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1. Foreword

Egyptian Society of Laboratory Medicine (ESLM)

The Association was founded by a group of Clinical Pathology professors where professor Sabry Salam (Ain Shams University) in collaboration with professor Samir Hanna (Ain Shams University) and professor Nassih Amin (Cairo University) performed all administrative procedures for establishing ESLM 1989.
Vision: To boost the profession of Clinical Pathology in Egypt and the Arab World to be equivalent to international practice.

ESLM Mission was to create a journal of laboratory medicine, organize an annual conference, change the profession code and assess laboratory devices. These missions are now fulfilled. New missions include provision of professional (managerial and technical) support for achieving laboratory accreditation and excellence.

ESLM has more than 400 registered members. ESLM organizes an annual conference which is attended by more than one thousand professionals from the Egyptian universities, the Ministry of Health, the armed forces and the police, as well as some of the Arab countries. The annual conferences aim at communicating the latest knowledge and technology in laboratory medicine in the form of lectures and workshops. In addition, the annual conferences are accompanied by an exhibition that demonstrates the latest devices and laboratory technologies located in the world as well as information systems. ESLM also issues the Journal of Laboratory Medicine where researches in the field of laboratory medicine can be published after being thoroughly evaluated by the magazine's scientific board. The journal recently has been declared as an international one. .

ESLM board in collaboration with esteemed professors in the field of accreditation prepared this guideline "for good laboratory practice" in compliance with:

- ISO 15189
- NCCLS: GP26-A3
- "Minimal Requirements for Designing Medical Labs and Fulfillment of its Managerial and Technical Requirements

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2. Scope

This guideline specifies the requirements for ensuring the competence of medical laboratories.

3. Terms and Definitions

3-01 Accreditation – Procedure by which an authoritative body gives formal recognition that an organization or person is competent to carry out specific tasks [modified from ISO/IEC 17000].

3-02 Certification – Procedure by which a third party gives written assurance that a service conforms to specified requirements [modified from ISO/IEC 17000].

3-03 Examination – Set of operations having the object of determining the value or characteristics of a property; **NOTES:** a) In some disciplines (e.g., microbiology), an examination is the total activity of a number of tests, observations, or measurements [ISO 15189 (3.3)]; b) In this document, the term "examination" replaces the term "test"; however, for the purposes of this guideline, readers can consider the terms equivalent.

3-04 Examination procedure – Set of operations, described specifically, used in the performance of examinations according to a given method [ISO 15189].

Note 1: Examination procedure will be referred to in this guideline as "Analytical Procedure:

Note 2: Technical requirements for the examination procedure will be referred to "Analytical requirements".

3-05 External quality assessment – Evaluation of the laboratory's performance on examination of samples of external origin for the purposes of determining adequacy of the laboratory's pre-examination, examination, and post-examination activities [ISO Guide 43-1].

3-06 Inter-laboratory comparison: performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions

3-07 Path of workflow (clinical laboratory) – Sequential processes in pre-examination, examination, and post-examination clinical laboratory activities that transform a physician's order into laboratory information.

3-08 Post-examination procedures – Processes following the examination including systematic review, formatting and interpretation, authorization for release, reporting and transmission of the results, and storage of samples of the laboratory examinations [ISO 15189 (3.9)].

3-09 Pre-examination procedures – Steps starting, in chronological order, from the clinician's request and including the examination requisition, preparation of the patient, collection of the primary sample, and transportation to and within the laboratory, and ending when the analytical examination procedure begins. ISO 15189 [3.10].

3-10 Primary sample – Set of one or more parts initially taken from a system [ISO 15189 (3.11)]

3-11 Procedure – Specified way to carry out an activity of a process [ISO 9000 (3.4.5)].

3-12 Process – Set of interrelated or interacting activities which transform inputs into outputs [ISO 9000:2000 (3.4.1)].

3-13 Quality control – Part of quality management focused on fulfilling quality

requirements [ISO 9000:2000 (3.2.10)].

3-14 Quality management – Coordinated activities to direct and control an organization with regard to quality

3-15 Quality system essentials – Set of coordinated activities that function as building blocks for quality management.

3-16 Sample – One or more parts taken from a system and intended to provide information on the system, often to serve as a basis for decision on the system or its production; **NOTES:** a) Example: A volume of serum taken from a larger volume of serum [ISO 15189 (3.14)] b) In this document, the term "sample" replaces the term "specimen"; however, for the purposes of this guideline, readers can consider the terms equivalent.

3-17 Validation – Confirmation through the provision of objective evidence that the requirements for a specific intended use or application have been fulfilled [ISO 9000 (3.8.5)]; **NOTES:** a) Example: Validation of the performance of a new diagnostic tool such as an internally developed, analyte-specific method or reagents, or a laboratory-developed information system; b) Manufacturers are required to validate instruments and methods before market release, e.g., FDA approval or European CE mark.

3-18 Verification – Confirmation through the provision of objective evidence that specified requirements have been fulfilled. [ISO 9000 (3.8.4)]; **NOTES:** a) Example: Verification of commercial information systems, instruments, and methods; and calibration verification of results obtained on automated analyzers; b) Commercial systems need to have their manner of use verified in the user laboratory.

4. Managerial Requirements

4.1 Organization

4.1.1 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.

4.1.2 Ethical commitment

Laboratory management shall ensure that all laboratory staff are free from commercial, financial, or influences that may adversely affect the quality of their work.

The laboratory quality management system shall ensure that laboratory staff treats human samples and patients' information according to relevant legal requirements and with high confidentiality.

4.1.3 Laboratory director

The laboratory director shall be a competent person who has delegated responsibility for the services provided.

The laboratory director responsibilities shall include professional, scientific, consultative, organizational, administrative and educational matters relevant to the services offered by the laboratory. The duties and responsibilities of the laboratory director shall be documented.

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.

4.2 Management Responsibilities

4.2.1 Quality management system

The Laboratory management shall provide and implement the quality management system which covers all aspects of laboratory services.

The effectiveness and the continual improvement of the quality management system shall be regularly appraised based on:

a. Explaining the regulatory and accreditation requirements to all laboratory staff.
b. Establishing the quality policy and quality objectives and its follow up.
c. Defining competency, responsibilities and authorities of all laboratory staff.
d. Establishing communication processes and management reviews.
e. providing resources for pre-examination, examination and post-examination activities.

4.2.2 Quality policy

Laboratory management shall establish, implement, communicate and maintain a quality policy that:

a. Is appropriate to the purpose and context of the organization and supports its strategy.
b. Provides a framework for establishing and reviewing quality objectives.
c. Includes a commitment to satisfy applicable requirements
d. includes a commitment to continual improvement of the quality manual.

4.2.3 Quality objectives

Laboratory management shall establish needed quality objectives that shall be measurable and consistent with the quality policy.

4.2.4 Laboratory communications

Laboratory management shall have an effective means of communication between laboratory staff. Records of items discussed in communications and meetings shall be kept of items discussed in communications and meetings.

Laboratory management shall establish appropriate communication between the laboratory and its stakeholders to improve the efficiency of the laboratory's workflow processes and quality management system.

4.2.5 Quality manager responsibilities

quality manager establishes the quality management system, promotes awareness of laboratory staff to accreditation and regulation requirements and reports to laboratory management changes are made on laboratory policy, objectives, resources and the performance of the quality management system and any need for improvement.

4.3 Documents and Records

The laboratory shall provide a suitable environment for storage of documents and records to prevent damage, deterioration or loss. The laboratory shall provide accessible documents which are protected from unauthorized changes.

Documents shall include, at least, the following:

a. Quality policy and quality objectives.
b. Quality manual.
c. Required Procedures.
d. Applicable regulations, standards and other normative documents.

4.3.1 Quality manual

Clinical laboratory that operates within a quality management system shall have a single quality manual that documents the policies, and includes or refers to the processes, procedures, and forms used by the laboratory's management staff to implement the quality system essentials throughout all the clinical disciplines in the laboratory.

The laboratory shall have a means to communicate the contents of the quality manual to all non -managerial staff as well. This may be accomplished by having each employee read the quality manual or by having a training program in which staff learn the specific quality system essential responsibilities that apply to their jobs.

4.3.2 Document control

a. All laboratory documents shall be included within laboratory document list and shall be identified by 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 and authority for issue.

b. All laboratory quality management system documents shall be reviewed and updated and obsolete controlled documents are dated and marked as obsolete.

4.3.3 Record management

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.

Laboratory shall store records in a manner that maintains integrity, protects accessibility, and facilitates retrieval with high confidentiality of patient-specific information.

The laboratory shall define the retention period of various records related to the quality management system. Reported results shall be retrievable for as long as medically relevant or as required by regulation.

Records shall include, at least, the following:

a. Staff qualifications, training and competency records.
b. Supplier selection and performance, and the approved supplier list.
c. Request for examination.
d. Records of receipt of samples in the laboratory.
e. Information on reagents and materials used for examinations.
f. Laboratory work books or work sheets.
g. Software verification.
h. Equipment calibration and maintenance.
i. Method verification data.
j. Instrument printouts and retained data.
k. Examination results and reports.
l. Internal audit and external assessment reports.
m. Occurrence reports.
n. External quality assessment reports (proficiency testing).

4.4 Personnel

To ensure the quality of laboratory services to its customers and job satisfaction of laboratory personnel, the laboratory shall have a documented procedure for personnel management and maintain records for all the following key elements:

a. Establishment of job qualifications that meet governmental, accreditation, and organizational requirements. Development of a recruitment and retention program.
b. Maintenance of current job descriptions that are based on job duties in the path of workflow.
c. Training and ongoing competency assessment based on work processes and procedures in the portion of the path of workflow performed in that job.
d. A plan to ensure adequate staffing for the work to be done.Provision of opportunities to participate in and document professional growth and development; and Working within the organization's performance appraisal and rewards programs.
e. Records of continuing education and achievements.
f. Reports of accidents and exposure to occupational hazards.
g. Immunization status, when relevant to assigned duties.

4.4.1 Personnel qualifications

Laboratory management shall document personnel qualifications which reflect the appropriate education, training, abilities, experience and skills needed, and shall be appropriate to the tasks will be performed.

4.4.2 Personnel introduction to the organizational environment

The laboratory shall have a program to introduce new staff to the organization, the department or area in which the person will work, the terms and conditions of employment, health and safety requirements (including fire and emergency), and occupational health services.

4.4.3 Job descriptions

The laboratory shall have documented job descriptions that describe responsibilities, authorities and tasks for all personnel.

4.4.4 Training

The laboratory shall provide training programme for all personnel which include 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 and confidentiality of patient information.

Personnel that are undergoing training shall be supervised at all times. The effectiveness of the training program shall be periodically reviewed.

4.4.5 Competence assessment

Following appropriate training, the laboratory shall assess the personnel competency to perform assigned managerial or technical tasks. Reassessment shall take place at regular intervals. Retraining shall occur when necessary.

Competence of laboratory staff can be assessed by using any of the following:

a. Direct observation of routine work processes and procedures, including safety practices.
b. Direct observation of equipment maintenance and function checks.
c. Examination of specially provided samples, such as previously examined samples, Inter-laboratory comparison materials, or split samples.
d. Monitoring the recording and reporting of examination results.Review of work records.
e. Assessment of problem solving skills.

4.4.6 Reviews of staff performance

The laboratory shall ensure that reviews of staff performance are satisfactory for the needs of the laboratory and of the individual to improve the quality of service given to the customers and encourage productive working relationships.

4.4.7 Continuing education and professional development

A continuing education program 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 program shall be periodically reviewed.

4.5 Purchasing and Inventory

4.5.1 Purchasing control

The laboratory shall develop a documented procedure for the selection and purchasing of external services, equipment, reagents and consumables that affect the quality of its service.

The laboratory shall select and approve suppliers based on stated criteria that meet the laboratory' s requirements.

A list of selected and approved suppliers shall be maintained.

The laboratory shall periodically monitor and evaluate the performance of suppliers to ensure that purchased services or items consistently meet the stated criteria.

4.5.2 Inventory control

The laboratory must have an established documented inventory control system in operation.

The laboratory storage area must be sufficient to maintain appropriate levels of "working" supplies, consumables and reagents that handle current workload demands.

All storage areas must be well organized and temperature and humidity controlled.

The laboratory must have a system which highlights the need to place supply orders, tracks orders, and defines alternate plans for delayed deliveries of supplies.

4.6 Service Agreement and Referral Laboratories

4.6.1 Service agreements

The laboratory shall have documented procedures for the establishment and review of agreements for providing medical laboratory services.

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 the provider of the laboratory services, including the examination processes to be used, shall be defined, documented and understood.
b. The laboratory shall have the capability and resources to meet the requirements.
c. Laboratory personnel shall have skills and expertise for performance of the intended examinations.
d. Examination procedures selected shall be appropriate to meet the customers' needs.
e. Customers 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.

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.

4.6.2 Examination by referral laboratories

The laboratory shall maintain a list of all referral laboratories, contracts with referral laboratories. Requests and results of all samples referred are kept for a pre-defined period.

The laboratory shall have a documented procedure for selecting and evaluating referral laboratories.

The procedure shall ensure that the laboratory shall select the referral laboratories monitoring their quality of performance and ensuring that the referral laboratories are competent to perform the requested examinations. Records of such periodic monitoring are maintained.

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 without alterations that could affect clinical interpretation. The report shall indicate which examinations were performed by a referral laboratory.

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.

4.7. Laboratory Information Management

4.7.1 Required facilities:
The clinical laboratory shall have defined processes for receiving and handling patient information. The processes need to ensure the accessibility, security, confidentiality, and privacy of patient information in both paper-based and electronic information systems.

Where required, that laboratory also shall have processes and procedures for charging and billing for provision of examination services.

The laboratory shall have an established process for implementing an information (computer) system that meets established requirements for:

a. Computer environment
b. Documented processes and procedures.
c. System security.
d. Data entry and reports.
e. Data retrieval and storage, including backup procedures.
f. Hardware and software.
g. System maintenance.
h. Interfaces.
i. Networks.

4.7.2 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.

4.7.3 Required Activities and Documentation

The laboratory shall document the purpose of a LIS, written SOPs for the operation of the LIS, and should be appropriate and specific to the day-to-day activities of the laboratory staff as well as the daily operations of the Information Technology staff.

The laboratory shall verify that the results of examinations, associated information and comments are 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).

The laboratory shall document LIS interaction with other devices or programs with validation data and results including data entry, data transmission, calculations, storage and retrieval.

The laboratory shall use both abnormal and normal data to test the system.

The laboratory shall document any changes or modifications to the system, and the laboratory director or designee shall approve all changes before they are released for use.

Computer time-stamped audit trails shall be used by the LIS. The laboratory's LIS policies must ensure that LIS access is limited to authorized individuals.

4.8. Facility Maintenance, Environmental Conditions and Safety

4.8.1 Laboratory and office facilities

The laboratory shall provide procedures to ensure that governmental, accreditation, and organizational requirements for current and planned space are met.

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. In sample collection areas, the laboratory shall consider accommodations for disabled patients, comfort, confidentiality, safety, quality, prevailing practices, and optimization of collection conditions.
b. Access to areas affecting the quality of examinations is controlled. Access control should take into consideration safety, confidentiality.

c. Medical information, patient samples, and laboratory resources are safeguarded from unauthorized access.
d. Facilities to ensure laboratory-specific environmental requirements for examination. These include, for example, energy sources, lighting, ventilation, noise, water and waste disposal.
e. Communication systems within the laboratory are appropriate to the size and complexity of the facility to ensure the efficient transfer of information.
f. Safety facilities and devices are provided and their functioning regularly verified.

4.8.2 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.

4.8.3 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.

4.8.4 Facility safety

Clinical Laboratory Safety shall provide guidance in the following areas:

a. Management responsibilities.
b. Facility management (design, identification of hazards, housekeeping practices, etc.).
c. Chemical safety.
d. Emergency preparedness (fire, evacuations, electrical equipment, first aid, etc.).
e. Biologic safety (biologic materials handling, transport, and waste, safety cabinets, personal protective equipment, hand washing; etc.).
f. Personnel (staffing; training; responsibilities; reporting of incidents, accidents, and occupational illness; etc.).

All laboratory staff shall receive safety training for blood borne pathogens, PPE, Chemical Hygiene/Hazard Communications, use of safety equipment in the laboratory, transportation of

potentially infectious material, waste management/biohazard containment, and general safety/local laws related to safety. The laboratory shall document safety training. Safety training must be completed before any employee begins working in the laboratory and on a regular basis thereafter.

The employer shall assess the workplace to determine if hazards are likely to be present which necessitate the use of Personal Protective Equipment (PPE) and provide access to PPE to all laboratory staff at risk. All laboratory employees must use PPE if there is a potential for exposure to blood o other potentially infectious material through any route (e.g., skin, eyes, other mucous membranes).

Laboratory shall provide Safety Equipment e.g. Fire extinguishers, emergency shower, eye wash, and sharps containers, in compliance with general safety/local laws. Periodic inspection and/or function checks of applicable safety equipment shall be documented.

The laboratory shall have Material Safety Data Sheets (MSDS) or equivalent in the workplace for each hazardous chemical that they use.

The laboratory shall document safety-related incidents. These incidents shall be submitted, reviewed, and signed by the laboratory Manager or designee on a regular basis, not to exceed one month from time of submission. Safety reports shall be incorporated into the Quality Management program allowing the laboratory to note trends and correct problems to prevent recurrence.

The laboratory shall have a means (such as a safety committee or a safety audit) to ensure that personnel have access to required safety documents (e.g., Material Safety Data Sheets, Chemical Hygiene Plan); safety requirements are continuously met; and personnel comply with the requirements.

4.9 Consulting Services

The laboratory professional staff shall establish arrangements for communicating with users on the following:

a. Advice on choice of examinations and use of the services, including repeat frequency, required type of sample, clinical indications and limitations of examination procedures.
b. Interpretation of the results of examinations.
c. Immediate notification of critical (alert) value.
d. Promoting the effective utilization of laboratory services.

4.10 Customer Satisfaction and Staff Suggestions

The laboratory shall regularly assess the satisfaction of its customers (e.g. patients and physicians) with the quality of the provided laboratory services.

Laboratory management shall encourage staff to make suggestions for the improvement of any aspect of the laboratory service. Suggestions shall be evaluated and feedback will be provided to the staff.

Laboratory management shall take actions to improve laboratory services based on the analysis of the satisfaction assessment results and the staff suggestions.

Laboratory management shall maintain records of information and suggestions collected in addition to action taken.

4.11 Occurrence Management

4.11.1 User's complaint

The laboratory shall have a documented procedure for the management of complaints received from physicians, healthcare providers, patients, laboratory staff or other parties. Records shall be maintained of all complaints and their investigation and the action taken.

4.11.2 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 laboratory's occurrence management process shall ensure that:

a. Designation of personnel responsible for resolving the problem.
b. Determination of the root cause and the extent of the nonconformity.
c. Defining the immediate action to be taken.
d. Cessation of examination and reporting as necessary.
e. Notification of the requesting physician, where appropriate.
f. Recalling the released results of any nonconforming examination.
g. Designation of authorized personnel for resuming examination.
h. Evaluation the need for corrective action to ensure that nonconformities do not recur evaluating.
i. Implementation and recording of corrective action needed.

j. Documentation of each episode of nonconformity and reviewing records at regular intervals to evaluate the effectiveness of the corrective action taken.

4.12 Risk Management

The laboratory shall have a documented procedure for:

a. Identification of the potential hazards to which people may be exposed and the potential adverse events.
b. Determination of the root cause of potential risks.
c. Determination of probabilities of occurrence and severity of consequences
d. Modification of processes and implementation of preventive actions to reduce or eliminate the identified probable risks.
e. Periodic revision of the effectiveness of the preventive action taken.

The laboratory shall 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. Contingency plan shall be periodically tested.

4.13 Assessment

4.13.1 External quality assessment

The laboratory shall enroll in external quality assessment programs that provide an external means of verifying laboratory's analytical performance.

4.13.2 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 quality indicators shall be documented to include the objectives, methodology, frequency of measurement, interpretation, limits and action plan.

The laboratory must record investigation of key indicators and record corrective and/or preventive actions taken.

The indicators shall be periodically reviewed, to ensure their continued appropriateness.

4.13.3 Internal audit

The laboratory shall have a defined documented program for conducting internal audits to monitor all activities in the quality management system and to determine its effectiveness and compliance with the requirements of this Standard and with laboratory' s requirements.

The cycle for internal audit shall be completed in one year. The frequency of auditing will be based on the status and the importance of the processes performed in the managerial and technical areas to be audited, as well as the results of previous assessments.

Audits shall be conducted by personnel trained to assess the performance of managerial and technical of the quality management system. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process.

Personnel responsible for the area being audited shall take immediate corrective action and when necessary appropriate preventive action to eliminate the identified nonconformities.

All findings of both compliance and noncompliance in addition to the proposed corrective actions shall be documented in an organized format and maintained to allow for follow-up through resolutions.

4.13.4 Assessment by external organizations

Medical laboratories can be subjected for assessment by many different external organizations to determine if regulations, standards, and requirements are being met.

The laboratory shall take appropriate corrective actions and if required, appropriate preventive s to deal with recorded nonconformities and to ensure the continuous compliance with the requirements of this Standard.

Records of the reviews and of the corrective actions and preventive actions taken shall be maintained.

4.14 Process Improvement

Laboratory management shall ensure that the laboratory has a continual improvement plan that enhance the effectiveness of the quality management system, including the pre-examination, examination and post-examination processes and that address highest priority areas.

Action plan for improvement shall be developed based on risk assessments; internal audits; external assessments; proficiency test results; quality indicators; customer satisfaction surveys, user's complaint and non-conformity reports.

Laboratory management shall provide access to suitable educational and training opportunities for all laboratory personnel.

The laboratory shall determine and report the effectiveness of the improvement activities to the quality management.

4.15 Management Review

Laboratory management shall review the quality management system at planned intervals to ensure its continuing suitability, adequacy and effectiveness and support of patient care.

4.15.1 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, suitability of procedures, sample requirements and reported reference intervals.
b. Changes in the volume and scope of work, personnel, and premises that could affect the quality management system.
c. Assessment of user feedback and staff suggestions.
d. Internal audits and external assessments.
e. Risk management.
f. Quality indicators.
g. Results of external quality assessment program.
h. Occurrences.
i. Performance of suppliers.
j. Results of previous continual improvement.
k. Quality objectives.
l. Follow-up actions from previous management review.

4.15.2 Review output

Laboratory management shall address the possible need for continual improvement and changes to quality policy, objectives, processes and other elements of the quality management system.

The output from the management review shall be incorporated into a record that documents any decisions made during management review with its defined timeframe, resource needed and responsible personnel. The record shall be communicated to laboratory staff.

5. Technical requirements

5.1 Pre-analytical Requirements

5.1.1 Pre-analytical processes definition

Pre-analytical processes include all activities from the time the laboratory examinations are ordered (either by a written requisition or by a computer system order) through the time that the samples are processed and delivered to the laboratory examination location or transported to referral laboratories.

For anatomic pathologists and cytotechnologists, pre-analytical activities extend from the time the tissue is removed or collected to the point where the slides are prepared and ready for diagnostic assessment and interpretation.

The path of laboratory pre-analytical workflow includes actions performed by physicians, nurses, other clinical and allied health professionals, clerks, non-laboratory sample collection personnel, transporters, and couriers. The completeness and correctness of these actions influence both sample quality and total turnaround time, and thus the accuracy and value of the laboratory examination result. Therefore, it is incumbent upon the laboratory to ensure that processes and procedures performed by non-laboratory personnel within the entire laboratory path of workflow are taught to such personnel, are understood, and followed and meet applicable requirements.

5.1.2 General

The laboratory must write and document procedures and information that explain the basis for staff training in “how it happens here” for all pre-analytical activities to ensure the consistency, quality, and integrity of the generated data. These procedures must be written in a manner and language that is appropriate to the personnel conducting them and must be readily available in the work areas and accessible to them.

All laboratory personnel must document and maintain verification that they have reviewed and understood all relevant pre-analytic procedures so that there is evidence that they are knowledgeable of the pre-analytical process.

5.1.3 Information for patients and users

The laboratory must have information available for patients and users of the laboratory services.

The information must 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. Which laboratory examinations can be ordered STAT (i.e., performed as urgent or high-priority).
f. Instructions for completion of the request form; and if an electronic request is used, how to enter laboratory examination orders into computer systems.
g. Instruction for preparation of the patient.
h. Instructions for patient-collected samples.
i. Instructions for transportation of samples, including any special handling needs.
j. Any requirements for patient consent (e.g. consent to disclose clinical information family history to relevant healthcare professionals, where referral is needed).
k. The laboratory's criteria for accepting and rejecting samples.
l. A list of factors known to significantly affect the performance of the examination or the interpretation of the results.

m. Availability of clinical advice on ordering of examinations and on interpretation of examination results.
n. The laboratory's policy on protection of personal information.
o. The laboratory's complaint procedure.
p. Instructions are also to be provided for blood bank requests including name of blood component or product requested; name of therapeutic procedure (e.g., therapeutic phlebotomy or therapeutic apheresis); and collection or transfusion of autologous blood.

The laboratory must 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), must be explained to the patient and user.

5.1.4 Pre-analytical workflow

Examination Ordering → Sample Collection and handling → Sample Transport → Sample Receipt → Pre-analytical handling, preparation, and storage

5.1.4.1 Examination ordering

A properly completed request form (whether in electronic or paper format) must accompany each sample delivered to the laboratory.

The format of the request form and the manner in which requests are to be communicated to the laboratory should be determined in discussion with the users of laboratory services.

The laboratory must 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 must be willing to cooperate with users or their representatives in clarifying the user's request.

The request form must include the following data:

a. Patient identification: gender, date of birth, and the location/contact details of the patient, at least two unique identifiers and provisions for providing anonymity where needed (e.g., HIV examinations).

   NOTE: Unique identification includes an alpha and/or numerical identifier such as a hospital number, or personal health number.

b. Authorized requester and destination of the results report (e.g., patient location or physician's office address).
c. Type of primary sample and, where relevant, the anatomic site of origin.
d. Examinations requested and whether any of them is ordered STAT (i.e., needed to be performed as urgent or high priority).
e. Clinically relevant information about the patient and the request, for examination performance and result interpretation purposes.

NOTE: Information needed for examination performance and results interpretation may include the patient's ancestry, family history, travel and exposure history, communicable diseases, and other clinically relevant information. Financial information for billing purposes, financial audit, resource management and utilization reviews may also be collected. The patient should be aware of the information collected and the purpose for which it is collected.

f. Sample collection date and time.
g. Date and time of sample receipt.
h. The collector's (phlebotomist's) identity.

5.1.4.2 Sample collection and handling

5.1.4.2.1 General

The environment in which sample collection is performed must not compromise the safety of the patient or the staff nor the quality of the sample collection process. Adequate privacy during reception and sampling should be available and appropriate to the type of information being requested and primary sample being collected.

The laboratory must have documented procedures for the proper collection and handling of primary samples. These procedures must 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 must be recorded and included in all documents containing examination results and must be communicated to the appropriate personnel.

NOTE: All procedures carried out on a patient need the informed consent of the patient.

For most routine laboratory procedures, consent can be inferred when the patient presents himself or herself at a laboratory with a request form and willingly submits to the usual collecting procedure, for example, venipuncture. Patients in a hospital bed should normally be given the opportunity to refuse.

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.

5.1.4.2.2 Instructions for pre-collection activities

The laboratory's instructions for pre-collection activities must 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).

Before sample collection, the patient should be assessed to verify that all preparation requirements have been met. Patient assessment should also include an evaluation of any age-specific conditions that might influence the collection approach. It also should include an assessment of the appropriate collection site, contraindications, hazards, or potential complications. The assessment may also include a verification of the clinical indication for the examination.

5.1.4.2.3 Instructions for collection activities

Specific collection instructions are to be provided to all sample collection areas within and outside the organization for activities involved in sample collection.

The laboratory's instructions for collection activities must include the following:

a. Verifying the identity of the patient from whom a primary sample is collected.

b. Verification that the patient meets pre-analytical 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 must be determined and communicated to the appropriate clinical staff.

e. Proper labeling of samples *in the presence of the patient* with the date of collection and time, where applicable, on the label and/or request.

f. Recording the identity of the person who collected the sample and the collection date, and, when needed, recording of the collection time.

g. Information about the following for both in-laboratory and referral laboratory examination:

h. Collection containers.

i. Type and amount of sample to be collected.

j. Special timing; and − preservatives or anticoagulants.

k. Instructions for proper storage conditions before collected samples are delivered to the laboratory.

l. Proper disposal of materials used in the collection.

5.1.4.3 Sample transport

Instructions need to be provided for any special preservation or handling of samples before their arrival in the laboratory. Instructions are also to be available for proper and safe packaging, shipping, or transportation of samples from the point of collection to the laboratory.

The laboratory must have a documented procedure for monitoring the transportations of samples to ensure they are transported:

a. Within the time frame appropriate to the nature of the requested examination.
b. Within the temperature range specified in the collection instructions; and with the designated preservatives to ensure the integrity of samples.
c. In a manner that complies with all applicable safety requirements.

In case of sample shipping, a shipping procedure must be documented that addresses preparing shipments by following all federal and local transportation of dangerous goods regulations (e.g., International Air Transport Association (IATA)) by laboratory personnel who are certified in hazardous materials/dangerous goods transportation safety regulations.

5.1.4.4 Sample receipt

It is important that samples be promptly received, evaluated for acceptability, accurately accessioned, and appropriately processed.

The sample inspection process must involve verification of the sample container label information with the request form or log sheet. Any discrepant or missing information must be verified promptly, before samples are processed or stored by laboratory personnel.

The laboratory needs to provide clear instructions for handling and storage of samples and tissues before examination is performed. The instructions should designate where and how the different types of samples are to be stored during hours in which the laboratory's routine receiving area(s) is/are not open.

Instructions need to be provided for:

a. Receiving samples into the laboratory (e.g., emptying pneumatic tubes, retrieving samples from pass through drawers and windows, emptying courier and mailing containers).
b. Evaluating sample labeling and paperwork for completeness and correctness.

c. Evaluating the condition of the sample against criteria for acceptance or rejection by authorized personnel.

Examples of rejection criteria include but is not limited to:

a. Insufficient patient information
b. Unlabeled sample
c. Sample label and patient name on the test request form do not match.
d. Broken or leaking tube/container
e. Lacking patient preparation in samples requiring preparation.
f. Sample collected in wrong tube/container; for example, using the wrong preservative or non-sterile container.
g. Inadequate volume for the quantity of preservative
h. Insufficient quantity for the test requested.
i. Prolonged transport time, or other poor handling during transport.
j. Examples of specific rejection criteria that depend on the requested test:
k. Hemolyzed sample (depending on the requested test).
l. Grossly lipemic samples (depending on the requested test).

Other Specific rejection criteria depends on the requested test

d. The rejected sample should be recorded in a rejection log and the requester shall notified about its rejection.

NOTE: Some laboratories may choose to monitor the percent of rejected samples as a Key Performance Indicator (KPI) for their pre-analytical processes.

% of rejected Samples = No. of rejected samples / Total No. of samples

e. Accessioning samples into the information system (whether paper or electronic).
f. Processing samples (e.g., centrifuging, aliquoting, inoculating media).
g. Expediting the receipt, processing, and handling of samples marked as urgent (e.g., STAT). The instructions must 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.

The laboratory must maintain and document an audit trail (sample tracking mechanism) for every sample from collection to disposal or storage to ensure that all samples submitted to the laboratory are actually received, accounted for, and assayed in a timely manner. Audit trails

must verify the date and time an activity was performed and the personnel responsible for that activity.

All sample aliquots (portions) need to be traceable to the original (i.e., source) sample, and the original sample needs to be traceable to the source individual.

The laboratory needs to have a process for actions to be taken when samples lack proper identification or when there is uncertainty in the identification of an irreplaceable or critical sample, such as cerebrospinal fluid or biopsy tissue.

The laboratory should have a process for providing feedback on issues related to sample quality to those who collect samples.

5.1.4.5 Pre-analytical handling, preparation and storage

The laboratory must have procedures and appropriate facilities for securing patient samples and avoiding deterioration, loss, or damage during pre-analytical activities and during handling, preparation and storage.

Twenty-four-hour monitoring of storage conditions (using personnel and/or electronic monitoring with alert systems) and laboratory procedures for response to alerts must be in place to ensure the integrity of samples is maintained.

Laboratory procedures must also include time limits for requesting additional examinations or further examinations on the same primary sample (sample stability time).

5.2 Analytical Requirements

5.2.1 Environmental conditions

Laboratory work areas must have sufficient space so that there is no hindrance to the work or employees.

The environmental conditions (such as the temperature and humidity….) must commensurate with the nature of work inside the lab and the need of the different used instruments and reagents. The lab must keep a log to ensure the work within the permissible limits. The lab must record incidence where the environmental conditions were violated and the taken corrective actions.

Proper power supply, ventilation, water supply, sewage system and waste disposal must be available

Accession of the working areas of a lab must be in accordance to authorization list.

5.2.2 Instrument requirements

The laboratory must have a documented procedure for the selection of equipment including but not limited to analyzers, auxiliary equipment (as centrifuges, pipettes, microscopes, hardware and software etc.)

The laboratory must have master lists for all available instruments (analyzers and auxiliary).

Each instrument must have a record including:

a. Instrument identification name
b. manufacturer's name, model and serial number
c. contact information for the vendor and service provider
d. location of the equipment
e. operator manual or guide for users
f. date and condition of the received equipment
g. certificate of verification supplied by the vendor
h. calibration certificate (specially for auxiliaries)
i. maintenance contract (when applicable)
j. service reports for preventive or repair maintenance

NOTE 1: Records for any instrument must be retained as long as the instrument is available in the laboratory

NOTE 2: If specific water type is required, the laboratory must document the acceptance limits for the readings used to judge the quality of the water and document evidence of corrective action taken when water quality exceeded the defined tolerance limits.

The laboratory must have standard operating procedures (SOPs) for each instrument written in a manner appropriate to all users to understand. SOPs must fulfill the requirements and instructions of the manufacturer. Any modification must exceed the manufacturer's instructions and must be highlighted in the SOPs.

Standard operating procedures must include:

a. Steps to operate the instrument
b. Scheduled maintenance plan performed by the operator/vendor representative

c. Environmental conditions required for the instrument
d. Decontamination procedures
e. Hazards and safety precautions
f. If specific water type is required, the lab must ensure to keep records for maintenance of the water station and records for testing of the water quality.

Authorization list for users must be documented

Standard operating procedures must be available in the working area

Standard operating procedures have to be reviewed periodically and retired of obsolete SOPs must be removed and achieved for suitable retention period

5.2.3 Verification/Validation and comparability for analytes:

The laboratory shall have a documented procedure for the selection of reagents, calibrators, controls, consumables used in the analysis procedure.

Verification/ validation and comparability must be carried out in accordance to a reference.

Validation of a product is the responsibility of the manufacturer. The manufacturer provides the data or the certificate that guarantees that validation took place and is within acceptance criteria.

The laboratory must have a procedure to verify that the manufacturer's calms hold true.

Verification should be done before enrollment of the testing procedure in the routine work.

Verification of the testing procedure must include testing of accuracy, precision, analytical measurement range and biological reference values.

Any change in the procedure specified by the manufacturer will need to be validated by the laboratory.

Comparability is needed when an analyte is performed using different methodologies or different analyzers. Correction factors for compensating for constant and proportional difference between the analyses can be applied to unify the reporting for a particular customer.

Verification/validation and comparability must be performed by authorized persons and the reports must be signed.

The allowable error for each test parameter must be assigned in accordance to a reference.

5.2.4 Standard operating procedures for the analytes

The laboratory must have a list of the tests performed in the premises

Standard operating procedure for each analyte has to be written in a manner appropriate to all users to understand.

Standard operating procedures must fulfill the requirements and instructions of the manufacturer. Any modification must exceed the manufacturer's instructions and must be highlighted in the SOPs.

SOPs must be available in the working area

SOPs have to be reviewed periodically and retired of obsolete SOPs must be removed and achieved for suitable retention period.

SOPs must include:

a. Name of the analyte and purpose of its determination
b. Principle/method of the assay
c. Type of sample
d. Patient preparation (when relevant)
e. Type of container
f. Calibration procedure
g. Quality control procedure
h. Interferences (lipemia, hemolysis, drugs etc…)
i. Principle for calculation of results
j. Reportable range
k. Reference range
l. Alert/panic values
m. Laboratory interpretation of results
n. Potential sources of variation (when applicable)
o. References used to write the SOP for each analyte
p. Policy for retesting (when applicable)
q. Policy for reflex testing (when applicable)
r. The laboratory shall determine measurement uncertainty for each measurement procedure. Measurement uncertainty must be reviewed periodically

5.2.5 Internal quality control

The lab must have internal quality control procedure to ensure the consistency, quality and integrity of generated data.

For quantitative tests, it is necessary to use control material with assigned values.

For qualitative tests, positive and negative controls are used.

Quality control samples must be tested in the same manner as specimens.

The laboratory must follow the instructions of the manufacturer of the quality control material as regards its reconstitution (when applicable) and its required storage conditions as regards temperature, duration, protection from light etc…

The frequency of running the control material and rules for acceptance/rejection of the results must be stated in accordance to references.

Quality control logs must document the following:

a. Name of the material
b. Name of the manufacturer
c. Lot number of the material
d. Concentration of the material when used for quantitative tests
e. Open date
f. Expiry date
g. Stability after reconstitution
h. Name of person who performed the reconstitution and the testing
i. Range within which the result of the control material is accepted
j. Type of error as suggested by the used acceptance/rejection rules (systematic or random error)
k. Corrective action taken

NOTE 1: Retention duration of the log must be specified
NOTE 2: Parallel testing of new lots is recommended for quantitative tests during the transaction between different lot numbers.
NOTE 3: Quality control data must be reviewed periodically to detect trends or shifts

NOTE 4: Assurance by rerun of quality control material must be done after any corrective action to violated quality control result, change of analytically critical reagent, major preventive maintenance, change of critical instrument component and calibration.

NOTE 5: In the event that the QC data is determined to be unaccepted, the lab must re-evaluate all customers' test results since the last acceptable QC to determine if a significant clinical difference has occurred.

5.2.6 Proficiency testing/Inter-laboratory comparison

The laboratory must have a documented procedure for proficiency testing/ inter-laboratory comparison participation.

The laboratory shall participate in an inter-laboratory comparison program(s) (such as an external quality assessment program or proficiency testing program) appropriate to the examination and interpretations of examination results.

The laboratory must follow the instructions of the manufacturer of the proficiency testing material as regards its reconstitution (when applicable) and its required storage conditions as regards temperature, duration, protection from light etc…

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.

The laboratory must integrate inter-laboratory comparison samples into the routine workflow in a manner that follows, as much as possible, the handling of patient samples

Returned results for the proficiency testing or the inter-lab comparison are interpreted in accordance to rules for acceptance/rejection.

Corrective action must be taken whenever a proficiency tested sample or inter-laboratory comparison fails.

PT/inter-laboratory comparison reports must be reviewed periodically and retained for suitable periods.

NOTE 1: PT reports can be used for linearity assessment

5.3 Post-analytical Requirements

5.3.1. Reports

5.3.1.1 Report format

Reports generated manually or electronically should include the following elements:

a. Patient name, address and unique no. (If possible)
b. Date (and time where appropriate) of sample collection.
c. Name of the physician ordering the examination (when appropriate).
d. Identification of the examination(s) ordered.
e. Date and time of receipt in the laboratory.
f. Results of the examination(s) with reference range (where appropriate).
g. Method used (where appropriate).
h. Results of the Examination(s) with Reference range(s) (where appropriate).
i. Interpretation of results (where appropriate).
j. Other comments (e.g. other causes for low or high results, sample adequacy… etc.).
k. Names and addresses of laboratories that performed the test including referral laboratories.
l. All required signature (which may be in electronic form).
m. The assay report date.
n. Specimen source (e.g. blood, CSF, urine).
o. Units of measurements
p. Age and gender of patient.

The laboratory should have processes that ensures that the final report is legible, interpretable and without mistakes. Also it ensures verification of accurate transcription and transmission of examination results and reports.

5.3.1.2. Report turnaround time

The assay results should be sent from the point of data entry (whether entered from analyzer interface or manually) to the final report destination in an accurate and timely manner.

The laboratory needs to have instructions when examinations are delayed.

Also the laboratory needs a process to monitor its turnaround times and to ensure that reports are meeting requirements.

5.3.1.3. Alert or critical values report

Each laboratory must define alert or critical values. Procedures should be in place when assay results fall within established critical ranges. The procedure should ensure that results were heard correctly.

5.3.1.4. Referral laboratories report

Reports by referral lab should be retained by the laboratory for the time period defined by the lab.

5.3.1.5. Preliminary reports

There should be a process to identify the tests that need a preliminary report and the time needed to issue a final report e.g TB Results.

5.3.1.6. Corrected Report

A procedure for correcting an erroneous result on a laboratory report should be available. The erroneous result and the corrected result should be maintained. This is done for both electronic and paper reports. The procedure should clarify the disparities e.g. between the cytological and histological results.

In addition, the laboratory should have a system that identifies the analyst performing and completing the test result modification along with date and time.

A log or a record must be kept for result modification which should be reviewed and signed at least monthly by laboratory director. Proper error correction techniques should be utilized and documented

5.3.1.7 Archiving reports

All reports must be safely and securely retained by the laboratory for a defined period of time. Retention time periods should meet or exceed the time defined by the regulatory body.
The archived reports easily and readily retrievable within specified time frame. They should be archived on or off-site.

5.3.2. Sample storage and disposal

5.3.2.1 Sample storage

5.3.2.1.1 Sample stability

Sample stability is needed to be ensured. The laboratory should define the time in which examination can be repeated or added to a stored sample. Retention conditions (e.g. temperature, exposure to light) to ensure stability and retention time should be defined.

A procedure is needed for the retention time and conditions of the following samples:

a. bone marrow smears.
b. Tissue blocks and slides
c. blood films.
d. blood samples
e. cytopathology slides.
f. Media on abnormal cytogenetic cases.
g. blood donor and transfusion recipient blood samples.

This procedure should meet governmental and Accreditation requirements.

5.3.2.2. Sample retrieval

Defined procedures are needed for sample retrieval to facilitate accessibility.

5.3.2.3 Sample disposal

A defined procedure is needed for the disposal of the retained sample.