

NABL 220A



National Accreditation Board for Testing and Calibration Laboratories (NABL)

Document Review Checklist (as per ISO 15189: 2012)

ISSUE NO.: 01
ISSUE DATE: 11-Feb-2021

AMENDMENT NO.: --
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Document Review Checklist (as per ISO 15189: 2012)

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 quality manual / management system document in conformance with the requirements of ISO 15189: 2012.

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'

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Document Review Checklist (as per ISO 15189:2012)

(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 location details of the laboratory	
2.	Legal identity	
3.	Type of Laboratory	
4.	Details on other accreditations	
5.	Information on disciplines applied	
6.	Scope of the Laboratory	
7.	Required details of senior management	
8.	Proposed personnel to release the results	
9.	Organization chart of the Laboratory	
10.	Details of staff	
11.	List of equipment/ Reference materials/ reference standards	
12.	Internal audit	
13.	Management Review	
14.	PT/ ILC	
15.	Any general points	

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Part 'B' - Remarks on Quality Manual/ Management System Document

The Assessor must review the laboratory's documented management system to verify compliance with the requirements of ISO 15189: 2012 and it can be assessed further to verify that the documented management system is indeed implemented as described, record conclusion/ comments related to any requirements. All non-conformity (ies) must be identified and reported.

		DOCUMENTATION	
REQUIREMENTS OF ISO 15189:2012			REMARK
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	
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				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;		
				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		

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				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);		
			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;		
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				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.			
				<i>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.</i>			
			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			

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				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);			
			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.			
			NOTE: The documentation can be in any form or type of medium, providing it is				

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				<i>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								
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:							

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			— 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		
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			laboratory to a referral laboratory or consultant.		
			<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.		

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		4.5.2	PROVISION OF EXAMINATION RESULTS			
			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):			

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		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		
		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.	
		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.		
		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	

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		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;		
	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</i>			

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		they are readily accessible and protected from unauthorized alterations. 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 <table><tr><td>a</td><td>supplier selection and performance, and changes to the approved supplier list;</td></tr><tr><td>b</td><td>staff qualifications, training and competency records;</td></tr><tr><td>c</td><td>request for examination;</td></tr><tr><td>d</td><td>records of receipt of samples in the laboratory;</td></tr><tr><td>e</td><td>information on reagents and materials used for examinations (e.g. lot documentation, certificates of supplies, package inserts);</td></tr><tr><td>f</td><td>laboratory work books or work sheets;</td></tr><tr><td>g</td><td>instrument printouts and retained data and information;</td></tr><tr><td>h</td><td>examination results and reports;</td></tr><tr><td>i</td><td>instrument maintenance records, including internal and external calibration records;</td></tr><tr><td>j</td><td>calibration functions and conversion factors;</td></tr><tr><td>k</td><td>quality control records;</td></tr><tr><td>l</td><td>incident records and action taken;</td></tr><tr><td>m</td><td>accident records and action taken;</td></tr><tr><td>n</td><td>risk management records;</td></tr><tr><td>o</td><td>nonconformities identified and immediate or corrective action taken;</td></tr><tr><td>p</td><td>preventive action taken;</td></tr><tr><td>q</td><td>complaints and action taken;</td></tr><tr><td>r</td><td>records of internal and external audits;</td></tr><tr><td>s</td><td>interlaboratory comparisons of examination results;</td></tr><tr><td>t</td><td>records of quality improvement activities;</td></tr><tr><td>u</td><td>minutes of meetings that record decisions made about the laboratory's quality management activities;</td></tr><tr><td>v</td><td>Records of management reviews.</td></tr></table> All of these quality and technical records shall be available for laboratory management review (see 4.15).	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.		
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