



National Accreditation Board for Testing and Calibration Laboratories (NABL)

Assessment Forms and Checklist (based on ISO/IEC 17043: 2023)

ISSUE NO.: 01
ISSUE DATE: 16-Oct-2023

AMENDMENT NO.: 01
AMENDMENT DATE: 15-Nov-2023

AMENDMENT SHEET

S. No.	Amendment No.	Page No.	Clause No.	Date of Amendment	Amendment	Reasons	Signature QA Team	Signature Competent Authority
1.	01	33	8.4	15.11.2023	As highlighted	Internal review	-Sd/-	-Sd/-
2.								
3.								
4.								
5.								
6.								
7.								
8.								
9.								
10.								

CONTENTS

S. No.	Title	Page No.
	Amendment sheet	1
	Contents	2
1.	NAF (PT) 1 - Assessment Schedule	3
2.	NAF (PT) 1A - Attendance Sheet (Opening / Closing Meeting)	4
3.	NAF 2 - Assessor's Observation	5
4.	NAF (PT) 3 - PT Schemes Verified by the Assessment Team	6
5.	NAF (PT) 4 - Summary on Non-Conformities	7
6.	NAF (PT) 6 - Summary of the Assessment	8
7.	Form (PT) 72 - Recommended Scope of Accreditation	9
8.	Form 74 - Declaration of Impartiality & Confidentiality	10
9.	Assessor Checklist 1 – By Lead Assessor	11
10.	Assessor Checklist 1 – By Technical Assessor/Expert	37

ASSESSMENT SCHEDULE

Name of the PT Provider:		Address:	
Person responsible for Proficiency Testing Activities (PT Co-ordinator):			
Date of Assessment:		Site (s): PT provider / Subcontractor	
Type of Assessment: Initial Assessment / Onsite Surveillance / Re-Assessment / Supplementary Visit			
Discipline: Testing/ Calibration/ Medical/ Inspection		Sub-discipline:	
Assessment Standard: ISO / IEC 17043: 2023 Specific Criteria of NABL: NABL 181			
Assessment Timings		Opening/Closing Meeting Date/Time	Daily Debriefing Date / Time
Morning: AM to PM Afternoon: PM to PM		Opening Meeting: Closing Meeting:	(at the end of each day) Day 1: Day 2:
Name and Expertise of the Assessor	Schedule of Department/ Section/ Activity to be Assessed (date wise)		
	Day 1		Day 2
	Morning	Afternoon	Morning
Lead Assessor			
Technical Assessor 1			
Technical Assessor 2			
Technical Assessor 3			
Technical Assessor 4			
Technical Assessor 5			
Technical Assessor 6			
Technical Assessor 7			
Observer (only for observation)			
I declare that the assessment schedule has been prepared after discussing with the assessment team members.			
Signature of Lead Assessor			

National Accreditation Board for Testing and Calibration Laboratories					Documents
Doc. No.: NABL 183(A)		Assessment Forms and Checklist (Based on ISO/IEC 17043: 2023)			Document Sharing Hub
Issue No.: 01	Issue Date: 16-Oct-2023	Amend. No.: 01	Amend. Date: 15-Nov-2023	Page 4 of 56	

National Accreditation Board for Testing and Calibration Laboratories					Documents
Doc. No.: NABL 183(A)	Assessment Forms and Checklist (Based on ISO/IEC 17043: 2023)			Document Sharing H	
Issue No.: 01	Issue Date: 16-Oct-2023	Amend. No.: 01	Amend. Date: 15-Nov-2023	Page 5 of 56	

PT SCHEME(S) VERIFIED BY THE ASSESSMENT TEAM
(To be filled in by each Technical Assessor/Expert)

[illegible]

ASSESSOR'S SUMMARY ON NON-CONFORMITY

(Please use separate sheet for raising each Non-Conformity)

Name of the PT Provider:			
Name of the Assessor			
Date of Assessment:	PT Scheme:	Activity Assessed:	
NC No.			
Non-Conformity Statement:			
Cl. No. of ISO 17043: 2023 & NABL 133 Cl. No. / NABL Specific criteria:			
Signature & Name of PT provider Representative		Signature & Name of Assessor	
CORRECTION PROPOSED BY THE PTP			
Signature of PT Provider Representative			
ASSESSOR'S COMMENTS ON CORRECTION PROPOSED BY THE LABORATORY:			
(PTP to provide corrective action and root cause analysis along with the evidences of corrective actions)			
Signature of Assessor			
LEAD ASSESSOR'S REMARKS ON NON-CONFORMITY, IF ANY:			
Signature & Name of Lead Assessor			

SUMMARY OF THE ASSESSMENT

Sl.	Item	Details												
1.	Name of the PT Provider													
2.	Person responsible for Proficiency Testing Activities (PT Co-ordinator):													
3.	Date of Assessment							Field:	PTP					
4.	Discipline(s)	Testing/Calibration/Medical/Inspection												
5.	Facility	Permanent/ Site/ Mobile												
6.	Type of Assessment	Initial Assessment/ Onsite Surveillance/ Re-assessment / Supplementary visit												
7.	Assessment Team Capacity													
8.	Date of earlier visit	Non-Conformities during earlier visit have/ have not been discharged. (Yes or No)												
9.	Total no. of non-conformities							Number of NC(s)						
		Clause 4												
		Clause 5												
		Clause 6												
		Clause 7												
		Clause 8												
		Total												
10.	Comment(s) of Assessment Team on compliance of laboratory to:													
	NABL 133*													
	NABL 142*													
	Specific Criteria*													
	*(Lead Assessor to comment on the basis of observations of Technical Assessor(s))													
11.	Assessment Summary													
12.	Recommendation of Assessment team as per ISO 17043: 2023													
13.	Only if accreditation is recommended, date by which the Corrective Action to be submitted by the PTP for the above Non-conformities (Max. 30 days):													
14.	The requirements of NABL 133 have been explained by the Lead Assessor and understood by the PTP													
Enclosures	NAF 6	NAF 5	NAF 4	NAF 3	NAF 2	NAF 1	Check list	Form 72	Form 74	Form 45	TA/DA Forms	Any other supporting documents/ records		
Page Nos.														
Acknowledgement by Authorised Representative of PT Provider & Date								Signature of Lead Assessor& Date						

RECOMMENDED SCOPE OF ACCREDITATION

Name of the PT Provider:					Date of Assessment	
Discipline:		Sub-disciplines:		Location:		
S. No.	Type of PT Scheme*	Proficiency Testing Scheme/ Type of PT Item/ Matrix	Measurand/ Characteristic/ Type of measurand/ Type of characteristic/ Analyte/ Parameter	Range of Measurement (if applicable)	Periodicity (Minimum)	Assessment Technique used by Assessor(s) (Witness / Document review / Interviewing / File Review (Record Review))
Signature & Name of authorized Representative of PT provider		Signature & Name of Assessor(s)		Signature & Name of Lead Assessor		

DECLARATION OF IMPARTIALITY & CONFIDENTIALITY
(to be filled in by each Assessor and enclosed with the Assessment report)

Name		Assessor ID: (To be filled in by NABL Sect.)
Designation		
Organisation		
Address		
Capacity	Lead Assessor / Technical Assessor / Technical Expert / Observer	
CAB* Assessed		
Date of Assessment		
Type of Assessment	QM Adequacy / Pre-Assessment / Initial assessment / Onsite Surveillance / Re-Assessment / Supplementary visit	

*CAB – Conformity Assessment Body (Testing / Medical / Calibration laboratory / Proficiency Testing Provider (PTP) / Reference Material Producer (RMP))

I _____, hereby declare that I have not offered any consultancy, guidance, supervision or other services to the CAB (e.g. internal audit), in any way.

I am / am not* an ex-employee of the CAB and am/ am not* related to any person of the management of the CAB.

I got an opportunity to go through various documents like Quality Manual, Procedural Manuals, Work instructions, Internal reports etc. of the above CAB and other related information that might have been given by NABL. I undertake to maintain strict confidentiality of the information acquired in course of discharge of my responsibility and shall not disclose to any person other than that required by NABL.

*Strike out which is not applicable

Date:

Place:

Signature

ASSESSOR CHECKLIST 1 – BY LEAD ASSESSOR

(To be filled in by the Lead Assessor)

Checklist 1 – By Lead Assessor

The following pages present a checklist of the criteria from ISO/IEC 17043: 2023, which is the basis for the NABL General requirements for proficiency testing. The PT provider's policies and procedures must meet full requirements of ISO/IEC 17043: 2023. **The actual standard must be referred for the definitive language and interpretation.**

#The Assessment team must complete this checklist, put initials on each page. The following symbols may be used for completing this checklist.

++ COMPLIANCE
+ COMPLIANCE WITH REMARK
NA NOT APPLICABLE
BLANK NOT ASSESSED

The Lead Assessor / Assessor(s) must review the PT provider's documented system and verify compliance with the requirements of ISO/IEC 17043:2023 is indeed implemented as described, record in OBSERVATION/CONCLUSION related to any requirements on the space provided or use the bottom of the page or use separate sheet(s). All non-conformity (ies) must be identified and reported separately on each sheet of NAF-4. This checklist be submitted as a part of the assessment report.

PT PROVIDER ASSESSED	
CITY/TOWN	
ASSESSMENT DATE (S)	
NAME OF THE ASSESSOR / CAPACITY IN THE TEAM	
SIGNATURE	

#-Applicable for Offline Assessments

Assessor shall enter comment in "REMARK" box for each sub clause.

REQUIREMENTS OF ISO/IEC 17043: 2023		DOCUMENTATION		
		IMPLEMENTATION		REMARK
4 GENERAL REQUIREMENTS				
4.1 IMPARTIALITY				
4.1.1	PT activities shall be undertaken impartially.			
4.1.2	The PT provider shall be structured and managed so as to safeguard impartiality.			
4.1.3	The PT provider shall be responsible for the impartiality of its PT activities and shall not allow commercial, financial or other pressures to compromise its impartiality.			
4.1.4	The PT provider shall monitor its activities and its relationships to identify threats to its impartiality. This monitoring shall include the relationships of its personnel. <i>NOTE A relationship can be based on ownership, governance, management, personnel, shared resources, finances, contracts or marketing (including branding). Such relationships do not necessarily present a PT provider with a threat to impartiality.</i>			
4.1.5	If a threat to impartiality is identified, its effect shall be eliminated or minimized so that the impartiality is not compromised.			
4.1.6	The PT provider shall have top management commitment to impartiality.			
4.2 CONFIDENTIALITY				
4.2.1	The PT provider shall be responsible, through legally enforceable agreements, for the management of all information obtained or created during the performance of PT activities. The PT provider shall inform the client in advance of the information it intends to place in the public domain. Apart from information that the client makes publicly available, or when agreed between the PT provider and the client, all other information is considered proprietary information and shall be regarded as confidential. <i>NOTE The terms “proprietary” and “confidential” do not preclude publication for academic and new insights of information purposes, provided that neither clients nor participants can be identified, including by inference.</i>			
4.2.2	When the PT provider is required by law or authorized by contractual arrangements to release confidential information, the client concerned shall be notified of the information released, unless prohibited by law.			
4.2.3	Information about the participant or customer from a source other than the participant or customer (e.g. complainant or regulator) shall be kept confidential by the PT provider. The identity of the source shall be kept confidential by the PT provider and shall not be shared with the participant or the customer, unless agreed by the source.			
4.2.4	Personnel, including any committee members, contractors, personnel of external bodies, or persons acting on the PT provider’s behalf, shall keep confidential all information obtained or created during the performance of the PT activities.			
4.2.5	The identity of participants in a PT scheme shall be confidential and known only to persons involved in the operation of the PT scheme, unless the participant or the customer waives confidentiality.			
5 STRUCTURAL REQUIREMENT				
5.1	The PT provider shall be a legal entity, or a defined part of a legal entity, that is legally responsible for its PT activities. <i>NOTE For the purposes of this document, a governmental PT provider is deemed to be a legal entity on the basis of its governmental status.</i>			
5.2	The PT provider shall identify management that has overall responsibility for the PT activities.			

REQUIREMENTS OF ISO/IEC 17043: 2023			DOCUMENTATION		
			IMPLEMENTATION		
					REMARK
5.3	The PT provider shall define and document the PT schemes for which it conforms with this document. The PT provider shall only claim conformity with this document for those PT schemes.				
5.4	The PT provider shall carry out PT activities in such a way so as to meet the requirements of this document and address the requirements of participants, customers, regulatory authorities, and organizations providing recognition. These requirements apply to all PT activities performed in its permanent facilities and any other facility or site.				
5.5	The PT provider shall:				
	a	define its organization and management structure, its place in any parent organization and the relationships between the management, technical operations and support services;			
	b	specify the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the results of its PT activities;			
	c	document its procedures to the extent necessary to ensure the consistent application and validity of its PT activities.			
5.6	The PT provider shall have personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including:				
	a	implementation, maintenance and improvement of the management system;			
	b	identification of deviations from the management system or from the procedures while performing the PT activities;			
	c	initiation of actions to prevent or minimize such deviations;			
	d	reporting to its management on the performance of the management system and any need for improvement;			
	e	ensuring the effectiveness of the PT activities.			
5.7	The PT provider management shall ensure that:				
	a	communication takes place regarding the effectiveness of the management system and the importance of meeting the requirements of participants, customers, regulatory authorities, and organizations providing recognition;			
	b	the integrity of the management system is maintained when changes to the management system are planned and implemented.			

REQUIREMENTS OF ISO/IEC 17043: 2023		DOCUMENTATION			
		IMPLEMENTATION			
		OBSERVATIONS/CONCLUSION			
6	RESOURCE REQUIREMENTS				
	6.1 GENERAL				
	6.1.1	The PT provider shall have access to the personnel, facilities, equipment, systems and support services necessary to manage and perform its PT activities.			
	6.1.2	Measurements or tests conducted under the responsibility of the PT provider, related to PT item characterization or for assessing homogeneity and stability, shall be conducted in accordance with the relevant requirements of ISO/IEC 17025. <i>NOTE 1 The relevant requirements are requirements that relate to the validity of the measurement or test results, which can impact the validity of PT activities (e.g. metrological traceability). They are not intended to include management system requirements or other requirements unrelated to the PT activities.</i> <i>NOTE 2 In the medical area, the relevant requirements of ISO 15189 apply in place of ISO/IEC 17025.</i>			
	6.1.3	Where the PT item is a material that meets the definition of "reference material", it shall be produced under conditions that meet the relevant requirements of ISO 17034. <i>NOTE 1 Such materials include reference materials for quality control (e.g. chemical solutions with or without reference values) and reference materials with certified property values (CRMs).</i> <i>NOTE 2 The relevant requirements are requirements that relate to the validity of operations to produce a reference material that directly impacts the PT activities (e.g. mixing, or handling and storage). They are not intended to include management system requirements or other requirements not directly related to the PT activities (e.g. contents of certificates).</i> <i>NOTE 3 In the medical area, the relevant requirements of ISO 15194 can apply for CRMs in place of ISO 17034, when applicable.</i>			
	6.2 PERSONNEL				
	6.2.1	The PT provider shall have access to a sufficient number of competent personnel to perform its PT activities.			
	6.2.2	The PT provider shall ensure that the personnel have the competence to:			
		a perform PT activities for which they are responsible; and			
		b evaluate the significance of deviations.			
	6.2.3	The PT provider shall have a process for managing competence of its personnel.			
	6.2.4	All personnel of the PT provider (either internal or external) that can influence the PT activities shall act impartially.			
	6.2.5	The PT provider shall have documented information demonstrating competence of its personnel, that can influence the results of its PT activities. Documented information shall include requirements for education, qualification, training, technical knowledge, skills and experience.			

REQUIREMENTS OF ISO/IEC 17043: 2023			DOCUMENTATION	
			IMPLEMENTATION	
			OBSERVATIONS/CONCLUSION	
	6.2.6	The PT provider shall, where appropriate, authorize personnel to perform specific activities within PT schemes, including but not limited to the following:		
	a	plan PT schemes;		
	b	assess data/information to determine stability and homogeneity, if applicable, as well as assigned values and associated uncertainties of the properties or characteristics of the PT item;		
	c	evaluate the performance of PT participants;		
	d	give opinions and interpretations as well as advice to the participants;		
	e	review and authorize PT reports.		
6.3 FACILITIES AND ENVIRONMENTAL CONDITIONS				
	6.3.1	To ensure the validity of the PT activities, the PT provider shall ensure that there are appropriate facilities for the operation of the PT scheme.		
	6.3.2	The PT provider shall ensure that the environmental conditions do not compromise the PT activities, including operations that are undertaken at sites away from the PT provider's permanent facilities or that are undertaken by external service providers.		
	6.3.3	The PT provider shall document environmental conditions that can influence the validity of the PT items and any measurements or tests carried out, including conditions that are required by relevant specifications and measurement or test methods. The PT provider shall control, monitor and periodically review these conditions and shall record all relevant monitoring activities. If environmental conditions compromise the validity of PT activities, the activities shall be halted (see 7.5.4). EXAMPLE Examples of such conditions include biological sterility, dust, electromagnetic disturbances, radiation, illumination (light), humidity, electrical supply, temperature, sound and vibration levels, as appropriate to the technical activities concerned.		
	6.3.4	Access control to, and use of, areas affecting the PT activities shall be managed. The PT provider shall determine the extent of access control based on its circumstances.		
	6.3.5	There shall be appropriate separation between neighbouring areas in which there are incompatible PT activities. Action shall be taken to prevent cross-contamination, interference or adverse influences on PT activities.		
6.4 EXTERNALLY PROVIDED PRODUCTS AND SERVICES				
	6.4.1	The PT provider shall not use external service providers for the following activities:		
	a	the design and planning of PT schemes;		
	b	the evaluation of performance;		
	c	the authorization of reports.		
		<i>NOTE This does not prevent the PT provider from using advice or assistance from any advisors, experts or steering groups.</i>		
	6.4.2	The PT provider shall have procedures to ensure that the experience and technical competence of the providers of external products and services are sufficient for their assigned tasks and that they comply with the relevant clauses of this document and other appropriate documents.		
	6.4.3	The PT provider shall inform participants and customers, in advance and in writing, of products and services that are or can be provided externally, when they affect the validity of the PT activities.		
	6.4.4	The PT provider shall have a procedure and retain records for:		

REQUIREMENTS OF ISO/IEC 17043: 2023				DOCUMENTATION				
				IMPLEMENTATION				
				OBSERVATIONS/CONCLUSION				
			a	defining, reviewing and approving the PT provider's requirements for externally provided products and services;				
			b	defining the criteria for selection of the external providers and for evaluating and monitoring their performance;				
			c	ensuring that externally provided products and services conform to the PT provider's established requirements and, when applicable, to the relevant requirements of this document, before they are used or directly provided to the customer or participant;				
			d	taking any actions arising from the performance monitoring and evaluation of the external providers.				
		6.4.5	The PT provider shall communicate its requirements to external providers for:					
				a	the products and services to be provided;			
				b	the acceptance criteria;			
				c	competence, including any required qualification of the organization or personnel involved;			
				d	PT activities that the PT provider or its customers intend to perform at the external provider's premises.			
		6.4.6	The PT provider shall be responsible to the participants or customers for the externally provided products and services. <i>NOTE In cases where the customer or a regulatory authority specifies which external provider is to be used, being responsible can be interpreted as taking actions to minimize any undesired effects that directly affect the validity of PT activities.</i>					

REQUIREMENTS OF ISO/IEC 17043: 2023			DOCUMENTATION			
			IMPLEMENTATION			
			OBSERVATIONS/CONCLUSION			
7	PROCESS REQUIREMENTS					
	7.1	ESTABLISHING, CONTRACTING AND COMMUNICATING THE PT SCHEME OBJECTIVES				
	7.1.1	7.1.1		Review of requests, tenders and contracts		
		7.1.1.1	The PT provider shall have a procedure for the review of requests, tenders and contracts. The procedure shall ensure that:			
			a	the objectives of the PT scheme are sufficiently defined and in agreement with the customers' needs;		
			b	the requirements are adequately defined, documented and understood;		
			c	the PT provider has the capability and resources necessary to meet the requirements;		
			d	the PT scheme is technically appropriate taking into account the needs of the given application or field of application.		
		NOTE 1 This review is particularly important when a customer requests a PT scheme to be created for a specific purpose or for a different level or frequency of participation from that normally offered.				
		NOTE 2 This review can be simplified when the PT scheme is fully described in a catalogue or other notice and the participant is enrolling for a routine PT round.				
		7.1.1.2	The review shall cover all aspects of the request, including any externally provided products and services.			
		7.1.1.3	Records of such reviews, including any significant changes, shall be retained. Records shall also be retained of pertinent discussions with a customer relating to their requirements, or the results of the PT activities.			
		7.1.1.4	The customer shall be informed of any deviation from the contract.			
		7.1.1.5	If a request or contract is amended after the PT scheme is underway, the contract review shall be repeated, and any amendments shall be communicated to all affected personnel.			
		7.1.2	7.1.2		PT scheme communication	
	7.1.2.1		The PT provider shall make detailed information available about the PT scheme to participants and customers. This information shall include:			
			a	objectives and relevant details of the PT scheme;		
			b	criteria to be met for participation;		
			c	criteria for determining the assigned value and the evaluation of performance;		
			d	confidentiality arrangements;		
e			critical timelines;			
f			any fees for participation;			
g	details of how to apply.					