



Medical Laboratory Science Council of Nigeria



Laboratory Accreditation Checklist

For Clinical and Medical Laboratories

Table of Content (To be completed after review)

INTRODUCTION

Laboratories play a critical role in the diagnosis, management and control of diseases. Available literature demonstrates that diagnoses contribute 60-70% to clinical decisions. It is therefore imperative that accurate and reliable laboratory results are generated from medical laboratories. This can only be ensured if laboratories are deemed competent to offer quality and timely laboratory services.

The International Organization for Standardization (ISO) has developed ISO 15189 as the standard for medical laboratories. This document defines the standards for quality and competence. Because of its comprehensive approach to issues of laboratory quality and competence, accreditation of laboratories using this standard has been accepted internationally when recognition is granted by an authoritative body such as Medical Laboratory Science Council of Nigeria (MLSCN).

This checklist was developed to carry out independent assessment of medical laboratories, for use by MLSCN certified assessors to conduct a thorough evaluation of factors affecting the production of qualitative test data in an efficient, safe and prompt manner.

DISCLAIMER

This document is prepared with ISO 15189: 2012 Medical Laboratories –Requirements for quality and competence. The majority of its contents, therefore, mirrors this standard. MLSCN therefore advises that the contents of this checklist should be appropriately reference by all users. By this statement, MLSCN is not responsible for any improper referencing by any individual or group as a result of use of this checklist.

LABORATORY PROFILE

Date of Assessment	Date of Last Assessment	Type of Assessment : Preliminary / Initial / Renewal / Surveillance / Non-Routine / Verification
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Name(s), Affiliation(s) and Signatures of Assessor(s)

Lead Assessor

Technical Assessors

Laboratory Name	Laboratory Number
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Laboratory Address

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Laboratory/Head of Laboratory Telephone	Fax	Email
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Laboratory Level (check only one)			Type of Laboratory/Laboratory Affiliation (check only one)		
<input type="checkbox"/> National	<input type="checkbox"/> Reference	<input type="checkbox"/> Regional / Provincial	<input type="checkbox"/> Public	<input type="checkbox"/> Hospital	<input type="checkbox"/> Private
<input type="checkbox"/> District	<input type="checkbox"/> Zonal	<input type="checkbox"/> Field	<input type="checkbox"/> Research	<input type="checkbox"/> Non-hospital Outpatient Clinic	<input type="checkbox"/> Other – Please specify: _____

Field / Disciplines

Laboratory Staffing Summary		
<i>Profession</i>	<i>Number of Full Time Employees</i>	<i>Remarks</i>

ISO 15189:2012 Clause No.	Standard	If Yes, Where is evidence of implementation documented	If No, Remark	Minor NC or Major NC	N/A
4 Management requirements					
4.1 Organization and management responsibility					
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	Does your laboratory management have arrangements to ensure the following:				
a	No involvement in any activities that would diminish confidence in the laboratory's competence, impartiality, judgment 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	Potential conflicts in competing interests may exist, they shall be openly and appropriately declared				
d	Procedures to ensure that human samples, tissues or remains according to relevant legal requirements				
e	Confidentiality of information is maintained				
4.1.1.4 Laboratory director	Does the laboratory have a competent person(s) with medical, scientific and technical background direct the laboratory services?.				
	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 fulfill 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	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				
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				
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.				
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 fulfill 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.				
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. 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; — page number to total number of pages (e.g. "Page 1 of 5," "Page 2 of 5,"); — authority for issue.				
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, initialed 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	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.				
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	Unless otherwise specified in the				

of examination results	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 both 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 fulfill 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.				
	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 nonconformities	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.				
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).				
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.				
4.12 Continual improvement	<p>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.</p> <p>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.</p> <p>The effectiveness of the actions taken shall be determined through a focused review or audit of the area concerned (see also 4.14.5).</p>				
	<p>Laboratory management shall ensure that the laboratory participates in continual improvement activities that encompass relevant areas and outcomes of patient care.</p> <p>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.</p>				
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.				
	The date and, where relevant, the time of amendments to records shall be captured along with the identity of personnel making the amendments (see 5.8.6).				
	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.				
	Records shall include, at least, the following:				
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	Inter-laboratory 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.				
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).				
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 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				
b	are implemented, effective, and maintained.				
	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.				
	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.				
	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	The laboratory shall evaluate the				

management	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.				
	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.				
	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.				
	The laboratory should establish quality indicators for systematically monitoring and evaluating the laboratory's contribution to patient care (see 4.12)				
	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.				
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 inter - laboratory 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);				
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 analyze 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	The output from the management				

output	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.				
	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.				
	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.				
5 Technical requirements					
5.1 Personnel					
5.1.1 General	The laboratory shall have a documented procedure for personnel management and maintain records for all personnel to indicate compliance with requirements.				
5.1.2 Personnel qualifications	Laboratory management shall document personnel qualifications for each position. The qualifications shall reflect the appropriate education, training, experience and demonstrated skills needed, and be appropriate to the tasks performed.				
	The personnel making judgments with reference to examinations shall have the applicable theoretical and practical background and experience.				
5.1.3 Job descriptions	The laboratory shall have job descriptions that describe responsibilities, authorities and tasks for all personnel.				
5.1.4 Personnel introduction to the organizational environment	The laboratory shall have a programme to introduce new staff to the organization, the department or area in which the person will work, the terms and conditions of employment, staff facilities, health and safety requirements (including fire and emergency), and occupational health				

	services.				
5.1.5 Training	The laboratory shall provide training for all personnel which includes the following areas:				
a	the quality management system;				
b	assigned work processes and procedures;				
c	the applicable laboratory information system;				
d	health and safety, including the prevention or containment of the effects of adverse incidents;				
e	ethics;				
f	confidentiality of patient information.				
	Personnel that are undergoing training shall be supervised at all times.				
	The effectiveness of the training programme shall be periodically reviewed.				
5.1.6 Competence assessment	Following appropriate training, the laboratory shall assess the competence of each person to perform assigned managerial or technical tasks according to established criteria.				
	Reassessment shall take place at regular intervals. Retraining shall occur when necessary.				
	Competence of laboratory staff can be assessed by using any combination or all of the following approaches under the same conditions as the general working environment				
a	direct observation of routine work processes and procedures, including all applicable safety practices;				
b	direct observation of equipment maintenance and function checks;				
c	monitoring the recording and reporting of examination results;				
d	review of work records;				
e	assessment of problem solving skills;				
f	examination of specially provided samples, such as previously examined samples, inter-laboratory comparison materials, or split samples.				
5.1.7 Reviews of staff performance	In addition to the assessment of technical competence, the laboratory shall ensure that reviews of staff performance consider the needs of the laboratory and of the individual in order to maintain or improve the quality of service given to the users and encourage productive working relationships.				
5.1.8 Continuing	A continuing education				

education and professional development	programme shall be available to personnel who participate in managerial and technical processes. Personnel shall take part in continuing education. The effectiveness of the continuing education programme shall be periodically reviewed.				
	Personnel shall take part in regular professional development or other professional liaison activities.				
5.1.9 Personnel records	Records of the relevant educational and professional qualifications, training and experience, and assessments of competence of all personnel shall be maintained.				
	These records shall be readily available to relevant personnel and shall include but not be limited to:				
a	educational and professional qualifications;				
b	copy of certification or license, when applicable;				
c	previous work experience;				
d	job descriptions;				
e	introduction of new staff to the laboratory environment;				
f	training in current job tasks;				
g	competency assessments;				
h	records of continuing education and achievements;				
i	reviews of staff performance;				
j	reports of accidents and exposure to occupational hazards;				
k	immunization status, when relevant to assigned duties.				
5.2 Accommodation and environmental conditions					
5.2.1 General	The laboratory shall have space allocated for the performance of its work that is designed to ensure the quality, safety and efficacy of the service provided to the users and the health and safety of laboratory personnel, patients and visitors. The laboratory shall evaluate and determine the sufficiency and adequacy of the space allocated for the performance of the work.				
	Where applicable, similar provisions shall be made for primary sample collection and examinations at sites				

	other than the main laboratory premises, for example point-of-care testing (POCT) under the management of the laboratory.				
5.2.2 Laboratory and office facilities	The laboratory and associated office facilities shall provide an environment suitable for the tasks to be undertaken, to ensure the following conditions are met.				
a	Access to areas affecting the quality of examinations is controlled. Access control should take into consideration safety, confidentiality, quality and prevailing practices.				
b	Medical information, patient samples, and laboratory resources are safeguarded from unauthorized access.				
c	Facilities for examination allow for correct performance of examinations. These include, for example, energy sources, lighting, ventilation, noise, water, waste disposal and environmental conditions.				
d	Communication systems within the laboratory are appropriate to the size and complexity of the facility to ensure the efficient transfer of information.				
e	Safety facilities and devices are provided and their functioning regularly verified.				
5.2.3 Storage facilities	Storage space and conditions shall be provided that ensure the continuing integrity of sample materials, documents, equipment, reagents, consumables, records, results and any other items that could affect the quality of examination results.				
	Clinical samples and materials used in examination processes shall be stored in a manner to prevent cross contamination.				
	Storage and disposal facilities for dangerous materials shall be appropriate to the hazards of the materials and as specified by applicable requirements.				
5.2.4 Staff facilities	There shall be adequate access to washrooms, to a supply of drinking water and to facilities for storage of personal protective equipment and clothing.				
5.2.5 Patient sample collection	Patient sample collection facilities shall have separate reception/waiting and collection areas. Consideration				

facilities	shall be given to the accommodation of patient privacy, comfort and needs (e.g. disabled access, toilet facility) and accommodation of appropriate accompanying person (e.g. guardian or interpreter) during collection.				
	Facilities at which patient sample collection procedures are performed (e.g. phlebotomy) shall enable the sample collection to be undertaken in a manner that does not invalidate the results or adversely affect the quality of the examination.				
	Sample collection facilities shall have and maintain appropriate first aid materials for both patient and staff needs.				
5.2.6 Facility maintenance and environmental conditions	Laboratory premises shall be maintained in a functional and reliable condition. Work areas shall be clean and well maintained.				
	The laboratory shall monitor, control and record environmental conditions, as required by relevant specifications or where they may influence the quality of the sample, results, and/or the health of staff. Attention shall be paid to factors such as light, sterility, dust, noxious or hazardous fumes, electromagnetic interference, radiation, humidity, electrical supply, temperature, sound and vibration levels and workflow logistics, as appropriate to the activities concerned so that these do not invalidate the results or adversely affect the required quality of any examination.				
	There shall be effective separation between laboratory sections in which there are incompatible activities. Procedures shall be in place to prevent cross-contamination where examination procedures pose a hazard or where work could be affected or influenced by not being separated.				
	The laboratory shall provide a quiet and uninterrupted work environment where it is needed.				
5.3 Laboratory equipment, reagents, and consumables					
5.3.1 Equipment					

5.3.1.1 General	The laboratory shall have a documented procedure for the selection, purchasing and management of equipment.				
	The laboratory shall be furnished with all equipment needed for the provision of services (including primary sample collection, sample preparation, sample processing, examination and storage). In those cases where the laboratory needs to use equipment outside its permanent control, laboratory management shall ensure that the requirements of this International Standard are met.				
	The laboratory shall replace equipment as needed to ensure the quality of examination results.				
5.3.1.2 Equipment acceptance testing	The laboratory shall verify upon installation and before use that the equipment is capable of achieving the necessary performance and that it complies with requirements relevant to any examinations concerned (see also 5.5.1)				
5.3.1.3 Equipment instructions for use	Equipment shall be operated at all times by trained and authorized personnel.				
	Current instructions on the use, safety and maintenance of equipment, including any relevant manuals and directions for use provided by the manufacturer of the equipment, shall be readily available.				
	The laboratory shall have procedures for safe handling, transport, storage and use of equipment to prevent its contamination or deterioration.				
5.3.1.4 Equipment calibration and metrological traceability	The laboratory shall have a documented procedure for the calibration of equipment that directly or indirectly affects examination results. This procedure includes:				
a	taking into account conditions of use and the manufacturer's instructions;				
b	recording the metrological traceability of the calibration standard and the traceable calibration of the item of equipment;				
c	verifying the required measurement				

	accuracy and the functioning of the measuring system at defined intervals;				
d	recording the calibration status and date of recalibration;				
e	ensuring that, where calibration gives rise to a set of correction factors, the previous calibration factors are correctly updated;				
f	safeguards to prevent adjustments or tampering that might invalidate examination results.				
	<p>Metrological traceability shall be to a reference material or reference procedure of the higher metrological order available.</p> <p>Where this is not possible or relevant, other means for providing confidence in the results shall be applied, including but not limited to the following:</p> <ul style="list-style-type: none"> — use of certified reference materials; — examination or calibration by another procedure; — mutual consent standards or methods which are clearly established, specified, characterized and mutually agreed upon by all parties concerned. 				
5.3.1.5 Equipment maintenance and repair	The laboratory shall have a documented programme of preventive maintenance which, at a minimum, follows the manufacturer's instructions.				
	Equipment shall be maintained in a safe working condition and in working order. This shall include examination of electrical safety, emergency stop devices where they exist and the safe handling and disposal of chemical, radioactive and biological materials by authorized persons. At a minimum, manufacturer's schedules or instructions, or both, shall be used.				
	Whenever equipment is found to be defective, it shall be taken out of service and clearly labelled. The laboratory shall ensure that defective equipment is not used until it has been repaired and shown by verification to meet specified acceptance criteria. The laboratory shall examine the effect of any defects on previous examinations and institute immediate action or				

	corrective action (see 4.10).				
	The laboratory shall take reasonable measures to decontaminate equipment before service, repair or decommissioning, provide suitable space for repairs and provide appropriate personal protective equipment.				
	When equipment is removed from the direct control of the laboratory, the laboratory shall ensure that its performance is verified before being returned to laboratory use.				
5.3.1.6 Equipment adverse incident reporting	Adverse incidents and accidents that can be attributed directly to specific equipment shall be investigated and reported to the manufacturer and appropriate authorities, as required.				
5.3.1.7 Equipment records	Records shall be maintained for each item of equipment that contributes to the performance of examinations. These equipment records shall include, but not be limited to, the following:				
a	identity of the equipment;				
b	manufacturer's name, model and serial number or other unique identification;				
c	contact information for the supplier or the manufacturer;				
d	date of receiving and date of entering into service;				
e	location;				
f	condition when received (e.g. new, used or reconditioned);				
g	manufacturer's instructions;				
h	records that confirmed the equipment's initial acceptability for use when equipment is incorporated in the laboratory;				
i	maintenance carried out and the schedule for preventive maintenance;				
j	equipment performance records that confirm the equipment's ongoing acceptability for use;				
k	damage to, or malfunction, modification, or repair of the equipment.				
	The performance records referred to in j) shall include copies of reports/certificates of all calibrations and/or verifications including dates, times and results, adjustments, the acceptance criteria and due date of the next calibration and/or verification,				

	to fulfill part or all of this requirement.				
	These records shall be maintained and shall be readily available for the lifespan of the equipment or longer, as specified in the laboratory's Control of Records procedure (see 4.13).				
5.3.2 Reagents and consumables					
5.3.2.1 General	The laboratory shall have a documented procedure for the reception, storage, acceptance testing and inventory management of reagents and consumables.				
5.3.2.2 Reagents and consumables — Reception and storage	Where the laboratory is not the receiving facility, it shall verify that the receiving location has adequate storage and handling capabilities to maintain purchased items in a manner that prevents damage or deterioration.				
	The laboratory shall store received reagents and consumables according to manufacturer's specifications.				
5.3.2.3 Reagents and consumables — Acceptance testing	Each new formulation of examination kits with changes in reagents or procedure, or a new lot or shipment, shall be verified for performance before use in examinations.				
	Consumables that can affect the quality of examinations shall be verified for performance before use in examinations.				
5.3.2.4 Reagents and consumables — Inventory management	The laboratory shall establish an inventory control system for reagents and consumables.				
	The system for inventory control shall segregate uninspected and unacceptable reagents and consumables from those that have been accepted for use.				
5.3.2.5 Reagents and consumables — Instructions for use	Instructions for the use of reagents and consumables, including those provided by the manufacturers, shall be readily available.				
5.3.2.6 Reagents and consumables — Adverse incident reporting	Adverse incidents and accidents that can be attributed directly to specific reagents or consumables shall be investigated and reported to the manufacturer and appropriate authorities, as required.				

5.3.2.7 Reagents and consumables — Records	Records shall be maintained for each reagent and consumable that contributes to the performance of examinations. These records shall include but not be limited to the following:				
a	identity of the reagent or consumable;				
b	manufacturer's name and batch code or lot number;				
c	contact information for the supplier or the manufacturer;				
d	date of receiving, the expiry date, date of entering into service and, where applicable, the date the material was taken out of service;				
e	condition when received (e.g. acceptable or damaged);				
f	manufacturer's instructions;				
g	records that confirmed the reagent's or consumable's initial acceptance for use;				
h	performance records that confirm the reagent's or consumable's ongoing acceptance for use.				
	Where the laboratory uses reagents prepared or completed in-house, the records shall include, in addition to the relevant information above, reference to the person or persons undertaking their preparation and the date of preparation.				
5.4 Pre-examination processes					
5.4.1 General	The laboratory shall have documented procedures and information for pre-examination activities to ensure the validity of the results of examinations.				
5.4.2 Information for patients and users	The laboratory shall have information available for patients and users of the laboratory services. The information shall include as appropriate:				
a	the location of the laboratory;				
b	types of clinical services offered by the laboratory including examinations referred to other laboratories;				
c	opening hours of the laboratory;				
d	the examinations offered by the laboratory including, as appropriate, information concerning samples required, primary sample volumes, special precautions, turnaround time, (which may also be provided in general categories or for groups of				

	examinations), biological reference intervals, and clinical decision values;				
e	instructions for completion of the request form;				
f	instruction for preparation of the patient;				
g	instructions for patient-collected samples;				
h	instructions for transportation of samples, including any special handling needs;				
i	any requirements for patient consent (e.g. consent to disclose clinical information and family history to relevant healthcare professionals, where referral is needed);				
j	the laboratory's criteria for accepting and rejecting samples;				
k	a list of factors known to significantly affect the performance of the examination or the interpretation of the results;				
l	availability of clinical advice on ordering of examinations and on interpretation of examination results;				
m	the laboratory's policy on protection of personal information;				
n	the laboratory's complaint procedure.				
	The laboratory shall have information available for patients and users that includes an explanation of the clinical procedure to be performed to enable informed consent. Importance of provision of patient and family information, where relevant (e.g. for interpreting genetic examination results), shall be explained to the patient and user.				
5.4.3 Request form information	The request form or an electronic equivalent shall allow space for the inclusion of, but not be limited to, the following:				
a	patient identification, including gender, date of birth, and the location/contact details of the patient, and a unique identifier;				
b	name or other unique identifier of clinician, healthcare provider, or other person legally authorized to request examinations or use medical information, together with the destination for the report and contact details;				
c	type of primary sample and, where relevant, the anatomic site of origin;				

d	examinations requested;				
e	clinically relevant information about the patient and the request, for examination performance and result interpretation purposes;				
f	date and, where relevant, time of primary sample collection;				
g	date and time of sample receipt.				
	The laboratory shall have a documented procedure concerning verbal requests for examinations that includes providing confirmation by request form or electronic equivalent within a given time.				
	The laboratory shall be willing to cooperate with users or their representatives in clarifying the user's request.				
5.4.4 Primary sample collection and handling					
5.4.4.1 General	The laboratory shall have documented procedures for the proper collection and handling of primary samples. The documented procedures shall be available to those responsible for primary sample collection whether or not the collectors are laboratory staff.				
	Where the user requires deviations and exclusions from, or additions to, the documented collection procedure, these shall be recorded and included in all documents containing examination results and shall be communicated to the appropriate personnel.				
	Special procedures, including more invasive procedures, or those with an increased risk of complications to the procedure, will need a more detailed explanation and, in some cases, written consent.				
	In emergency situations, consent might not be possible; under these circumstances it is acceptable to carry out necessary procedures, provided they are in the patient's best interest.				
5.4.4.2 Instructions for pre-collection activities	The laboratory's instructions for pre-collection activities shall include the following:				
a	completion of request form or				

	electronic request;				
b	preparation of the patient (e.g. instructions to caregivers, phlebotomists, sample collectors and patients);				
c	type and amount of the primary sample to be collected with descriptions of the primary sample containers and any necessary additives;				
d	special timing of collection, where needed;				
e	clinical information relevant to or affecting sample collection, examination performance or result interpretation (e.g. history of administration of drugs).				
5.4.4.3 Instructions for collection activities	The laboratory's instructions for collection activities shall include the following:				
a	determination of the identity of the patient from whom a primary sample is collected;				
b	verification that the patient meets pre-examination requirements [e.g. fasting status, medication status (time of last dose, cessation), sample collection at predetermined time or time intervals, etc.];				
c	instructions for collection of primary blood and non-blood samples, with descriptions of the primary sample containers and any necessary additives;				
d	in situations where the primary sample is collected as part of clinical practice, information and instructions regarding primary sample containers, any necessary additives and any necessary processing and sample transport conditions shall be determined and communicated to the appropriate clinical staff;				
e	instructions for labelling of primary samples in a manner that provides an unequivocal link with the patients from whom they are collected;				
f	recording of the identity of the person collecting the primary sample and the collection date, and, when needed, recording of the collection time;				
g	instructions for proper storage conditions before collected samples				

	are delivered to the laboratory;				
h	safe disposal of materials used in the collection.				
5.4.5 Sample transportation	The laboratory's instructions for post-collection activities shall include packaging of samples for transportation.				
	The laboratory shall have a documented procedure for monitoring the transportations of samples to ensure they are transported:				
a	within a time frame appropriate to the nature of the requested examinations and the laboratory discipline concerned;				
b	within a temperature interval specified for sample collection and handling and with the designated preservatives to ensure the integrity of samples;				
c	in a manner that ensures the integrity of the sample and the safety for the carrier, the general public and the receiving laboratory, in compliance with established requirements.				
5.4.6 Sample reception	The laboratory's procedure for sample reception shall ensure that the following conditions are met.				
a	Samples are unequivocally traceable, by request and labelling, to an identified patient or site.				
b	Laboratory-developed and documented criteria for acceptance or rejection of samples are applied.				
c	Where there are problems with patient or sample identification, sample instability due to delay in transport or inappropriate container(s), insufficient sample volume, or when the sample is clinically critical or irreplaceable and the laboratory chooses to process the sample, the final report shall indicate the nature of the problem and, where applicable, that caution is required when interpreting the result.				
d	All samples received are recorded in an accession book, worksheet, computer or other comparable system. The date and time of receipt and/or registration of samples shall be recorded. Whenever possible, the identity of the person receiving the sample shall also be recorded.				

e	Authorized personnel shall evaluate received samples to ensure that they meet the acceptance criteria relevant for the requested examination(s).				
f	Where relevant, there shall be instructions for the receipt, labelling, processing and reporting of samples specifically marked as urgent. The instructions shall include details of any special labelling of the request form and sample, the mechanism of transfer of the sample to the examination area of the laboratory, any rapid processing mode to be used, and any special reporting criteria to be followed.				
	All portions of the primary sample shall be unequivocally traceable to the original primary sample.				
5.4.7 Pre-examination handling, preparation and storage	The laboratory shall have procedures and appropriate facilities for securing patient samples and avoiding deterioration, loss or damage during pre-examination activities and during handling, preparation and storage.				
	Laboratory procedures shall include time limits for requesting additional examinations or further examinations on the same primary sample.				
5.5 Examination processes					
5.5.1 Selection, verification and validation of examination procedures					
5.5.1.1 General	The laboratory shall select examination procedures which have been validated for their intended use. The identity of persons performing activities in examination processes shall be recorded.				
	The specified requirements (performance specifications) for each examination procedure shall relate to the intended use of that examination.				
5.5.1.2 Verification of examination procedures	Validated examination procedures used without modification shall be subject to independent verification by the laboratory before being introduced into routine use.				
	The laboratory shall obtain information from the				

	manufacturer/method developer for confirming the performance characteristics of the procedure.				
	The independent verification by the laboratory shall confirm, through obtaining objective evidence (in the form of performance characteristics) that the performance claims for the examination procedure have been met. The performance claims for the examination procedure confirmed during the verification process shall be those relevant to the intended use of the examination results.				
	The laboratory shall document the procedure used for the verification and record the results obtained. Staff with the appropriate authority shall review the verification results and record the review.				
5.5.1.3 Validation of examination procedures	The laboratory shall validate examination procedures derived from the following sources:				
a	non-standard methods;				
b	laboratory designed or developed methods;				
c	standard methods used outside their intended scope;				
d	validated methods subsequently modified.				
	The validation shall be as extensive as is necessary and confirm, through the provision of objective evidence (in the form of performance characteristics), that the specific requirements for the intended use of the examination have been fulfilled.				
	The laboratory shall document the procedure used for the validation and record the results obtained. Staff with the authority shall review the validation results and record the review.				
	When changes are made to a validated examination procedure, the influence of such changes shall be documented and, when appropriate, a new validation shall be carried out.				
5.5.1.4 Measurement uncertainty of measured	The laboratory shall determine measurement uncertainty for each measurement procedure in the examination phase used to report				

quantity values	measured quantity values on patients' samples. The laboratory shall define the performance requirements for the measurement uncertainty of each measurement procedure and regularly review estimates of measurement uncertainty.				
	The laboratory shall consider measurement uncertainty when interpreting measured quantity values. Upon request, the laboratory shall make its estimates of measurement uncertainty available to laboratory users.				
	Where examinations include a measurement step but do not report a measured quantity value, the laboratory should calculate the uncertainty of the measurement step where it has utility in assessing the reliability of the examination procedure or has influence on the reported result.				
5.5.2 Biological reference intervals or clinical decision values	The laboratory shall define the biological reference intervals or clinical decision values, document the basis for the reference intervals or decision values and communicate this information to users.				
	When a particular biological reference interval or decision value is no longer relevant for the population served, appropriate changes shall be made and communicated to the users.				
	When the laboratory changes an examination procedure or pre-examination procedure, the laboratory shall review associated reference intervals and clinical decision values, as applicable.				
5.5.3 Documentation of examination procedures	Examination procedures shall be documented. They shall be written in a language commonly understood by the staff in the laboratory and be available in appropriate locations.				
	Any condensed document format (e.g. card files or similarly used systems) shall correspond to the documented procedure.				
	All documents that are associated with the performance of examinations, including procedures, summary documents, condensed document format and product instructions for				

	use, shall be subject to document control.				
	In addition to document control identifiers, documentation shall include, when applicable to the examination procedure, the following:				
a	purpose of the examination;				
b	principle and method of the procedure used for examinations;				
c	performance characteristics (see 5.5.1.2 and 5.5.1.3);				
d	type of sample (e.g. plasma, serum, urine);				
e	patient preparation;				
f	type of container and additives;				
g	required equipment and reagents;				
h	environmental and safety controls;				
i	calibration procedures (metrological traceability);				
j	procedural steps;				
k	quality control procedures;				
l	interferences (e.g. lipaemia, haemolysis, bilirubinemia, drugs) and cross reactions;				
m	principle of procedure for calculating results including, where relevant, the measurement uncertainty of measured quantity values;				
n	biological reference intervals or clinical decision values;				
o	reportable interval of examination results;				
p	instructions for determining quantitative results when a result is not within the measurement interval;				
q	alert/critical values, where appropriate;				
r	laboratory clinical interpretation;				
s	potential sources of variation;				
t	references.				
	If the laboratory intends to change an existing examination procedure such that results or their interpretations could be significantly different, the implications shall be explained to users of the laboratory services after validating the procedure.				
5.6 Ensuring quality of examination results					
5.6.1 General	The laboratory shall ensure the quality of examinations by performing them under defined conditions.				

	Appropriate pre and post-examination processes shall be implemented (see 4.14.7, 5.4, 5.7 and 5.8).				
	The laboratory shall not fabricate any results.				
5.6.2 Quality control					
5.6.2.1 General	The laboratory shall design quality control procedures that verify the attainment of the intended quality of results.				
5.6.2.2 Quality control materials	The laboratory shall use quality control materials that react to the examining system in a manner as close as possible to patient samples.				
	Quality control materials shall be periodically examined with a frequency that is based on the stability of the procedure and the risk of harm to the patient from an erroneous result.				
5.6.2.3 Quality control data	The laboratory shall have a procedure to prevent the release of patient results in the event of quality control failure.				
	When the quality control rules are violated and indicate that examination results are likely to contain clinically significant errors, the results shall be rejected and relevant patient samples re-examined after the error condition has been corrected and within-specification performance is verified. The laboratory shall also evaluate the results from patient samples that were examined after the last successful quality control event.				
	Quality control data shall be reviewed at regular intervals to detect trends in examination performance that may indicate problems in the examination system. When such trends are noted, preventive actions shall be taken and recorded.				
5.6.3 Interlaboratory comparisons					
5.6.3.1 Participation	The laboratory shall participate in an inter-laboratory comparison programme(s) (such as an external quality assessment programme or proficiency testing programme) appropriate to the examination and interpretations of examination results.				

	The laboratory shall monitor the results of the inter-laboratory comparison programme(s) and participate in the implementation of corrective actions when predetermined performance criteria are not fulfilled.				
	The laboratory shall establish a documented procedure for inter-laboratory comparison participation that includes defined responsibilities and instructions for participation, and any performance criteria that differ from the criteria used in the inter-laboratory comparison programme.				
	Inter-laboratory comparison programme(s) chosen by the laboratory shall, as far as possible, provide clinically relevant challenges that mimic patient samples and have the effect of checking the entire examination process, including pre-examination procedures, and post-examination procedures, where possible.				
5.6.3.2 Alternative approaches	Whenever an inter-laboratory comparison is not available, the laboratory shall develop other approaches and provide objective evidence for determining the acceptability of examination results.				
	Whenever possible, this mechanism shall utilize appropriate materials. Examples of such materials may include: — certified reference materials; — samples previously examined; — material from cell or tissue repositories; — exchange of samples with other laboratories; — control materials that are tested daily in inter-laboratory comparison programmes.				
5.6.3.3 Analysis of inter-laboratory comparison samples	The laboratory shall integrate inter-laboratory comparison samples into the routine workflow in a manner that follows, as much as possible, the handling of patient samples.				
	Inter-laboratory comparison samples shall be examined by personnel who routinely examine patient samples using the same procedures as those used for patient samples.				
	The laboratory shall not communicate with other participants in the inter-laboratory comparison programme about sample data until after the date for submission of the data.				

	The laboratory shall not refer inter-laboratory comparison samples for confirmatory examinations before submission of the data, although this would routinely be done with patient samples.				
5.6.3.4 Evaluation of laboratory performance	The performance in inter-laboratory comparisons shall be reviewed and discussed with relevant staff.				
	When predetermined performance criteria are not fulfilled (i.e. nonconformities are present), staff shall participate in the implementation and recording of corrective action. The effectiveness of corrective action shall be monitored. The returned results shall be evaluated for trends that indicate potential nonconformities and preventive action shall be taken.				
5.6.4 Comparability of examination results	There shall be a defined means of comparing procedures, equipment and methods used and establishing the comparability of results for patient samples throughout the clinically appropriate intervals. This is applicable to the same or different procedures, equipment, different sites, or all of these.				
	The laboratory shall notify users of any differences in comparability of results and discuss any implications for clinical practice when measuring systems provide different measurement intervals for the same measurand (e.g. glucose) and when examination methods are changed.				
	The laboratory shall document, record and, as appropriate, expeditiously act upon results from the comparisons performed. Problems or deficiencies identified shall be acted upon and records of actions retained.				
5.7 Post-examination processes					
5.7.1 Review of results	The laboratory shall have procedures to ensure that authorized personnel review the results of examinations before release and evaluate them against internal quality control and, as appropriate, available clinical information and previous examination				

	results.				
	When the procedure for reviewing results involves automatic selection and reporting, review criteria shall be established, approved and documented (see 5.9.1).				
5.7.2 Storage, retention and disposal of clinical samples	The laboratory shall have a documented procedure for identification, collection, retention, indexing, access, storage, maintenance and safe disposal of clinical samples.				
	The laboratory shall define the length of time clinical samples are to be retained. Retention time shall be defined by the nature of the sample, the examination and any applicable requirements.				
	Safe disposal of samples shall be carried out in accordance with local regulations or recommendations for waste management.				
5.8 Reporting of results					
5.8.1 General	The results of each examination shall be reported accurately, clearly, unambiguously and in accordance with any specific instructions in the examination procedures.				
	The laboratory shall define the format and medium of the report (i.e. electronic or paper) and the manner in which it is to be communicated from the laboratory.				
	The laboratory shall have a procedure to ensure the correctness of transcription of laboratory results.				
	Reports shall include the information necessary for the interpretation of the examination results.				
	The laboratory shall have a process for notifying the requester when an examination is delayed that could compromise patient care.				
5.8.2 Report attributes	The laboratory shall ensure that the following report attributes effectively communicate laboratory results and meet the users' needs:				
a	comments on sample quality that might compromise examination results;				
b	comments regarding sample suitability with respect to acceptance/rejection criteria;				

c	critical results, where applicable;				
d	interpretive comments on results, where applicable, which may include the verification of the interpretation of automatically selected and reported results (see 5.9.1) in the final report.				
5.8.3 Report content	The report shall include, but not be limited to, the following:				
a	a clear, unambiguous identification of the examination including, where appropriate, the examination procedure;				
b	the identification of the laboratory that issued the report;				
c	identification of all examinations that have been performed by a referral laboratory;				
d	patient identification and patient location on each page;				
e	name or other unique identifier of the requester and the requester's contact details;				
f	date of primary sample collection (and time, when available and relevant to patient care);				
g	type of primary sample;				
h	measurement procedure, where appropriate;				
i	examination results reported in SI units, units traceable to SI units, or other applicable units;				
j	biological reference intervals, clinical decision values, or diagrams/nomograms supporting clinical decision values, where applicable;				
k	interpretation of results, where appropriate;				
l	other comments such as cautionary or explanatory notes (e.g. quality or adequacy of the primary sample which may have compromised the result, results/interpretations from referral laboratories, use of developmental procedure);				
m	identification of examinations undertaken as part of a research or development programme and for which no specific claims on measurement performance are available;				
n	identification of the person(s) reviewing the results and authorizing the release of the report (if not contained in the report, readily available when needed);				

o	date of the report, and time of release (if not contained in the report, readily available when needed);				
p	page number to total number of pages (e.g. "Page 1 of 5", "Page 2 of 5", etc.).				
5.9 Release of results					
5.9.1 General	The laboratory shall establish documented procedures for the release of examination results, including details of who may release results and to whom. The procedures shall ensure that the following conditions are met.				
a	When the quality of the primary sample received is unsuitable for examination, or could have compromised the result, this is indicated in the report.				
b	When examination results fall within established "alert" or "critical" intervals: — a physician (or other authorized health professional) is notified immediately [this includes results received on samples sent to referral laboratories for examination (see 4.5)]; — records are maintained of actions taken that document date, time, responsible laboratory staff member, person notified and examination results conveyed, and any difficulties encountered in notifications.				
c	Results are legible, without mistakes in transcription, and reported to persons authorized to receive and use the information.				
d	When results are transmitted as an interim report, the final report is always forwarded to the requester.				
e	There are processes for ensuring that results distributed by telephone or electronic means reach only authorized recipients. Results provided orally shall be followed by a written report. There shall be a record of all oral results provided.				
5.9.2 Automated selection and reporting of results	If the laboratory implements a system for automated selection and reporting of results, it shall establish a documented procedure to ensure that:				
b	the criteria for automated selection				

	and reporting are defined, approved, readily available and understood by the staff;				
c	there is a process for indicating the presence of sample interferences (e.g. haemolysis, icterus, lipaemia) that may alter the results of the examination;				
d	there is a process for incorporating analytical warning messages from the instruments into the automated selection and reporting criteria, when appropriate;				
e	results selected for automated reporting shall be identifiable at the time of review before release and include date and time of selection;				
f	there is a process for rapid suspension of automated selection and reporting.				
5.9.3 Revised reports	When an original report is revised there shall be written instructions regarding the revision so that:				
a	the revised report is clearly identified as a revision and includes reference to the date and patient's identity in the original report;				
b	the user is made aware of the revision;				
c	the revised record shows the time and date of the change and the name of the person responsible for the change;				
d	the original report entries remain in the record when revisions are made.				
	Results that have been made available for clinical decision making and revised shall be retained in subsequent cumulative reports and clearly identified as having been revised.				
	When the reporting system cannot capture amendments, changes or alterations, a record of such shall be kept.				
5.10 Laboratory information management					
5.10.1 General	The laboratory shall have access to the data and information needed to provide a service which meets the needs and requirements of the user.				
	The laboratory shall have a documented procedure to ensure that				

	the confidentiality of patient information is maintained at all times.				
5.10.2 Authorities and responsibilities	The laboratory shall ensure that the authorities and responsibilities for the management of the information system are defined, including the maintenance and modification to the information system(s) that may affect patient care.				
	The laboratory shall define the authorities and responsibilities of all personnel who use the system, in particular those who:				
a	access patient data and information;				
b	enter patient data and examination results;				
c	change patient data or examination results;				
d	authorize the release of examination results and reports.				
5.10.3 Information system management	The system(s) used for the collection, processing, recording, reporting, storage or retrieval of examination data and information shall be:				
a	validated by the supplier and verified for functioning by the laboratory before introduction, with any changes to the system authorized, documented and verified before implementation;				
b	documented, and the documentation, including that for day to day functioning of the system, readily available to authorized users;				
c	protected from unauthorized access;				
d	safeguarded against tampering or loss;				
e	operated in an environment that complies with supplier specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription;				
f	maintained in a manner that ensures the integrity of the data and information and includes the recording of system failures and the appropriate immediate and corrective actions;				
g	in compliance with national or international requirements regarding data protection.				
	The laboratory shall verify that the results of examinations, associated information and comments are				

	<p>accurately reproduced, electronically and in hard copy where relevant, by the information systems external to the laboratory intended to directly receive the information (e.g. computer systems, fax machines, e-mail, website, personal web devices). When a new examination or automated comments are implemented, the laboratory shall verify that the changes are accurately reproduced by the information systems external to the laboratory intended to directly receive information from the laboratory.</p>				
	<p>The laboratory shall have documented contingency plans to maintain services in the event of failure or downtime in information systems that affects the laboratory's ability to provide service.</p>				
	<p>When the information system(s) are managed and maintained off-site or subcontracted to an alternative provider, laboratory management shall be responsible for ensuring that the provider or operator of the system complies with all applicable requirements of this International Standard.</p>				

Follow up on last year findings

Other Observation and Comments

Name and Signature of Assessor with date