staff members and the range, volume and complexity of the work it performs. In cases where a RMP is part of a larger organization, RMP activities may already be incorporated in a document covering the organization's total range of operations.

Clause 4.1.2 c) requires the RMP to conduct all testing and calibration in support of the production of reference materials in compliance with the requirements of ISO/IEC 17025/ ISO 15189.

If the RMP performs testing and measurement that significantly affects the uncertainty of the assigned property value of a RM, the RMP shall participate in the proficiency testing programs as required in ILAC P9 for the tests and measurements it performs. If a laboratory acts as a subcontractor, the RMP shall require the laboratory to participate in proficiency testing programs, as required to meet ILAC P9 for the tests and calibrations it performs. When proficiency testing programs are not available, other means to demonstrate competence, e.g. use of measurement audits and check samples, shall be considered.

4.2 Organization and Management

The applicant Reference Material Producers shall provide photocopies of appropriate document(s) in support of the legal identify claimed (eg. Registration Certificate under Indian companies Act, Limited Liability Act, Societies Registration Act, Any Government notification in support of establishment of institution / or any approval from local or regulatory bodies etc.) The name of the organization shall not be different from the name given in the proof of legal identity certificate

If the RMP is part of an organization which has laboratory/ inspection body, the roles of key personnel such as Quality Manager/Technical Manager, etc 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.

4.3 Document and Information Control
Document approval and issue & Document Changes

RMP shall have a master list of internal documents as well as external documents identifying the current revision status of documents in the management system, shall be established and be readily available to preclude the use of invalid and/or obsolete documents.

RMP shall define the periodicity for review of documents but the periodicity of the review shall be at least once in a year or earlier as per the policy defined by RMP.

RMP shall retain the obsolete documents for 2 years or more as per policy defined by RMP.

If the reference material producer's document control system allows for the amendment of documents by hand, pending the re-issue of the documents, the procedures and authorities for such amendments shall be defined. Amendments shall be clearly marked, initialed and dated. A revised document shall be formally re-issued within 3 months.

4.4 Request, Tender and Contract Reviews

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 no contract agreement may be needed for those cases. However, the RMP shall ensure its capability before taking up the activity.

NOTE 1: *Capability means that the reference material producer has access to, for example, the necessary equipment, intellectual and information resources and that its personnel have the skills and expertise necessary for the production of the reference materials in question. The review of the 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 to provide a customer with reference materials from stock or custom-produced.*

4.5 Use of Subcontractors

RMPs shall document, in the 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 an ILAC / IAF signatory accreditation body. 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 5.15 of ISO Guide 34:2009). 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 initial 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 shall 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. Assignment of and decision on Property Values,
3. Authorization of property values and issue of certificate.

RMP may subcontract activities other than above to a competent subcontractor. However, the RMP shall ensure that such services are subcontracted to competent laboratories conforming to relevant requirements of ISO Guide 34:2009 and the relevant ISO standards as given below:

A competent subcontractor is one which is accredited an ILAC signatory accreditation body for the specific scope as per ISO/IEC 17025/ ISO 15189 for testing, calibration and measurement activities. 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 4.14 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.

4.6 Procurement of Services and Supplies

Same as per the Standard ISO Guide 34: 2009

4.7 Customer Service

Same as per the Standard ISO Guide 34: 2009

4.8 Complaints

Same as per the Standard ISO Guide 34: 2009

4.9 Control of Non-conforming Work and/or Reference Materials

Common examples of non-conforming work include environmental conditions in the testing or calibration areas exceeded the specified limits, tests performed using instruments with overdue calibration, acceptance criteria of quality control not met, and unsatisfactory performance in proficiency testing schemes, etc. It is important that RMPs should not just correct the problem but shall initiate actions which include a determination of the significance of the non-conforming work and this should include an investigation of whether the non-conforming work is an isolated incident or is due to some underlying causes with a possibility of recurrence.

In the later case, corrective actions, in addition to corrections, are also needed. It should be emphasized that all personnel of the RMP need to be familiar with the procedures for handling non-conforming work and/or reference materials. They should follow the documented procedures whenever non-conforming work and/or reference material is

identified. Training on the procedures is essential to ensure that relevant staff understands the procedures.

Records of nonconforming work and/or reference materials should be maintained as part of the RMP's quality records (The records should include information on the nonconforming work and/or reference materials, actions taken, results of evaluation of the significance and extent of the nonconforming work, etc). Internal audit should include checking the effectiveness of implementation of this aspect.

4.10 Corrective Actions

Same as per the Standard ISO Guide 34: 2009

4.11 Preventive Actions

Same as per the Standard ISO Guide 34: 2009

4.12 Improvement

Same as per the Standard ISO Guide 34: 2009

4.13 Records

Technical records shall, as applicable, include all original observations and raw data and provide a traceable link between the reference materials produced and the information on the certificates or documentation of the reference materials. This applies equally to electronic and paper record systems. If a RMP uses an Information Management System, the system should meet all the relevant requirements, including audit trail, data security, safety and integrity, etc. It should be fully validated and records of validation should be maintained. RMPs should keep back-up copies of electronic records within their retention period. They should also have a system to ensure that electronic records remain accessible within that period even though the hardware and software of their computer system are being updated from time to time.

The record system should allow for ready retrieval of original observations and data pertinent to any issued reports or certificates.

For each Reference material produced, the records system should retain and provide ready access to the following detailed information:

(i) The full description of the reference material;
(ii) The unique identification of the reference material;
(iii) The test or calibration method or procedure used in the production process;
(iv) Identification of equipment and reference materials used in the production process;
(v) All data relating to the preparation and manufacturing of the candidate materials;
(vi) Original observations during the test or calibration and calculations based on the observed data;
(vii) Data and the statistical calculations for homogeneity and stability studies;
(viii) Data used in the assignment of property values and their uncertainties, including those data which have been rejected and the reasons for rejection;
(ix) Identification of persons performing the work;
(x) An exact copy/ Photocopy & not second/ third Original of the issued documentation or certificate of the reference material produced.

Original observations should be recorded immediately preferably into bound notebooks, or onto properly designed proforma worksheets using indelible pen. Instrument printouts should be kept when they are available. Where data processing systems are used, records of raw data should be retained (unless data are automated and stored electronically).

Errors in calculations and incorrect transfer of data are major causes of incorrect results. Calculations and data transfers should be checked by another person, then initialed and dated by the reviewer except in the case when there is no other suitable person available for this purpose.

4.14 Internal Audits

The RMP shall, periodically (minimum once in a year) 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 ISO Guide 34.

The internal audit programme shall address all elements of the standard ISO Guide 34 including the technical and production activities leading to the finished product (reference material) and Sub- contractor's activities.

The audit program should generally include horizontal audit and/or vertical audit or both, so that all the sections/ departments are audited for every aspect/ clause of the management system and ISO Guide 34 standard.

The audits shall be carried out by qualified* (relevant qualification) and trained** personnel. The auditor shall understand the technical requirements they are auditing and are trained as per standard ISO Guide 34 including auditing techniques/processes. Records in form of Certificate shall be established as evidence of the internal auditor training.

** Relevant qualification for a chemical testing activity means that the personnel should be a chemist. The Qualification requirement may be relaxed, provided a technical expert with relevant qualification, accompanies the trained personnel for conduct of audit. However, in exceptional cases, inter-department personnel can also conduct the internal audit ensuring independency of their activity.*

*** NABL accepts trained personnel who have undergone a 4 day or 5 day course from reputed organization as per ISO/IEC 17025 and/or ISO 15189 and gained knowledge on ISO Guide 34 (either through self study self-evaluation mode or internal training or external training of atleast 8 hours accompanied with a certificate). However, the trained personnel shall demonstrate the competence of ISO Guide 34 to the assessment team.*

Internal audit shall be independent of the activity which is being audited. Personnel shall not audit their own activities.

Internal audit may be done by Internal person or external person (used for purpose of internal audit) to establish the extent of conformity of the RMP to documented requirements and/ or standard ISO Guide 34.

When audit findings cast doubt on the effectiveness of the operations or on the integrity of the reference materials or on the correctness of their documentation, the reference material producer shall take timely corrective actions and shall notify, in writing, its customers whose activities may have been adversely affected.

All audit findings and corrective actions that arise from them shall be recorded. The reference material producer's management shall ensure that these actions are discharged within an appropriate and agreed timeframe.

Audit findings shall have compliance part and/ or Non- Compliance part, Observations, checklist used as evidence of conduct of internal audit.

Audit records may be retained for a minimum period of three years.

NOTE: *The cycle for internal auditing should normally be completed in one year.*

4.15 Management Reviews

In accordance with a predetermined schedule and procedure, the reference material producer's top management shall periodically (Minimum once a year and preferably after Internal audit (IA) and / or after closure of IA Non – Conformities) 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:

a. the suitability of policies and procedures;
b. reports from managerial and supervisory personnel;
c. the outcome of recent internal audits
d. corrective
e. and preventive actions;
f. assessments by external bodies;
g. changes in volume and type of work;
h. feedback from customers;
i. recommendations for improvement
j. including complaints;
k. other relevant factors such as resources,
l. staff training and, where required,
m. technical issues relating to the competence of the subcontractor and
n. distributor of the reference materials.

The inputs to a management review should generally include the analysis and summary on the above topics, as relevant, instead of just an agenda having the above items listed.

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. The typical format of the Minutes of Meeting of MRM may be:

Sl. No	Agenda Points	Discussion	Decision taken	Timescale

5. CRITERIA FOR SECTION 5 OF ISO GUIDE 34:2009

5.1 General

There are technical standards published by international organizations, or other well recognized professional bodies, that may be applicable to the production of certain reference materials. If such applicable technical standard exists, a RMP should, as far as possible, follow such standards in its production of the reference materials.

The criteria cover the production of certified and non-certified reference materials.

For non-certified reference materials, the production requirements are less stringent than for certified reference materials. Homogeneity and stability assessments are always required to establish that the degree of homogeneity and stability is fit for purpose.

Where replacement batches of reference materials are produced by applying the same procedures used for previous batches to similar starting materials which lead to final products with equivalent properties, appropriate verification assessments are required to ensure that uncertainty estimations obtained on previous batches remain applicable for the new batch.

To fulfil the minimum requirements for a non-certified reference material, the following may not be necessary:

a) designing interlaboratory exercises, assessing commutability, assigning property values and establishing uncertainty budgets;
b) providing detailed information to users on the homogeneity study; however, information on the degree of homogeneity shall be provided;
c) providing detailed information to users on the stability study; however, information on the degree of stability shall be provided;
d) characterization of the material;
e) assignment of property values and their uncertainties;
f) establishing metrological traceability of assigned values.

5.2 Personnel

This criteria defines the requirements of accredited / applicant RMP to select and appoint Quality Manager, Technical manager and Authorized signatory. 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 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 Guide 30, Guide 31, Guide 34 & 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.

RMP staff 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.

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

5.3 Subcontractors

All requirements as stated in the clause 4.5 of this document (NABL 191) apply in addition to those given below as read with clause 5.3 of ISO Guide 34.

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

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

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 5.2 (Personal), 5.5 (Production), 5.6 (Accommodation and environmental conditions), 5.7 (Material handling

and storage), 5.8 (Material processing), 5.9 (Measurement methods), 5.10 (Measuring equipment), 5.11 (Data evaluation), 5.12 (Metrological traceability), 5.13 (Assessment of homogeneity), 5.14 (Assessment of stability), 5.15 (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 and a 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.

5.4 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 Guide 34 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 described vide clause 5.4.2 of ISO Guide 34. Technical experts may be used on an ad-hoc basis either in-house or external (considering 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 Guide 34 should be evaluated. Changes should be approved by the person authorized (in accordance with clause 5.2.6 of ISO Guide 34:2009), 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 4.4.2 of ISO Guide 34:2009.

Production and purchasing of starting material largely depends 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.

5.5 Production Control

Although effective control of each stage of the production process is needed, there are also certain critical steps in each stage where the quality of the reference material can be significantly affected. An analysis of such critical control points can be carried out and a plan that is designed to ensure that these critical control points are effectively controlled and monitored is a useful means to ensure the quality of reference materials. If the activity

for processing has been subcontracted, then process for control over the subcontractor shall be established. Appropriate records for this purpose shall be maintained.

Records shall be maintained to provide evidence that there is effective control of each stage of reference material production, e.g. records of inspection, testing, etc.

5.6 Accommodation 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 5.7.2 of ISO Guide 34:2009). 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 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 and electromagnetic influences. The location of all items of equipment likely to be affected by these factors should be chosen to eliminate or minimize any adverse effects.

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.

5.7 Material Handling and Storage

It should be emphasized that the requirements of this section apply to all stages of the production - from the receipt of the raw material to the finished reference material. If during some stages of production, the material has to go out of the direct control of the RMP, the RMP should provide necessary written instructions to the party responsible for handling the material. When storing the material, the storage environmental conditions should be specified.

When the same equipment is used for different materials, the facility should ensure that no cross-contamination or carry-over contamination is taking place. Work instructions for cleaning of equipment, change over process, etc shall be documented.

All persons handling the materials (including those of the subcontractor's (if relevant) shall be trained on the proper handling procedures. They should be aware of the precautions to be taken whilst handling the material, as required by clause 5.2.2 of ISO Guide 34:2009. It is the responsibility of the RMP to ensure that the packing and labeling of the reference materials meet the safety and transport related regulatory requirements.

Reference material must be stored separately from the test materials and other materials in such a way that any adverse effects on their quality/integrity as well as misuse and loss are excluded. If particular storage conditions are specified (e.g. cooling) compliance shall be monitored and documented. Where applicable, safety measures for occupational health and environmental protection are taken according to the relevant dangerous properties (toxic, flammable, explosive, radioactive etc).

Access to rooms and facilities where CRM are stored as well as withdrawal of CRM shall be regulated and documented.

5.8 Material Processing

Preparation of the material (such as drying, mixing of ingredients, spiking with analytes, etc) is a form of material process. The main purpose of further preparation of the starting material is to generate a homogeneous batch of stable material with property levels as required. In addition, the prepared material should be similar to the typical test samples used with the test methods for whose quality assurance the CRM is intended.

The procedures for material processing, may include, as relevant, any of the activities as stated in clause 5.8 a) to h).

These processes required shall be included at the stage of production planning and documented work instructions shall be available and followed by the RMP or the Sub-contractor, if sub-contractor is used for any of the activity.

Each of the material processing steps as described above may require to be subdivided in to different steps. In that case work instructions additional documentations shall be created. For example:

The packaging process generally includes following steps:

- Specification of packaging units and containers
- Splitting the batch among the packaging units
- Filling into the designated containers
- Labeling

When splitting the batch, homogeneity among the packaging units must be ensured.

The requirement of the containers depends on the type of reference material. General requirement are as follows:

- The container must be such that the reference material is protected against adverse effect of ambient condition (air moisture, oxygen, light etc.).

- The reference material must be inert against the inner surface of the containers.

For storing the packaged material, appropriate storage conditions must be specified and appropriate storage capacity has to be made available. Storage conditions are derived from available information about stability relevant factors and where applicable dangerous properties of reference material according to the relevant regulations of dangerous goods.

When the same equipment is used for processing different materials, the equipment should be thoroughly cleaned between uses to prevent possible cross-contamination.

All material processing procedures should be carried out by trained personnel and requirements of clause 5.2.2 of ISO Guide 34:2009 are applicable.

When candidate reference materials are sent to subcontractors for testing, they shall be uniquely labeled, suitably packed and stored in suitable conditions during transport. Instructions on the storage conditions should be given to the subcontractors.

In cases where the certified values are based on data obtained in the material processing procedure, the requirements relating to the assignment of property values and their uncertainties apply to the material process procedures. In such cases, the material process procedures should comply with the requirements for measurement methods and metrological traceability given in clauses 5.9 and 5.12 of ISO Guide 34:2009. The requirements for measuring equipment given in clause 5.10 of ISO Guide 34:2009 also apply to those items of equipment used in the material processing stage which contributes to the uncertainty of the assigned values of the reference materials.

5.9 Measurement Methods

Same as per the Standard ISO Guide 34: 2009

5.10 Measuring Equipment

Same as per the Standard ISO Guide 34: 2009

5.11 Data Evaluation

Homogeneity and stability assessments, characterization and assignment of property values and their uncertainties in all involve evaluation of data. The RMP shall use appropriate statistical techniques for data evaluation. The general and statistical principles for certification of a given reference material in ISO Guide 35, where appropriate, shall be followed.

5.12 Metrological Traceability

Metrological traceability is the property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty.

Metrological traceability requires an established calibration hierarchy. For measurements with more than one input quantity in the measurement model, each of the input quantity values should itself be metrological traceable and the calibration hierarchy involved may form a branched structure or a network. The effort involved in establishing metrological

traceability for each input quantity value should be commensurate with its relative contribution to the measurement result.

Metrological traceability of a measurement result does not ensure that the measurement uncertainty is adequate for a given purpose or that there is an absence of mistakes.

A comparison between two measurement standards may be viewed as a calibration if the comparison is used to check and, if necessary, correct the quantity value and measurement uncertainty attributed to one of the measurement standards.

The ILAC considers the elements for confirming metrological traceability to be an unbroken metrological traceability chain to an international measurement standard or a national measurement standard, a documented measurement uncertainty, a documented measurement procedure, accredited technical competence, metrological traceability to the SI, and calibration intervals (see ILAC-P10).

The suitability of the metrological traceability utilized by the RMP is important. In cases where the metrological traceability cannot be achieved through an unbroken chain of calibrations, clause 5.12.2 of ISO Guide 34:2009 provides other alternative means. If a CRM is used for establishing metrological traceability, the CRM used shall have comparatively small uncertainty (refer to Note below) and higher in the metrological traceability hierarchy. The uncertainties in the certified values of the CRM used shall be suitable for establishing metrological traceability appropriate to the RMs being produced.

Note: *The RMP should consider the competence of the producer of any certified reference material it uses to provide the metrological traceability of the assigned value of its CRM. A competent RMP or testing/calibration organization which may be a National Metrology Institute which is a signatory to the CIPM MRA, participates regularly in BIPM or Regional Key Comparisons, and has the relevant CMCs been included in Appendix C of the BIPM Key Comparison Database (KCDB).*

5.13 Assessment of Homogeneity

For a CRM it must be ensured that the certified values are valid for all packaging units. In addition, the certified values must be valid for all samples from a packaging unit. Under normal circumstances, the degree of homogeneity assessment of a RM with respect to the property of interest should be performed. It is not acceptable to assume the homogeneity of a property value based on the assessment of another value unless correlation is demonstrated with analytes that are tested for homogeneity. If homogeneity testing is done only on a subset of the assigned values, the requirement given in clause 5.12.3.1 of ISO Guide 34:2009 applies.

When data from assessment of homogeneity are used for assigning the property values, the requirements for metrological traceability (Clause 5.12 of ISO Guide 34:2009) and characterizations (Clause 5.15 of ISO Guide 34:2009) apply to the test procedures used.

Note: *Assessment of Homogeneity need to be done by RMP; however other related activities like testing, etc as per initial planning may be sub-contracted.*

5.14 Assessment of Stability

For a CRM it must be ensured that the certified values are valid until the end of utilization period (expiry date) specified in the certificate. This validity applies to unopened packaging units under proper storage.

Under normal circumstances, stability assessment for each and every certified property value should be performed. It is not acceptable to assume the stability of a property value based on the assessment of another value unless correlation is demonstrated with analytes that are tested for stability.

Prediction of stability using a model is generally not acceptable unless such model is well established and widely accepted in the discipline concerned.

In cases where data from assessment of stability are used for assigning the property values, the requirements for metrological traceability (Clause 5.12 of ISO Guide 34:2009) and characterization (Clause 5.15 of ISO Guide 34:2009) apply to the test procedures used.

Stability assessment should include assessment of the effects of shipment. This includes studies with actual shipping under maximum stress conditions, e.g., distance, and temperature.

Stability assessment should include assessment of the effects of use. This includes studies with multiple subsamples and any requirements for changed temperature for storage before sub sampling. In stability testing the temporal change of certified values is investigated over an appropriate period. Any associated uncertainty could be expressed within the long term stability assessment or as considerations described in the certificate.

Note: *Assessment of Stability need to be done by RMP; however other related activities like testing, etc as per initial planning may be sub-contracted.*

5.15 Characterization

When a property value of interest is derived from an “empirical method”, the RMP should use that particular “empirical method” for characterization. Details of the characterization procedures used should be recorded. When more than one laboratory is engaged for characterization, then all of them should use the same “empirical method”. Such property values are only meaningful when applied to the same “empirical method”. Therefore, to be more useful, the empirical methods used should be those published by standard writing bodies or widely recognized professional bodies in the field concerned.

5.16 Assignment of Property Values and their Uncertainties

As CRMs are often used by laboratories for establishing their metrological traceability, it is important that the uncertainties of the assigned values are estimated using methods which are generally more rigorous than for other purposes. The uncertainties include not just the measurement uncertainty of the characterization procedure but also other contributions.

Uncertainty in this Section covers both “measurement uncertainty” of a quantity value and “uncertainty” associated with a nominal property (i.e. property of a phenomenon, body, or substance, where the property has no magnitude e.g. colour chart, DNA sequence, etc).

The estimate of uncertainty should include at least the effects of characterization, homogeneity, transport and long term storage. The effects of any of the above are known to be zero, and then the same can be mentioned / recorded.

5.17 Certificates or Documentation for Users

This requirement pertains to the Certificates/documentation that is required to accompany the reference material as received by the user. A RMP may perform tests or calibrations for the production of reference materials. Such tests or calibration should be performed in accordance with relevant requirements of ISO/IEC 17025. It has to be however noted that the requirement for reporting of results (i.e. clause 5.10 of ISO/IEC 17025:2005) only applies to internal testing and calibration reports and does not apply to certificates and documentation of the reference materials issued to users.

The contents of certificates for certified reference materials shall comply with the requirements of ISO Guide 31. If the certificate also contains non-certified values, a clear distinction shall be made between certified and non-certified values.

The documentation for non-certified reference materials shall include information on homogeneity and stability and on the period of validity of the stated information. It shall also contain information for the user on the proper application and storage conditions of the reference material.

In some cases which are covered by specific legislation (e.g. most pharmacopoeia assay standards), the uncertainties of the assigned values are not stated since they are considered to be negligible in relation to the defined limits of the method-specific assays for which they are used.

The results of each calibration or measurement (or series of either) carried out by the RMP or the sub-contractor shall be reported in accordance with ISO/IEC 17025 and shall carry NABL symbol.

Internal reports of the RMP should not be confused with a certificate of analysis or certification report which is supplied with a reference material to the customer.

A RMP is allowed to contract out some of its tasks to competent subcontractors. It may not be necessary to indicate which parts of the production process have been subcontracted in the certificate of CRMs or the documentation for RMs.

Certificates or documentation for a certified reference material or non-certified reference material should contain a unique identification of its production process. This identification may take the form of a reference number, the name of the process or in other suitable information.

5.18 Distribution Service

Same as per the Standard ISO Guide 34: 2009

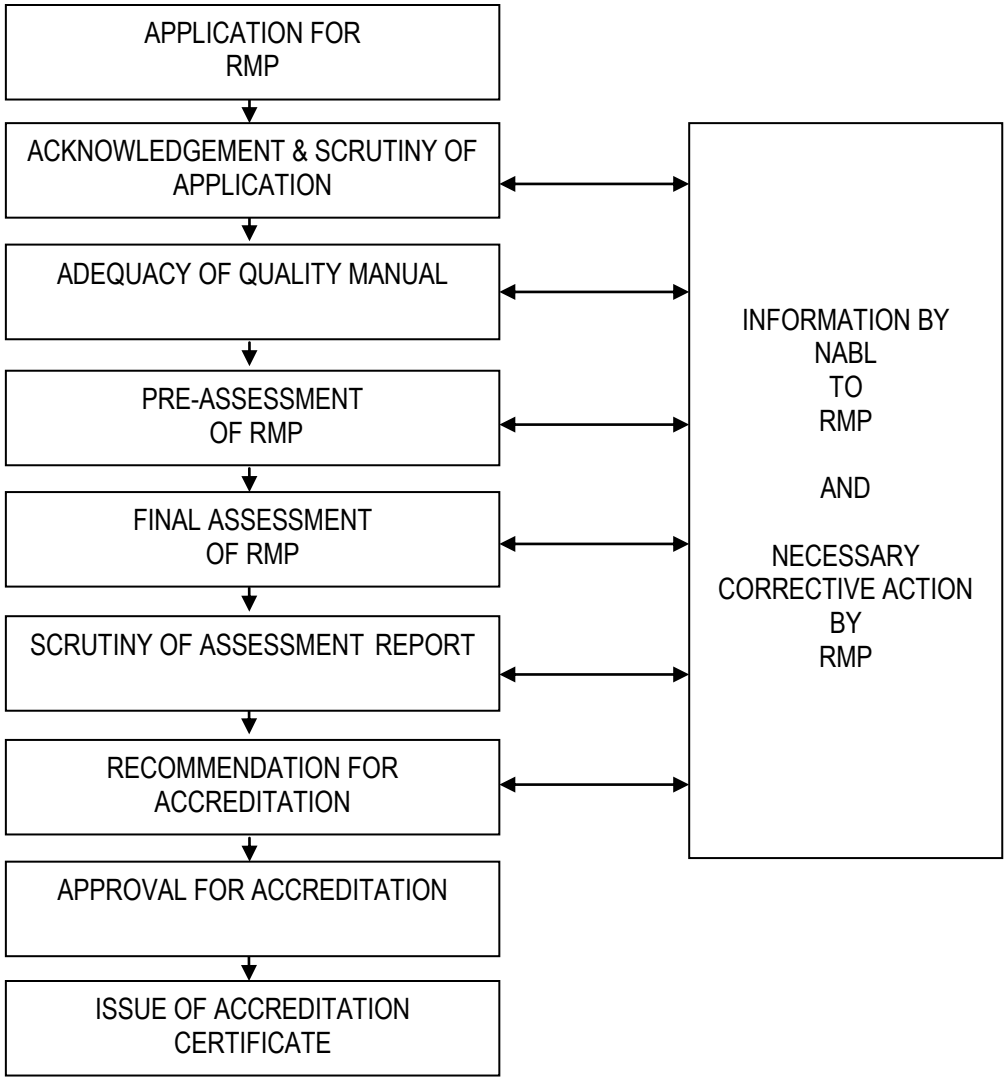
ANNEXURE I

SAMPLE SCOPE

Sl No	Type of RM / CRM Category , Subcategory	Reference Material Sub-subcategory	Properties to be certified (Analyte/ Parameter etc)	Range of property	Assigned value, uncertainty and best reference value capability (as relevant)	Characterisation technique used	Activities being subcontracted (e.g. assessment of homogeneity, stability, characterization, testing, calibration, measurements etc. if any)
1	Category: Chemical Composition Subcategory : Metals	Ferrous (Steels)	Carbon	0.08% - 1.10%	Assigned value-0.09% (MU-0.0001%) (best reference value capability – 0.0001%)	Inter-laboratory comparison	Testing activity subcontracted to M/s ABC laboratory
2	Category: Biological and Clinical Properties Subcategory : Bacteriology & Mycology	Reference cultures	*E. Coli*	-	Qualitative	Primary method	Sub-contracting not done

ANNEXURE II

RMP Accreditation Procedure



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