

NABL 220D



National Accreditation Board for Testing and Calibration Laboratories (NABL)

Document Review Checklist (as per ISO 15189: 2022)

ISSUE NO.: 01
ISSUE DATE: 21-Jun-2023

AMENDMENT NO.: --
AMENDMENT DATE: --

AMENDMENT SHEET

S. No.	Amendment No.	Page No.	Clause No.	Date of Amendment	Amendment	Reasons	Signature QA Team	Signature Competent Authority
1.								
2.								
3.								
4.								
5.								
6.								
7.								
8.								
9.								
10.								

National Accreditation Board for Testing and Calibration Laboratories				
Doc. No.: NABL 220D	Document Review Checklist (as per ISO 15189: 2022)			
Issue No.: 01	Issue Date: 21-Jun-2023	Amend. No: --	Amend. Date: --	Page No.: 1 of 40

CONTENTS

Sl.	Title	Page No.
	Amendment Sheet	1
	Contents	2
1.	Document Review Checklist (as per ISO 15189: 2022)	3
2.	Form 74	40

National Accreditation Board for Testing and Calibration Laboratories				
Doc. No.: NABL 220D	Document Review Checklist (as per ISO 15189: 2022)			
Issue No.: 01	Issue Date: 21-Jun-2023	Amend. No: --	Amend. Date: --	Page No.: 2 of 40

Document Review Checklist (as per ISO 15189: 2022)

Lead assessor is required to review the information provided by the laboratory in line with NABL policies relevant to applicant medical testing laboratories. This document review checklist is for providing remarks / comments on the overall completeness of the information on the application forms and the management system document in conformance with the requirements of ISO 15189: 2022.

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'

National Accreditation Board for Testing and Calibration Laboratories				
Doc. No.: NABL 220D	Document Review Checklist (as per ISO 15189: 2022)			
Issue No.: 01	Issue Date: 21-Jun-2023	Amend. No: --	Amend. Date: --	Page 01 of 10

Document Review Checklist (as per ISO 15189:2022)

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

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

Part 'A' - Comments on Completeness of Application (NABL 153)

S. No.	Requirements as per Application form	Adequate/ Inadequate (if inadequate, mention comments)
1.	Name and address of the laboratory	
2.	Legal identity	
3.	Type of CAB	
4.	Other sources of sample collection	
5.	Details on other accreditations	
6.	Information on disciplines applied	
7.	Scope of the CAB	
8.	Required details of senior management	
9.	Proposed personnel to review, release, and reporting of results	
10.	Organization chart of the Laboratory	
11.	Details of staff	
12.	List of equipment/ Reference materials/ reference standards	
13.	Internal audit	
14.	Management Review	
15.	PT/ ILC	
16.	Any general points	

Part 'B' - Remarks on Management System Document

The Assessor must review the laboratory's documented management system to verify compliance with the requirements of ISO 15189: 2022 and record conclusion/ comments related to any requirements. All non-conformity (ies) must be identified and reported.

National Accreditation Board for Testing and Calibration Laboratories			
Doc. No.: NABL 220D	Document Review Checklist (as per ISO 15189: 2022)		
Issue No.: 01	Issue Date: 21-Jun-2023	Amend. No: --	Amend. Date: --

REQUIREMENTS OF ISO 15189: 2022			DOCUMENTATION	REMARK
4. GENERAL REQUIREMENTS			Compliance/ Non-compliance/ To be verified during the assessment	
4.1	Impartiality			
	a)	Laboratory activities shall be undertaken impartially. The laboratory shall be structured and managed to safeguard impartiality.		
	b)	The laboratory management shall be committed to impartiality.		
	c)	The laboratory shall be responsible for the impartiality of its laboratory activities and shall not allow commercial, financial or other pressures to compromise impartiality.		
	d)	The laboratory shall monitor its activities and its relationships to identify threats to its impartiality. This monitoring shall include relationships of its personnel. <i>NOTE A relationship that threatens the impartiality of the laboratory can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing (including branding), and payment of a sales commission or other inducement for the referral of new laboratory users, etc. Such relationships do not necessarily present the laboratory with a threat to impartiality.</i>		
	e)	If a threat to impartiality is identified, the effect shall be eliminated or minimized so that the impartiality is not compromised. The laboratory shall be able to demonstrate how it mitigates such threat.		
4.2	Confidentiality			
	4.2.1	Management of information The laboratory shall be responsible, through legally enforceable agreements, for the management of all patient information obtained or created during the performance of laboratory activities. Management of patient information shall include privacy and confidentiality. The laboratory shall inform the user and/or the patient in advance, of the information it intends to place in the public domain. Except for information that the user and/or the patient makes publicly available, or when agreed between the laboratory and the patient (e.g. for the purpose of responding to complaints), all other information is considered proprietary information and shall be regarded as confidential.		
	4.2.2	Release of information When the laboratory is required by law or authorized by contractual arrangements to release confidential information, the patient concerned shall be notified of the information released, unless prohibited by law. Information about the patient from a source other than the patient (e.g. complainant, regulator) shall be kept confidential by the laboratory. The identity of the source shall be kept confidential by the laboratory and shall not be shared with the patient, unless agreed by the source.		

National Accreditation Board for Testing and Calibration Laboratories				
Doc. No.: NABL 220D	Document Review Checklist (as per ISO 15189: 2022)			
Issue No.: 01	Issue Date: 21-Jun-2023	Amend. No: --	Amend. Date: --	Page No.: 01 of 40

	4.2.3 Personnel responsibility	Personnel, including any committee members, contractors, personnel of external bodies, or individuals with access to laboratory information acting on the laboratory's behalf, shall keep confidential all information obtained or created during the performance of laboratory activities.		
4.3	Requirements regarding patients	Laboratory management shall ensure that patients' well-being, safety and rights are the primary considerations. The laboratory shall establish and implement the following processes:		
	a)	opportunities for patients and laboratory users to provide helpful information to aid the laboratory in the selection of the examination methods, and the interpretation of the examination results;		
	b)	provision of patients and users with publicly available information about the examination process, including costs when applicable, and when to expect results;		
	c)	periodic review of the examinations offered by the laboratory to ensure they are clinically appropriate and necessary;		
	d)	where appropriate, disclosure to patients, users and any other relevant persons, of incidents that resulted or could have resulted in patient harm, and records of actions taken to mitigate those harms;		
	e)	treatment of patients, samples, or remains, with due care and respect;		
	f)	obtaining informed consent when required;		
	g)	ensuring the ongoing availability and integrity of retained patient samples and records in the event of the closure, acquisition or merger of the laboratory;		
	h)	making relevant information available to a patient and any other health service provider at the request of the patient or the request of a healthcare provider acting on their behalf;		
	i)	upholding the rights of patients to care that is free from discrimination.		
5	STRUCTURAL REQUIREMENTS			
5.1	Legal entity	The laboratory or the organization of which the laboratory is a part shall be an entity that can be held legally responsible for its activities. <i>NOTE For the purposes of this document, a government laboratory is deemed to be a legal entity on the basis of its government status.</i>		
5.2	Laboratory director			
	5.2.1 Laboratory director competence	The laboratory shall be directed by a person, or persons however named, with the specified qualifications, competence, delegated authority, responsibility, and resources to fulfil the requirements of this document.		
	5.2.2 Laboratory director responsibilities	The laboratory director is responsible for the implementation of the management system, including the application of risk management to all aspects of the laboratory operations so that risks to patient care and opportunities to improve are systematically identified and addressed. The duties and responsibilities of the laboratory director shall be documented.		
	5.2.3 Delegation of duties	The laboratory director may delegate either selected duties or responsibilities, or both, to qualified and competent personnel and such delegation shall be documented.		

National Accreditation Board for Testing and Calibration Laboratories

Doc. No.: NABL 220D Document Review Checklist (as per ISO 15189: 2022)

Issue No.: 01 Issue Date: 21-Jun-2023 Amend. No.: -- Amend. Date: --

Page 001 of 140



Document Sharing Hub

		However, the laboratory director shall maintain the ultimate responsibility for the overall operation of the laboratory.		
5.3	Laboratory activities			
	5.3.1	General The laboratory shall specify and document the range of laboratory activities, including laboratory activities performed at sites other than the main location (e.g. POCT, sample collection) for which it conforms with this document. The laboratory shall only claim conformity with this document for this range of laboratory activities, which excludes externally provided laboratory activities on an ongoing basis.		
	5.3.2	Conformance with requirements Laboratory activities shall be carried out in such a way as to meet the requirements of this document, the users, regulatory authorities and organizations providing recognition. This applies to the complete range of specified and documented laboratory activities, regardless of where the service is provided.		
	5.3.3	Advisory activities Laboratory management shall ensure that appropriate laboratory advice and interpretation are available and meet the needs of patients and users.		
		The laboratory shall establish arrangements for communicating with laboratory users on the following when applicable:		
		a) advising on choice and use of examinations, including required type of sample, clinical indications and limitations of examination methods, and the frequency of requesting the examination;		
		b) providing professional judgments on the interpretation of the results of examinations;		
		c) promoting the effective utilization of laboratory examinations;		
		d) advising on scientific and logistical matters such as instances of failure of sample(s) to meet acceptability criteria.		
5.4	Structure and authority			
	5.4.1	General The laboratory shall:		
		a) define its organization and management structure, its place in any parent organization, and the relationships between management, technical operations and support services;		
		b) specify the responsibility, authority, lines of communication and interrelationship of all personnel who manage, perform or verify work affecting the results of laboratory activities;		
		c) specify its procedures to the extent necessary to ensure the consistent application of its laboratory activities and the validity of the results.		
	5.4.2	Quality management The laboratory 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 for performing laboratory activities;		

National Accreditation Board for Testing and Calibration Laboratories				
Doc. No.: NABL 220D	Document Review Checklist (as per ISO 15189: 2022)			
Issue No.: 01	Issue Date: 21-Jun-2023	Amend. No: --	Amend. Date: --	Page No.: 1 of 40

		c)	initiation of actions to prevent or minimize such deviations;		
		d)	reporting to laboratory management on the performance of the management system and any need for improvement;		
		e)	ensuring the effectiveness of laboratory activities. <i>NOTE These responsibilities can be assigned to one or more persons.</i>		
	Objectives and policies				
	a)	Laboratory management shall establish and maintain objectives and policies (see 8.2) to:			
		1)	meet the needs and requirements of its patients and users;		
		2)	commit to good professional practice;		
		3)	provide examinations that fulfil their intended use;		
		4)	conform to this document.		
	b)	Objectives shall be measurable, and consistent with policies. The laboratory shall ensure that the objectives and policies are implemented at all levels of the laboratory organization.			
	c)	Laboratory management shall ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented.			
	d)	The laboratory shall establish quality indicators to evaluate performance throughout key aspects of pre-examination, examination, and post-examination processes and monitor performance in relation to objectives (see 8.8.2). <i>NOTE Types of quality indicators include the number of unacceptable samples relative to the number received, the number of errors at either registration or sample receipt, or both, the number of corrected reports, the rate of achievement of specified turnaround times.</i>			
	Risk management				
	a)	Laboratory management shall establish, implement, and maintain processes for identifying risks of harm to patients and opportunities for improved patient care associated with its examinations and activities, and develop actions to address both risks and opportunities for improvement (see 8.5).			
	b)	The laboratory director shall ensure that these processes are evaluated for effectiveness and modified, when identified as being ineffective. <i>NOTE 1 ISO 22367 provides details for managing risk in medical laboratories.</i> <i>NOTE 2 ISO 35001 provides details for laboratory biorisk management.</i>			
6	RESOURCE REQUIREMENTS				
6.1	General The laboratory shall have available the personnel, facilities, equipment, reagents, consumables and support services necessary to manage and perform its activities.				
6.2	Personnel				
	6.2.1	General			
		a)	The laboratory shall have access to a sufficient number of competent persons to perform its activities.		
		b)	All personnel of the laboratory, either internal or external, that could influence the laboratory activities shall act impartially, ethically, be competent and work in accordance with the laboratory's management system. <i>NOTE ISO/TS 22583 provides guidance for supervisors and operators of POCT equipment.</i>		

National Accreditation Board for Testing and Calibration Laboratories				
Doc. No.: NABL 220D	Document Review Checklist (as per ISO 15189: 2022)			
Issue No.: 01	Issue Date: 21-Jun-2023	Amend. No: --	Amend. Date: --	Page No.: 8 of 14

		c)	The laboratory shall communicate to laboratory personnel the importance of meeting the needs and requirements of users as well as the requirements of this document.		
		d)	The laboratory shall have a program to introduce personnel to the organization, the department or area in which the person will work, the terms and conditions of employment, staff facilities, health and safety requirements, and occupational health services.		
	6.2.2	Competence requirements			
		a)	The laboratory shall specify the competence requirements for each function influencing the results of laboratory activities, including requirements for education, qualification, training, re-training, technical knowledge, skills and experience.		
		b)	The laboratory shall ensure all personnel have the competence to perform laboratory activities for which they are responsible.		
		c)	The laboratory shall have a process for managing competence of its personnel, that includes requirements for frequency of competence assessment.		
		d)	The laboratory shall have documented information demonstrating competence of its personnel. <i>NOTE Examples of competence assessment methods that can be used in any combination include:</i> — direct observation of an activity, — monitoring the recording and reporting of examination results, — review of work records, — assessment of problem-solving skills, — examination of specially provided samples, e.g. previously examined samples, interlaboratory comparison materials, or split samples.		
	6.2.3	Authorization The laboratory shall authorize personnel to perform specific laboratory activities, including but not limited to, the following:			
		a)	selection, development, modification, validation and verification of methods;		
		b)	review, release, and reporting of results;		
		c)	use of laboratory information systems, in particular: accessing patient data and information, entering patient data and examination results, changing patient data or examination results.		
	6.2.4	Continuing education and professional development A continuing education programme shall be available to personnel who participate in managerial and technical processes. All personnel shall participate in continuing education and regular professional development, or other professional liaison activities. The suitability of the programmes and activities shall be periodically reviewed.			
	6.2.5	Personnel records The laboratory shall have procedures and retain records for:			
		a)	determining the competence requirements specified in 6.2.2 a);		
		b)	position descriptions;		
		c)	training and re-training;		
		d)	authorization of personnel;		

National Accreditation Board for Testing and Calibration Laboratories					
Doc. No.: NABL 220D	Document Review Checklist (as per ISO 15189: 2022)				
Issue No.: 01	Issue Date: 21-Jun-2023	Amend. No: --	Amend. Date: --	Page 001 of 140	

		e)	monitoring competence of personnel.		
6.3	Facilities and environmental conditions				
6.3.1	General The facilities and environmental conditions shall be suitable for the laboratory activities and shall not adversely affect the validity of results, or the safety of patients, visitors, laboratory users, and personnel. This shall include pre-examination related facilities and sites other than the main laboratory premises where examinations are performed, as well as POCT. The requirements for facilities and environmental conditions necessary for the performance of the laboratory activities shall be specified, monitored, and recorded. <i>NOTE 1 ISO 15190 provides details for facility and environmental conditions.</i> <i>NOTE 2 Environmental conditions that can adversely affect the validity of results include, but are not limited to: adventitious amplified nucleic acid, microbial contamination, dust, electromagnetic disturbances, radiation, lighting conditions (illumination), humidity, electrical supply, temperature, sound and vibration.</i>				
6.3.2	Facility controls Facility controls shall be implemented, recorded, monitored, periodically reviewed, and shall include:				
	a)	control of access, taking into consideration safety, confidentiality, quality, and safeguarding medical information and patient samples;			
	b)	prevention of contamination, interference, or adverse influences on laboratory activities that can arise from energy sources, lighting, ventilation, noise, water and waste disposal;			
	c)	prevention of cross-contamination, where examination procedures pose a risk, or where work can be affected or influenced by lack of separation;			
	d)	provision of safety facilities and devices, where applicable and regularly verifying their functioning; EXAMPLES The operation of emergency release, intercom and alarm systems for cold rooms and walk-in freezers, accessibility of emergency showers, eyewash and resuscitation equipment.			
	e)	maintenance of laboratory facilities in a functional and reliable condition.			
6.3.3	Storage facilities				
	a)	Storage space, with conditions that ensure the continuing integrity of samples, equipment, reagents, consumables, documents and records, shall be provided.			
	b)	Patient samples and materials used in examination processes shall be stored in a manner that prevents cross contamination and deterioration.			
	c)	Storage and disposal facilities for hazardous materials and biological waste shall be appropriate to the classification of the materials in the context of any statutory or regulatory requirements.			
6.3.4	Personnel facilities There shall be adequate access to toilet facilities and a supply of drinking water, as well as facilities for storage of personal protective equipment and clothing.				

National Accreditation Board for Testing and Calibration Laboratories					
Doc. No.: NABL 220D	Document Review Checklist (as per ISO 15189: 2022)				
Issue No.: 01	Issue Date: 21-Jun-2023	Amend. No: --	Amend. Date: --	Page No.: 001 of 01	

		Space for personnel activities, such as meetings, quiet study and a rest area, should be provided.		
	6.3.5	Sample collection facilities Sample collection facilities shall:		
		a) enable collection to be undertaken in a manner that does not invalidate results or adversely affect the quality of examinations;		
		b) consider privacy, comfort and needs (e.g. disabled access, toilet facility) of patients and accommodation of accompanying persons (e.g. guardian or interpreter) during collection;		
		c) provide separate patient reception and collection areas;		
		d) maintain first aid materials for both patients and personnel.		
		<i>NOTE ISO 20658 provides details for sample collection facilities.</i>		
6.4	Equipment			
	6.4.1	General The laboratory shall have processes for the selection, procurement, installation, acceptance testing (including acceptability criteria), handling, transport, storage, use, maintenance, and decommissioning of equipment, in order to ensure proper functioning and to prevent contamination or deterioration. <i>NOTE Laboratory equipment includes hardware and software of instruments, measuring systems, and laboratory information systems, or any equipment that influences the results of laboratory activities, including sample transportation systems.</i>		
	6.4.2	Equipment requirements		
		a) The laboratory shall have access to equipment required for the correct performance of laboratory activities.		
		b) Where the equipment is used outside the laboratory's permanent control, or equipment manufacturer's functional specification, laboratory management shall ensure that the requirements of this document are met.		
		c) Each item of equipment that can influence laboratory activities shall be uniquely labelled, marked or otherwise identified and a register maintained.		
		d) The laboratory shall maintain and replace equipment as needed to ensure the quality of examination results.		
	6.4.3	Equipment acceptance procedure The laboratory shall verify that the equipment conforms to specified acceptability criteria before being placed or returned into service. Equipment used for measurement shall be capable of achieving either the measurement accuracy or measurement uncertainty, or both, required to provide a valid result (see 7.3.3 and 7.3.4 for details). <i>NOTE 1 This includes equipment used in the laboratory, equipment on loan, or equipment used in point of care settings, or in associated or mobile facilities, authorized by the laboratory.</i> <i>NOTE 2 The verification of equipment acceptance testing can be, where relevant, based on the calibration certificate of the returned equipment.</i>		

National Accreditation Board for Testing and Calibration Laboratories				
Doc. No.: NABL 220D	Document Review Checklist (as per ISO 15189: 2022)			
Issue No.: 01	Issue Date: 21-Jun-2023	Amend. No: --	Amend. Date: --	Page No.: 10 of 10

		6.4.4	Equipment instructions for use		
		a)	The laboratory shall have appropriate safeguards to prevent unintended adjustments of equipment that can invalidate examination results.		
		b)	Equipment shall be operated by trained, authorized, and competent personnel.		
		c)	Instructions for the use of equipment, including those provided by the manufacturer, shall be readily available.		
		d)	The equipment shall be used as specified by the manufacturer, unless validated by the laboratory (see 7.3.3).		
		6.4.5	Equipment maintenance and repair		
		a)	The laboratory shall have preventive maintenance programs, based on manufacturer's instructions. Deviations from the manufacturer's schedules or instructions shall be recorded.		
		b)	Equipment shall be maintained in a safe working condition and working order. This shall include electrical safety, any emergency stop devices and the safe handling and disposal of hazardous materials by authorized personnel.		
		c)	Equipment that is defective or outside specified requirements, shall be taken out of service. It shall be clearly labelled or marked as being out of service, until it has been verified to perform correctly. The laboratory shall examine the effect of the defect or deviation from specified requirements and shall initiate actions when non-conforming work occurs (see 7.5).		
		d)	When applicable, the laboratory shall decontaminate equipment before service, repair or decommissioning, provide suitable space for repairs and provide appropriate personal protective equipment.		
		6.4.6	Equipment adverse incident reporting Adverse incidents and accidents that can be attributed directly to specific equipment shall be investigated and reported to either the manufacturer or supplier, or both, and appropriate authorities, as required. The laboratory shall have procedures for responding to any manufacturer's recall or other notice, and taking actions recommended by the manufacturer.		
		6.4.7	Equipment records Records shall be maintained for each item of equipment that influences the results of laboratory activities. These records shall include the following, where relevant:		
		a)	manufacturer and supplier details, and sufficient information to uniquely identify each item of equipment, including software and firmware;		
		b)	dates of receipt, acceptance testing and entering into service;		
		c)	evidence that equipment conforms with specified acceptability criteria;		
		d)	the current location;		
		e)	condition when received (e.g. new, used or reconditioned);		
		f)	manufacturer's instructions;		
		g)	the program for preventive maintenance;		
		h)	any maintenance activities performed by the laboratory or approved external service provider;		

National Accreditation Board for Testing and Calibration Laboratories			
--	--	--	--

Doc. No.: NABL 220D	Document Review Checklist (as per ISO 15189: 2022)		
---------------------	--	--	--

Issue No.: 01	Issue Date: 21-Jun-2023	Amend. No.: --	Amend. Date: --
---------------	-------------------------	----------------	-----------------

Page No.: 20 of 49



Document Sharing Hub