

NABL 220B



National Accreditation Board for Testing and Calibration Laboratories (NABL)

Document Review Checklist (as per ISO/IEC 17043: 2010)

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

AMENDMENT NO.: --
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Document Review Checklist (as per ISO/IEC 17043: 2010)

Lead assessor is required to review the information provided by the Proficiency Testing Provider (PTP) in line with NABL policies relevant to applicant PTP. 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/IEC 17043: 2010.

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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Document Review Checklist (as per ISO/IEC 17043:2010)

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

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

Part 'A' - Comments on Completeness of Application (NABL 180)

S. No.	Requirements as per Application form	Adequate/ Inadequate (if inadequate, mention comments)
1.	Name and location details of the PTP	
2.	Legal identity	
3.	Details on other accreditations	
4.	Information on PT Schemes	
5.	Scope of the PTP	
6.	Required details of senior management	
7.	Proposed personnel to give opinions and interpretations; and authorize the issue of proficiency testing reports	
8.	Organization chart of the PTP	
9.	Details of staff	
10.	Details of Steering/ Advisory committee	
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/IEC 17043: 2010 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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4 TECHNICAL REQUIREMENTS			
4.1	GENERAL		
	The development and operation of proficiency testing schemes shall be undertaken by proficiency testing providers having competence to conduct inter-laboratory comparisons and access to expertise with the particular type of proficiency test items. Proficiency testing providers or their subcontractors shall also have competence in the measurement of the properties being determined. <i>NOTE ISO/IEC 17025 or ISO 15189 can be used to demonstrate the competence of a proficiency testing provider's laboratory, or the laboratory subcontracted to perform tests or measurements related to the proficiency testing schemes. ISO Guide 34 can be used to demonstrate the competence of producers of reference materials that provide proficiency test items.</i>		
4.2	PERSONNEL		
4.2.1	The proficiency testing provider shall have managerial and technical personnel with the necessary authority, resources and technical competence required to perform their duties.		
4.2.2	The proficiency testing provider's management shall define the minimum levels of qualification and experience necessary for the key positions within its organization and ensure those qualifications are met.		
4.2.3	The proficiency testing provider shall use personnel who are either employed by, or under contract to it. Where contracted and additional technical and key support personnel are used, the proficiency testing provider shall ensure that such personnel are supervised and competent and that they work in accordance with the management system. <i>NOTE Where technical experts are used on an ad-hoc basis or as part of an advisory or steering group (see 4.4.1.4), the existence of formal agreements through, for example, group terms of reference or other means, can be considered to satisfy this requirement.</i>		
4.2.4	The proficiency testing provider shall authorize specific personnel to:		
	a) select appropriate proficiency test items;		
	b) plan proficiency testing schemes;		
	c) perform particular types of sampling;		
	d) operate specific equipment;		

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		e)	conduct measurements to determine stability and homogeneity, as well as assigned values and associated uncertainties of the measurands of the proficiency test item;			
		f)	prepare, handle and distribute proficiency test items;			
		g)	operate the data processing system;			
		h)	conduct statistical analysis;			
		i)	evaluate the performance of proficiency testing participants;			
		j)	give opinions and interpretations; and			
		k)	authorize the issue of proficiency testing reports.			
	4.2.5	The proficiency testing provider shall maintain up-to-date records of the relevant authorization(s), competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel. This information shall be readily available and shall include the date on which competence to perform their assigned tasks was assessed and confirmed.				
	4.2.6	The proficiency testing provider shall formulate the objectives with respect to the education, training, and skills for each staff member involved with the operation of the proficiency testing scheme. The proficiency testing provider shall have a policy and procedures for identifying training needs and providing training of personnel. The training programme shall be relevant to the present and anticipated needs of the proficiency testing provider. <i>NOTE It is advisable to consider the need to retrain staff periodically. Staff training policies can take account of technological change, the need to demonstrate ongoing competence and aim at continual skills upgrading.</i>				
	4.2.7	The proficiency testing provider shall ensure that staff receives the necessary training to ensure competent performance of measurements, operation of equipment and any other activities which affect the quality of the proficiency testing scheme. The effectiveness of training activities shall be evaluated. <i>NOTE Objective measures can be used to assess the attainment of competence.</i>				
4.3 EQUIPMENT, ACCOMODATION AND ENVIRONMENT						
	4.3.1	The proficiency testing provider shall ensure that there is appropriate accommodation for the operation of the proficiency testing scheme. This includes facilities and equipment for proficiency test item manufacturing, handling, calibration, testing, storage and despatch, for data processing, for communications, and for retrieval of materials and records.				

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	4.3.2	The proficiency testing provider shall ensure that the environmental conditions do not compromise the proficiency testing scheme or the required quality of operations. Particular care shall be taken when operations are undertaken at sites away from the proficiency testing provider's permanent facilities or are undertaken by subcontractors. The technical requirements for accommodation and environmental conditions that can affect the proficiency testing shall be documented.		
	4.3.3	Access to and use of areas affecting the quality of proficiency testing schemes shall be controlled. The proficiency testing provider shall determine the extent of control based on its particular circumstances.		
	4.3.4	The proficiency testing provider shall identify environmental conditions that can significantly influence the quality of the proficiency test items and any testing and calibration carried out, including conditions that are required by relevant specifications and measurement procedures. The proficiency testing provider shall control and monitor these conditions, and shall record all relevant monitoring activities. Relevant proficiency testing activities shall be stopped when the environmental conditions jeopardize the quality or the operations of the proficiency testing scheme. <i>NOTE Conditions can include, for example, biological sterility, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, and sound and vibrations levels, as appropriate to the technical activities concerned.</i>		
	4.3.5	There shall be effective separation between neighbouring areas in which there are incompatible activities. Action shall be taken to prevent cross-contamination.		
	4.3.6	Proficiency testing providers shall ensure that performance characteristics of laboratory methods and equipment used to confirm the content, homogeneity and stability of proficiency testing items are appropriately validated and maintained.		
4.4	DESIGN OF PROFICIENCY TESTING SCHEMES			
	4.4.1	Planning		
	4.4.1.1	The proficiency testing provider shall identify and plan those processes which directly affect the quality of the proficiency testing scheme and shall ensure that they are carried out in accordance with prescribed procedures. <i>NOTE Stakeholders' interests can be considered in developing a plan and relevant information.</i>		
	4.4.1.2	The proficiency testing provider shall not subcontract the planning of the proficiency testing scheme (see 5.5.2). <i>NOTE The proficiency testing provider can utilize advice or assistance from any advisors, experts or steering group (see 4.4.1.4).</i>		

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		4.4.1.3	The proficiency testing provider shall document a plan before commencement of the proficiency testing scheme that addresses the objectives, purpose and basic design of the proficiency testing scheme, including the following information and, where appropriate, reasons for its selection or exclusion:		
		a)	the name and address of the proficiency testing provider;		
		b)	the name, address and affiliation of the coordinator and other personnel involved in the design and operation of the proficiency testing scheme;		
		c)	the activities to be subcontracted and the names and addresses of subcontractors involved in the operation of the proficiency testing scheme;		
		d)	criteria to be met for participation;		
		e)	the number and type of expected participants in the proficiency testing scheme;		
		f)	selection of the measurand(s) or characteristic(s) of interest, including information on what the participants are to identify, measure, or test for in the specific proficiency testing round;		
		g)	a description of the range of values or characteristics, or both, to be expected for the proficiency test items;		
		h)	the potential major sources of errors involved in the area of proficiency testing offered;		
		i)	requirements for the production, quality control, storage and distribution of proficiency test items;		
		j)	reasonable precautions to prevent collusion between participants or falsification of results, and procedures to be employed if collusion or falsification of results is suspected;		
		k)	a description of the information which is to be supplied to participants and the time schedule for the various phases of the proficiency testing scheme;		
		l)	for continuous proficiency testing schemes, the frequency or dates upon which proficiency test items are to be distributed to participants, the deadlines for the return of results by participants and, where appropriate, the dates on which testing or measurement is to be carried out by participants;		
		m)	any information on methods or procedures which participants need to use to prepare the test material and perform the tests or measurements;		
		n)	procedures for the test or measurement methods to be used for the homogeneity and stability testing of proficiency test items and, where applicable, to determine their biological viability;		
		o)	preparation of any standardized reporting formats to be used by participants;		

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			p)	a detailed description of the statistical analysis to be used;		
			q)	the origin, metrological traceability and measurement uncertainty of any assigned values;		
			r)	criteria for the evaluation of performance of participants;		
			s)	a description of the data, interim reports or information to be returned to participants;		
			t)	a description of the extent to which participant results, and the conclusions that will be based on the outcome of the proficiency testing scheme, are to be made public; and		
			u)	actions to be taken in the case of lost or damaged proficiency test items.		
		4.4.1.4	The proficiency testing provider shall have access to the necessary technical expertise and experience in the relevant field of testing, calibration, sampling or inspection, as well as statistics. This may be achieved, if necessary, by establishing an advisory group (named as appropriate).			
		4.4.1.5	Technical expertise shall be used, as appropriate, to determine matters such as the following:			
			a)	planning requirements as listed in 4.4.1.3;		
			b)	identification and resolution of any difficulties expected in the preparation and maintenance of homogeneous proficiency test items, or in the provision of a stable assigned value for a proficiency test item;		
			c)	preparation of detailed instructions for participants;		
			d)	comments on any technical difficulties or other remarks raised by participants in previous proficiency testing rounds;		
			e)	provision of advice in evaluating the performance of participants;		
			f)	comments on the results and performance of participants as a whole and, where appropriate, groups of participants or individual participants;		
			g)	provision of advice for participants (within limits of confidentiality), either individually or within the report;		
			h)	responding to feedback from participants; and		
			i)	planning or participating in technical meetings with participants.		

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	4.4.2	Preparation of proficiency test items			
	4.4.2.1	The proficiency testing provider shall establish and implement procedures to ensure that proficiency test items are prepared in accordance with the plan described in 4.4.1. <i>NOTE It is advisable that the proficiency testing provider give due consideration to the preparation of sufficient numbers of proficiency test items, in order to allow for the need to replace any such proficiency test items lost or damaged during distribution, or intended to be provided for use after the results of the proficiency testing scheme have been evaluated. Such uses can include training aids for participants or use as a reference material.</i>			
	4.4.2.2	The proficiency testing provider shall establish and implement procedures to ensure appropriate acquisition, collection, preparation, handling, storage and, where required, disposal of all proficiency test items. The procedures shall ensure that materials used to manufacture proficiency test items are obtained in accordance with relevant regulatory and ethical requirements.			
	4.4.2.3	Proficiency test items shall match in terms of matrix, measurands and concentrations, as closely as practicable, the type of items or materials encountered in routine testing or calibration.			
	4.4.2.4	In proficiency testing schemes that require participants to prepare or manipulate, or both prepare and manipulate, the proficiency test item and submit it to the proficiency testing provider, the proficiency testing provider shall issue instructions for preparation, packaging and transport of the proficiency test item.			
	4.4.3	Homogeneity and stability			
	4.4.3.1	Criteria for suitable homogeneity and stability shall be established and shall be based on the effect that inhomogeneity and instability will have on the evaluation of the participants' performance. <i>NOTE 1 The requirements in this subclause are intended to ensure that every participant receives comparable proficiency test items, and that these proficiency test items remain stable throughout the proficiency testing. Careful planning, manufacture and shipping are necessary to achieve this, and testing is usually needed to confirm it.</i>			

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