result is only complete if it is accompanied by a statement of the uncertainty in the measurement. A measurement result should therefore be specified as X ± U, where X is the best estimate of the measurand and is equal to the average of repeat observants. U is the uncertainty of the measurement. Measurands are particular quantities subject to measurement (temperature, time, speed, volume etc.).

UM is defined as a non- negative parameter, associated with the result of a measurement that characterizes the dispersion of the values that could reasonably be attributed to the measurand. When the uncertainty in a measurement is evaluated and stated, the fitness for purpose of the measurement can be properly judged. The use of good practice – such as traceable calibration, careful calculation, good record keeping, and checking – can reduce measurement uncertainties

UM is evaluated from the statistical distribution/analysis of the results of series of measurements obtained under specified repeatability conditions. The repeat measurements are spread or dispersed around a specific value (arithmetic average/mean). This spread (standard deviation) is the uncertainty interval where the measurement result is expected to lie. The wider the interval, the more uncertain we are about the assigned value; similarly, if the interval is small, the uncertainty of the measurement result as an assigned value is also small.

UM is expressed as a standard deviation (or a multiple of a standard deviation) or the half-width of an interval having a stated level of confidence. Uncertainty is expressed in terms of a coverage factor, together with a size of the uncertainty interval, and state a level of confidence i.e. By using the coverage factor k = 2, to give a level of confidence of approximately 95 percent.

Calibration Certificate:

The result from the calibration of a measuring equipment or measurement standard is given in a calibration certificate/report. It can be in either hard copy or electronic format and at a minimum displays:

- Name and address of the calibrating laboratory.
- Unique identification of the certificate
- Name and address of the client
- The identification of the equipment calibrated (by manufacturer or brand and type and by the unique identification number, as specified by the inventory).
- Date the calibration was performed.
- The environmental conditions during calibration
- Standards used with their valid calibration, uncertainty & traceability (traceability certificate of reference standard)
- Identification of the method used
- The calibration results obtained and units of measurement including: A record of the

readings obtained during the calibration for each of the calibration values and record of the calculation of the accuracy and precision for all sets of values.

- Any use limitations on the equipment calibrated
- The correction factor (if any)
- The uncertainty of measurement result
- Coverage factor/confidentiality limits (levels)
- Validity of the latest calibration
- The authority under which the certificate is issued (The name, function and signature of the person authorizing the certificate)
- NABL symbol since calibrating lab must be NABL accredited

Calibration of equipment can be outsourced to an external accredited calibration laboratory. For in-house calibration/calibration verification of instruments in the HIV testing laboratory, use a calibrated tachometer-for rotational speed of the centrifuge; a calibrated digital temperature sensor-for checking the temperature of a refrigerator, incubator etc., a calibrated glass thermometer- for temperature checking of oven, water bath etc.; calibrated weights-for the balance which in turn is used to calibrate pipettes, calibrated timers to calibrate timers of centrifuges and those used to alert the technician to read test results in specified time intervals .

Calibration is a QA function. The quality of serviceable instruments is only verified and not up graded directly by calibration. Upgrading is accomplished through repair, maintenance and through the action of new procurement.

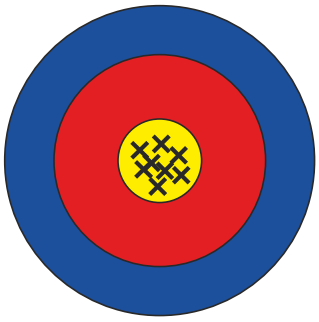
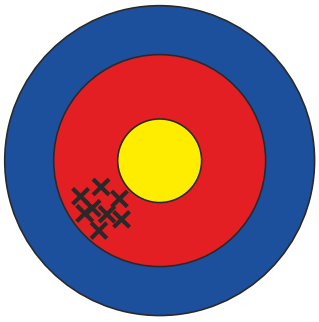
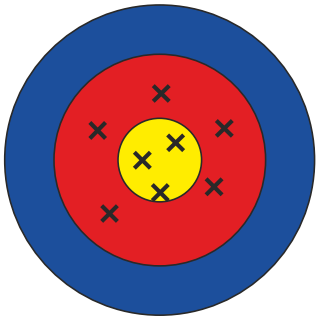
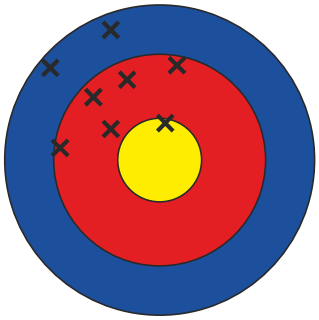
v. Performance/ Function Evaluation:

Routine checking/monitoring of instrument performance parameters verifies that the equipment has remained within specified range of accuracy & precision and that it is working according to the manufacturer's specification. This should be done before using the instrument initially as often as recommended by the manufacturer (performed periodically-daily, weekly, monthly). These function checks should also be done following any instrument repairs. Some examples of function checks are daily monitoring of temperature and checking the accuracy of wavelength calibration.

Accuracy: The closeness of agreement between the result of a measure and the true value of measurement. Calibration is used to determine the accuracy of an instrument. Accuracy is measured in terms of bias/error. (Figure 4.3).

Precision (Repeatability): Precision is the closeness of agreement between the results of successive measurements of a defined procedure several times under prescribed conditions. Precision is measured in terms of imprecision. It is evaluated statistically using standard deviation, coefficient of variation or confidence interval. (Figure 4. 3).

Figure 4.3: Accuracy and Precision

	Accurate	Inaccurate (systematic error)
Precise		
Imprecise (reproducibility error)		

vi. Equipment Maintenance, Service and Repair: Equipment maintenance is the scheduled, regular and systematic cleaning, decontamination, adjustment, or replacement of instrument and equipment parts that have the potential to fail (e.g. tubing, motor brushes, and rubber gaskets). The aim is to minimize equipment malfunction or failure by detecting minor problems early and before they cause shut down or malfunction of equipment. This preventive maintenance is performed periodically viz. daily, weekly, monthly, annually but at a minimum the manufacturer's recommendations should be followed.

- **Daily Maintenance** - Assure that all equipment is clean, add controls or calibrators to each run, daily monitor temperatures of refrigerators, freezers, incubators and the room temperature, check wavelength calibration, assure that the printer paper is adequate, check that waste containers are empty, rinse sample ports with distilled water or acceptable cleaners, clean up all spills, check reagent levels, dispose of bio-hazardous waste properly and check autoclave indicator paper
- **Weekly Maintenance** - keep optical and other components free from dust and surfaces of instruments clean. Prepare fresh batches of reagents as needed, defrost refrigerators and clean water baths.
- **Monthly Maintenance** - Perform electronic or optical checks on all components. Many automated and semi -automated instruments have built-in programs for calibration.
- **Biannual Maintenance** - Clean or change filters; check fluid lines and tubing for signs of deterioration or dirt and replace as needed. Re-grease and recalibrate all pipettes as needed

and check electrical connections and wiring.

- **Yearly Maintenance** - Change all fluid lines and tubing of major instruments, recalibrate pipettes and call the factory representative (if possible) to arrange for a service visit.

Steps to implementing a maintenance program include

- Assigning responsibility for the oversight of all laboratory equipment,
- Developing written policies and procedures for maintaining equipment including routine maintenance plans for each piece of equipment that specify the frequency with which all maintenance tasks should be performed,
- Developing the format for records, creating logs and forms, and establishing the processes to maintain records,
- Training of staff on the use and maintenance of the equipment, and ensuring that all staff understand their specific responsibilities.

vii. Equipment Inventory, Documentation and Records: An equipment inventory system assists in the control of equipment. Records should be maintained for each piece of equipment contributing to the performance of examinations. Each piece of equipment should have a dedicated logbook documenting all characteristics including:

a. Identity / name of the equipment.
b. Manufacturer's name, type identification, serial number or other unique identification.
c. Manufacturer's contact person with appropriate contact details.
d. Date equipment was received and date it was implemented in laboratory service.
e. Condition when received (e.g. new, used, reconditioned etc.).
f. Checks that equipment complies with performance specifications e.g. analytical capability, acceptable limits for operation, troubleshooting guide, etc.
g. Validation records to confirm that the equipment was found to be suitable for use
h. Current location.
i. Manufacturer's instructions manual or reference to where this can be accessed.
j. Calibration frequencies, reminders and records.
k. Adjustment and acceptance criteria and acceptance failures.
l. Maintenance plan and maintenance record.
m. Damage, malfunction, modification, repair and service records.
n. Responsibility for equipment management.
o. Date equipment was removed from service.

To ensure that the laboratory does not run out of spare parts, an inventory record of those used most frequently should be kept for each piece of equipment. The record should include: part name and number; average use of the part, and the minimum to keep on hand; cost, the date when the part is placed into storage and when it is used (in and out stock log) and quantity of each part remaining in inventory.

Equipment documents and records are an essential part of the quality system. The policies and procedures for maintenance should be defined in appropriate documents. Keeping good equipment records will allow for systematic evaluation of any problems that arise. Each major piece of equipment will have its own equipment maintenance document which should include: step-by-step instructions for safe handling, transport, storage and use; how to prevent contamination and deterioration; information on routine maintenance including frequency of performance and how to keep records of maintenance; instructions for carrying out function checks, frequency of performance, and how to record the results; directions for calibrating the instrument; guide for troubleshooting; any required manufacturer's service and repair and a list of any specific items needed for use and maintenance, such as spare parts.

When computers or automated examination equipment is used for the collection, processing, recording, reporting, storage or retrieval of examination data, the laboratory must ensure that:
a) Computer software, including that built into equipment, is documented and suitably validated as adequate for use in the facility; b) Procedures are established and implemented for protecting the integrity of data at all times; c) Computers and automated equipment are maintained to ensure proper functioning and are provided with environmental and operating conditions necessary for maintaining the integrity of data; d) Computer programs and routines are adequately protected to prevent access, alteration or destruction by casual or unauthorized persons.

Reconstruction of the history of each piece of equipment from acquisition to decommission should be traceable from the equipment records. These records should be readily available for the life span of the equipment or for any time period required by national, regional and local regulations.

viii. Troubleshooting: Problems with equipment may present in many ways. The operator may notice small changes such as drift in QC or calibrator values, or obvious flaws in equipment function. Sometimes, the equipment fails to operate. While training operators it is important to teach them to troubleshoot equipment problems in order to quickly get the equipment functioning and resume testing as rapidly as possible. When an instrument drift is observed, it is necessary to repeat the preventive maintenance procedures as a first step to resolving the problem. If this does not work, proceed with troubleshooting processes.

Manufacturers or user manuals frequently provide a flowchart that can help determine the source of problems. Is the problem related to a poor sample? Has the sample been collected and stored properly? Are factors such as turbidity or coagulation affecting instrument performance? Is there a problem with the reagents? Have they been stored properly, and are they still in date? Have new lot numbers been introduced without updating instrument calibration? Is there a problem with the water or electrical supply? Is there a problem with the equipment?

One change should be made at a time. If the equipment is the problem, the manufacturer's instructions or SOPs must be reviewed to verify that all procedures are being followed correctly. Equipment that does not function properly must not be used. When In-house efforts have failed, find a way to continue testing until equipment can be repaired. Options for testing include referring tests to an identified accredited laboratory or using a validated, calibrated and maintained backup instrument or storing samples appropriately until the testing is possible. Help from manufacturer or other technical expert must be then sought. A malfunction label/ notice must be placed on equipment so all staff are aware that it is not in use.

Documentation must be complete. A problem log record must be developed for each piece of equipment and details to be noted include the date when the problem occurred, removed from service, reason for breakdown or failure, corrective action taken, date returned to use, change in maintenance or function checks.

ix. Defective Equipment Management: Whenever equipment is found to be defective thorough function checks or other monitors of performance, protocols dictate that;

a. It should be isolated and taken out of service
b. It should be clearly labelled or marked as being out of service. One must examine the effect of this defect on previous examinations
c. A list of the measures taken to reduce contamination shall be provided to the person working on the equipment
d. Reasonable measures must be taken to decontaminate equipment prior to service, repair or decommissioning
e. Suitable space for repairs and appropriate personal protective equipment (PPE) should be provided
f. Equipment must be appropriately stored until it has been repaired
g. And after repair, before being put to use again, equipment must be shown by means of calibration, verification, or function checks, that it meets specified acceptance criteria

x. Retiring Equipment / Disposition: It is necessary to have a policy and procedure for retiring older laboratory equipment. This will usually occur when it is indicated by experts that the instrument is not functioning and is not repairable, or when it is outmoded and should be replaced with new equipment. Once a piece of equipment is fully retired and it has been determined that it has no further use, it should be disposed off in an appropriate and safe manner. When disposing off equipment, salvage any usable parts, particularly if the equipment is being replaced with another similar one. Any potential biohazards must be considered and all safety disposal procedures must be followed.

xi. Oversight and Supervision: It is the responsibility of the laboratory in charge to oversee all the equipment management systems in the laboratory; ensure that all persons who will be using

the instruments have been appropriately trained and understand how to correctly operate the instrument, troubleshoot, perform all necessary performance checks and routine maintenance procedures. Specific person/s must be designated to oversee and deal with all aspects of equipment management. Oversight of equipment management includes ensuring that all procedures are followed; procedures are updated when necessary, all records are routinely reviewed.

Annexures:

4.1 Temperature Controlled Units (Refrigerators and freezers; Incubators)
4.2 Incubators
4.3 Centrifuge
4.4 Pipettes
4.5 Electronic balance
4.6 ELISA System

Key points

The laboratory should be furnished with all items of equipment required for the provision of services. Laboratory equipment

- Should be selected and shown upon installation and in routine use to be capable of achieving the performance required (validation);
- A list of working equipment should be maintained with unique identification, serial number, model, name of manufacturer, date of installation, current location, calibration status and records of maintenance, function checks and performance assessment;
- Every equipment should be labeled to indicate the unique identity, functional status , calibration or verification status and the date when next calibration or re-verification is due
- Equipment should be maintained in safe working condition, including examination of electrical and mechanical safety, emergency stop devices, and safe handling and disposal of chemical and biological materials by authorized persons.
- Laboratory management should establish a documented program that regularly monitors and demonstrates proper calibration, and preventive maintenance of equipment that, at a minimum, follows the manufacturer's recommendations.
- Up-to-date instructions and SOPs on the use and maintenance of equipment, including any relevant manuals and directions for use provided by the manufacturer, should be readily available for use by laboratory personnel. The equipment should only be operated by authorized personnel.
- Records should be maintained for each item of equipment contributing to the performance of examinations.
- Whenever equipment is found to be defective, it should be taken out of service, clearly labeled, appropriately decontaminated and stored until it has been repaired. It should be recalibrated before being put into use again.

Laboratory supplies and inventory management

For successful performance, every testing laboratory should have sufficient supplies to meet the requirements of the customer/scope of the laboratory. For an HIV testing laboratory, these supplies could be categorized as consumables, reagents and kits. Providing a dependable, uninterrupted supply of good quality kits and consumables is important for the success of the NACP.

Inventory is a stock or store of supplies. It is a part of the supply chain which also consists of storage and distribution. Inventory management includes those systems and processes that identify inventory requirements, set targets, provide replenishment techniques and report actual and projected inventory status. Inventory management thus will be successful if the storage and distribution infrastructure is efficient. A good inventory is vital for successful operation and customer satisfaction.

Inventory for HIV testing has some special characteristics. It has to deal with the different quantities required for three types of test (1st, 2nd and 3rd), their storage conditions and shelf life. HIV testing is dynamic, requiring change to be incorporated as and when directed by the national guidelines. The necessity to adhere to the testing algorithm leaves no option for substitution especially if there is a stock out of kits. On the other hand if the laboratory purchases too many supplies, then they have to redistribute the excess stock to prevent wastage.

Definitions:

- **Reagents** are chemicals and biological agents that are used in laboratory testing for detecting or measuring an analyte, the substance being measured or determined.
- **Consumables** are items that are used once while performing a test and are not reused.
- **Inventory** is a stock or store of supplies
- **Inventory management** comprises the procedures that govern how supplies are ordered, received, stored, handled, distributed and re-ordered.
- **Full supply** is a situation wherein sufficient quantities of all commodities are available to meet all needs of laboratory.
- **Standard protocol for inventory control** is when orders are placed at regular intervals. A product is ordered only if it has reached its minimum/reorder stock level.
- **Lead time** is the amount of time it takes to fill and process orders and deliver product to the receiving facility.

Inventory Management System:

Every laboratory should have a good inventory management system. The purpose of inventory management is to ensure a continuous, uninterrupted supply of quality products as and when needed. The role of this system is to:

- **Identify how much to order** or issue as much as is required to meet laboratory demands (anticipated / expected), ensure a continuous supply of reagents and consumables (at no time should a test be denied for lack of supplies) and protect against stock outs or overstock leading to expired products.
- **Understand when to change the quantity of order or issue** - Forecast a supply based on requirement (anticipate a likely increase / decrease in requisitions) so that excess stock does not lead to expired goods due to non-utilisation.
- **Know when to order or issue** - Identify / define buffer stocks and reorder levels
- **Maintain a continuum of services**

Components of Inventory Management:

The Components of Inventory management includes

- Requirement
- Procurement
- Disposal of expired stock

Requirements : includes personnel, supplies, infrastructure and documentation.

Personnel - Designate a responsible staff member for inventory management and describe his/her roles and responsibilities.

Supplies - Select products that are appropriate based on the testing protocols, cost, training of personnel, and infrastructure for storage and transportation. The designated person prepares a list of all supplies that would be required to successfully carry out the tests under the laboratory's scope. These include:

- The test kits (as applicable)
- The equipment / reagents / consumables not provided with the kit (read the kit literature under 'equipment / reagents / consumables required but not provided e.g. micropipettes, pipette tips, wash buffers etc.)
- Material required for performing the tests as per Good Clinical Laboratory Practices (GCLP).
- Material required for safety issues including Personal Protective Equipment, spill management, sharp policy, biomedical waste management and Post Exposure Prophylaxis. Though this may not directly affect the performance of the test, they form a part of the quality policy of every testing laboratory and should be complied with at all times

A comprehensive checklist based on the above can be used as a record for procurement, storage and distribution. (Annexure 5.1)

Infrastructure: Storage area and equipment - The minimum infrastructure required would be a well-ventilated and well lit storage area that can be efficiently secured, a separate storage area for chemicals as per their Material Supplies Data Sheet requirements, and cold storage for kits

and reagents as required (walk in coolers / cold room / refrigerators / deep freezers). Store the supplies in such a way that First Expiry First Out (FEFO) can be followed. Storage areas should be in a controlled environment and have adequate capacity.

Documentation: Every testing facility should maintain a 'stock register'. (Annexure 5.2) The stock register should be updated every time a supply is distributed / procured. A QSP describing inventory control should be developed and implemented.

Procurement

The key objectives of procurement are that the consumables must be of the desired specifications, in the appropriate quantities, of good quality and at competitive price.

- From whom to procure? Presently, under the programme kits are supplied by the SACS/NACO and the other supplies are purchased by the testing centres through a grant made available to each testing facility. The method of procurement should be as per guidelines of the funding agency, which should be well documented.

A typical procurement cycle consists of selecting / identifying the commodity, quantifying the commodity, re-quantifying based on budget, identifying the suppliers, procuring product brochures from suppliers, preparing specifications, placing an order to the vendor whose sample/s satisfies the specifications and who has provided the lowest quotation, inspecting samples and approving, making a payment, documenting receipt and payment, updating the stock register, distributing and collecting consumption data.

A good procurement process is transparent, accountable, provides good quality products and should be well documented.

- How much to procure? Forecast the quantity required based on the number of tests likely to be performed over a defined period, and the minimum reorder level/ buffer stock required. A minimum reorder level/ buffer stock is the minimum stock maintained to protect the testing facility against stock-outs. The defined period would depend on the storage infrastructure available at each testing centre, the shelf life of the supplies and the down time for procurement. Also, adjust the estimated quantity for products that may be lost (expiry, wastage, breakage, etc.), and those required for QC purposes. Order only as many as can be procured from the budget provided. Never order kits or consumables more than the storage space can hold.

While re-ordering (based on the lead time and buffer stock/ reorder level and the actual supplies in hand i.e. physical count), place an order to meet the requirement as described above.

- How are the supplies to be accepted, stored and used?

- Use the checklist when accepting supplies. (Annexure 5.3)
- On receipt, all materials should be inspected and approved [test if required]
- If temperature sensitive parameters are required for quality, these should be checked and ascertained
- Check the packing for integrity
- Check the expiry date and any certificate of analysis / conformity if required
- Document all the kits, reagents and consumables in the stock register
- Stack properly in the designated locations based on their requirement for temperature, storage (coolers / refrigerators are required for storage of testing kits). Store all supplies as per requirements on each supply label.
- All supplies should be used on a First-Expiry-First out (FEFO) basis.

- When to place a re-order? Whenever the kit stock reaches minimum level, place an order keeping in mind the lead time. Calculate the minimum stock level with the help of the following formula:

Minimum Stock Level = Maximum lead time x Maximum Usage
(In weeks) (In a week)

Disposal of Expired Stock:

In an efficiently managed inventory system, situation where stocks expire should not arise. A system of redistribution of close to expiry kits should be implemented. In an unlikely event of expired stock the under mentioned steps to be followed:

- During monthly stock checks, expiry dates for all supplies, must be checked to ensure that no stock is kept in circulation that is out of date.
- Expired stock must be removed from use immediately upon discovery for disposal.
- Inform the local authority for collecting/sending the expired stock.
- If stock need to be disposed of, follow the Material Safety Data Sheet (MSDS) and the national biomedical waste management rules.
- Maintain records of the same.

Key points

Inventory management involves

- Assignment of responsibility
- Analysing needs
- Establishing minimum stock needs
- Development of forms and logs
- Establishment of a system for receiving and storing
- Maintaining inventory systems in all storage areas

Personnel

The success of QMS in a laboratory regardless of the design, ultimately depends upon its human resource. Qualified, trained and motivated personnel are the backbone of the QMS. When implementing a QMS the organizational structure must be well defined in the form of an **organizational chart** which is a diagram that shows the structure of an organization and the interrelationships, designations and reporting hierarchy. Personnel policies must be documented and available to all employees.

The laboratory personnel / staff include:

- Head of the Institute
- Head of the department
- Laboratory/section in charge/s
- Quality Manager
- Safety Officer
- Technical Manager
- Technical Staff

Job descriptions that specify tasks, responsibilities and authorities for all personnel must be established and well defined. When assigning responsibilities, education, demonstrated skill, training and experience must be considered. Deputies for all key managerial and technical personnel must be specified and communicated. Authorized signatories must demonstrate knowledge and competence in the concerned speciality. The qualification norms for authorized signatories are according to NACO/NABL guidelines.

Head of the Institute provides commitment in terms of administrative support and resource mobilization so as to ensure that the laboratory is directed towards adopting the QMS approach.

Head of the Department has the overall responsibility for professional, scientific, advisory, organizational, administrative and educational matters relevant to the services offered by the laboratory and coordinates with the Head of the Institute for allocation of resources and garnering administrative support for the laboratory. The Head of the Department also designates the Quality Manager who would monitor and maintain day-to-day activities pertaining to QMS.

The Laboratory/Section In charge coordinates with the Head, Quality Manager and Technical Staff to ensure that the QA of the technical aspects of the laboratory is adequate and authorizes the release of reports. In the event of non-conformances, s/he ensures that results of test examinations are not reported until all corrective actions have been taken and the test system is properly functioning; provides training to personnel; annually evaluates and documents the performance of all testing personnel.

The Quality Manager, appointed by the HOD has delegated authority and direct responsibility to ensure processes needed for the QMS are established, implemented and maintained. S/he oversees compliance with the QMS requirements. S/he reports directly to the level of management at which decisions are made on policy and resources. The Quality Manager must be trained and experienced in medical laboratory science and trained in the quality management system. The quality manager must have undergone a four day training course on laboratory QMS from a reputed institute.

Safety Officer should be appointed wherever possible to ensure that the safety policies and programmes are followed consistently throughout the laboratory. The safety officer executes these duties on behalf of the head of the institute or laboratory. The person designated should possess the professional competence necessary to suggest, review and approve specific activities that follow appropriate bio-containment and biosafety procedure/s. S/he should apply relevant international, national and local rules, regulations and guidelines, as well as assist the laboratory in developing the safety manual/standard operating procedures. The safety officer should also be able to communicate effectively with administrative, technical and support personnel.

The Technical Manager needs to have applicable theoretical and practical background as well as experience in the examinations or interpretations on which s/he make professional decisions. S/he is responsible for day-to-day supervision of the lab operation, as well as personnel performing testing and reporting test results. Monitors examinations to ensure that acceptable levels of analytic performance are maintained; ensures that all remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications;

The technical Staff must:

- Follow the laboratory's procedures for specimen handling and processing, test analysis reporting and maintaining records of test examinations
- Maintain records that demonstrate that proficiency testing samples are tested in the same manner as patient specimens
- Adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed
- Follow the laboratory's established policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance
- Be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the supervisor or HOD; and
- Document all corrective actions taken when test systems deviate from the laboratories established performance specifications

All quality management issues can only be addressed and fully implemented if institutional head commits to and provides full support including resources to the system.

A broad outline of steps (Table 6.1) to be taken by personnel at different levels for instituting QMS is provided:

Table 6.1: Laboratory Personnel/Staff and their Roles in maintaining the QMS:

Level	Action
Head of the Institute	▸ Ensures commitment for implementation of QMS ▸ Ensures commitment in terms of administrative support & resource mobilisation and allocation
Head of the Department	▸ Coordination with the Head of the Institution to ensure administrative support & resources ▸ Overall responsibility for professional, scientific, advisory, organisational, administrative and educational matters relevant to the services offered by the laboratory ▸ Designates Quality Manager and Laboratory In-charge, wherever required ▸ Provides advisory services to clinicians
Laboratory/Section In charge	▸ Coordinates with the Head and Quality Manager and Technical Staff to ensure the implementation of quality assurance measures in the laboratory ▸ Authorizes the release of reports ▸ Provides advisory services to clinicians
Quality/Technical Manager	In consultation with the Laboratory In charge & Head of the Department: ▸ Defines, implements and monitors standards of performance and continual quality improvement in the laboratory ▸ Plan trainings and re-trainings of staff including competency evaluations
Safety Officer	▸ Biosafety, biosecurity and technical compliance discussions/meetings ▸ Periodic internal safety audits on technical methods, procedures and protocols, biological agents/materials and equipment

Level	Action
Safety Officer	▸ Verifies that all staff receives appropriate safety training and continuing education ▸ Ensures proper waste management and emergency adverse incident management
Technical Staff	▸ Develops documents according to document system QSP plan ▸ Carries out processes as per the documented policies & procedures

All personnel must know their roles and responsibilities in the QMS so as to collectively contribute and make it effective. Qualified and trained personnel who have the authority to provide the laboratory's services and who understand both technical and managerial aspects (Head of the department and/or Laboratory In charge) should head this effort and should direct the technical personnel. Once the Quality Management System is established, the competency of personnel must be assessed initially and periodically. It must be verified that all persons have been trained appropriately for their set of responsibilities and periodically assessed and retrained if necessary.

Personnel Training:

Laboratory management must have procedures for the training for all staff . Training must be documented for all individuals, including healthcare providers performing testing, staff engaged in the performance of supportive tasks such as data entry, accessioning and reporting, supervisory and management staff. Training programs should include the following elements:

- Job Tasks (assigned work processes and procedures)
- QMS
- Safety and Health
- Ethics including confidentiality of information
- Governmental reporting requirements
- Applicable laboratory information system including computer systems

The laboratory must introduce new personnel/staff to their assigned work processes and procedures with the applicable laboratory information system, the terms and conditions of employment, staff facilities, and orient them to the laboratory facility and safety (including prevention or containment of the effects of adverse events, fire and emergency) the QMS and the ethical code of conduct. This must be planned, documented and implemented; the laboratory in-charge/HOD must provide continuing education on an annual basis to laboratory staff commensurate with the scope of their duties. Records of all trainings must be maintained.

Competence Assessment:

To determine if staff possesses and continues to demonstrate the skill in which they were trained, an individual's competence is assessed

- After initial training and before working independently and six months thereafter
- Periodically throughout employment (at least once a year)
- Whenever job responsibilities change

Competence assessment applies to all laboratory personnel who perform responsibilities in the path of workflow. When competence assessment fail to meet established criteria, root cause(s) analysis should be performed and appropriate retraining is initiated and documented.

Competence assessment methods include but are not limited to

- Testing blinded samples, PT samples, split sample testing, replicate testing
- Periodic written test
- Compliance with policies and procedures
- Observation for compliance with safety protocols
- Direct observation of routine patient test performance, including patient preparation, specimen handling , processing and testing
- Monitoring the recording and reporting of test results
- Review of intermediate test results or worksheet, QC results records, PT results and preventive maintenance
- Direct observation of performance of instrument maintenance and function checks
- Evaluation of problem solving skills

Review of Staff Performance:

Reviews of staff performance must be undertaken at least annually. It must be ensured that these reviews consider the needs of the laboratory and of the individual in order to maintain and improve the quality of service given to the users. Productive working relationships must be encouraged.

Continuing Education and Professional Development:

A continuing education program must be available to personnel who participate in managerial and technical processes.

Personnel Records/Files:

The records listed are not required to be stored in the laboratory, but can be maintained in other specified locations, providing they remain accessible as needed.

The laboratory must maintain the following personnel records

a. Personal information including educational and professional qualifications; previous work experience

b. Copy of the degree/ diploma certificates
c. Registration with local/ national authorities, wherever applicable
d. Copy of appointment letter
e. References from pervious employment
f. Roles and responsibilities
g. Job description and authorization
h. Records of competency evaluations, training, continuing education
i. Performance evaluation
j. Health records including history of exposure to occupational hazards and immunization status.
k. Hepatitis B vaccine should be offered to all the laboratory staff and the protective antibody titres subsequent to vaccination should be checked and documented.

Key points

Following personnel related aspects should be addressed while implementing QMS:

- The qualifications and experience of authorized signatories and technical staff should be followed unless otherwise specified.
- The number of staff employed should be appropriate to the workload of the laboratory.
- The roles, responsibilities and reporting hierarchy of the staff should be clearly outlined and documented. The staff should also understand the nature of work assigned to them and must be authorized to perform the tasks independently.
- A programme for technical training and updating skills on regular basis should be in place. The laboratory management should be committed for providing continuing education and professional development opportunities for staff.
- Laboratory should organize competency evaluation of staff, the frequency and method of which should be decided by the laboratory.
- Laboratory should organise performance reviews to evaluate an individual's job performance periodically.
- All personnel/staff must maintain confidentiality of information and ethical code regarding patients.

Laboratory Safety and Biosecurity

The laboratory can be a potential source of physical, chemical and biological safety hazards e.g. fire, breakage of glassware, sharps, spillages, pressure equipment and gas cylinders, extremes of heat and cold and radiation. However, with proper laboratory design and safety program these hazards can be prevented. Biosecurity is the protection of pathogens, toxins, and sensitive information from loss, theft and subsequent misuse.

The laboratory work space and services must be maintained in such a way that various tasks can be performed without compromising the quality of work or the safety of laboratory staff, other health care personnel, patients, visitors , the community or environment. All laboratories must comply with the national and state regulations.

Developing a Laboratory Safety Program:

Safety Officer

A designated laboratory safety officer must be assigned the responsibility for developing a safety program and organizing appropriate safety measures and safety trainings and drills for the laboratory. The steps for designing a safety management program include developing a safety manual to provide written procedures for safety and biosafety in the laboratory; organizing safety training and exercises that teach staff to be aware of potential hazards and how to apply safety practices and techniques, setting up a process to conduct risk assessments, as well as ongoing laboratory safety audits to look for potential safety problems. Laboratory safety audits can be undertaken using a safety checklist (Annexure 7.2).

The Safety Officer's job responsibilities include the following:

- All staff members are trained on safety and vaccinated against Hepatitis B. Records are available to corroborate this
- Ensure that there is an adequate supply of appropriate equipment for safety and biosafety, such as PPE; fire extinguishers and fire blankets
- Ensure appropriate storage and cabinets for flammable and toxic chemicals
- Provide eye washers and emergency shower; waste disposal supplies and equipment; first aid equipment
- Conduct and record weekly inspections to ensure that the laboratory is safe and in a good condition. Fire extinguishers and eye-wash stations are inspected, tested and service is up-to-date. First Aid kit is replenished when necessary
- Organize periodic (at least yearly) fire drills and laboratory evacuation procedures, handling of incidents and basic security precautions
- Ensure that the Material Safety Data Sheets (MSDS) are available in the respective laboratory sections and that the staff have read and understood them
- Ensure all incidents are documented and attended to immediately

- Conduct periodic safety audit with the help of a checklist

Safety Policies: The following safety policies must be in place to ensure the continued safety of laboratory staff and any authorized individual who may enter the laboratory:

Standard Precautions Policy:
This policy defines all human biologic specimens as potentially infectious and addresses topics of consideration when dealing with potentially infectious specimens, such as hand care, PPE, working with open lesions, handling contaminated needles and other sharp objects, autoclaving, and disposal of materials.

Chemical Hygiene Policy:
This policy addresses aspects of safe chemical handling, including storage, utilization and disposal of chemicals, with the goal of minimizing exposures and risks associated with those chemicals. MSDS provide information about the identities and hazards of chemicals, required appropriate labelling, exposure, first aid, spill management etc.

Waste Management Policy:
This policy details appropriate measures to take when disposing of waste materials to ensure continued human and environmental health.

General Safety Policies:
These policies address less specific topics as they relate to laboratory safety, such as fire and electrical safety.

Safety Equipment:
These policies typically detail all available safety equipment, their purposes, and proper utilization

Safety Training:
Training should include information about standard precautions, infection control, chemical and physical safety, how to use personal protective equipment (PPE), how to dispose of hazardous waste, and what to do in case of emergencies. Documentation related to the completion of safety trainings must be maintained. Safety trainings must be completed before any laboratory personnel begin working in the laboratory, and on a regular basis thereafter. Ongoing safety training must take place each calendar year.

Safety Incident Reporting
Safety-related incidents including injuries (needle prick, sharps injury, falls, burns, etc.); chemical exposure; malfunctioning equipment posing a safety risk (e.g. potential for electrical