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ICMR Guidelines for Good Clinical Laboratory Practices (GCLP) 2021

**ICMR
Guidelines for
Good Clinical Laboratory Practices
(GCLP) 2021**

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Good Clinical Laboratory Practices Guidelines, 2021

2nd edition

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FOREWORD

Globally, in the last few decades there has been a rapid expansion in the different branches of health care services, as well as in the field of medical research. Consumer awareness and expectation of health care have simultaneously improved with increasing demands for high quality care, including laboratory services. It is well recognized that laboratory quality will significantly improve if the entire process is addressed in the quality system. Towards this goal, the laboratories should meticulously implement Good Clinical Laboratory Practices (GCLP) that will ensure timely and accurate processing of biological samples enabling early and accurate diagnosis and patient safety leading to desired clinical outcomes.

With the objective of promoting uniformity in maintaining quality of laboratory services, the Indian Council of Medical Research released the first GCLP guidelines in the year 2008. Keeping in view of recent advances, the ICMR has now revised the 2008 document. The revised **Guidelines for Good Clinical Laboratory Practices 2021** aim to establish minimum criteria which should be followed by clinical and research laboratories involved in examining human samples, in routine healthcare delivery and clinical research, respectively. GCLP compliance will certainly empower clinical laboratories and clinical researchers to provide data that are reliable. Adoption of these GCLP guidelines by laboratories in public sector, private sector and research institutions will be a significant step forward in the betterment of health care services and health research in India.

The efforts of the team of scientists and experts from ICMR and from other institutions who worked meticulously in bringing out the Guidelines for GCLP 2021 deserve appreciation.



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PREFACE

Over the years, clinical laboratories have gained tremendous importance in health care services. Laboratory investigations are essential for medical diagnosis in patient care as well as medical research. Reliability of laboratory data/report is therefore of paramount importance. Good Clinical Laboratory Practices (GCLP) is essential to be implemented in the field of medical research and health care services to ensure reliability of laboratory data. Keeping this in view, ICMR constituted an Advisory Committee to develop the Guidelines for GCLP in the year 2008. This document has now been revised as **Guidelines for Good Clinical Laboratory Practices 2021** to be adopted uniformly in medical laboratories involved in clinical research and/or patient care in India.

One major addition in the scope of updated guidelines is the inclusion of clinical research involving human participants. The guidelines are also projected to establish facilities with evolving strategies in pre-examination and examination processes of samples from clinical research and testing laboratories to assure the quality, reliability and integrity of the data generated.

The directives require that guidelines for compliance monitoring procedures for GCLP and the guidelines for conduct of test facility inspection and study audit must be followed periodically to ensure reliability and integrity of data generated by laboratories.

ICMR is expected to play a lead role in providing support and training activities to all medical research institutions, universities and clinical research laboratories to promote uniform adoption of these guidelines which will enable in improving the safety and integrity of test results and to follow the quality standards, ethical conduct and regulatory compliance as mandated by GCLP guidelines.



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CONTENTS

| | | |
|---------------|--|--------|
| ABBREVIATIONS | | i-ii |
| DEFINITIONS | | iii-vi |
| Chapter-1 | INTRODUCTION | 1 |
| Chapter-2 | SCOPE | 2 |
| Chapter-3 | LEVELS OF LABORATORIES | 3-5 |
| | 3.1 Primary Level | 4 |
| | 3.2 Secondary Level | 4 |
| | 3.3 Tertiary Level | 4 |
| | 3.4 Reference Laboratories, Research Laboratories and Specific Disease Reference Laboratories | 5 |
| | 3.5 For Collection Centres | 5 |
| Chapter-4 | INFRASTRUCTURE | 6 |
| Chapter-5 | PERSONNEL, TRAINING AND DEVELOPMENT | 7-12 |
| | 5.1 General | 7 |
| | 5.2 Personnel | 8 |
| | 5.3 Training | 9 |
| Chapter-6 | EQUIPMENT | 12-15 |
| Chapter-7 | REAGENTS AND MATERIALS | 15 |
| Chapter-8 | PRE EXAMINATION PROCESS | 17-18 |
| | 8.1 Patient Preparation | 17 |
| | 8.2 Primary Sample Collection | 17 |
| | 8.3 Primary Sample Collection Device | 17 |
| | 8.4 Samples of Clinical Research/Trial | 17 |
| | 8.5 Sample Labeling and Documentation | 18 |
| | 8.6 Requisition Form/Test Request Form | 18 |
| | 8.7 Transportation of Samples | 18 |
| Chapter-9 | SAMPLE ACCEPTANCE/REJECTION | 19 |
| Chapter-10 | EXAMINATION PROCESSES | 20-21 |
| | 10.1 General | 20 |
| | 10.2 Examination Procedures | 21 |
| | 10.3 Performance characteristics | 21 |
| Chapter-11 | RELEASE OF TEST RESULTS | 22 |

| | | |
|--------------|--|-------|
| Chapter-12 | SAMPLE STORAGE/DISPOSAL | 22-23 |
| | 12.1 Sample storage | 22 |
| | 12.2 Sample/Chemical/e-waste disposal | 23 |
| Chapter-13 | SAFETY IN LABORATORIES | 23-34 |
| | 13.1 General Safety Measures | 23 |
| | 13.2 Laboratory Safety Chemical Hygiene Plan | 24 |
| | 13.3 Laboratory Hygiene and Sanitation | 25 |
| | 13.4 Personal Hygiene | 26 |
| | 13.5 Electrical safety | 26 |
| | 13.6 Biosafety Precautions | 26 |
| | 13.7 Biological safety cabinets (BSCs) | 34 |
| Chapter-14 | ETHICAL CONSIDERATIONS | 34 |
| Chapter-15 | QUALITY MANAGEMENT | 36 |
| Chapter-16 | INTERNAL QUALITY CONTROL | 37-39 |
| | 16.1 IQC for Quantitative Tests | 38 |
| | 16.2 IQC for Qualitative Tests | 39 |
| | 16.3 Reagent Lot Verification | 39 |
| Chapter-17 | EXTERNAL QUALITY ASSESSMENT/ PROFICIENCY TESTING | 40 |
| Chapter-18 | INTERNAL AUDIT | 41 |
| Chapter-19 | TECHNICAL AUDIT CHECKLIST | 41 |
| Chapter-20 | RISK MANAGEMENT | 42 |
| Chapter-21 | QUALITY INDICATORS | 42 |
| Chapter-22 | DATA MANAGEMENT | 44-47 |
| | 22.1 Data integrity | 44 |
| | 22.2 Confidentiality | 44 |
| | 22.3 Data Security | 45 |
| | 22.4 Laboratory Record | 46 |
| References | | 48 |
| Annexure 1-7 | | 50-56 |
| Figure 1-2 | | 57-58 |

ABBREVIATIONS

| | |
|-------|--|
| AERB | Atomic Energy Regulatory Board |
| AMR | Analytical Measurement Range |
| APAC | Asia Pacific Accreditation Cooperation |
| BARC | Bhabha Atomic Research Centre |
| BSC | Biological Safety Cabinet |
| CHC | Community Health Centre |
| CHP | Chemical Hygiene Plan |
| CLSI | Clinical and Laboratory Standards Institute |
| CRR | Clinical Reportable Range |
| CV | Coefficient of Variation |
| EC | Ethics Committee |
| ELISA | Enzyme-Linked Immunosorbent Assay |
| EQA | External Quality Assessment |
| FRU | First Referral Unit |
| GCP | Good Clinical Practice |
| GMT | Good Microbiological Techniques |
| HEPA | High-Efficiency Particulate Air |
| HIS | Hospital Information System |
| HIV | Human Immunodeficiency Virus |
| IDSP | Integrated Disease Surveillance Program |
| IPD | Inpatient Department |
| IQ | Installation Qualification |
| IQC | Internal Quality Control |
| IRL | Intermediate level Reference Laboratory |
| ISO | International Organization for Standardization |
| LIS | Laboratory Information System |
| MRA | Mutual Recognition Agreement |

| | |
|-------|---|
| NABL | National Accreditation Board for Testing and Calibration Laboratories |
| NPL | National Physical Laboratory |
| NRL | National Reference Laboratory |
| OPD | Out Patients Department |
| OQ | Operational Qualification |
| PHC | Primary Health Centre |
| PPE | Personal Protective Equipment |
| PQ | Performance Qualification |
| QA | Quality Assurance |
| QC | Quality Control |
| QMS | Quality Management System |
| QS | Quality System |
| RNTCP | Revised National TB Control Program |
| RPR | Rapid Plasma Reagin |
| RTI | Reproductive Tract Infections |
| SDI | Standard Deviation Index |
| SDS | Safety Data Sheet |
| SI | International System of Units |
| SOP | Standard Operating Procedure |
| SRL | State Reference Laboratory |
| STDs | Sexually Transmitted Diseases |
| TDM | Therapeutic Drug Monitoring |
| UID | Unique Identification Number |

DEFINITIONS

Analytical sensitivity: The assay's ability to detect very low concentrations of a given substance in a biological specimen.

Analytical specificity: Refers to the ability of an assay to measure particular organism or substance, rather than others, in a sample.

Batch No.: Concentration, specificity, pH, Impurities, etc. of the various components varies in different batches thus information of batch no., date of manufacturing and date of expiry of reagent/kits should be clearly mentioned on the label.

Bias: Difference between the expectation of a test result or measurement result and a true value.

Biological reference Interval: Specified interval of the distribution of values taken from a biological reference population.

Calibration: The set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards.

Competence: Demonstrated ability to apply knowledge and skills.

Critical interval: Interval of examination results for an alert (critical) test that indicates an immediate risk to the patient of injury or death.

Examination: Set of operations having the object of determining the value or characteristics of a property.

External Quality Assessment/ Proficiency Testing (EQA/PT): Refers to a system in which the performance of a laboratory is assessed periodically and retrospectively by an independent external agency to indicate to the any shortcomings in the laboratory's performance through external Quality Assessment (EQA) program/ Proficiency Testing.

Internal Quality Control (IQC): Refers to the set of procedures undertaken by the laboratory personnel for the *continuous and immediate* monitoring of laboratory work in order to decide whether the results are reliable enough to be released.

Investigator: The individual responsible for the conduct of the clinical trial whose role is as defined by ICH GCP.

Laboratory Director: Person(s) with responsibility for, and authority over, a laboratory.

Measurement Error: To describe the difference between the Laboratory measurement and the true value of the measurand.

Measuring Range: Range of concentrations within which the assay is accurate and precise should be documented.

Outlier: The observation in a sample, so far separated in value from the remainder as to suggest that it may be from a different population, or the result of an error in measurement. (ISO 3534-1).

Post-examination processes/post analytical phase: Processes following the examination including review of results, retention and storage of clinical material, sample (and waste) disposal, and formatting, releasing, reporting and retention of examination results.

Precision: Closeness of agreement between independent test/measurement results obtained under stipulated conditions. For numerical expression of precision, the term “Imprecision” is used, which is the ‘dispersion of results of measurements obtained under specified conditions.’

Pre-examination processes/pre analytical phase: Processes that start, in chronological order, from the clinician’s request and include the examination request, preparation and identification of the patient, collection of the primary sample(s) and transportation to and within the laboratory, and end when the analytical examination begins.

Primary Samples Specimen: Discrete portion of a body fluid, breath, hair or tissue taken for examination, study or analysis of one or more quantities or properties assured to apply for the whole.

Quality Control (QC): Process of monitoring and evaluating the performance of work by measuring that performance against established standards.

Quality Assurance (QA): All planned or systematic actions necessary to provide adequate confidence that a service or product will satisfy given requirements for quality. QA is the comprehensive term that refers to all aspects of operation starting from preparation of the patient to sample collection, sample analysis, recording of the result and its dispatch.

Quality Management System: It includes all activities of the overall management function that determine quality policy objectives, implement them by means such as quality planning, quality control, quality assurance and quality improvement within the system.

Quality Manual: The Quality Manual is the overall guiding document that defines the quality system through policies established by the laboratory.

Raw Data: All original records and documentation, or verified copies of these, generated by observations and activities during the conduct of the work. They are necessary for the reconstruction and evaluation of the reported results. Also called “source data”.

Risk management: Risk management is an approach towards identifying and preventing the error from occurring, thereby avoiding harm to the person.

Safety Data Sheet (SDS): All Chemicals/Reagents are graded on a scale which poses a severe or potentially life-threatening hazard, thus MSDS of all chemicals should be available handy to all users.

Sample: One or more parts taken from a primary sample.

Shift: Shift in the mean occur when an **abrupt** change is followed by **six or more consecutive** QC results that fall on one side of the mean but typically within 95% range as if clustered around a new mean. On the sixth occasion this is called a shift.

Stability/Shelf Life: The shelf life and stability data of all reagents/ kits should be documented in agreement with the manufacturer’s specifications.

Sponsor: An individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of a clinical trial

Standard Operating Procedures (SOP): SOP contain step-by-step written instructions for each procedure performed in the laboratory. These instructions are

essential to ensure that all procedures are performed consistently by everyone in the laboratory.

Trends: Trends occur when values gradually, but continually, move in one direction over six or more analytical runs. Trends may display values across the mean, or they may occur only on one side of the mean. On the sixth occasion, this is determined to be a trend and results are rejected.

Trial protocol: The overall study protocol approved by the sponsor which describes the entire activities which make up the study.

Uncertainty of Measurement: Is the expression used to represent the unavoidable error. It is the foremost responsibility of the laboratory to evaluate the reliability and quantify the unavoidable laboratory error for every analyte.

Validation: It is the process of confirmation, through the provision of objective evidence, that the requirement for a specific intended use or application has been fulfilled

Verification: It refers to the laboratory's confirmation of the performance of equipment based on given specifications or requirements. Also, confirms that the instrument is working correctly for its intended purpose.

1.0 INTRODUCTION

All laboratories engaged in testing of biological samples need to establish confidence in the quality and reliability of the results of these tests. These expectations are fulfilled by following Good Laboratory Practices (GLP) which are a set of principles that define a quality system concerned with the organisational process and the conditions under which laboratory studies are planned, performed, monitored, recorded, archived and reported. It is intended to promote quality test data.

Similarly, for relying on conclusions drawn from the clinical data there is a need to follow Good Clinical Practices (GCP) which are standards for the design, conduct, performance, monitoring, auditing, recording, analysing, and reporting of clinical trials that provide assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected. Clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with GCP and the applicable regulatory requirement(s).

Implementation of GLP principles for the examination of clinical samples forms the basis of Good Clinical Laboratory Practices (GCLP). GCLP aims to ensure timely and accurate processing of biological samples enabling early and accurate diagnosis and patient safety leading to desired clinical outcomes. The Indian Council of Medical Research (ICMR) released the first GCLP guidelines in the year 2008 which have now been revised in view of recent advances.

Recently, considering the wide spectrum and potential for clinical research in our country, ICMR released the National Ethical Guidelines for Biomedical and Health Research involving Human participants in 2017¹. To ensure that all researchers follow these ethical principles, Ministry of Health and Family Welfare, Government of India had notified the New Drugs and Clinical Trials Rules-2019, that came into force from 19th March 2019². Under the Rules, Chapter IV entitled “Ethics Committee for biomedical and health research” states that Ethics Committees reviewing biomedical and health research should register with the authority designated by the

Central Government in the Ministry of Health and Family Welfare, Department of Health Research (DHR).

All Clinical research involving human participants should be conducted in accordance with the basic and general ethical principles. The researcher and the team are responsible for protecting the dignity, rights, safety and well-being of the participants enrolled in the study. They should have the appropriate qualifications and competence in research methodology and should be aware of and comply with the scientific, medical, ethical, legal and social requirements of the research proposal.

The proposed revised **guidelines for Good Clinical Laboratory Practices (GCLP), 2021** aim to establish minimum criteria which should be followed by clinical and research laboratories involved in examining human samples, in routine healthcare delivery and clinical research, respectively, in addition to internationally accepted guidelines. The intent of GCLP guidelines is that when laboratories adhere to this process, it ensures the quality and integrity of data, allows accurate reconstruction of experiments, monitors data quality and allows comparison of test results regardless of performance location. GCLP compliance empowers clinical laboratories and clinical researchers to provide data/reports that are reliable and reproducible.

In India, National Accreditation Board for Testing and Calibration Laboratories (NABL) has been providing accreditation services to medical laboratories based on International Standard (ISO 15189: 2012) which specifies requirements for competence and quality that are particular to medical laboratories³.

The laboratories should adhere to requisite regulatory, national and state regulations, as applicable.

2.0 SCOPE

All clinical laboratories wherein human samples are processed, may be tested under the following disciplines (but not limited to) for diagnosis, patient care, disease control and clinical research should follow Good Clinical Laboratory Practices:

- 2.1 Microbiology and Infectious disease Serology
- 2.2 Haematology and Blood Banking
- 2.3 Molecular Biology and Molecular Pathology
- 2.4 Clinical Pathology
- 2.5 Clinical Biochemistry-routine and special (TDM, Immunoassays)
- 2.6 Histopathology and Cytopathology
- 2.7 Genetics

3.0 LEVELS OF LABORATORIES

In India, the laboratory services are integrated with the 3-tier public health system at the primary, secondary and tertiary levels. Besides these, there are Reference Laboratories, Research Laboratories and Specific Disease Reference Laboratories to provide services for complex and special tests. Medical laboratories as per NABL are classified⁴ as below; irrespective of the place they are operating and are equally applicable to both public and private sector:

- a. Small sized: A laboratory receiving samples of up to 100 patients/participants per day
- b. Medium sized: A laboratory receiving samples of up to 101- 400 patients/participants per day
- c. Large sized: A laboratory receiving samples of more than 401-1000 patients/participants per day
- d. Very large sized: A laboratory receiving more than 1000 patients/participants per day
- e. Multiple location: A laboratory with more than one location in the same district with same legal identity

Levels of Public health care:

| | |
|------------------|--|
| Grass root level | Sub Centre |
| Primary level | Primary Health Centre (PHC) |
| Secondary level | Community Health Centres (CHC) / Sub-district Hospital (SDH) |
| Tertiary Level | District Hospital (DH)/ Medical College |

3.1 Primary Level

Primary Health Centres⁵ (PHC) are basic structural and functional unit of public health services acting as referral units for SCs and referring cases to CHCs.

3.2 Secondary level

The secondary level of health care essentially includes Community Health Centers⁶ (CHCs), constituting the First Referral Units (FRUs) and the Sub-district hospitals. The CHCs act to provide referral health care for cases from PHCs and for cases in need of specialist care approaching the centre directly. Sub-district (Sub-divisional) hospitals are below the district and above the block level (CHC) hospitals and act as First Referral Units for the Tehsil/Taluk/Block population in which they are geographically located.

3.3 Tertiary level

Laboratories are equipped with advanced diagnostic and investigation facilities to provide tertiary level health care⁷. These hospitals receive referrals from the primary as well as the secondary levels.

Table-1

| Levels of laboratories | Primary | Secondary | Tertiary |
|------------------------------------|---|--|--|
| Capacity and Infrastructure | <ul style="list-style-type: none"> • Appropriate staff strength | <ul style="list-style-type: none"> • Appropriate staff strength • Designated area for clinical laboratory including sample collection and storage. | <ul style="list-style-type: none"> • Appropriate staff strength • Easy access to IPD and OPD • Adequate space- Layout should ensure logical flow of specimens from receipt to disposal • Separate and demarcated areas for sample collection, sample processing, hematology, biochemistry, clinical pathology and reporting. |
| Clinical Lab. Services | <ul style="list-style-type: none"> • Essential Laboratory services in PHC⁸: ICMR-NEDL, 2019 | <ul style="list-style-type: none"> • Essential Laboratory services in CHC and sub-district level hospital⁸: ICMR-NEDL, 2019 | <ul style="list-style-type: none"> • Essential Laboratory services in District hospital⁸: ICMR-NEDL, 2019 • Facility of emergency laboratory services |

| Levels of laboratories | Primary | Secondary | Tertiary |
|--------------------------|--|--|--|
| Quality Assurance | <ul style="list-style-type: none"> Regular internal quality control (IQC) with possible inter-laboratory comparison | <ul style="list-style-type: none"> Monitoring of laboratory at this level includes both IQC and EQA | <ul style="list-style-type: none"> Standard operating procedures (SOP) should be well documented and implemented Appropriate training of personnel on SOPs and guidelines External validation of lab reports on regular basis |

All Levels of laboratories should follow biomedical and waste management guidelines that are intended to help safe disposal of contaminated waste and safety of health workers and the community.

3.4 Reference Laboratories, Research Laboratories and Specific Disease Reference Laboratories

The Reference Laboratories, Research Laboratories and Specific Disease Reference Laboratories serve a disease condition of national importance. Medical colleges, research institutions can be designated by appropriate authority for ensuring high standards of quality in one or more particular disease condition. The National and State/Intermediate level Reference Laboratory (NRL/SRL or IRL) provides scientific and technical assistance, offers counseling and expert advice on topics linked to surveillance, standardization of diagnostic techniques and control of the disease for which the Reference Laboratory is responsible. They may also provide scientific and technical training for personnel and coordinate scientific and technical studies in collaboration with other laboratories or organizations.

3.5 Collection Centres: In addition to the above-mentioned levels of laboratories, there are separate collection facilities which do not carry out diagnostic services but only collect samples/specimen⁴.

4.0 INFRASTRUCTURE

4.1 Infrastructure of the laboratory varies with the requirements of the clinical research/services provided by the laboratory, but the basic requirements should meet the regulatory and international standards. Infrastructure of a laboratory directly impacts the quality of research data, efficiency and safety of laboratory workers. The management of the laboratory is responsible for providing adequate resource to staff, to ensure efficient working of a laboratory.

Good laboratory design should consider the following (in concordance with local regulatory authority)-

- 4.1.1 Signage-signage within or outside the facility should be made available containing the following information – Name, registration number, services offered, working hours, contact number, fees for different tests & services.
- 4.1.2 Essential Health and Safety regulations- use safety signage, as applicable.
- 4.1.3 Emergency (fire, chemical spillage, lab accidents etc) and Disaster management plan.
- 4.1.4 Uninterrupted power supply.
- 4.1.5 Laboratory grade water for examination purpose
- 4.1.6 Ventilation, environment control (temperature, humidity, magnetic field, vibration, etc.) and lighting arrangements
- 4.1.7 Communication facility with referral centres
- 4.1.8 Transport of specimen/samples to referral centres
- 4.1.9 Lab areas containing carcinogens, radioisotopes, biohazards, and lasers should be properly marked with the appropriate warning signs.

4.2 To avoid cross contamination the basic infrastructure facilities should have separate designated areas for (as applicable)-

- 4.2.1 Reception area or waiting area where requisition forms are received and reports disbursed
- 4.2.2 Specimen (Primary sample) collection room/area, toilet, privacy for special purposes e.g. semen collection, facilities for disabled persons

- 4.2.3 Examination work area (segregation wherever applicable)
- 4.2.4 Space for handling radio-active materials (as per BARC requirements)
- 4.2.5 Waste disposal facility including biomedical waste
- 4.2.6 Facility for cleaning of glassware, sterilization /disinfection
- 4.2.7 Area for meetings/trainings/administrative work
- 4.2.8 Separate area for eating and storing food, drinks etc.
- 4.2.9 Toilet for staff with appropriate eye wash and body wash facility

4.3 Storage

- 4.3.1 Specimen/Sample/slide storage facility including cold storage wherever applicable
- 4.3.2 Reagents and consumables storage facility
- 4.3.3 Record/archive room/area

4.4 Restricted Access -Only authorized personnel should have access to examination area and record keeping area or information systems.

4.5 Additional infrastructure facilities may be added for special tasks as and when needed.

5.0 PERSONNEL, TRAINING AND DEVELOPMENT

5.1 General- Personnel are the most important laboratory resource. Each laboratory should designate a head of the laboratory (Laboratory Director) who is responsible for the overall operation and administration of the laboratory, including the employment of competent personnel, equipment, safety, laboratory policies, quality processes, all testing (including proficiency testing) and test reports. A Quality Manager should be designated to independently monitor and maintain quality management system in a regular manner. He/She should report to the management of the laboratory for the functions related to quality management system.

The strength of staff employed should be appropriate to the level of facility and the workload. The organizational structure of the laboratory must support an optimal *Path of Workflow*⁹ from collection to reporting of result, by allowing processes that yield efficient sample handling while minimizing error.

5.2 PERSONNEL

5.2.1 Laboratory Director has the principal responsibility for setting up an organization that can support the quality system model. The Director should ensure that delegated duties are properly performed and must be accessible to provide onsite, telephone, or electronic consultation. The Laboratory Director is responsible for developing policies, assigning authority and responsibility to the appropriate persons, optimizing resources, reviewing the organizational aspects of the system for optimal functioning of quality processes and also ensuring that personnel follow the quality policies established by the laboratory.

5.2.2 Quality Manager assists in developing policies, quality system procedures and facilitating and implementing the quality management system (QMS) in an independent manner. The Quality Manager shall communicate all aspects of the quality management system processes directly to the laboratory director or head of the laboratory. It is strongly advised that quality manager undergoes training on current standard³. He/She may be one of the technical personnel with additional responsibility as Quality Manager, in the case of smaller laboratories.

5.2.3 Document Control

All original documents (master copy) should be retained in a secure area and only controlled copies are distributed to users such as laboratory director, quality manager and other relevant personnel. Obsolete documents should be archived as per the retention policy guidelines. The previous original copies must be obsolete and retained for reference. It is preferable to distribute documents in electronic form in read only format.

5.2.4 Review of documents in QMS

All documents must be reviewed periodically/at least annually for improvements. Laboratory personnel must be trained on the revised procedures before effective date.

5.2.5 Laboratory/Technical personnel are responsible for understanding the organizational structure of the laboratory. The laboratory personnel shall follow

the quality policies and procedures in their daily work routine as described in the laboratory developed quality manual. It is advised that personnel are thoroughly oriented towards this current GCLP document as well as applicable requirements of the current ISO 15189 Standard³.

5.3 TRAINING

Training is a process to provide knowledge and develop skills in order to meet requirements. Personnel should be appropriately trained to achieve quality outcomes in the laboratory and produce accurate, reliable, and timely test results.

5.3.1 Various types of training:

Broadly these trainings may be divided into induction training and on-the-job training or a combination of these types. Training may be internal or external; trainers may be internal or external.

The goal of the laboratory's training program for technical personnel is to ensure that the employees-

- a) Possess the necessary knowledge, skills and abilities to perform assigned work
- b) Follow laboratory policies, procedures, and guidelines
- c) Are able to perform accurate examinations
- d) Acquire a working environment which is stress free and conducive for work

Induction Training: This training orients a newly joined person to the organization, laboratory's facility, culture, and values. Training is given at the time of joining. It provides the newly joined person with better understanding of the role he or she is going to play in helping the organization and laboratory achieve its goals. It should cover applicable policies, processes and procedures and requirements. Job introduction topics may include personnel introduction, laboratory terminology, attendance, dress requirements, ergonomics, facility communications, computer systems, security and privacy, and the quality management system.

On the Job Training: All laboratory personnel involved in specimen collection, processing, examination and reporting should take GCLP training. The frequency of this training must be sufficient to ensure that employees remain familiar with the GCLP requirements applicable to them. The laboratory must employ an adequate number of qualified personnel to perform all functions associated with the volume and complexity of tasks and testing performed.

Managerial and technical personnel engaged in the conduct of laboratory testing related to clinical research must have the education, training, and experience commensurate with their assigned functions.

5.3.3 Evaluation of training:

- The laboratory should have a policy that refers to the program and processes used for assessing effectiveness of trainings. Evaluation can be done post training, after some duration to see effective implementation and understanding.
- Evaluation must be conducted and recorded for all tasks upon completion of an employee's initial training, for new methods or instruments prior to starting patient testing and prior to reporting patient results, for new and changed processes and procedures and when personnel responsibilities change.

5.3.4 Competence assessment:

- Laboratory should conduct periodic competence assessment of all personnel, preferably once a year. Competency assessments should be done to ensure that the personnel maintain their competency to perform assigned jobs promptly, accurately and without errors.
- Competency assessments must compare employee performance against a documented standard and clearly verify competency or lack of competency for each evaluated task. Competency records need to identify what was reviewed or observed, when it was reviewed or observed, who did the review or observation, and what was the outcome.

- Individuals responsible for competency assessments should have the education and experience to evaluate the complexity of the testing being assessed.
- All records created for retraining and reassessments need to include the outcome, be signed by the individual and management, and retained in the individual's personnel file.
- Competency assessment must include, but are not limited to:
 - Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing, and testing.
 - Monitoring the recording and reporting of test results.
 - Direct observation of performance of instrument maintenance and function checks.
 - Assessment of test performance through testing previously analyzed samples, internal blind testing samples or external proficiency testing samples.
 - Review of worksheets, quality control records and preventive maintenance records.
 - Assessment of problem-solving skills.
- Personnel should be tested for visual colour discrimination. Personnel performing testing or other tasks that require colour discrimination should be evaluated for difficulty with visual colour discrimination. Evaluation limited to discrimination of those coloured items pertinent to the job is sufficient.
- The laboratory management should be committed for providing continuing professional education program and training opportunities to laboratory personnel. Such a program, adequate to meet the needs of all personnel, must be documented and evidence of ongoing adherence by all laboratory personnel must be readily available. Action plan for improvement in the training programs should be determined and revised according to the feedback received from previous evaluations, past

performance, user feedback, complaints, audit findings and management inputs.

- The laboratory should maintain a personal file of all personnel employed in the laboratory.

List of information and documents for personal file

- Personal details
- Educational qualification with copy of degree/diploma, training certificates, and awards/recognition received, experience etc.
- Registration with state authority (if applicable)
- Copy of appointment letter.
- Medical fitness certificate from registered medical practitioner in format and information (especially ECG, chest X-ray, color blindness, immunizations received etc.) and its regular updates.
- Performance appraisal records of periodic evaluation, if any
- Vaccination records
- Accidents/Incidents records

Training records should include the following information:

- Title of the training event
 - Identity of the trainer(s)
 - Items covered during the training
 - Training dates
 - Names of the person being trained
 - An attestation including the trainee's signature should be recorded indicating commitment to comply with procedures as trained
- Although there are no specific retraining requirements for personnel returning after an extended absence, the laboratory should determine training or retraining needs individually.

6.0 EQUIPMENT

Each laboratory should prepare a list of equipment required for functioning of the laboratory depending on the type of tests performed. Equipment includes hardware and software of instruments, measuring systems, and laboratory information systems. Laboratory equipment should be of adequate capacity to meet work load requirement.

Equipment should be suitably located in the laboratory so as to allow accessibility and sequential utilization thus minimizing the need for frequent movement of manpower, specimens or reagents. The following should be ensured:

- Equipment should be selected to meet the requirements of the laboratory in terms of design and capacity.
- All equipment should be qualified before it is put to clinical use {Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ)}. Few small equipment are exceptions like vortex mixture and Point-of-care testing (POCT) devices.
- All equipment should be in good working condition at all times. Periodic inspection, cleaning and maintenance of equipment should be done. Maintenance should be done as recommended by manufacturer or more- as required e.g. with overuse or aging of equipment.
- An equipment log book (Annexure-1 and 2) should be maintained for all equipment. Laboratories should maintain necessary instructions for operation and maintenance of equipment in the form of SOP, a copy of the same should be readily available near the equipment.
- All equipment should undergo calibration and verification. Conducting or performing the calibration process involves applying a standard value to the laboratory instrument and observing how it behaves. Calibration frequency should be as defined by the manufacturer or as per norm³. In case of examination systems such as automated analyzers the calibration should be done by the manufacturer/company engineer. All automated examination systems such as cell counters, clinical biochemistry auto-analyzers, automated coagulometers and ELISA readers etc., shall be calibrated at a regular interval as per SOPs. Raw data generated during calibration should be maintained as a record.
- The equipment should be calibrated in a manner that metrological traceability shall be to SI Units through a reference material or reference procedure of the higher metrological order available. It can generally be obtained through calibration from National Measurement Institutes i.e.

National Physical Laboratory (NPL-India) for legal metrology and Bhabha Atomic Research Centre (BARC), Mumbai for radiological measurement or a calibration laboratory accredited by any of the MRA partners of Asia Pacific Accreditation Cooperation (APAC) having accreditation for the specific scope.

- Various types of equipment may be calibrated in-house by using reference materials or comparative techniques. In such cases, reference materials should demonstrate traceability to SI units or the appropriate measurement standards. Such an activity should be done only if the laboratory has the competence and meets the applicable requirements.
- Equipment performance should be verified by running IQC material having matrix similar to sample to be examined, as far as feasible. Outlier parameter, root cause analysis and corrective actions record should be maintained.
- A preventive maintenance program for all equipment should be created and implemented. This can be done by preparing a checklist/format/calendar for equipment maintenance, as applicable. The maintenance program to be developed in the laboratory should include the following components:
 - i. A preventive maintenance program for all equipment should be in place. This involves periodic performance checks as recommended by the manufacturer.
 - ii. Maintenance of a register of all equipment indicating serial numbers, unique identification numbers and specific locations in the laboratory.
 - iii. There shall be provision for harmonization of instrument e.g. if 2/3 analysers are available for a test then, both should be harmonized. At the minimum a six monthly comparison should be done if they are used as back-up or simultaneously.
 - iv. All equipment to be properly checked by the qualified and trained person to ensure safety of the users e.g. earthing check six monthly
 - v. Records of all break downs to be maintained.
- Maintenance contracts including warranty cards, telephone numbers of personnel to be contacted in case of equipment malfunction should be kept

safely but within reach of the user. User manual should be readily available for reference. The laboratory personnel should be aware of trouble shooting/corrective measures.

6.1 Disposal of equipment

Laboratories should ensure that there are proper procedures in place for condemnation and disposal of equipment that is unserviceable or that is no longer required. This will take old and potentially unsafe equipment out of service, making sure hazardous materials are properly handled and allowing availability of proper storage space as applicable.

6.2 The Condemnation

The procedures for condemnation and disposal of obsolete equipment should be laid down by the laboratory in the form of SOP. Criteria for condemnation and disposal of equipment that are obsolete, unserviceable, unfit and hazardous equipment disposal should be as per the SOP and/or the relevant existing policies or local national guidelines for disposal as applicable.

7.0 REAGENTS, KITS AND MATERIALS

7.1 Use, maintenance and storage of reagents, kits and materials form major part of basic infrastructure for smooth functioning of diagnostic and clinical research laboratories.

7.1.1 All reagents, kits and materials of standard quality supplied from a reputed supplier must be fit for the purpose of analysis viz. analytical grade, HPLC grade, etc.

7.1.2 Quality of newly purchased reagents should be verified against suitable control/reference material/retained sample prior to use. In-house prepared reagents should also be checked periodically for stability and a record of the same should be maintained and defined in SOP.

7.1.3 Reagents- Description of reagents, kits and materials in terms of name, batch/Lot/Cat. no., date of manufacture, etc. should be available in inventory log/register. Details relevant to usage like sensitivity, specificity, measuring

range, shelf life, label, SDS, storage and disposal should be mentioned in the SOP.

7.1.4 Label: Labeling of reagents/bottles/containers, kits, chemicals etc. plays an indispensable role in the safe and accurate testing. Following information should be clearly mentioned in the label of all reagents-

- Name of the reagent
- Date of receiving/opening
- Strength or concentration
- Storage conditions
- Date of expiry
- Opened by-initial/sign

7.1.5 Storage: All reagents, consumables, stains, media, kits, and antimicrobials should be stored as recommended by the manufacturer.

7.1.6 Preparation of working solutions: Working solutions should be prepared within the laboratory as per SOP and following information should be mentioned on the label-

- Name of the solution
- Date of preparation
- Content of the solution
- Strength or concentration
- Storage conditions
- Expiration date
- Prepared by (name)

7.1.7 Disposal of Unusable/Expired Reagent: All unused reagents, kits and materials etc. are to be disposed as per the national and international guidelines.

7.1.8 Medical Disposables- All Medical disposables and consumables should be used as per the specifications of manufacturer, especially products meant for single use should not be re-used.

7.1.9 Water Quality- should be checked for its grade and presence of interference elements. Distilled deionised water¹⁰ should be used for testing.

7.1.10 All radio-active material should be used, stored and disposed as per the Atomic Energy Regulatory Board (AERB) guidelines.

8.0 PRE EXAMINATION PROCESS

Pre-examination is the biggest contributor to laboratory errors, hence this phase should get adequate focus and monitoring to ensure accurate result generation by laboratory.

8.1 Patient preparation: Patient preparation as per the prescription or requirement is the first important step in sample collection. If ignored, it could be a source of variation. Some tests require that the patient be on fasting. There may also be special timing for sample collection e.g.- blood sugar, hormone, etc.

8.2 Primary sample collection: SOP for Primary sample should be available to all personnel at collection site and they should be well trained to follow all the steps. Specimen collection can be done at the patient's bedside, in the laboratory or in the field.

8.3 Primary sample collection device: Standard precautions should be followed during specimen collection. Specimen collection devices used should be of standard make, if not should be verified before use. Closed system (evacuated collection devices) of specimen collection has many advantages and is generally preferred over syringe and needle. Specimens must be collected, labelled, handled and transported in a manner as recommended by manufacturer of the device or the kit/test method.

Appropriate tube/container in terms of volume, with or without anticoagulant, etc. should be used. Specimen should be secured so that there is no leakage, spillage or contamination.

8.4 Samples of clinical Research/Trial: In addition to the above mentioned general requirements related to the specimen collection the following should be adhered to-

- Appropriate counselling should be done before specimen collection and written consent has to be taken. Attention should be paid to patient's sensibilities during the entire process.

All clinical samples whether is for diagnostic or clinical research should be considered "INFECTIOUS" and handled accordingly.

8.5 Sample Labeling and Documentation: Specimen should be labelled with at least two unique identifiers e.g.- Name, age etc. Specimen labeling using bar-codes is an option that may reduce errors. Label may include (but not limited to) following details-

- Patient's name, age, gender
- Patient ID
- Tests requested
- Time and date of specimen collection

8.6 Requisition Form/Test Request Form:

- The requisition form should be completed by the doctor/health worker requesting the tests and sent along with the specimen/patient to the laboratory.
- It should contain the patient's identity, age, location, date and time of specimen collection, investigations requested and source of sample (e.g. for culture and histopathology).
- The TRF should be signed by the phlebotomist and the patient/doctor to indicate consent for specimen collection.
- The referring doctor should be encouraged to mention the provisional or working diagnosis and relevant clinical and treatment history in the space provided (Annexure-3).

8.7 Transportation of samples- When samples are collected in field or outside the laboratory (e.g. in collection facilities), these need to be transported for analysis to a laboratory. In all cases, transportation of samples should ensure sample integrity and stability for obtaining right results. Transport of the samples⁴ should be managed as per the SOP. Personnel handling the samples should be trained for all transport procedures. During transport of sample following points should be taken care of-

- Analyte stability
- Temperature requirement
- Preservation (if any)
- Photosensitivity (if any)
- Integrity and stability of samples
- Special Packaging requirements (in case of shipment)
- Timeliness
- Safety of the personnel handling the sample
- Tracking System for samples (as far as possible)

9.0 SAMPLE ACCEPTANCE/REJECTION

9.1 All specimens should be checked when received in the laboratory for fitness for testing. These checks should include appropriate container, quantity/volume (in case of blood/urine sample), temperature on receipt, quality of sample (in case of tissue samples), any leakage, etc. (Refer Section 11.0).

- Record should be maintained for acceptance/ rejection (with reasons and actions specified) of all the samples received in the laboratory, as per the predefined criteria.
- If laboratory rejects any sample, a communication should be made to the patient/doctor and need for recollection.
- Laboratory should exercise utmost care in the collection of precious specimen like histopathology, CSF, etc., whose recollection is either not possible or is difficult.
- Laboratories should maintain a record of specimens which were rejected prior to analysis. Rejection details along with reason for rejection should be maintained (Annexure 4).

9.2 Specimen rejection details can be used by laboratories to identify the need and areas for personnel training. For example, if specimen contamination is detected, the containers should be checked for sterility prior to collection or for the lot/batch. This information should be shared with the medical, nursing and other personnel engaged in specimen collection and transportation.

9.3 Criteria for sample rejection: Specimen rejection criteria should always be upfront mentioned in SOP's of respective tests. Terms for rejection of samples may include but not limited to the following-

- Unlabeled sample
- Broken or leaking tube/container
- Insufficient patient information
- Specimen label and patient name/UID on the test request form do not match
- Haemolyzed sample (depending on the test)
- Non fasting sample (if fasting is required)
- Specimen collected in a wrong tube, wrong preservative, non-sterile container
- Insufficient specimen volume for the test requested
- Prolonged transport time

9.4 Actions required for rejected samples:

- Inform authorized person
- Request another specimen
- Record rejected specimen
- Retain rejected specimen based on preset criteria

10.0 EXAMINATION PROCESSES

10.1 General

- The laboratory should select examination procedures which have been verified or validated for their intended use.
- The identity of persons performing activities in examination processes shall be recorded.
- Examination procedures (SOP) should be documented. These should be written in a language commonly understood by the staff in the laboratory and be available in appropriate locations.
- SOPs help to ensure uniformity, consistency, compliance with regulations, efficiency, quality output and control over the process. The laboratory personnel must be well trained on the SOPs.

10.2 Examination Procedures

Quality Planning (QP) is concerned with establishing and validating processes that meet customer needs. Applies to selection and evaluation of new methods and instruments, as well as selection and design of QC procedures.

The test procedure should include the following but not limited to-

- Name of test
- Scope of test
- Purpose of examination
- Principle and method of procedure
 - Limit of detection (Examination sensitivity)
 - Analytical Measurement Range (AMR)
 - Specimen type, sample collection, processing and storage
- Reagents, equipment, glassware and other accessories
- Procedural steps
 - Calculations
 - QC procedures
 - Interferences
 - Biological Reference range
 - Clinical significance, Inference and limitation of the test
 - Critical alert values
 - Hazardous materials, Precautions & Safety
 - Limitations and potential sources of variation
 - References

10.3 Performance characteristics of a method include the following-

- Precision
- Accuracy
- Range / Analytical Measurement Range (AMR)
- Clinical Reportable Range (CRR) – when sample is diluted to report higher values not covered by AMR

- Biological Reference Interval (BRI)
- Analytical Sensitivity
- Analytical Specificity

11.0 RELEASE OF TEST RESULTS

Test report (Annexure-5) should include but not limited to the following:

- 11.1 Name and Unique Patient Identification Number
- 11.2 Date and Time of Specimen Collection
- 11.3 Date and Time of Test done and result reported
- 11.4 Name and address of the Laboratory
- 11.5 Name/Source of sample (e.g. – whole blood, urine etc.)
- 11.6 Test results, method, measurement units and biological reference interval or clinical decision limit or cut-off values (as applicable)
- 11.7 Duly signed by authorised signatory
- 11.8 Authorization for amendment procedure should be specified in the SOP. All amended reports should be released with an appropriate comment. The laboratory should also record reason for editing data.
- 11.9 Laboratories should maintain a list of tests with critical values. They should provide critical (alert) values to clinicians on telephone, e.g., – (a) Glucose value of 45 mg/dl., b) frozen section biopsy report is required while operating a patient with suspicion of cancer, c) Growth of a particular organism in culture for early diagnosis and treatment.
- 11.10 Automatic release of reports can be applied if the laboratory has the necessary LIS/middleware capability and have competency to implement it.

12.0 SAMPLE STORAGE/DISPOSAL

12.1 Sample storage: Storage of samples e.g. – conditions, methods of storage, stability of analyte, retention time, etc. should be followed as per the requirement of the users and applicable national regulatory guidelines⁴. Every effort should be made

to retain blocks and slides in histopathology and cytopathology. If, however, they are returned to the patient, this must be documented and records maintained.

12.2 Sample/Chemical/e-waste disposal: Samples after retention period, if any, should be segregated in colour coded bags at source or in sharps container, as applicable. These should be handed over to approved local biomedical waste disposal agency¹¹.

- Care should be taken in disposal of hazardous chemicals, if any used by the laboratory.
- Care should be taken in disposal of computer hardware and other items. Refer to e-waste disposal guidelines.

13.0 SAFETY IN LABORATORIES

Personnel working in laboratories may be exposed to risks from various chemicals, infectious materials, fire hazard, electrical shock, gas leak etc. The environment is also at risk of being contaminated by hazardous materials used and wastes generated in the laboratory.

The laboratories should prepare their own safety manual covering the hazard and their mitigation plan and train staff on them. Policies should outline the use of sharps, disposal of bio-waste, reagents, sharps and other wastes generated in the laboratory in accordance with the local and national regulations.

It is essential to train all personnel in standard precautions. A code of practice is a listing of the most essential laboratory practices and procedures that are basic to good microbiological technique. Safety in laboratories therefore includes **protection of both the personnel and the environment** from hazardous materials.

13.1 General Safety Measures

- All laboratory personnel should be aware of the laboratory safety policies and procedures and follow these at all times.
- List of hazardous materials used in the laboratory should be prepared. All hazardous materials should be accounted for on a periodic basis.
- Eye wash facility should be available as “stand-alone” facility or attached to sink.

- Biohazard symbol (Figure-1) should be used on all container/equipment containing biohazardous material.
- Laboratory personnel should be thoroughly trained in managing fire, and non-fire emergencies such as large spillage, gas leakage etc.
- Adequate fire extinguishers should be readily available in the laboratory.
- Accident/incident/injuries record of laboratory personnel should be maintained and reported to the designated authority. The report should include description of the event, factors contributing to the event and information on first aid or other health care provided. This information can be analysed periodically towards effectively controlling and preventing future events. The records should be checked periodically even in the absence of fresh entries.
- Do not chew gum, drink, smoke or eat while working in the lab.
- Laboratory glassware should never be utilized as food or beverage containers.
- Always wear appropriate clothing: chemically resistant lab coats or aprons are recommended.
- Handle needles, syringes and other sharps carefully. Use self-sheathing needles whenever possible. Dispose all sharps in an appropriate sharps container.
- Do not dispose chemicals down the drain. Most chemicals must be disposed as hazardous waste. This practice should be implemented strictly.
- Compressed gas cylinders should be secured to prevent them from being knocked over. Cylinders should be capped when the regulator is removed or not in use.
- In the event of a chemical splashing into your eye(s) or on your skin, immediately flush the affected area(s) with running water for at least 20 minutes/ eye wash facility.

13.2 Laboratory Safety Chemical Hygiene Plan (CHP): CHP is created to protect laboratory workers from harm due to hazardous chemicals. The CHP is a written document stating the policies, procedures and responsibilities that protect workers from the health hazards associated with the hazardous chemicals used in that particular workplace.

The content of the CHP was established directly from the requirements of the laboratory standard and includes the following information:

- SOPs relevant to the safety and health considerations related to the use of hazardous chemicals in the laboratory.
- Identification of hazards and their mitigating strategies.
- Control measures to reduce individual exposure to chemicals.
- Provisions for medical consultations and examinations.
- Laboratory procedures to be followed in case of any accident/emergency shall require prior approval before implementation.
- Provisions for additional personnel protection for work with carcinogens, reproductive toxins, and chemicals with high acute toxicity known as “particularly hazardous substances.”
- Measures to fulfil the requirement that fume hoods and other protective equipment function properly.

13.3 Laboratory Hygiene and Sanitation

Laboratory hygiene and sanitation deal with the basic upkeep, tidiness, and maintenance of a safe laboratory.

- Laboratory area should have restricted access. Visitors and children should not be allowed to enter the testing area.
- Laboratory personnel should follow safe hygienic practices which include hand washing, wearing protective clothing, gloves, eye protection etc.
- Workbench cleaning should be done before starting and after finishing work daily with sodium hypochlorite or equivalent material.
- Equipment should be cleaned every time before starting and after finishing work
- Basic biomedical safety training should be given to housekeeping so that he/she must be aware of lab waste and working materials. They should be protected against Tetanus.

- Effective Pest control should be exercised.
- All lab staff handling samples should be vaccinated against Hepatitis B and titres measured to ensure effective protection.

13.4 Personal Hygiene

- Never smell, inhale or taste laboratory chemicals.
- Always wash hands with soap and water after removing gloves and before leaving the work area.
- Never eat, drink, chew gum or tobacco, smoke or apply cosmetics in the laboratory.
- Remove Personal Protective Equipment (PPE) such as gloves and lab coats before leaving the lab.
- Remove gloves before handling common items like phones, instruments, door knobs, etc.
- Do not block emergency showers, eye washes, exits or hallways.

13.5 Electrical safety

Electrical safety help prevent the misuse of electronic instruments, electric shocks and other injuries, and ensure that any damaged equipment, cords, or plugs are reported to the appropriate authorities so that they can be repaired or replaced.

- Earthing check to be done annually
- Make sure all electrical panels are unobstructed and easily accessible.
- Wherever possible, avoid using extension cords.

13.6 Biosafety Precautions

Laboratory facilities are designated as Basic – Biosafety Level 1 and – Biosafety Level 2, Containment – Biosafety Level 3, and maximum containment – Biosafety Level 4. Biosafety level designations are based on a composite of the design features, construction, containment facilities, equipment, practices and operational procedures required for working with agents from the various risk groups.

Table 2. Classification of infective microorganisms by risk group

| |
|--|
| <p>Risk Group 1 (no or low individual and community risk) A microorganism that is unlikely to cause human or animal disease.</p> |
| <p>Risk Group 2 (moderate individual risk, low community risk) A pathogen that can cause human or animal disease but is unlikely to be a serious hazard to laboratory workers, the community, livestock or the environment. Laboratory exposures may cause serious infection, but effective treatment and preventive measures are available and the risk of spread of infection is limited.</p> |
| <p>Risk Group 3 (high individual risk, low community risk) A pathogen that usually causes serious human or animal disease but does not ordinarily spread from one infected individual to another. Effective treatment and preventive measures are available.</p> |
| <p>Risk Group 4 (high individual and community risk) A pathogen that usually causes serious human or animal disease and that can be readily transmitted from one individual to another, directly or indirectly. Effective treatment and preventive measures are not usually available.</p> |

*Source: *Laboratory Biosafety Manual, WHO, 3rd Edition, 2004*¹²

- The backbone of the practice of biosafety is risk assessment. The laboratory director or principal investigator is responsible for ensuring that adequate and timely risk assessments are performed, and for working closely with the institution's safety committee and biosafety personnel to ensure that appropriate equipment and facilities are available to support the work being considered. Once performed, risk assessments should be reviewed routinely and revised when necessary, taking into consideration the acquisition of new data having a bearing on the degree of risk and other relevant new information from the scientific literature.
- Diagnostic and health-care laboratories (public health, clinical or hospital-based), all should be designed for Biosafety level 2 or above. As no laboratory has complete control
- Over the specimens it receives, laboratory workers may be exposed to organisms in higher risk groups than anticipated.

Table 3. Summary of biosafety level requirements (Bio-safety level)

| | 1 | 2 | 3 | 4 |
|---|----|-----------|---------------------|-----|
| Isolation of laboratory ^a | No | No | Yes | Yes |
| Room sealable for decontamination | No | No | Yes | Yes |
| Ventilation: | | | | |
| — inward airflow | No | Desirable | Yes | Yes |
| — controlled ventilating system | No | Desirable | Yes | Yes |
| — HEPA-filtered airexhaust | No | No | Yes/No ^b | Yes |
| Double-door entry | No | No | Yes | Yes |
| Airlock | No | No | No | Yes |
| Airlock with shower | No | No | No | Yes |
| Anteroom | No | No | Yes | — |
| Anteroom with shower | No | No | Yes/No ^c | No |
| Effluent treatment | No | No | Yes/No ^c | Yes |
| Autoclave: | | | | |
| — on site | No | Desirable | Yes | Yes |
| — in laboratory room | No | No | Desirable | Yes |
| — double-ended | No | No | Desirable | Yes |
| Biological safety cabinets | No | Desirable | Yes | Yes |
| Personnel safety monitoring capability ^d | No | No | Desirable | Yes |

^a Environmental and functional isolation from general traffic.

^b Dependent on location of exhaust (Air must be discharged in such a way as to avoid interference with the air balance of the cabinet or the building exhaust system)

^c Dependent on agent(s) used in the laboratory.

^d For example, window, closed-circuit television, two-way communication.

Source: *Laboratory Biosafety Manual*¹²

13.6.1 Basic laboratories – Biosafety Levels 1 and 2

13.6.1.1 Code of practice: This code is a listing of the most essential laboratory practices and procedures that are basic to GMT. In many laboratories and national laboratory program, this code may be used to develop written practices and procedures for safe laboratory operations.

13.6.1.2 Access: The international biohazard warning symbol and sign (Figure 1) must be displayed on the doors of the rooms where microorganisms of risk group 2 or higher risk groups are handled. Only authorized persons should be allowed to enter the laboratory working areas.

13.6.1.3 Personal protection: Laboratory coveralls, gowns or uniforms must be worn at all times for work in the laboratory. Appropriate gloves must be worn for all procedures that may involve direct or accidental contact with blood, body fluids and other potentially infectious materials or infected animals. After use, gloves should be removed aseptically and hands must then be washed. Personnel must wash their hands after handling infectious materials and animals and before they leave the laboratory working areas. Safety glasses, face shields (visors) or other protective devices must be worn when it is necessary. Eating, drinking, smoking, applying cosmetics and handling contact lenses is prohibited in the laboratory working areas. Storing human foods or drinks anywhere in the laboratory working areas is prohibited.

13.6.1.4 Laboratory working areas: The laboratory should be kept neat, clean and free of materials that are not pertinent to the work. Work surfaces must be decontaminated after any spill of potentially dangerous material and at the end of the day's work. All contaminated materials, specimens and cultures must be decontaminated before disposal or cleaning for reuse.

13.6.1.5 Design features: The laboratories should have the following design features:

- Ample space must be provided for the safe conduct of laboratory work and for cleaning and maintenance.
- Walls, ceilings and floors should be smooth, easy to clean, impermeable to liquids and resistant to the chemicals and disinfectants normally used in the laboratory. Floors should be slip-resistant.
- Bench tops should be impervious to water and resistant to disinfectants, acids, alkalis, organic solvents and moderate heat.
- Illumination should be adequate for all activities. Undesirable reflections and glare should be avoided.
- Hand-washing basins, with running water if possible, should be provided in each laboratory room, preferably near the exit door. Doors should have vision panels, appropriate fire ratings, and preferably be self-closing.
- At biosafety level 2, an autoclave or other means of decontamination should be available in appropriate proximity to the laboratory.

- Safety systems should cover fire, electrical emergencies, and emergency shower facilities.
- In the planning of new facilities, consideration should be given to the provision of mechanical ventilation systems that provide an inward flow of air without recirculation. If there is no mechanical ventilation, windows should be able to be opened.
- A dependable supply of good quality water is essential. There should be no cross connections between sources of laboratory and drinking-water supplies.
- There should be a reliable and adequate electricity supply and emergency lighting to permit safe exit.
- Good maintenance of the installation is mandatory. Physical and fire security must be considered. Other measures should be considered and applied, as appropriate.

13.6.1.6 Equipment should be selected considering the following:

- Designed to prevent or limit contact between the operator and the infectious material.
- Constructed of materials that are impermeable to liquids, resistant to corrosion and meet structural requirements.
- Fabricated to be free of burrs, sharp edges and unguarded moving parts.
- Designed, constructed and installed to facilitate simple operation and provide for ease of maintenance, cleaning, decontamination and certification testing; glassware and other breakable materials should be avoided, whenever possible.

13.6.1.7 Health and medical surveillance: The employing authority, through the laboratory director, is responsible for ensuring that there is adequate surveillance of the health of laboratory personnel. The objective of such surveillance is to monitor for occupationally acquired diseases.

13.6.1.8 Guidelines for the surveillance of laboratory workers handling microorganisms at Biosafety Level 1: Historical evidence indicates that the microorganisms handled at this level are unlikely to cause human disease or animal disease of veterinary importance. Ideally, however, all laboratory workers should undergo a pre-employment health check at which their medical history is recorded.

13.6.1.9 Guidelines for the surveillance of laboratory workers handling microorganisms at Biosafety Level 2: A pre-employment health check is necessary. The person's medical history should be recorded and a targeted occupational health assessment performed. Records of illness should be kept by the laboratory management. Women of childbearing age should be made aware of the risk to an unborn child of occupational exposure to certain microorganisms, e.g. Rubella virus. The precise steps taken to protect the foetus will vary, depending on the microorganisms to which the women may be exposed.

13.6.1.10 Waste handling: Waste is anything that is to be discarded. In laboratories, decontamination of wastes and their ultimate disposal are closely interrelated. In terms of daily use, few if any contaminated materials will require actual removal from the laboratory or destruction. The overriding principle is that all infectious materials should be decontaminated, autoclaved or incinerated within the laboratory.

13.6.1.11 Decontamination: Steam autoclaving is the preferred method for all decontamination processes. Materials for decontamination and disposal should be placed in containers, e.g. autoclavable plastic bags that are colour-coded according to whether the contents are to be autoclaved and/or incinerated.

13.6.1.12 Handling and disposal procedures for contaminated materials and wastes: Identification and separation system for infectious materials and their containers should be adopted. National and international regulations must be followed.

Categories should include: (a) Non-contaminated (non-infectious) waste that can be reused or recycled or disposed of as general, "household" waste, (b) Contaminated

(infectious) “sharps” – hypodermic needles, scalpels, knives and broken glass should always be collected in puncture-proof containers fitted with covers, decontaminated by autoclaving and disposed.

13.6.2 The containment laboratory –Biosafety Level 3

13.6.2.1 Code of practice: The code of practice for basic laboratories – Biosafety Levels 1 and 2 applies except where modified as follows-

- The international biohazard warning symbol and sign (Figure 1) displayed on laboratory access doors must identify the biosafety level and the name of the laboratory supervisor who controls access, and indicate any special conditions for entry into the area, e.g. immunization.
- Open manipulations of all potentially infectious material must be conducted within a biological safety cabinet or other primary containment device. Respiratory protective equipment may be necessary for some laboratory procedures or working with animals infected with certain pathogens. Laboratory protective clothing must be of the type with solid-front or wrap-around gowns, scrub suits, coveralls, head covering and, where appropriate, shoe covers or dedicated shoes.

13.6.2.2 Laboratory design and facilities:

- The laboratory must be separated from the areas that are open to unrestricted traffic flow within the building. Additional separation may be achieved by placing the laboratory at the blind end of a corridor, or constructing a partition and door or access through an anteroom (e.g. a double-door entry or basic laboratory – Biosafety Level 2), describing a specific area designed to maintain the pressure differential between the laboratory and its adjacent space. The anteroom should have facilities for separating clean and dirty clothing and preferably a shower.
- Anteroom doors may be self-closing and interlocking so that only one door is open at a time. A break-through panel may be provided for emergency exit use.

- Surfaces of walls, floors and ceilings should be water-resistant and easy to clean. Openings through these surfaces (e.g. for service pipes) should be sealed to facilitate decontamination of the room(s).
- The laboratory room must be sealable for decontamination. Air-ducting systems must be constructed to permit gaseous decontamination.
- The building ventilation system should be constructed in a way that air from the containment laboratory – Biosafety Level 3 is not recirculated to other areas within the building. Air may be High-Efficiency Particulate Air (HEPA) filtered, reconditioned and recirculated within that laboratory.
- An autoclave for the decontamination of contaminated waste material should be available in the containment laboratory¹¹.

13.6.2.3 Laboratory equipment: The principles for the selection of laboratory equipment, including biological safety cabinets are the same as for the basic laboratory – Biosafety Level 2. However, at Biosafety Level 3, manipulation of all potentially infectious material should be conducted within a biological safety cabinet or other primary containment device.

13.6.2.4 Health and medical surveillance: Same as Biosafety Levels 1 and 2 also apply to containment laboratories – Biosafety Level 3, except where, medical examination of personnel is necessary and after a satisfactory clinical assessment, the examinee may be provided with a medical contact card with photo and personal details.

13.6.3 The maximum containment laboratory – Biosafety Level 4

The maximum containment laboratory – Biosafety Level 4 is designed for work with Risk Group 4 microorganisms. Before such a laboratory is constructed and put into operation, intensive consultations should be held with institutions that have had experience of operating a similar facility. Operational maximum containment laboratories – Biosafety Level 4 should be under the control of national or other appropriate health authorities.

13.7 Biological safety cabinets (BSCs)

Biological safety cabinets are designed to protect the operator, the laboratory environment and work materials from exposure to infectious aerosols and splashes that may be generated when manipulating materials containing infectious agents, such as primary cultures, stocks and diagnostic specimens (Annexure-6). Aerosol particles are created by any activity that imparts energy into a liquid or semiliquid material, such as shaking, pouring, stirring or dropping liquid onto a surface or into another liquid.

Other laboratory activities, such as streaking agar plates, inoculating cell culture flasks with a pipette, using a multichannel pipette to dispense liquid suspensions of infectious agents into microculture plates, homogenizing and vortexing infectious materials, and centrifugation of infectious liquids, or working with animals, can generate infectious aerosols.

Aerosol particles of less than 5 µm in diameter and small droplets of 5–100 µm in diameter are not visible to the naked eye. The laboratory worker is generally not aware that such particles are being generated and may be inhaled or may cross contaminate work surface materials. BSCs, when properly used, have been shown to be highly effective in reducing laboratory-acquired infections and cross-contaminations of cultures due to aerosol exposures. BSCs also protect the environment.

14.0 ETHICAL CONSIDERATIONS

Personnel working in clinical and/or research laboratories should be aware of their ethical responsibilities and follow the basic and general ethical principles. The researcher and the team are responsible for protecting the dignity, rights, safety and well-being of the participants enrolled in the study, which are governed by the following principles¹:

- ***Principle of voluntariness*** whereby respect for the right of the subject/participant to agree or not to agree to participate in research, or to withdraw from research at any time, is paramount. The informed consent process ensures that participants' rights are safeguarded.
- ***Principle of non-exploitation*** whereby research participants are equitably selected so that the benefits and burdens of the research are distributed fairly

and without arbitrariness or discrimination. Sufficient safeguards to protect vulnerable groups should be ensured.

- ***Principle of social responsibility*** whereby the research is planned and conducted so as to avoid creation or deepening of social and historic divisions or in any way disturb social harmony in community relationships.
- ***Principle of ensuring privacy and confidentiality*** whereby to maintain privacy of the potential participant, her/his identity and records are kept confidential and access is limited to only those authorized. However, under certain circumstances (suicidal ideation, homicidal tendency, HIV positive status, when required by court of law etc.) privacy of the information can be breached in consultation with the EC for valid scientific or legal reasons as the right to life of an individual supersedes the right to privacy of the research participant.
- ***Principle of risk minimization*** whereby due care is taken by all stakeholders (including but not limited to researchers, ECs, sponsors, regulators) at all stages of the research to ensure that the risks are minimized and appropriate care and compensation is given if any harm occurs.
- ***Principle of professional competence*** whereby the research is planned, conducted, evaluated and monitored throughout by persons who are competent and have the appropriate and relevant qualification, experience and/or training.
- ***Principle of maximization of benefit*** whereby due care is taken to design and conduct the research in such a way as to directly or indirectly maximize the benefits to the research participants and/or to the society.
- ***Principle of institutional arrangements*** whereby institutions where the research is being conducted, have policies for appropriate research governance and take the responsibility to facilitate research by providing required infrastructure, manpower, funds and training opportunities.
- ***Principle of transparency and accountability*** whereby the research plan and outcomes emanating from the research are brought into the public domain through registries, reports and other scientific publications while safeguarding the right to privacy of the participants. Stakeholders involved

in research should disclose any existing conflict of interest and manage it appropriately. The research should be conducted in a fair, honest, impartial and transparent manner to guarantee accountability. Related records, data and notes should be retained for the required period for possible external scrutiny/ audit.

- ***Principle of totality of responsibility*** whereby all stakeholders involved in research are responsible for their actions. The professional, social and moral responsibilities compliant with ethical guidelines and related regulations are binding on all stakeholders directly or indirectly.
- ***Principle of environmental protection*** whereby researchers are accountable for ensuring protection of the environment and resources at all stages of the research, in compliance with existing guidelines and regulations.

15.0 QUALITY MANAGEMENT

Quality is the ability of a product or service to satisfy stated or implied needs of a specific customer achieved by conforming to established requirements and standards.

“Quality is doing the right things and doing those things right”.

A solid base for quality is to establish a strong foundation of Quality culture at all levels; this will conveniently lead to achieving all goals.

The watchwords are **“SAY WHAT YOU DO, DO WHAT YOU SAY & PROVE IT”.**

Quality Hierarchy

- Quality Control
- Quality Assurance
- Quality Management

Quality Control (QC): Defined as “part of quality management focused on fulfilling quality requirements.” Quality control is more the inspection aspect of quality management. An alternate definition is “the operational techniques and activities used to fulfil requirements for quality.”

Quality Assurance (QA): Quality assurance can be defined as “part of quality management focused on providing confidence that quality requirements will be fulfilled.” The confidence provided by quality assurance is twofold – internally to management and externally to customers, government agencies, regulators, certifiers, and third parties.

An alternate definition is “all the planned and systematic activities implemented within the quality system that can be demonstrated to provide confidence that a product or service will fulfil requirements for quality.

Quality Management System (QMS): Incorporates the organizational structure, resources, responsibilities, document hierarchy, interaction of processes and procedures needed to implement quality management of the laboratory. The quality management system describes the integration of all processes required to fulfill its quality policy and objectives and meet the needs and requirements of the users.

Whereas, QC refers to the process of minimizing examination errors, QA encompasses procedures adopted for minimizing errors that may occur at any stage.

16.0 INTERNAL QUALITY CONTROL

The first essential in setting up internal quality control (IQC) of a test procedure in the laboratory is to select the proper IQC procedure to implement, i.e. choosing the statistical criteria or control rules, and the number of control measurements, according to the quality required for the test and the observed performance of the method⁴. Practice of IQC includes-

- Recognition of errors which arise within the laboratory during examination stage (testing)-
 - Taking steps to minimize errors.
 - Equipment calibration and method verification / validation.
- Quality control checks for both quantitative and qualitative tests.

16.1 IQC for Quantitative Tests

- Levy Jennings's (LJ) chart is the most common graphical tool to plot daily QC values. Most of the current analyzers have inbuilt software to do this automatically, if this is not available, it can be done manually using excel sheet. Laboratories can also opt for commercially available IQC tools, LIS modules, middleware modules, etc.

From these charts trends and shifts in IQC of a test can be easily identified.

Calculate/Obtain lab's mean and SD, CV% from the IQC data (periodically/monthly). Only valid data should be considered for establishing mean/SD.

Irrespective of the size, all labs shall analyze two levels IQC once daily.

- 24 x 7 operating labs shall run:
 - i) Two levels of QCs once in the peak hour daily
 - ii) One level every 8 hrs. (Total 3 times in a day)

When one level QC is used-

Reject test run if following errors occur:

- Value is outside 3 SD (1_{3s})
- 2 consecutive values are outside 2 SD on the same side, but within 3 SD (2_{2s})
- 10 consecutive values or above or below the mean, but within 2 SD (10x)

When two level QC are used:

Reject test run if following errors occur:

- Either QC value is outside 3 SD (1_{3s})
- Both QC values are outside 2 SD on the same side, but within 3SD (2_{2s})
 - Difference between the two level QC values is >4 SD i.e. one level QC is >2 SD and other level QC is <2 SD (R_{4s})
 - 10 consecutive values of the same level QC are above or below the mean, but within 2 SD (10x)
- 5 consecutive values of one level QC and 5 consecutive values of the other level QC are above or below the mean, but within 2 SD (10x)

Note 1: The laboratory personnel performing the test should determine the appropriate corrective action to be taken for QC data that fall outside the established tolerance limits. Corrective action should be documented with the technician's initials and date.

Note 2: Tests for which control material is not available or when running of control is not viable due to low volume of tests, the laboratory should apply alternate quality control techniques such as-

- Retesting of any randomly chosen specimen/s
- Replicate test of specimen by different method, different machine and different person, wherever applicable
- Correlation of test results with other parameters

The laboratory should review trend of Measurement Uncertainty or CV% to identify any significant trends and shifts and maintain the records of review.

16.2 IQC for Qualitative Tests

For qualitative tests, positive and negative controls should be included with each run. For staining procedures, gram stains require both Gram positive and Gram negative control organisms to be used once per week. QC should also be run whenever a new lot of the stain procedure kit is used and/or any of the four components of the stain procedure kit is replaced with a new lot.

16.3 Reagent lot Verification- Uniformity of results is of paramount importance. Each change in reagent lots can adversely affect the consistency and quality of patient results. Assuring lot-to-lot uniformity is particularly important for those analytes that are serially measured over time such as CBC, HbA1c, TSH, tumor markers and liver enzymes, etc.

Performance of a new lot of reagents should be compared against the existing lot before the existing lot is finished. Other alternatives to patient samples preferred for checking lot to lot variability may be⁴-

1. Reference materials or QC products provided by the method manufacturer with method-specific and reagent-lot-specific target values.
2. Proficiency testing materials with peer-group established means.

17.0 EXTERNAL QUALITY ASSESSMENT/ PROFICIENCY TESTING (EQA/PT)

EQA/PT is the evaluation of participant performance against pre-established criteria by means of inter laboratory comparisons. Participation in EQA/PT program is the best measure of accuracy of a test for clinical laboratories. Hence, clinical laboratories should enroll for all tests in this program, as far as feasible.

Benefits of EQA/PT participation:

- Assesses the overall performance of laboratory for each test
- Serves as an early warning system for problems
- Identifies systematic problems
- Provides objective evidence of laboratory quality
- Identifies training needs

The EQA/PT schemes usually have the following salient steps-

1. The laboratory enrolls in a EQA/PT scheme/s
2. The EQA/PT provider sends EQA/PT items to participating laboratories at defined interval.
3. The participating labs analyze the samples and return their results to the EQA/PT provider within the timeline, usually through a web portal.
4. The results are evaluated by the EQA/PT provider and the laboratories are provided with statistical data and performance score (e.g.: Z score, SDI, etc.). The laboratory can review its own performance and also compare with other participants/peers.
5. The laboratories must take appropriate corrective and preventive actions when the score deviates from the acceptable limits.
6. The participating laboratories are expected to use the information regarding their performance to make appropriate changes and improvements in their operational processes, as and when needed.

Rightly used and understood EQA/PT participation will stimulate technical competence of a laboratory.

If EQA/PT program for a particular analyte is not available, an appropriate inter-laboratory comparison or any other alternate method (retesting of retained item, testing by different personnel, use of certified reference materials etc.) is recommended.

EQA/PT providers who run these programs get accreditation¹³ under ISO/IEC 17043:2010. Laboratories should enroll in an accredited EQA/PT program⁴, if available.

18.0 INTERNAL AUDIT

Audit is a process of critical review of the functioning and evaluation of services. Internal audit is a process of comprehensive review of the functioning and evaluation of services. Internal audit is the systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the specific criteria are complied with. Internal audit can be effectively carried out by examining documents, specimens, equipment, procedures, environmental conditions, examination procedures, personnel competence, records and reports. Effective internal audit will identify the problems and weak points in the system and suggest remedial measures. Laboratory shall conduct one complete cycle of internal audit at least once in twelve months.

Internal audit should be done by a person who has been trained as an auditor. It is recommended that all internal auditors undergo 4-day Standard and Internal auditor training³.

19.0 TECHNICAL AUDIT CHECKLIST

A technical audit checklist (Annexure-7) needs to be maintained by each laboratory. A model technical audit checklist is provided in Annexure-7, which needs to be maintained by each laboratory. Laboratories may adapt this to make it more comprehensive and relevant.

20.0 RISK MANAGEMENT

Risk is a combination of the probability of occurrence of harm and the severity of that harm¹⁴ (ISO/ISE Guide 51)

- Hazard: Potential source of harm
- Harm: Physical injury or damage to the health of people
- Severity: Measure of the possible consequences of a hazard¹⁵

RISK MANAGEMENT: “The laboratory shall evaluate the impact of work processes and potential failures on examination results as they affect patient safety, and shall modify processes to reduce or eliminate the identified risks and document decisions and actions taken”.

Risk management Process: Laboratories should create a process map that outlines all the steps of the testing process from physician order to reporting the result (wherever applicable) (Figure-2).

21.0 QUALITY INDICATORS

- It is essential for the laboratory to establish quality indicators towards monitoring and evaluating performance throughout critical aspects of pre-examination, examination and post-examination processes.
- **Purpose of Quality Indicators**
 - Give information about the performance
 - Determine the quality of services
 - Highlight potential quality concerns
 - Identify areas that need further study & investigation
 - Track changes over time

Characteristics of good Quality Indicators

- Measurable
- Achievable

- Actionable
- Balanced
- Timed

Examples of Quality Indicators

Pre-examination-

- Specimen Container labeling Error
- Specimens rejected
- Specimens without mandatory history
- Specimens received beyond stability period
- Specimen quantity inadequate
- Specimen label and TRF details not matching

Examination-

- IQC – Improvement in % CV of analytes over 12 month period
- PT – Improvement in PT performance (e.g. x score, SDI, etc.)
- Equipment downtime
- Kit non-availability
- Trainings conducted

Post Examination-

- Inpatient laboratory result availability (% of test results available for morning rounds as stipulated in the institution policy)
- Critical values reporting in defined time
- Turnaround time (achieved/defined)
- Clinician or customer satisfaction with laboratory services
- Complaints (number, critical, time to resolve, etc.)

Laboratory can define indicators beyond these also e.g. number of spills, cost per reportable test, productivity per technician, etc.

22.0 DATA MANAGEMENT

22.1 Data integrity: Data integrity is defined as paper-based or electronic data that is complete, accurate, consistent, and reliable through its lifecycle from the time of data creation, archival, scanning, retention upto destruction. Few countries have defined it as ALCOA acronym with respect to data integrity:

ALCOA:

- A-Attributable
- L-Legible
- C-Contemporaneous
- O-Original
- A-Accurate

Data integrity can be monitored by keeping a check on the following areas:

- Source Data Verification (SDV) through good documentation practices
- Data access and control
- Training of personnel involved in data collection
- Data monitoring: on-site, centralized, and risk-based monitoring
- Quality assurance

22.2 Confidentiality

- Confidentiality of data should be maintained including interim data results throughout the process.
- The ability to tamper with data such as changing, deleting or falsifying data should be restricted by clearly demarcating roles.
- This also prevents potential conflict of interest that may hamper data integrity.

22.2.1 Data integrity Audits

- Specific audits look out for any data or metadata that previously went unnoticed such as deleted or unchecked, misused, orphaned, or reprocessed data.
- The entire data lifecycle should be subjected to scrutiny by all departments involved in the trial such as, but not limited to, data management, safety,

quality risk management, and statisticians for compliance issues in areas of data management and data access control.

22.3 Data Security: It can be divided in to four components

22.3.1. *Hardware Security*

- a. Operating systems should be up to-date operating systems
- b. Malware Protection: All laboratory computers should have robust anti-virus software installed and configured for automated, regular virus definition updates and file scanning.
- c. Interfaced instruments: Laboratory instruments are exposed to similar security issues as laboratory computers. The instrument's operating system, hardware protection and Malware protection must be addressed.
- d. Mobile devices: There should be steps in place to develop secure authentication for mobile devices (e.g., smartphones, tablets, etc.) along with the ability to track and secure mobile devices remotely by locking or wiping out information.

22.3.2 *Network Security*

- a. On-premise hosting data security. This hosting option allows strong data security with data protected by the company firewall, although using cloud-based services.
- b. External and cloud-based hosting data security. There are availability of licensed fully external cloud-based "Software-as-a-service" offerings.
- c. For internet transmission of patient data, the minimum security requirements by utility Secure Socket Layer (SSL) protocols, which encrypt data using a private key, to protect patient confidentiality.

22.3.3 *Application Security*

- a. Passwords: All applications should be passwords enabled as the main method of user authentication. Organizations should formulate

procedures for creating, changing and safeguarding passwords that allow access to systems with critical data.

- b. Two-factor authentication: Applications utilized by laboratories should ideally have Two Factor authentication capabilities.
- c. Role-based access control: Laboratory information systems should also have the ability to control which users can use the system, what information they have access to, and what they can do with the data (e.g., read only, or the ability to change or delete data).

22.3.4 *Personnel Security*

- a. Employee training and compliance: Security awareness training should be provided for all employees at the time of their hire, and this initial training should be reinforced periodically with follow-up security reminders.
- b. Peripheral devices: Any IT hardware, namely computer terminals, should be viewed as a potential site for rouge employees to extract data via peripheral storage devices (e.g., USB thumb drives, eSATA disk drives).

Role of Laboratory data management starts with the creation of a new UID/ patient sample and includes recording details of the patient, findings or analysis, reporting of results and archiving the data for future reference and ensuring confidentiality at all stages, as required and applicable.

Laboratory data management is a highly specialised field. A laboratory may choose to manage data manually in the form of reports or through online system, but either way it is the responsibility of the laboratory to manage and store data as per their policy. But in both the cases, laboratory should have a documented procedure to ensure that the confidentiality of patient information is maintained at all times.

Disaster Recovery Plan: Laboratory should have a functional plan to manage data and ensure continuity of services in case of natural disasters like floods, earthquakes, extensive fire, etc.

22.4 Laboratory Record- All the released laboratory reports should be stored as per the national/ regulatory requirements.

22.4.1 The records can be maintained as physical copies (instrument printouts or as photocopies) or electronically (LIS/HIS).

- In hospital attached laboratories, Hospital Information System (HIS) manages all the activities of a hospital including laboratory, which is an integrated information system. Independent Laboratories are managed by Laboratory Information systems (LIS) which are designed to process and report data related to individual patients in a clinical setting. Whereas, Laboratory Information Management Systems (LIMS) are designed to process and report data related to batches of samples from drug trials and other entities.
- Use of LIS/LIMS enables a laboratory to track specimens from receipt, processing, testing and reporting to storage. It captures patient/research data electronically and integrated patient and specimen information and thus enable determination of patient outcomes and support patient management.

Procedure for adequate data protection and security including data editing and deleting should be developed and maintained by the laboratory.

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Annexure-5: Reporting Format

| |
|---------------------------------------|
| Lab Name/No. (if any) |
| Name..... |
| Age..... Sex..... |
| UID/OPD No. Referred by: |
| Date of specimen collection |
| Date & time of specimen receipt |
| Date & time of Report |
| Test Name |
| Method used..... |
| Test Result |
| |
| Reference Interval..... |
| |
| Interpretation |
| |
| |
| |
| Date of reporting..... |
| Authorized Signatory..... |

Annexure-6***Differences between Class I, II and III biological safety cabinets (BSCs)***

| BSC | FACE VELOCITY (M/S) | Airflow (%) | | Exhaust System |
|--|---------------------------|--------------|-----------|--|
| | | Recirculated | Exhausted | |
| Class IA | 0.36 | 0 | 100 | Hard Duct |
| Class IIA1 | 0.38–.51 | 70 | 30 | Exhaust to Room or Thimble Connection |
| Class IIA2 Vented to The Outside ^a | 0.51 | 70 | 30 | Exhaust to Room or Thimble Connection |
| Class IIB1A | 0.51 | 30 | 70 | Hard Duct |
| Class IIB2A | 0.51 | 0 | 100 | Hard Duct |
| Class IIIA | NA | 0 | 100 | Hard Duct |

NA, not applicable.

^a All biologically contaminated ducts are under negative pressure or are surrounded by negative pressure ducts and plenums.

Source: Laboratory Biosafety Manual, WHO, 3rd Edition, 2004

Annexure-7**TECHNICAL AUDIT CHECKLIST-**

- SOPs
- IQC Data – Precision statistics
- LJ Charts
- EQA data / Proficiency Testing
- Corrective actions taken QC/EQA outliers
- Sample handling, identification & storage
- Measurement traceability
- Equipment maintenance & Calibration
- Data on uncertainty of measurements

Figure-1
Biohazard Sign¹²



¹²*Adapted from Laboratory Bio-safety Manual, WHO, 2004*

Figure-2

RISK MANAGEMENT PROCESS¹⁶

¹⁶ Adapted from CLSI EP-23A, 2011, Vol-31, no.-18, Lab Quality control based on risk management

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