

NABL 217



National Accreditation Board for Testing and Calibration Laboratories (NABL)

Assessment Forms and Checklist (based on ISO 15189:2012)

ISSUE NO.: 06
ISSUE DATE: 16-Feb-2021

AMENDMENT NO.: 01
AMENDMENT DATE: 13-Jul-2023

AMENDMENT SHEET

S. No.	Page No.	Clause No.	Date of Amendment	Amendment	Reasons	Signature QA Team	Signature Competent Authority
1.	3, 5, 7, 8,9	--	13.07.2023	As highlighted	Internal Review	-Sd/-	-Sd/-
2.	10, 46	--		Text deleted	Internal Review		
3.	76	--		Assessor Checklist - 4 For Medical Imaging-Conformity Assessment Bodies	Medical Imaging included under Medical field		
4.							
5.							
6.							
7.							
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ASSESSMENT SCHEDULE

Name of the Laboratory:				
Contact Person for NABL:			Date of Assessment:	
Type of Assessment: <i>Initial Assessment / Onsite Surveillance / Re-Assessment / Supplementary Visit</i>				
Field: <i>Medical</i>		Discipline (s):		
Facility (s): <i>Permanent / Mobile / Site Facility</i>				
Assessment Standard: <i>ISO 15189: 2012</i> Specific Criteria of NABL:				
Assessment Timings		Opening/Closing Meeting Date/Time	Daily Debriefing (at the end of each day) Date / Time	
<i>Morning: AM to PM</i> <i>Afternoon: PM to PM</i>		<i>Opening Meeting:</i> <i>Closing Meeting:</i>	<i>Day 1:</i> <i>Day 2:</i> <i>Day 3:</i>	
Name and Expertise of the Assessor	Schedule of Locations/ Department/ Section/ Activity to be Assessed (date wise)			
	Day 1		Day 2	
	Morning	Afternoon	Morning	Afternoon
Lead Assessor				
Assessor 1				
Assessor 2				
Assessor 3				
Assessor 4				
Assessor 5				
Assessor 6				
Assessor 7				
Observer (only for observation)				
I declare that the assessment schedule has been prepared after discussing with the assessment team members.				
Signature and name of Lead Assessor				

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ATTENDANCE SHEET (OPENING & CLOSING MEETING)

[illegible]

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DETAILS OF TESTING / RE-TESTING / REPLICATE WITNESSED DURING ASSESSMENT
(To be filled in by the Technical Assessor)

Name of the Laboratory:		Location(s):	
Discipline:	Facility (Permanent / Mobile/ Site Facility):	Date(s) of Assessment:	
Materials or Products tested			
Component, parameter or characteristic tested/ Specific Test Performed/ Tests or type of tests performed			
Test Method Specification against which tests are performed and/or the techniques/ equipment used			
Range of Testing / Limits of detection			
% CV / Measurement Uncertainty expressed as ($\pm$) of Observed Value**			

1. Fresh Sample

Sample ID	
Tested by	
Results of Test Witnessed	

2. Re-testing/replicate testing of Retained Sample

Sample ID	
Date of Earlier Testing	
Earlier Tested by	
Earlier Reported Results	
Results of Test Witnessed	
Test conducted by (same person)	
Test conducted by (different person)	

3. Testing of CRM / SRM

Reference Material	
Specified Value	
Results of Test Witnessed	

Remarks:

Deviations observed, if any	
Conclusion on the technical competence of the lab for the test witnessed	

(Enclose/upload all supporting data sheets for tests witnessed)

(Signature & Name of Assessor)

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SUMMARY ON NON-CONFORMITIES

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

Name of the Laboratory			
Name of the Assessor/Capacity			
Date(s) of Assessment:		Discipline:	
NON-CONFORMITY STATEMENT:			
Cl. No. of (ISO 15189: 2012 / NABL 133 Clause No. / NABL Specific criteria (If applicable):			
Acceptance (Signature of laboratory's representative and propose the required corrective actions)		Signature & Name of Assessor	
CORRECTIVE ACTION PROPOSED BY THE LABORATORY			
Signature & Name Authorized Representative of Laboratory			
ASSESSOR'S COMMENTS ON CORRECTIVE ACTION PROPOSED BY THE LABORATORY: (Root cause analysis to be submitted along with the evidences of corrective actions)			
Signature of Assessor			
REMARKS BY LEAD ASSESSOR, IF ANY:			
Acceptance/Signature & Name of Lead Assessor			

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SUMMARY OF ASSESSMENT

Sl.	Item	Details						
1.	Name of the Laboratory							
2.	Date(s) of Assessment							
3.	Field							
4.	Discipline(s)							
5.	Facility	Permanent/ Mobile/ Site Facility						
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	<table border="1"> <tr> <td>Clause 4</td> <td></td> </tr> <tr> <td>Clause 5</td> <td></td> </tr> <tr> <td>Total</td> <td></td> </tr> </table>	Clause 4		Clause 5		Total	
Clause 4								
Clause 5								
Total								
10.	Comment(s) of Assessment Team on compliance of laboratory to:							
	NABL 133*							
	NABL 142*							
	NABL 163*							
	Specific Criteria* (wherever applicable)							
	*(Lead Assessor to comment on the basis of observations of Technical Assessor(s))							
11.	Assessment Summary							
12.	Recommendation of Assessment team as per ISO 15189: 2012							
13.	Only if accreditation is recommended, date by which the Corrective Action to be submitted by the laboratory 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 laboratory							
Enclosures	NAF 6	NAF 4						
	NAF 3A	NAF 1						
	NAF 1A	Check list 1						
	Check list 2	Check list 3						
	Form 72	Form 74						
	Form 45	TA/DA Forms						
	PT/EQAS Summary	Any other document						
No. of Pages								
Acknowledgement by Authorised Representative of Laboratory & Date		Signature of Lead Assessor & Date						

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RECOMMENDED SCOPE OF ACCREDITATION

[illegible]

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 / <u>Initial</u> 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 laboratory (e.g. internal audit), in any way.

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

I got an opportunity to go through various documents like Management System Document / Quality Manual (howsoever named), Procedural Manuals, Work instructions, Internal reports etc. of the above laboratory 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

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ASSESSOR CHECKLIST 1 (ISO 15189: 2012)

(To be filled in by the Lead Assessor)

The following pages present a checklist of the criteria from ISO 15189: 2012, which is the basis for the NABL General requirements for accreditation of Medical laboratories. The laboratory's policies and procedures must meet full requirements of ISO 15189: 2012, , NABL 133, NABL 142, NABL 163 and NABL specific criteria. **The actual standard must be referred for the definitive language and interpretation.**

#The Lead Assessor 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 must review the laboratory's documented system to verify conformity with the requirements of ISO 15189: 2012, assess to verify that the documented quality system is indeed implemented as described, record conclusion/comments related to any requirements on the space provided or use the bottom of the page or use separate sheet(s). All non-conformities must be identified and reported separately on each sheet of NAF-4. This checklist shall be submitted as a part of the assessment report.

Name of the Laboratory	
City/ Town	
Assessment Date (S)	
Lead Assessor's Name	
Signature	

#-Applicable for Offline Assessments

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

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REQUIREMENTS OF ISO 15189:2012			DOCUMENTATION		
			IMPLEMENTATION		
			REMARKS		
4	MANAGEMENT REQUIREMENTS				
4.1	ORGANIZATION AND MANAGEMENT RESPONSIBILITIES				
4.1.1	ORGANIZATION				
4.1.1.1	General				
	The medical laboratory (hereinafter referred to as 'the laboratory') shall meet the requirements of this International Standard when carrying out work at its permanent facilities, or in associated or mobile facilities.				
4.1.1.2	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.				
4.1.1.3	Ethical conduct				
	Laboratory management shall have arrangements in place to ensure the following:				
a	there is no involvement in any activities that would diminish confidence in the laboratory's competence, impartiality, judgement or operational integrity;				
b	management and personnel are free from any undue commercial, financial, or other pressures and influences that may adversely affect the quality of their work;				
c	where potential conflicts in competing interests may exist, they shall be openly and appropriately declared;				
d	there are appropriate procedures to ensure that staff treat human samples, tissues or remains according to relevant legal requirements;				
e	confidentiality of information is maintained.				
4.1.1.4	Laboratory Director				
	The laboratory shall be directed by a person or persons with the competence and delegated responsibility for the services provided. The responsibilities of the laboratory director shall include professional, scientific, consultative or advisory, organizational, administrative and educational matters relevant to the services offered by the laboratory. The laboratory director may delegate selected duties and/or responsibilities to qualified personnel; however, the laboratory director shall maintain the ultimate responsibility for the overall operation and administration of the laboratory. The duties and responsibilities of the laboratory director shall be documented. The laboratory director (or the designates for delegated duties) shall have the necessary competence, authority and resources in order to fulfil the requirements of this International Standard. The laboratory director (or designate/s) shall:				
a	provide effective leadership of the medical laboratory service, including budget planning and financial management, in accordance with institutional assignment of such responsibilities;				
b	relate and function effectively with applicable accrediting and regulatory agencies, appropriate administrative officials, the healthcare community, and the patient population served, and providers of formal agreements, when required;				

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				c	ensure that there are appropriate numbers of staff with the required education, training and competence to provide medical laboratory services that meet the needs and requirements of the users;	
				d	ensure the implementation of the quality policy;	
				e	implement a safe laboratory environment in compliance with good practice and applicable requirements;	
				f	serve as a contributing member of the medical staff for those facilities served, if applicable and appropriate;	
				g	ensure the provision of clinical advice with respect to the choice of examinations, use of the service and interpretation of examination results;	
				h	select and monitor laboratory suppliers;	
				i	select referral laboratories and monitor the quality of their service (see also 4.5);	
				j	provide professional development programmes for laboratory staff and opportunities to participate in scientific and other activities of professional laboratory organizations;	
				k	define, implement and monitor standards of performance and quality improvement of the medical laboratory service or services; <i>NOTE: This may be done within the context of the various quality improvement committees of the parent organization, as appropriate, where applicable.</i>	
				l	monitor all work performed in the laboratory to determine that clinically relevant information is being generated;	
				m	address any complaint, request or suggestion from staff and/or users of laboratory services (see also 4.8, 4.14.3 and 4.14.4);	
				n	design and implement a contingency plan to ensure that essential services are available during emergency situations or other conditions when laboratory services are limited or unavailable; <i>NOTE: Contingency plans should be periodically tested.</i>	
				o	plan and direct research and development, where appropriate.	
		4.1.2	MANAGEMENT RESPONSIBILITY			
		4.1.2.1	Management commitment			
					Laboratory management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improve its effectiveness by:	
			a		communicating to laboratory personnel the importance of meeting the needs and requirements of users (see 4.1.2.2) as well as regulatory and accreditation requirements;	
			b		establishing the quality policy (see 4.1.2.3);	
			c		ensuring that quality objectives and planning are established (see 4.1.2.4);	
			d		defining responsibilities, authorities and interrelationships of all personnel (see 4.1.2.5);	

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				e establishing communication processes (see 4.1.2.6); f appointing a quality manager, however named (see 4.1.2.7); g conducting management reviews (see 4.15); h ensuring that all personnel are competent to perform their assigned activities (see 5.1.6); i ensuring availability of adequate resources (see 5.1, 5.2 and 5.3) to enable the proper conduct of pre-examination, examination and post-examination activities (see 5.4, 5.5, and 5.7)			
			4.1.2.2	Needs of users Laboratory management shall ensure that laboratory services, including appropriate advisory and interpretative services, meet the needs of patients and those using the laboratory services. (See also 4.4 and 4.14.3).			
			4.1.2.3	Quality Policy Laboratory management shall define the intent of its quality management system in a quality policy. Laboratory management shall ensure that the quality policy: a is appropriate to the purpose of the organization; b includes a commitment to good professional practice, examinations that are fit for intended use, compliance with the requirements of this International Standard, and continual improvement of the quality of laboratory services; c provides a framework for establishing and reviewing quality objectives; d is communicated and understood within the organization; e is reviewed for continuing suitability.			
			4.1.2.4	Quality objectives and planning Laboratory management shall establish quality objectives, including those needed to meet the needs and requirements of the users, at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy. Laboratory management shall ensure that planning of the quality management system is carried out to meet the requirements (see 4.2) and the quality objectives. Laboratory management shall ensure that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.			
			4.1.2.5	Responsibility, authority and interrelationships Laboratory management shall ensure that responsibilities, authorities and interrelationships are defined, documented and communicated within the laboratory organization. This shall include the appointment of person(s) responsible for each laboratory function and appointment of deputies for key managerial and technical personnel.			

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			NOTE: It is recognized that in smaller laboratories individuals can have more than one function and that it could be impractical to appoint deputies for every function.			
		4.1.2.6	Communication			
			Laboratory management shall have an effective means for communicating with staff (see also 4.14.4). Records shall be kept of items discussed in communications and meetings.			
			Laboratory management shall ensure that appropriate communication processes are established between the laboratory and its stakeholders and that communication takes place regarding the effectiveness of the laboratory's pre-examination, examination and post-examination processes and quality management system.			
		4.1.2.7	Quality manager			
			Laboratory management shall appoint a quality manager who shall have, irrespective of other responsibilities, delegated responsibility and authority that includes:			
		a	ensuring that processes needed for the quality management system are established, implemented, and maintained;			
		b	Reporting to laboratory management, at the level at which decisions are made on laboratory policy, objectives, and resources, on the performance of the quality management system and any need for improvement;			
		c	ensuring the promotion of awareness of users' needs and requirements throughout the laboratory organization.			
4.2	QUALITY MANAGEMENT SYSTEM					
	4.2.1	GENERAL REQUIREMENTS				
		The laboratory shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard.				
		The quality management system shall provide for the integration of all processes required to fulfil its quality policy and objectives and meet the needs and requirements of the users.				
		The laboratory shall:				
	a	determine the processes needed for the quality management system and ensure their application throughout the laboratory;				
	b	determine the sequence and interaction of these processes;				
	c	determine criteria and methods needed to ensure that both the operation and control of these processes are effective;				
	d	ensure the availability of resources and information necessary to support the operation and monitoring of these processes;				
	e	monitor and evaluate these processes;				
	f	Implement actions necessary to achieve planned results and continual improvement of these processes.				
	4.2.2	DOCUMENTATION REQUIREMENTS				
	4.2.2.1	General				
		The quality management system documentation shall include:				
	a	statements of a quality policy (see 4.1.2.3) and quality objectives (see 4.1.2.4);				

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			b a quality manual (see 4.2.2.2); c procedures and records required by this International Standard; d documents, and records (see 4.13), determined by the laboratory to ensure the effective planning, operation and control of its processes; e copies of applicable regulations, standards and other normative documents. <i>NOTE: The documentation can be in any form or type of medium, providing it is readily accessible and protected from unauthorized changes and undue deterioration.</i>			
		4.2.2.2	Quality manual The laboratory shall establish and maintain a quality manual that includes a the quality policy (4.1.2.3) or makes reference to it; b a description of the scope of the quality management system; c a presentation of the organization and management structure of the laboratory and its place in any parent organization; d a description of the roles and responsibilities of laboratory management (including the laboratory director and quality manager) for ensuring compliance with this International Standard; e a description of the structure and relationships of the documentation used in the quality management system; f the documented policies established for the quality management system and reference to the managerial and technical activities that support them. All laboratory staff shall have access to and be instructed on the use and application of the quality manual and the referenced documents.			
4.3	DOCUMENT CONTROL The laboratory shall control documents required by the quality management system and shall ensure that unintended use of any obsolete document is prevented. NOTE: 1 Documents that should be considered for document control are those that may vary based on changes in versions or time. Examples include policy statements, instructions for use, flow charts, procedures, specifications, forms, calibration tables, biological reference intervals and their origins, charts, posters, notices, memoranda, software documentation, drawings, plans, agreements, and documents of external origin such as regulations, standards and text books from which examination procedures are taken. NOTE: 2 Records contain information from a particular point in time stating results achieved or providing evidence of activities performed and are maintained according to the requirements given in 4.13, Control of records. The laboratory shall have a documented procedure to ensure that the following conditions are met					

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	a	all documents, including those maintained in a computerized system, issued as part of the quality management system are reviewed and approved by authorized personnel before issue.		
	b	all documents are identified to include: — a title; — a unique identifier on each page; — the date of the current edition and/or edition number; — page number to total number of pages (e.g. "Page 1 of 5," "Page 2 of 5,"); — Authority for issue. NOTE: 'Edition' is used to mean one of a number of printings issued at separate times that incorporates alterations and amendments. 'Edition' can be regarded as synonymous with 'revision or version'.		
	c	current authorized editions and their distribution are identified by means of a list (e.g. document register, log or master index).		
	d	only current, authorized editions of applicable documents are available at points of use.		
	e	where a laboratory's document control system allows for the amendment of documents by hand, pending the re-issue of documents, the procedures and authorities for such amendments are defined, amendments are clearly marked, initialled and dated, and a revised document is issued within a specified time period.		
	f	changes to documents are identified.		
	g	documents remain legible.		
	h	documents are periodically reviewed and updated at a frequency that ensures that they remain fit for purpose.		
	i	obsolete controlled documents are dated and marked as obsolete.		
	j	at least one copy of an obsolete controlled document is retained for a specified time period or in accordance with applicable specified requirements.		
4.4	SERVICE AGREEMENTS			
	4.4.1	ESTABLISHMENT OF SERVICE AGREEMENTS		
		The laboratory shall have documented procedures for the establishment and review of agreements for providing medical laboratory services. Each request accepted by the laboratory for examination(s) shall be considered an agreement. Agreements to provide medical laboratory services shall take into account the request, the examination and the report. The agreement shall specify the information needed on the request to ensure appropriate examination and result interpretation. The following conditions shall be met when the laboratory enters into an agreement to provide medical laboratory services.		
	a	the requirements of the customers and users, and of the provider of the laboratory services, including the examination processes to be used, shall be defined, documented and understood (see 5.4.2 and 5.5).		
	b	the laboratory shall have the capability and resources to meet the requirements.		
	c	laboratory personnel shall have the skills and expertise necessary for the performance of the intended examinations.		
	d	examination procedures selected shall be appropriate and able to meet the customers' needs (see 5.5.1).		
	e	customers and users shall be informed of deviations from the agreement that impact upon the examination results.		
	f	reference shall be made to any work referred by the laboratory to a referral laboratory or consultant.		

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		<i>NOTE: 1 Customers and users may include clinicians, health care organizations, third party payment organizations or agencies, pharmaceutical companies, and patients.</i> <i>NOTE: 2 Where patients are customers (e.g. when patients have the ability to directly request examinations), changes in service should be reflected in explanatory information and laboratory reports.</i> <i>NOTE: 3 Laboratories should not enter into financial arrangements with referring practitioners or funding agencies where those arrangements act as an inducement for the referral of examinations or patients or interfere with the practitioner's independent assessment of what is best for the patient.</i>			
	4.4.2	REVIEW OF SERVICE AGREEMENTS			
		Reviews of agreements to provide medical laboratory services shall include all aspects of the agreement. Records of these reviews shall include any changes to the agreement and any pertinent discussions. When an agreement needs to be amended after laboratory services have commenced, the same agreement review process shall be repeated and any amendments shall be communicated to all affected parties.			
4.5	EXAMINATION BY REFERRAL LABORATORIES				
	4.5.1	SELECTING AND EVALUATING REFERRAL LABORATORIES AND CONSULTANTS			
		The laboratory shall have a documented procedure for selecting and evaluating referral laboratories and consultants who provide opinions as well as interpretation for complex testing in any discipline. The procedure shall ensure that the following conditions are met.			
	a	the laboratory, with the advice of users of laboratory services where appropriate, is responsible for selecting the referral laboratory and referral consultants, monitoring the quality of performance and ensuring that the referral laboratories or referral consultants are competent to perform the requested examinations.			
	b	arrangements with referral laboratories and consultants are reviewed and evaluated periodically to ensure that the relevant parts of this International Standard are met.			
	c	records of such periodic reviews are maintained.			
	d	a register of all referral laboratories, and consultants from whom opinions are sought, is maintained.			
	e	requests and results of all samples referred are kept for a pre-defined period.			
	4.5.2	PROVISION OF EXAMINATION RESULTS			

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			Unless otherwise specified in the agreement, the referring laboratory (and not the referral laboratory) shall be responsible for ensuring that examination results of the referral laboratory are provided to the person making the request. When the referring laboratory prepares the report, it shall include all essential elements of the results reported by the referral laboratory or consultant, without alterations that could affect clinical interpretation. The report shall indicate which examinations were performed by a referral laboratory or consultant. The author of any additional remarks shall be clearly identified. Laboratories shall adopt the most appropriate means of reporting referral laboratory results, taking into account turnaround times, measurement accuracy, transcription processes and interpretative skill requirements. In cases where the correct interpretation and application of examination results needs collaboration between clinicians and specialists from referring and referral laboratories, this process shall not be hindered by commercial or financial considerations.			
4.6	EXTERNAL SERVICES AND SUPPLIES					
	The laboratory shall have a documented procedure for the selection and purchasing of external services, equipment, reagents and consumable supplies that affect the quality of its service (see also 5.3). The laboratory shall select and approve suppliers based on their ability to supply external services, equipment, reagents and consumable supplies in accordance with the laboratory's requirements; however, it may be necessary to collaborate with other organizational departments or functions to fulfil this requirement. Criteria for selection shall be established. A list of selected and approved suppliers of equipment, reagents and consumables shall be maintained. Purchasing information shall describe the requirements for the product or service to be purchased. The laboratory shall monitor the performance of suppliers to ensure that purchased services or items consistently meet the stated criteria					
4.7	ADVISORY SERVICES					
	The laboratory shall establish arrangements for communicating with users on the following					
	a	advising on choice of examinations and use of the services, including required type of sample (see also 5.4), clinical indications and limitations of examination procedures and the frequency of requesting the examination;				
	b	advising on individual clinical cases;				
	c	professional judgments on the interpretation of the results of examinations (see 5.1.2 and 5.1.6);				
	d	promoting the effective utilization of laboratory services;				
	e	consulting on scientific and logistic matters such as instances of failure of sample(s) to meet acceptance criteria.				
4.8	RESOLUTION OF COMPLAINTS					
	The laboratory shall have a documented procedure for the management of complaints or other feedback received from clinicians, patients, laboratory staff or other parties. Records shall be maintained of all complaints and their investigation and the action taken (see also 4.14.3).					
4.9	IDENTIFICATION AND CONTROL OF NON-CONFORMITIES					

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	The laboratory shall have a documented procedure to identify and manage nonconformities in any aspect of the quality management system, including pre-examination, examination or post-examination processes. The procedure shall ensure that: a the responsibilities and authorities for handling nonconformities are designated; b the immediate actions to be taken are defined; c the extent of the nonconformity is determined; d examinations are halted and reports withheld as necessary; e the medical significance of any nonconforming examinations is considered and, where appropriate, the requesting clinician or authorized individual responsible for using the results is informed; f the results of any nonconforming or potentially nonconforming examinations already released are recalled or appropriately identified, as necessary; g the responsibility for authorization of the resumption of examinations is defined; h each episode of nonconformity is documented and recorded, with these records being reviewed at regular specified intervals to detect trends and initiate corrective action. <i>NOTE: Nonconforming examinations or activities occur in many different areas and can be identified in many different ways, including clinician complaints, internal quality control indications, instrument calibrations, checking of consumable materials, interlaboratory comparisons, staff comments, reporting and certificate checking, laboratory management reviews, and internal and external audits.</i> When it is determined that nonconformities in pre-examination, examination and post-examination processes could recur or that there is doubt about the laboratory's compliance with its own procedures, the laboratory shall take action to identify, document and eliminate the cause(s). Corrective action to be taken shall be determined and documented (see 4.10).			
4.10	CORRECTIVE ACTION The laboratory shall take corrective action to eliminate the cause(s) of nonconformities. Corrective actions shall be appropriate to the effects of the nonconformities encountered. The laboratory shall have a documented procedure for: a reviewing nonconformities; b determining the root causes of nonconformities; c evaluating the need for corrective action to ensure that nonconformities do not recur; d determining and implementing corrective action needed; e recording the results of corrective action taken (see 4.13); f Reviewing the effectiveness of the corrective action taken (see 4.14.5). <i>NOTE: Action taken at the time of the nonconformity to mitigate its immediate effects is considered "immediate" action. Only action taken to remove the root cause of the problem that is causing the nonconformities is considered "corrective" action</i>			
4.11	PREVENTIVE ACTION The laboratory shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems. The laboratory shall have a documented procedure for: a reviewing laboratory data and information to determine where potential nonconformities exist; b determining the root cause(s) of potential nonconformities;			

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	c	evaluating the need for preventive action to prevent the occurrence of nonconformities;		
	d	determining and implementing preventive action needed;		
	e	recording the results of preventive action taken (see 4.13);		
	f	Reviewing the effectiveness of the preventive action taken. <i>NOTE: Preventive action is a proactive process for identifying opportunities for improvement rather than a reaction to the identification of problems or complaints (i.e. nonconformities). In addition to review of the operational procedures, preventive action might involve analysis of data, including trend and risk analyses and external quality assessment (proficiency testing).</i>		
4.12	CONTINUAL IMPROVEMENT			
	The laboratory shall continually improve the effectiveness of the quality management system, including the pre-examination, examination and post-examination processes, through the use of management reviews to compare the laboratory's actual performance in its evaluation activities, corrective actions and preventive actions with its intentions, as stated in the quality policy and quality objectives. Improvement activities shall be directed at areas of highest priority based on risk assessments. Action plans for improvement shall be developed, documented and implemented, as appropriate. The effectiveness of the actions taken shall be determined through a focused review or audit of the area concerned (see also 4.14.5). Laboratory management shall ensure that the laboratory participates in continual improvement activities that encompass relevant areas and outcomes of patient care. When the continual improvement programme identifies opportunities for improvement, laboratory management shall address them regardless of where they occur. Laboratory management shall communicate to staff improvement plans and related goals.			
4.13	CONTROL OF RECORDS			
	The laboratory shall have a documented procedure for identification, collection, indexing, access, storage, maintenance, amendment and safe disposal of quality and technical records. Records shall be created concurrently with performance of each activity that affects the quality of the examination. <i>NOTE: 1: Records can be in any form or type of medium providing they are readily accessible and protected from unauthorized alterations.</i> The date and, where relevant, the time of amendments to records shall be captured along with the identity of personnel making the amendments (see 5.9.3). The laboratory shall define the time period that various records pertaining to the quality management system, including pre-examination, examination and post-examination processes, are to be retained. The length of time that records are retained may vary; however, reported results shall be retrievable for as long as medically relevant or as required by regulation. <i>NOTE: 2: Legal liability concerns regarding certain types of procedures (e.g. histology examinations, genetic examinations, paediatric examinations) may require the retention of certain records for much longer periods than for other records.</i> Facilities shall provide a suitable environment for storage of records to prevent damage, deterioration, loss or unauthorized access (see 5.2.6). <i>NOTE: 3: For some records, especially those stored electronically, the safest storage may be on secure media and an offsite location (see 5.10.3).</i> Records shall include, at least, the following			

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	a	supplier selection and performance, and changes to the approved supplier list;			
	b	staff qualifications, training and competency records;			
	c	request for examination;			
	d	records of receipt of samples in the laboratory;			
	e	information on reagents and materials used for examinations (e.g. lot documentation, certificates of supplies, package inserts);			
	f	laboratory work books or work sheets;			
	g	instrument printouts and retained data and information;			
	h	examination results and reports;			
	i	instrument maintenance records, including internal and external calibration records;			
	j	calibration functions and conversion factors;			
	k	quality control records;			
	l	incident records and action taken;			
	m	accident records and action taken;			
	n	risk management records;			
	o	nonconformities identified and immediate or corrective action taken;			
	p	preventive action taken;			
	q	complaints and action taken;			
	r	records of internal and external audits;			
	s	interlaboratory comparisons of examination results;			
	t	records of quality improvement activities;			
	u	minutes of meetings that record decisions made about the laboratory's quality management activities;			
	v	Records of management reviews.			
	All of these quality and technical records shall be available for laboratory management review (see 4.15).				
4.14	EVALUATION AND AUDITS				
	4.14.1	GENERAL			
		The laboratory shall plan and implement the evaluation and internal audit processes needed to:			
	a	demonstrate that the pre-examination, examination and post-examination and supporting processes are being conducted in a manner that meets the needs and requirements of users;			
	b	ensure conformity to the quality management system;			
	c	continually improve the effectiveness of the quality management system. The results of evaluation and improvement activities shall be included in the input to the management review (see 4.15). <i>NOTE: For improvement activities, see 4.10, 4.11, and 4.12.</i>			
	4.14.2	PERIODIC REVIEW OF REQUESTS, AND SUITABILITY OF PROCEDURES AND SAMPLE REQUIREMENTS			
		Authorized personnel shall periodically review the examinations provided by the laboratory to ensure that they are clinically appropriate for the requests received. The laboratory shall periodically review its sample volume, collection device and preservative requirements for blood, urine, other body fluids, tissue and other sample types, as applicable, to ensure that neither insufficient nor excessive amounts of sample are collected and the sample is properly collected to preserve the measurand.			
	4.14.3	ASSESSMENT OF USER FEEDBACK			
		The laboratory shall seek information relating to user perception as to whether the service has met the needs and requirements of users. The methods for obtaining and using			

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		this information shall include cooperation with users or their representatives in monitoring the laboratory's performance, provided that the laboratory ensures confidentiality to other users. Records shall be kept of information collected and actions taken.			
	4.14.4	STAFF SUGGESTIONS Laboratory management shall encourage staff to make suggestions for the improvement of any aspect of the laboratory service. Suggestions shall be evaluated, implemented as appropriate and feedback provided to the staff. Records of suggestions and action taken by the management shall be maintained.			
	4.14.5	INTERNAL AUDIT The laboratory shall conduct internal audits at planned intervals to determine whether all activities in the quality management system, including pre-examination, examination, and post-examination: a conform to the requirements of this International Standard and to requirements established by the laboratory, and b are implemented, effective, and maintained. <i>NOTE: 1: The cycle for internal auditing should normally be completed in one year. It is not necessary that internal audits cover each year, in depth, all elements of the quality management system. The laboratory may decide to focus on a particular activity without completely neglecting the others.</i> Audits shall be conducted by personnel trained to assess the performance of managerial and technical processes of the quality management system. The audit programme shall take into account the status and importance of the processes and technical and management areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined and documented. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall, wherever resources permit, be independent of the activity to be audited. <i>NOTE: 2: See ISO 19011 for guidance.</i> The laboratory shall have a documented procedure to define the responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.13). Personnel responsible for the area being audited shall ensure that appropriate action is promptly undertaken when nonconformities are identified. Corrective action shall be taken without undue delay to eliminate the causes of the detected nonconformities (see 4.10).			
	4.14.6	RISK MANAGEMENT The laboratory shall evaluate the impact of work processes and potential failures on examination results as they affect patient safety, and shall modify processes to reduce or eliminate the identified risks and document decisions and actions taken.			
	4.14.7	QUALITY INDICATORS The laboratory shall establish quality indicators to monitor and evaluate performance throughout critical aspects of pre-examination, examination and post-examination processes.			

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		EXAMPLE: Number of unacceptable samples, number of errors at registration and/or accession, number of corrected reports. The process of monitoring quality indicators shall be planned, which includes establishing the objectives, methodology, interpretation, limits, action plan and duration of measurement. The indicators shall be periodically reviewed, to ensure their continued appropriateness. <i>NOTE: 1: Quality indicators to monitor non-examination procedures, such as laboratory safety and environment, completeness of equipment and personnel records, and effectiveness of the document control system may provide valuable management insights.</i> <i>NOTE: 2: The laboratory should establish quality indicators for systematically monitoring and evaluating the laboratory's contribution to patient care (see 4.12).</i> The laboratory, in consultation with the users, shall establish turnaround times for each of its examinations that reflect clinical needs. The laboratory shall periodically evaluate whether or not it is meeting the established turnaround times.				
	4.14.8	REVIEWS BY EXTERNAL ORGANIZATIONS				
		When reviews by external organizations indicate the laboratory has nonconformities or potential nonconformities, the laboratory shall take appropriate immediate actions and, as appropriate, corrective action or preventive action to ensure continuing compliance with the requirements of this International Standard. Records shall be kept of the reviews and of the corrective actions and preventive actions taken. <i>NOTE: Examples of reviews by external accreditation organizations include: accreditation assessments, regulatory agencies' inspections, and health and safety inspections.</i>				
4.15	MANAGEMENT REVIEW					
	4.15.1	GENERAL				
		Laboratory management shall review the quality management system at planned intervals to ensure its continuing suitability, adequacy and effectiveness and support of patient care.				
	4.15.2	REVIEW INPUT				
		The input to management review shall include information from the results of evaluations of at least the following:				
		a the periodic review of requests, and suitability of procedures and sample requirements (see 4.14.2);				
		b assessment of user feedback (see 4.14.3);				
		c staff suggestions (see 4.14.4);				
		d internal audits (see 4.14.5);				
		e risk management (see 4.14.6)				
		f use of quality indicators (see 4.14.7);				
		g reviews by external organizations (see 4.14.8);				
		h results of participation in interlaboratory comparison programmes (pt/eqa) (see 5.6.3);				
		i monitoring and resolution of complaints (see 4.8);				
		j performance of suppliers (see 4.6);				
		k identification and control of nonconformities (see 4.9);				

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			l	results of continual improvement (see 4.12) including current status of corrective actions (see 4.10) and preventive actions (see 4.11);		
			j	performance of suppliers (see 4.6);		
			k	identification and control of nonconformities (see 4.9);		
			l	results of continual improvement (see 4.12) including current status of corrective actions (see 4.10) and preventive actions (see 4.11);		
			m	follow-up actions from previous management reviews;		
			n	changes in the volume and scope of work, personnel, and premises that could affect the quality management system;		
			o	Recommendations for improvement, including technical requirements.		
		4.15.3	REVIEW ACTIVITIES			
			The review shall analyse the input information for causes of nonconformities, trends and patterns that indicate process problems.			
			This review shall include assessing these opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.			
			The quality and appropriateness of the laboratory's contribution to patient care shall, to the extent possible, also be objectively evaluated.			
		4.15.4	REVIEW OUTPUT			
			The output from the management review shall be incorporated into a record that documents any decisions made and actions taken during management review related to:			
			a	improvement of the effectiveness of the quality management system and its processes;		
			b	improvement of services to users;		
			c	Resource needs.		
			<i>NOTE: The interval between management reviews should be no greater than 12 months; however, shorter intervals should be adopted when a quality management system is being established.</i> Findings and actions arising from management reviews shall be recorded and reported to laboratory staff. Laboratory management shall ensure that actions arising from management review are completed within a defined timeframe.			

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