

NABL 220C



National Accreditation Board for Testing and Calibration Laboratories (NABL)

Document Review Checklist (as per ISO 17034: 2016)

ISSUE NO.: 01
ISSUE DATE: 11-Feb-2021

AMENDMENT NO.: --
AMENDMENT DATE: --

Document Review Checklist (as per ISO 17034: 2016)

Lead assessor is required to review the information provided by the Reference Material Producers (RMP) in line with NABL policies relevant to applicant RMP. This document review checklist is for providing remarks / comments on the overall completeness of the information on the application forms and the quality manual / management system document in conformance with the requirements of ISO 17034: 2016.

Lead assessor is required to submit the Document Review Report (DRR) directly to NABL within 10 days along with duly filled Form-74 'Declaration of Impartiality and Confidentiality'.

Annexure- Form-74 'Declaration of Impartiality and Confidentiality'

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(Remarks / Comments of Lead Assessor on Application form &
Quality Manual / Management System Document)

Name and Address of the RMP	
Name of Lead Assessor (with Assessor ID)	
Date of Document Review	

Part 'A' - Comments on Completeness of Application (NABL 190)

S. No.	Requirements as per Application form	Adequate/ Inadequate (if inadequate, mention comments)
1.	Name and location details of the RMP	
2.	Legal identity	
3.	Details on other accreditations	
4.	Information on Reference Materials	
5.	Scope of the RMP	
6.	Required details of senior management	
7.	Proposed personnel to report, review and authorize the RM documents	
8.	Organization chart of the RMP	
9.	Details of staff	
10.	Details of Subcontractors	
11.	List of equipment/ Reference materials/ reference standards	
12.	Internal audit	
13.	Management Review	
14.	Any general points	

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Part 'B' - Remarks on Quality Manual/ Management System Document

The Assessor must review the laboratory's documented management system to verify compliance with the requirements of ISO 17034: 2016 and it can be assessed further to verify that the documented management system is indeed implemented as described, record conclusion/ comments related to any requirements. All non-conformity (ies) must be identified and reported.

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			DOCUMENTATION	
REQUIREMENTS OF ISO 17034:2016				REMARK
4	General requirements			
	4.1	Contractual matters		
	4.1.1	Any request, tender or contract concerning the production of an RM shall be reviewed, following documented policies and procedures established by the RMP, to ensure that: a) the requirements for RMs and their production are adequately defined, documented and understood; b) the RMP has the capability and resources to meet the requirements. NOTE 1 - Capability means that the RMP has access to, for example, the necessary equipment, knowledge and information resources and that its personnel have the skills and expertise necessary for the production of those RMs in question. The review of capability can include an assessment of previous RM production and/or the organization of interlaboratory characterization programmes using samples of similar composition to the RMs to be produced. NOTE 2 - A contract can be any written or verbal agreement. NOTE 3 - A request to prepare a specific RM can originate from the RMP.		
	4.1.2	The review shall include any work that needs to be subcontracted by the RMP.		
	4.1.3	The RMP shall maintain records of these reviews, including any changes, records of pertinent discussions with the customer relating to the customer's requirements, and subcontracted work.		
	4.2	Impartiality		
	4.2.1	The RMP shall be structured and managed so as to safeguard impartiality. NOTE - Impartiality implies that decisions are based on objective criteria and not on the basis of bias, prejudice, or preferring the benefit of one person over another for improper reasons.		
	4.2.2	The RMP shall: a) have arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work; b) identify risks to its impartiality on an on-going basis, which shall include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel; however, such relationships do not necessarily present an RMP with a risk to impartiality; c) be able to demonstrate, if a risk to impartiality is identified, how it eliminates or minimizes such risk; d) have top management commitment to impartiality. NOTE - A relationship that threatens the impartiality of the RMP can be based on ownership, governance, management, personnel, shared resources, finances or contracts for purposes other than the sale or production of RMs.		

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			DOCUMENTATION	
REQUIREMENTS OF ISO 17034:2016				REMARK
	4.3	Confidentiality		
	4.3.1	The RMP shall be responsible for and shall treat in an appropriate manner all information obtained, including confidential information. Where information is received from another individual or body, such information shall be regarded as confidential unless the individual or body concerned places the information in the public domain or agrees to its disclosure to others.		
	4.3.2	When the RMP is required by law or authorized by contractual arrangements to release confidential information, the individual or the body concerned shall, unless prohibited by law, be notified of the information provided.		
5	Structural requirements			
	5.1	The RMP shall be a legal entity, or a defined part of a legal entity, that can be held responsible for all its activities related to the production of RMs.		
	5.2	The RMP shall be organized and shall operate in such a way that it meets all the applicable requirements of this International Standard, whether carrying out work at its permanent facilities or at other sites (including associated temporary or mobile facilities).		
	5.3	The RMP shall: a) have a description of its legal status, define the organizational and management structure of the RMP, its place in any parent organization and the relations between management, technical operations, support services and subcontractors; b) define the parts of the organization covered by the management system for the production of RMs; c) specify the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of RMs produced; d) have managerial personnel, supported by technical personnel, with the authority and resources needed to discharge their duties and to identify the occurrence of departures from the management system or the procedures for the production of RMs and to initiate actions to prevent or minimize such departures; e) have technical management with overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of each operation which forms part of the RM production; f) appoint personnel (however named) who, irrespective of other duties and responsibilities, shall have defined responsibility and authority for ensuring that the requirements of this International Standard are implemented and followed at all times – these appointed personnel shall have direct access to the highest level of management at which decisions are taken on RM production policy or resources; g) have adequate provision (e.g. insurance or reserves) to cover liabilities arising from its activities.		
	5.4	The RMP management shall ensure that: a) internal and external communication mechanisms are established; b) communication takes place regarding the effectiveness of the management system; c) the importance of meeting customer and other requirements is communicated to the RMP personnel.		
6	Resource requirements			
	6.1	Personnel		

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					REMARK
	6.1.1	The RMP shall ensure that all personnel involved in RM production are supervised and competent and that they work in accordance with the RMP's management system.			
	6.1.2	Personnel, including subcontractors, personnel of external bodies, or other individuals acting on the RMP's behalf, shall comply with the policies and procedures for management of confidential information that are set by the RMP.			
	6.1.3	The RMP shall ensure the competence of all personnel, including technical management personnel, operating under its management system who undertake activities relating to the production of each particular type of RM. There shall be sufficient personnel having the necessary education, training, technical knowledge and experience for their assigned functions.			
	6.1.4	The RMP shall have procedures for identifying training needs and providing training of personnel. The training programme shall be relevant to the present and anticipated tasks of the RMP.			
	6.1.5	The RMP shall maintain records of job descriptions for its personnel involved in RM production activities.			
	6.1.6	The RMP shall authorize competent personnel to perform particular activities relating to RM production. The RMP shall maintain records of the authorizations, competence, educational and professional qualifications of those personnel. These records shall provide evidence that individuals have been adequately trained and that their competence to perform particular activities in the RM production has been assessed. This information shall be readily available and shall include the date on which the authorization and/or competence has been confirmed.			
	6.2	Subcontracting			
	6.2.1	Where an RMP uses subcontractors to undertake part of the production, including sampling, processing, handling, homogeneity and stability testing, characterization, storage or distribution of an RM, the RMP shall have procedures to ensure that the subcontractors' experience and technical competence are sufficient for their assigned tasks and that they comply with the relevant clauses of this International Standard and other appropriate standards. NOTE 1 - It is possible that an RMP does not have its own laboratory facilities or processing facilities, or it can choose not to use its own facilities. NOTE 2 - Subcontractors can be paid or unpaid.			
	6.2.2	The RMP shall select subcontractors on the basis of their ability to meet the requirements stipulated by the RMP.			
	6.2.3	RMPs shall not subcontract the following processes: — the production planning; — the selection of subcontractors; — the assignment of property values and their uncertainties; — the authorization of property values and their uncertainties; — the authorization of RM documents.			
	6.2.4	The RMP shall establish and maintain procedures to assess that all tasks performed by subcontractors comply with the requirements set by the RMP and with any relevant clauses of this			

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REQUIREMENTS OF ISO 17034:2016				DOCUMENTATION	
					REMARK
			International Standard.		
	6.2.5	Evidence of the subcontractor's competence shall be established and maintained, including records of evaluations and any audits made of their capability to carry out contracted tasks. NOTE - Examples of evidence are assessments of tasks performed for the RMP in the past, evidence of successful participation in relevant proficiency testing, conformity assessment certificates relevant for the task contracted and acceptable results on well-characterized materials of similar or equivalent nature to that of the candidate RM.			
	6.2.6	Where the competence of subcontractors cannot be ascertained via provision of documentary evidence, the RMP shall evaluate the competence of the subcontractor or supervise the operations carried out by the subcontractor.			
	6.2.7	The RMP shall ensure that results and the descriptions of procedures used by subcontractors are available to allow the technical evaluation of data.			
	6.2.8	When working with subcontractors, the RMP shall have personnel operating under its management system having sufficient knowledge of the subcontractor's task to evaluate the subcontractor's activity. NOTE - For testing activities, this includes knowledge of the task involved and familiarity with this International Standard and ISO/IEC 17025 for calibration and testing.			
6.3	Provision of equipment, services and supplies				
	6.3.1	The RMP shall have procedures in place for the selection of equipment, services and supplies that affect the quality of the RMs produced.			
	6.3.2	The RMP shall use only equipment, services and supplies that comply with specified requirements to ensure the quality of the RMs it produces.			
	6.3.3	The RMP shall ensure that equipment and consumable materials are not used until they have been inspected, calibrated or otherwise verified as complying with the specifications or requirements defined for the RM production activities.			
	6.3.4	The RMP shall maintain records of purchases of equipment, services and supplies, including records of the selection criteria used, confirmation of acceptance, and any commissioning data. NOTE - 6.3 applies to all equipment including material processing and measuring equipment. 7.7 includes more provisions on operation of measuring equipment.			
6.4	Facilities and environmental conditions				
	6.4.1	The RMP shall ensure that all laboratory facilities, calibration and testing areas (if applicable), material handling, storage, processing and packaging areas, energy sources, lighting, humidity, temperature, pressure and ventilation are such as to facilitate proper material handling, storage, processing and packaging, as well as proper performance of calibration and testing activities (if applicable).			
	6.4.2	When the environmental conditions could have an adverse effect on the RM, the environmental conditions in which the RM production activities are undertaken shall be monitored with appropriately calibrated equipment, and			

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