ASSESSOR GUIDE
FOR
LABORATORY PROGRAM

Contents

1. Introduction

Compliance certification is an incentive to improve quality and safety of collecting, processing, and testing samples of human origin. The National Accreditation Board for Hospitals and Healthcare Providers (NABH) provides third-party compliance certification to medical laboratories.

The on-site assessment is carried out by a team of NABH empanelled Assessor(s). The assessment is carried out systematically for comprehensive review of the quality and operational systems within the facility. The objective evidence so collected forms the basis for arriving at a judgment for recommendation of the team.

This guide has been prepared based on the general practices followed by simlar bodies and the experience of experts of the country. This document accordingly aims to:

a. Provide the guidance to the Assessors during the assessment

b. Ensure uniformity of assessment and reporting, and

c. Eliminate ambiguities or doubts about the interpretation of requirements(s).

2. Role of Assessment Team

The role of NABH Assessment team is to conduct on-site assessment of applicant lab and provide the report to NABH.

The objective of the on-site assessment is to obtain evidence on compliance with respect to NABH standards, applicable laws and regulations.

Since lab certification requires compliance with NABH Standards the assessment team should consider conformances against these standards in the assessment. Thus, the member(s) of the assessment team would be required to exercise their scientific judgmental skill and form their opinion regarding extent of conformance with respect to laid down criteria.

Notwithstanding the strength of the NABH system, the success of the scheme depends on the assessment team who performs on-site assessment and, thus, plays a vital role in determining the credibility and value.

Team members are required to maintain the confidentiality on the matters/ subjects related to laboratories.

Role of Assessor

Before the start of assessment, Assessor shall prepare an Assessment schedule in LAF 1. The Assessor should clearly understand the areas/ activities to be assessed. He must review the lab's documented system to verify compliance with the requirements of NABH standards. He should assess to verify that the documented SOPs, test methods and records are implemented & effective, as described and record observations in LAF 2. He should be completing the Checklist.

3. On-Site Assessment

The assessor(s) and the names of their organizations from which they belong are intimated to the lab for seeking their consent. NABH also assures that the team does not have any competitive position with the applicant organization. NABH also ensures that assessors do not have any direct/ in-direct relationship with the organization or they/ or their organization.

Consent is obtained for the date(s) of the assessment from the Assessor and organization. A written communication is sent to all the team members with the following documents:

- Application form of the organization
- Copy of internal audit report
- Copy of minutes of management review meeting
- Confidentiality form (NABH I&C_Lab 01)
- Travel expenditure form

Assessment Team shall meet and plan assessment programme. This shall include the distribution of work, if require amongst the Assessors. The format of the assessment schedule to be finalized is given at LAF-1.

4. Opening Meeting

Principal Assessor and the team shall have an opening meeting with lab representatives where they get acquainted with the lab and briefed the lab management about the objective and plan of the assessment.

5. Assessment

The assessment activities include:

- The Assessment Team shall proceed to various sections/ department of the lab as planned earlier.
- The Assessor(s) should verify the effectiveness of Quality System and related documents using audit techniques and shall raise non-conformities. The Assessor shall use LAF 2 to record the findings.
- The Assessor(s) should also thoroughly examine the technical competence of the lab in terms of manpower, qualification, experience, up to date knowledge, equipment and other related elements.

- The object of assessment is to ascertain by observations of the activities whether the work of the lab is being carried out in accordance with the 'Essential Standards for Medical Testing laboratories'. Assessor shall record detailed non conformities as they occur on LAF 3. Each non conformity shall be countersigned by the accompanying lab representative.

- During assessment, Assessors would discuss with the management representative of the lab whether the lab is participating in the External Quality Assurance Scheme (EQAS)/ Proficiency Testing Programme/ Inter-Laboratory Comparison Programme. They would look for their performance and action taken if the performance was unsatisfactory.

- The Checklist provided should be verified and completed during the course of the assessment.

6. Compilation of assessment report

The Assessment Report should consist of various documents in the order as indicated in LAF 4. Each form or checklist should be carefully filled in. The pages should be serially numbered.

Principal Assessor shall compile the observations from the assessors (LAF 2) and summary on non-compliance (LAF 3) from all the assessors. A copy of non conformities, if any raised in LAF 3 shall be given to laboratory.

7. Follow up

Laboratory shall have a maximum of 60 days to close all the non conformities and submit corrective actions to NABH. A copy of such corrective actions shall be forwarded to Assessor for their comments, whether to accept or otherwise.

Assessment Schedule - LAF 1

Name & address of Laboratory:	
Laboratory Coordinator:	**Date(s) of Visit:**
Type of Visit: *Assessment*	
Assessment Standard: *Essential Standards for Medical Laboratories*	

Assessment Timings	**Opening/Closing Meeting** Date/Time
Morning: AM to PM Afternoon: PM to PM	Opening Meeting: Closing Meeting:

Assessment schedule: Principal Assessor to provide details of activities taken up by individual assessors/ technical expert in the following format and obtained their signature.

(Separate sheets may be used for individual assessors)

Name and Expertise of the Assessor	Schedule of Department/ Section/ Activity to be Assessed (date wise)		
	Day 1		
	Morning	Afternoon	
Principal Assessor			
Assessor 1			
Observer/Expert			

Signature of Assessor

Assessor's Observations - LAF 2

Name of Laboratory:		
Date:	Area/ Department:	Activity Assessed:
Auditee:		

Sl.	**OBSERVATION**	**REMARKS**

Signature & Name of Assessor

Assessor's Summary on Non-Conformity - LAF 3

(Please use separate sheet for raising each Non Conformity)

Laboratory:	
Date:	Type of Assessment: *Assessment*
NON-CONFORMITY (NC) RAISED:	
Ref to Essential Standard for Medical Laboratories	
CORRECTIVE ACTION TAKEN/ PROPOSED BY THE LABORATORY: Signature & Name of Laboratory Representative	
REMARKS BY ASSESSOR, IF ANY: Signature & Name of Assessor	

Summary of the Assessment - LAF 4

Name & address of Laboratory:					
Laboratory Coordinator:			Date(s) of Visit:		
Type of Visit: *Assessment*					
Assessor 1:					
Assessor 2:					
Other/TE			Observer:		
Date of earlier visit and Purpose:					
ASSESSMENT SUMMARY:					
Recommendation by the team:					
Enclosures	**LAF 1**	**LAF 2**	**LAF 3**	**LAF 4**	
Date by which non conformities are to be closed by the laboratory (maximum 60 days:					
Acknowledgement by Authorised Signatory of laboratory & Date			Signature of Assessor & Date		

NABH I&C_LAB 01

Declaration of Impartiality, Confidentiality & Integrity

(to be filled in by each Assessor and enclosed with the Assessment report)

Name		**Assessor ID :** (To be filled in by NABH Sect.)
Designation		
Organisation		
Address		
Capacity	*Assessor / Observer*	
Health care organisation Assessed		
Date of visit(s)		
Type of visit	*Assessment*	

I _____, **hereby declare that**

i. I have not offered any consultancy, guidance, supervision or other services to the laboratory, in any way.

ii. I am/ am not* an ex-employee of the health care organisation and am/ am not* related to any person of the management of the health care organisation.

iii. I got an opportunity to go through various documents of the above hospital and other related information that might have been given by NABH. 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 NABH.

* strike out which is not applicable

Date: Place :	Signature

Checklist for use by the Assessor during on site assessment

Clause	Sub clause	Elements to be observed	Remarks
3.1	**3.1.1**	Name of Laboratory	
		Current valid Registration Number of laboratory, as applicable	
		Permanent location with full address	
		List of sample resource centre(s)	
		Evidence of size of laboratory (average number of patients per day for last six months)	
		Designation of person(s) as Quality Manager and Technical Manager	

		Responsibilities of Quality Manager includes:
		• Developing Quality Manual, Quality System Procedure (QSP) Manual, Sample Collection Manual, and Standard Operating Procedures (SOP's) as per the scope of laboratory in discussion with Technical Manager.
		• Conduct internal audit / Gap analysis for monitoring the implements of Quality Management System.
		• Guide / Take corrective and preventive action on the basis of:
		  • Gap during internal audit
		  • Feedback and complaints of lab-users
		  • Non conformity during day to day working
		• Develop and continuous monitoring of Quality Indicator
		• Prepare and present internal audit report in Management review meeting	

		Technical Manager shall be responsible for all technical operations.	
	3.1.2	Quality policy of the laboratory	
		Compilation of all the policies in a document (Quality Manual)	

		All documented procedures (QSP & SOPs) applicable to the laboratory	
	3.1.3	**Internal audit**	
		Internal audit plan	
		Last internal audit report(s)	
		Closure of Non-conformity found during internal audit	
	3.1.4	**Management Review**	
		Review of the internal audit report	
		Internal quality control report	
		External Quality Assurance report/ Inter-laboratory comparison/Split sample testing/ retained sample testing	
		Laboratory Service user / customer feedback/ complaint review report	
3.2		**Document control**	
		A list of all documents	
		Documents shall have a title, unique identification number, page number and total number of pages (e.g. 1 of 10)	
		All documents shall be reviewed, approved and issued by authorized person	
		Only current, authorized editions/issues/version of applicable documents are available at point of use.	
		Obsolete documents shall be properly labeled and removed from the work place	
		Documents can be stored in either electronic format or hard copy	
3.3		**Personnel**	
		Organogram	
		Job description/ roles & responsibilities for all the personnel	
		Records of all personnel working in the laboratory that includes copies of basic	

		and professional qualification, experience and training records (both internal and external).	
		Availability and usage of personal protective equipment	
		Staff health records	
		Training plan	
		Training records	
3.4		**Laboratory equipment & instruments**	
		Equipment List • Name of equipment/ reagent/ kit • Unique Identification Number/ Batch Number • Name of Manufacturer • Name and Number of contact engineer in case of breakdown • Calibration Status/ proper functioning status • Preventive Maintenance Status	
		Evidence to ensure proper functioning of all equipment.	
		Records of training of personnel operating the equipment.	
3.5	**3.5.1**	**Procurement**	
		Procedures for selection and use of purchased external services	
		Inventory Management System including Display of Material Safety Data Sheet	
		Kit verification procedure	
	3.5.2	**Outsourced Laboratory Services**	
		List and contract/MOU with outsourced laboratories.	
		List of the tests outsourced for analysis.	
		Procedure for sample storage and transport to outsourced laboratory.	
		Procedure for issuing the report to patients for such outsourced tests.	
3.6	**3.6.1**	**Laboratory space**	
		Accommodation and environment of	

		laboratory Housekeeping in laboratory	
		Housekeeping in laboratory	
		Sample collection area	
		Bio-medical waste disposal procedure and license/approval as per State Pollution Control Board/ Committee	
		Storage area	
		Fire exit signage (Self illuminating, Pictorial & Bilingual)	
		Directional signage	
	3.6.2	**Quality assurance**	
		Performance of internal control	
		Participation in Inter-laboratory comparisons/ External quality Assessment programme / retained sample testing	
		Corrective action taken on results of Internal and External quality checks.	
	3.6.3	**Pre- examination Process**	
		Sample collection procedure	
		Sample labeling procedure and maintaining traceability	
		Acceptance and rejection criteria and records	
	3.6.4	**Examination Process**	
		SOP's of all the test methods	
		Work instructions/ bench aids	
		Staff awareness regarding SOP's	
		List of reference values for all tests being conducted	
	3.6.5	**Post – examination Process**	
		List of persons with qualification who approve test results	
		Retention time of unused samples	
		Methods of discarding of unused specimens including SOP for the same.	
	3.6.6	**Reporting**	

		Test Request Form	
		Report format	
		List of critical values for tests and reporting records	
		Test report retention time policy	
		Patient confidentiality policy	
		Retention of copy of test report for an appropriate period of time	
3.7		**Continual quality Improvement**	
		Records and performance of Quality indicators like: • sample rejection rate • sample collection to processing time • internal control results • performance in quality assurance • reporting turn-around time etc. • Corrective action taken of complaints, feedback and non-conformance after root cause analysis.	
		Complaint and feedback record.	
		Complaint and feedback analysis record.	