



# National Accreditation Board for Testing and Calibration Laboratories (NABL)

## Guide for Internal Audit and Management Review for Conformity Assessment Bodies (Laboratories/PTP/ RMP/Biobank)

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## AMENDMENT SHEET

S. No.	Amendment No.	Page No.	Clause No.	Date of Amendment	Amendment	Reasons	Signature QA Team	Signature Competent Authority
1.	01	3	Introduction, 1.2, 2.5	22.02.2024	As highlighted	Inclusion of ISO 15189: 2022 and ISO/IEC 17043: 2023	-Sd-	-Sd-
		7	1.2					
		8	2.5					
		10	3.4					
		20	1.2					
		23	4.1					
2.	02	3, 5, 6, 8, 11, 13, 14	---	21.01.2026	As highlighted, Removal of reference to ISO 15189: 2012	<ul style="list-style-type: none"> <li>• Addition of ISO 20387: 2018</li> <li>• Withdrawal of ISO 15189: 2012</li> <li>• Formation of the Global Accreditation Cooperation Incorporated</li> </ul>	-Sd-	-Sd-
3.								
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## INTRODUCTION

General Requirements for the Competence of Testing and Calibration Laboratories, ISO/ IEC 17025: 2017 clause 8.8 and 8.9 requires that a laboratory shall periodically, and in accordance with a predetermined schedule and procedure, conduct:

- a) Internal audits of its activities to verify that its operations continue to comply with the requirements of the management system and ISO/ IEC 17025:2017, and
- b) Management reviews of its management system and its activities to ensure their continuing suitability and effectiveness, and to introduce any necessary changes or improvements.

Similar requirements are stated in ISO 15189: 2022, ISO/IEC 17043:2010, ISO/IEC 17043: 2023, ISO 17034:2016 and ISO 20387: 2018 in various clauses for Internal Audit and Management Review.

It is assumed that the CABs have implemented a management system that meets the requirement of ISO/IEC 17025:2017, ISO 15189: 2022, ISO/IEC 17043:2010, ISO/IEC 17043: 2023, ISO 17034: 2016 and ISO 20387: 2018.

This document has been prepared to give CABs guidance on how to establish a program for internal audit and management review. The document consists of two sections: Section A – Internal Audit and Section B – Management Review.

The guidelines given in this document are general in nature. The actual accomplishment of an internal audit or a management review depends on the size, scope and organisation structure of the CAB and, for the smaller CAB, many of the items described in this document can be carried out in a simplified manner.

NABL, at any time, may call for the internal audit and/ or management review reports from the CABs.

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## TERMINOLOGY

### Management System

The quality, administrative and technical systems that govern the operations of a CAB.

### Internal Audit

A systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

The term internal audit refers to an audit done by CAB to establish the extent of conformity to the documented requirements or standards as per the laid down procedure.

Note: In this document, the term 'internal audit' is used to emphasise that the audit is done by the CAB (wherever resources permit).

### Management Review

A formal evaluation by top management of the status and adequacy of management system in relation to quality policy and objectives.

### Person responsible for Management System

A member of staff with defined responsibility and authority for ensuring that the management system is implemented and followed at all times and shall have direct access to the highest level of management at which decisions are made on CAB policy or resources.

### Auditor

A person who is trained, qualified and harbouring the audit skills to perform audits.

### Auditee

Any individual being audited

Note: In this document the term 'Auditee' refers to the individuals working in the CAB.

### Observation

A statement of fact made during an audit and substantiated by objective evidence.

### Objective Evidence

Qualitative or quantitative information, records or statements of fact pertaining to the quality of an item or service or to the existence and implementation of a quality system element, which is based on observation, measurement or test and which can be verified.

### Non-Conformity

The non-fulfillment of specified requirements.

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## SECTION – A INTERNAL AUDIT

### 1. Objectives of Internal Audit

- 1.1. The CAB should conduct internal audits of its activities to verify that the operations continue to comply with the requirements of defined management system.
- 1.2. The internal audits should also ensure that the defined management system fulfils the requirements of ISO/ IEC 17025:2017 or ISO 15189: 2022 or ISO/IEC 17043:2010 or ISO/IEC 17043: 2023 or ISO 17034:2016 or ISO 20387: 2018.
- 1.3. The audit should also ensure whether or not the requirements of the CAB's Management System Document / Quality Manual and related documents are applied at all levels of work.
- 1.4. The non-conformities found during the internal audit should give valuable information for the improvement of the CAB's management system and technical competence, which is to be used as an input to management review.

### 2. Organization of Internal Audit

- 2.1. The internal audits should be carried out periodically according to predetermined schedule and procedure to verify that the CAB operations are continually complying with the defined requirements of the management system.
- 2.2. The audit should be programmed such that each element / activity of the management system is checked at least once a year irrespective of the size of the CAB, all the activities, all personnel, all procedures, all test methods to be covered in the internal audit. However, at the time of internal audit, the assessment of technical competence through witnessing the test/ calibration may not be necessary.
- 2.3. In large CABs it may be advantageous to establish a plan whereby the different element of management system or different sections of the CAB are audited throughout the year. If the entire management system cannot be audited in one session, then the CAB must ensure that all areas are audited throughout the year.
- 2.4. The person responsible for management system has the responsibility for planning and organizing the audit and he / she should ensure that the audits are carried out in accordance with the schedule plan.
- 2.5. The audits shall be carried out by qualified personnel who understand the technical requirements they are auditing and who are trained specifically in auditing techniques and processes. Wherever resources permit this audit shall be done by CAB personnel only to establish the extent of conformity of the CAB to documented requirements or standards.
- 2.6. The person responsible for management system may delegate the task of performing audits to personnel who are having sufficient technical knowledge with respect to the operations of the CAB, trained specifically in audit techniques and process. The auditors shall also understand requirements of ISO/IEC 17025:2017 or ISO 15189: 2022 or ISO/IEC 17043:2010 or ISO/IEC 17043: 2023 or ISO 17034:2016 or ISO 20387: 2018 (whichever is applicable) and NABL accreditation requirements.
- 2.7. In large CABs carrying out a wide range of technical activities, it may be necessary for audits to be carried out by team of individuals. One of the auditors may act as a lead auditor; however,

the responsibility of the conduct of audit lies with the person responsible for management system.

- 2.8. In small CABs, the person responsible for management system may carry out the audit, but the management should ensure that the activities of the quality manager are audited by another person.
- 2.9. The auditor shall be independent of the activity to be audited and personnel shall not audit their own activities.
- 2.10. Where a CAB has accreditation for site activities, or for sampling, these activities must be included in the audit program.

### 3. Planning of Audit

- 3.1. An audit plan needs to be established by the person responsible for management system and should include the audit scope, the audit criteria, the audit schedule, reference documents (such as the CAB's Management System Document / Quality Manual and audit procedure) and audit team members.
- 3.2. The audit program may include horizontal audit / vertical audit + (wherever feasible) so that all the sections / departments are audited for every aspect / clause of the management system and relevant standard.

**+ Horizontal Audit** - This examines one element in a process on more than one item. It is a detailed check of a particular aspect of the documentation and implementation of the management system.

**Vertical Audit** - This examines one sample looking at all of the inputs, operations and activities required to produce the output (result). It is a detailed check that all elements associated with the activity are implemented.

- 3.3. Each auditor should be assigned specific management system elements or functional departments to audit. Such assignments should be made by the person responsible for management system or the lead auditor in consultation with the auditors concerned. The auditors should have adequate technical knowledge of the activities they are to audit.
- 3.4. Working documents required to facilitate the auditor's investigations and to document and report results, may include:
  - ISO/ IEC 17025:2017 or ISO 15189: 2022 or ISO/IEC 17043:2010 or ISO/IEC 17043: 2023 or ISO 17034:2016 or **ISO 20387: 2018**
  - CAB's Management System Document / Quality Manual and associated documents such as system procedures, test methods, work instructions, records etc.
  - Checklist used for evaluating management system elements (normally prepared by the auditor assigned to audit that specific element).
  - Forms for reporting audit observations, such as non-conformity form or corrective action form. These forms should include nature of non-conformity, agreed corrective action, time required for corrective actions and confirmation that the corrective action has been taken and is effective.
- 3.5. An audit timetable should be developed by each auditor in conjunction with their auditee to ensure the smooth and systematic progress of the audit.

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- 3.6. Prior to the actual audit, a review of documents, manuals, previous audit reports and records should occur to check for compliance with the system criteria and to develop a checklist of key issues to be audited.

#### 4. Implementation of Internal Audit

- 4.1. The implementation of the audit consists of investigation and analysis.
- 4.2. The opening meeting would introduce the audit team, confirm the audit criteria, review the audit scope, explain the audit plan and procedure, clarify any relevant details, and confirm the timetable including the time or date and attendees for the closing meeting.
- 4.3. The investigation process for gathering objective evidence will involve asking questions, observing activities, examining facilities, and examining records. The auditor will be examining the conformity of the activities with the quality system.
- 4.4. The auditor will use the management system documents as reference (management system document / quality manual, system procedures, test methods, work instructions, records etc.), and compare what is actually happening with what these quality system documents state should happen.
- 4.5. At all times during the audit, the auditor will be seeking objective evidence that the management system requirements are being fulfilled. Evidence should be collected as efficiently and effectively as possible and without prejudice or upset to the auditees.
- 4.6. Non-conformities should be noted if they seem significant, even where they are not covered by checklists, and should be investigated further to identify the underlying problems.
- 4.7. All audit observations should be recorded. After all activities have been audited, the audit team should carefully review and analyse all of their observations to determine which are to be reported as non-conformities and which can be included as recommendations for improvement.
- 4.8. The audit team should prepare a clear concise report supported by objective evidence of non-conformities and recommendation for improvement. The non-conformities should be identified in terms of specific requirements of CAB's Management System Document / Quality Manual and related documents against which the audit has been conducted.
- 4.9. The audit team should hold a closing meeting with the top management of the CAB and those responsible for the functions concerned. The main purpose of this meeting is to present audit findings and report to top management in such a manner so as to ensure that they clearly understand the results of the audit, and take the appropriate corrective action based on root cause analysis.
- 4.10. The person responsible for management system should present observations, taking into account their perceived significance (both positive and negative aspects), and conclusions regarding the management system's compliance with the audit criteria. The non-conformities identified during the audit should be noted and the appropriate corrective action and time limit for actions should be agreed upon.

## 5. Follow up of Corrective Actions

- 5.1. The implementation of the agreed corrective action is the responsibility of the person responsible for management system.
- 5.2. When a non-conformity that may jeopardize the result of calibration / testing / medical testing / PT / RM / **Biobank** is discovered the corresponding activity should be halted until appropriate corrective action has been taken to lead to satisfactory results. In addition, results that may have been affected by the non-conforming work should be investigated and customers informed if the validity of corresponding certificates/ reports is in doubt.
- 5.3. The corrective actions procedure may need to be followed to reveal the root cause of some problems and to implement effective corrective actions.
- 5.4. The effectiveness of corrective actions should be checked by the person responsible for management system as soon as possible after the agreed time limit has elapsed and clear / close the non-conformity.

## 6. Records and Reports of Internal Audit

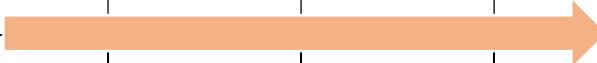
- 6.1. A complete record of the audit should be maintained even if non-conformity has not been found. These records provide the management with continuous history of performance. All records must be clearly documented and readily accessible.
- 6.2. Each non-conformity identified should be recorded, its nature, possible cause(s), corrective action required and appropriate time limit for its clearance.
- 6.3. The report should include the following information:
  - a. name(s) of the auditor(s)
  - b. date of audit
  - c. details of all areas audited and audit plan
  - d. the positive or good aspects of the operations
  - e. any non-conformity identified along with their document references
  - f. any recommendations for improvement
  - g. corrective actions agreed, time period allowed for completion, and person responsible for carrying out actions.
  - h. Cause analysis, corrective actions taken and date of confirmation of completion of corrective action.
  - i. signature of person responsible for management system / quality manager confirming closure of the non-conformities and corrective action taken.
- 6.4. The person responsible for management system should ensure that the report of the audit and, where appropriate, individual non-conformities, are seen by the CAB's top management. The trends in results of internal audit and the corrective actions should be analysed by the person responsible for management system and a report prepared for review by the top management at the management review meeting.
- 6.5. Audit records may be retained for a minimum period of three years.

## 7. Additional Unscheduled Audits

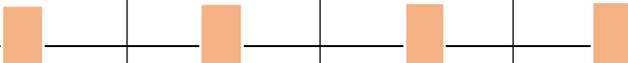
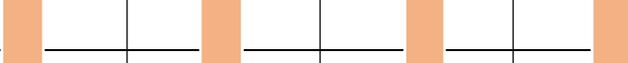
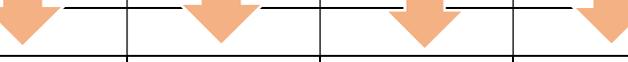
- 7.1. It may be necessary for CABs to carry out additional unscheduled audits whenever there is reason to doubt the effectiveness of the management system. For example, when a non-conforming work has been detected or the CAB has received a complaint which raises a doubt on its competence and therefore results etc.
- 7.2. The additional audit may confine to only that area where the non-conformity has been detected or the complaint has been received.
- 7.3. The procedure followed is similar to that of the full audit.

## A TYPICAL FORMAT FOR AUDIT PLAN

### 1. Horizontal audit plan

ISO/IEC 17025	DEPARTMEN T / CAB SECTION 1	DEPARTMEN T / CAB SECTION 2	DEPARTMEN T / CAB SECTION 3	DEPARTMEN T / CABSECTION N 4
Cl. 4.1				
Cl. 4.2				
Cl. 6.5				
				
Cl 7.4				
				
Cl 7.8				
				
Cl 8.4				

### 2. Vertical Audit plan

ISO/IEC 17025	DEPARTMEN T / CAB SECTION 1	DEPARTMEN T / CAB SECTION 2	DEPARTMEN T / CAB SECTION 3	DEPARTMEN T / CAB SECTION 4
Cl. 4.1				
Cl. 4.2				
Cl. 5				
				
Cl 6.5				
				
Cl 7.7				
				
Cl 8.9				

Note: These are examples may vary according to the size, scope, type and organisational structure of the CAB.

**A TYPICAL FORMAT FOR INTERNAL AUDIT NON-CONFORMITY**

Audit No.:	Date:	Auditor:
Department/ Section:	Activity Assessed:	Auditee:
NC No. :	Ref. to lab. documents & ISO / IEC 17025 or ISO 15189 or ISO/IEC 17043 or ISO 17034 or ISO 20387: 2018 Clause No.:	
<b>NON-CONFORMITY (NC) STATEMENT:</b>		
Signature of Auditor & date		
<b>CORRECTIVE ACTION PROPOSED:</b>		
Signature of Auditee & date		
<b>RESPONSIBILITY &amp; TIME REQUIRED FOR CORRECTIVE ACTION:</b>		
Signature of Auditee/ HOD/ Person responsible for management system & date		
<b>ROOT CAUSE:</b>		
Signature of Auditee & date		
<b>CORRECTIVE ACTION TAKEN:</b>		
Signature of Auditee & date		
<b>CORRECTIVE ACTION VERIFIED &amp; COMMENTS, IF ANY</b>		
Signature of Auditor & Person responsible for management system & date		

## SECTION - B

### MANAGEMENT REVIEW

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## 1. Objectives of Management Reviews

- 1.1. The top management of the CAB shall periodically conduct a review of the CAB's management system and technical activities to ensure their suitability and effectiveness and to introduce any necessary changes or improvements.
- 1.2. Management reviews should be planned to establish what changes, if any, are necessary to ensure that the management system for the CAB continue to meet both the CAB 's needs and the requirements of ISO/ IEC 17025:2017 or ISO 15189: 2022 or ISO/IEC 17043:2010 or ISO/IEC 17043: 2023 or ISO 17034:2016 or ISO 20387: 2018 whichever is applicable. Quality policy and objectives should be reviewed and revised if necessary.
- 1.3. Management review should also take note of changes that have taken place (or are expected to take place) in the organisation, facilities, equipment, procedures and / or activities of the CAB and ensure (through person responsible for management system) that management system continues to conform to the requirements of relevant standard.
- 1.4. The need for changes to the system may also arise as a result of findings from internal or external quality audits, inter-laboratory comparisons or proficiency tests, surveillance or reassessment visits by NABL / regulatory bodies, complaints from customers or change in policies of NABL or APAC/ Global Accreditation Cooperation Incorporated.

## 2. Organization of Management Review

- 2.1. The top management of the CAB should be responsible for conducting reviews of the management system.
- 2.2. Those members of top management have overall responsibility for the design and implementation of the CAB's management system, and for taking decisions resulting from the findings of internal audits, should be involved in management reviews. As a normal practice management review shall be organized after the internal audit.
- 2.3. The person responsible for management system should be responsible for ensuring that all reviews are conducted in a systematic manner according to an established procedure, and that the management reviews are recorded.
- 2.4. The person responsible for management system should also be ensure that any action identified during a review is implemented within the agreed time limit.

## 3. Planning of Management Reviews

- 3.1. Management reviews should be carried out at least once a year. The review should be planned and the meeting should be attended by the top management, including the person under whose authority the Management System Document / Quality Manual has been issued. It is essential that the head of the CAB, technical management, the person responsible for management system and the section heads are present.
- 3.2. It is recognized that in a small CAB, one person may be fulfilling more than one of the above functions. Good management reviews can occur even in single person CABs.

#### 4. Implementation of Management Reviews

- 4.1. The management review should be conducted in a systematic manner using a formal agenda.
- 4.2. The agenda of management review meeting should at least cover the requirements given in the corresponding clause of applicable standards e.g. ISO/IEC 17025:2017 or ISO 15189:2022 or ISO/IEC 17043:2010 or ISO/IEC 17043: 2023 or ISO 17034:2016 or ISO 20387: 2018
- 4.3. It should be the responsibility of the person responsible for management system to ensure that all actions arising from review are carried out as required. Actions and their effectiveness should be monitored at regular (perhaps monthly) management meetings.

#### 5. Records of Management Reviews

- 5.1. All management reviews should be documented. The documentation may be in the form of minutes of review meetings together with clear indications as to the actions to be taken, by whom and in what time limit.
- 5.2. It should be the responsibility of the person responsible for management system to ensure that all actions arising from reviews are recorded and discharged as required.
- 5.3. The records should be readily accessible and be retained for a minimum period of three years

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