Khyber Pakhtunkhwa Health Care Commission

MINIMUM SERVICE DELIVERY STANDARDS

REFERENCE MANUAL

Clinical Laboratories

KP HCC-08RM-Ed1

1st Edition

Minimum Service Delivery Standards

REFERENCE MANUAL

Clinical Laboratories

March 2022

Message from Chairman

Aristotle stated, “Quality is not an act, it is a habit.” In order to ensure that quality in the health care sector becomes a habit, the government established the Khyber Pakhtunkhwa Health Care Commission (KP HCC) through the Khyber Pakhtunkhwa Health Care Commission Act, 2015. The KP HCC is a statutory body of the Government of Khyber Pakhtunkhwa to regulate both public and private Health Care Establishments (HCEs) in the province.

Prior to 2015 the private health institutions including hospitals, nursing homes, maternity homes, medical & dental clinics, blood banks, clinical laboratory, x-ray clinics and operation theaters etc. were registered under the Medical and Health Institutions and Regulation of Health Care Services ordinance 2002 (Amendment Act, 2010), which was subsequently repealed through the Act of 2015.

The legal mandate of KP HCC is to regulate the health care services on sound and technical footings in the public and private sectors, make provisions for safe and high quality health care services to the people of Khyber Pakhtunkhwa, and to provide mechanism for banning quackery in all its forms and manifestations.

The Government of Khyber Pakhtunkhwa through the Health Care Commission is committed to improve and maintain the quality of health care. The KP HCC is already registering the various types of Health Care Establishments. The other mechanism to ensure optimum level of safety and quality is the framework of clinical governance. To achieve this end the KP HCC initiated the process of licensing of Health Care Establishments.

The former Board of the KP HCC strived very hard and visited the sister organizations in the other provinces for experience sharing. In order to save energies and resources, the Board adopted the Minimum Service Delivery Standards (MSDS) of the Punjab Healthcare Commission (PHC). I, on behalf of the Board and Khyber Pakhtunkhwa Health Care Commission, am very grateful for support provided by PHC in this regards.

The journey of ensuring quality is not easy and assistance of various stakeholders is required. I would specifically mention the all-out support of the Government of Khyber Pakhtunkhwa and especially the Minister for Health and Secretary to the Government of Khyber Pakhtunkhwa, Health Department. Without their support, initiation of licensing of the HCEs to ensure quality was not possible.

I would take this opportunity to reach out to all the health acre establishments to get themselves registered with KP HCC and implement the Minimum Service delivery Standards in their respective establishments to achieve the required quality of health care and get a license to function. Providing health care without getting license from KP HCC is illegal and may lead to legal consequences, including, but not limited to, closure of the facility.

Dr. Ikram Ghani
Chairman, Board of Commissioners

Foreword

Quality costs but poor quality costs higher. This is true for all walks of life; however, in the health sector its importance cannot be overemphasized. It ensures safety of patients as well health care providers. Patient safety is not new in the medical field but is relatively newer concept for general public. Regulation of health care services is now a priority at the national and provincial government level. In order to ensure quality of care and safety in health care system of Khyber Pakhtunkhwa, the provincial government established the Khyber Pakhtunkhwa Healthcare Commission (KP HCC) through the promulgation of Khyber Pakhtunkhwa Health Care Commission Act, 2015. KP HCC is a statutory body, constituted to regulate Health Care Establishments (HCEs), both in public and private sectors in the province, to improve quality of health care, and ensure safety of patients and health care providers.

To ensure quality the HCEs are regulated through assessment against set standards. The Punjab Healthcare Commission (PHC) developed the Minimum Service delivery Standards (MSDS) through extensive consultations with the stakeholders. PHC developed MSDS for Category I and II hospitals, providing in-patient care. Moreover, MSDS were also developed for different kinds of Category III HCEs, offering out-patient services, including Basic Health Units in the public sector, and the clinics of general practitioners, dental clinics, clinical laboratories, radiological diagnostic centers, as well as homeopathic clinics and Tibb clinics.

The former Board of Khyber Pakhtunkhwa Healthcare Commission took the right decision and approved adoption of the MSDS of Punjab in its 34th meeting on 6th January 2022. The KP HCC duly acknowledges this gesture of support by the Punjab Healthcare Commission.

Subsequent to adoption, appropriate amendments were required to adapt the MSDS to the local context and legal provisions of Khyber Pakhtunkhwa. This was a challenging assignment and despite shortage of staff, KP HCC made the required amendments, utilizing its internal resources. I would like to thank the former Board of KP HCC for its wholehearted effort towards improving the quality of healthcare through adoption of PHC MSDS. My thanks are also due to the whole KP HCC team for working tirelessly and completing the process of adaptation in a very short time. The role of senior management was commendable. Moreover, I am highly grateful to Dr. Shabnum Gul, Director Licensing, KP HCC for her contribution during the process of adaptation of this specific reference manual for clinical laboratories.

The MSDS Reference Manual for Clinical Laboratories comprises 37 standards and 118 indicators. It also provides the survey and scoring methodology, in addition to the guidelines to facilitate implementation and assessment of compliance.

Every journey begins with the first step and I firmly believe that this first step followed by implementation of the MSDS will lead to improved quality of healthcare in Khyber Pakhtunkhwa.

Dr. Nadeem Akhtar
Chief Executive Officer

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List of Acronyms & Abbreviations

A&E	Accident and Emergency
AAC	Access, Assessment, and Continuity of Care
ACR	Annual Confidential Report
ADR	Adverse Drug Reaction
BSBS	Bio Safety and Bio Security
BTS	Blood Transfusion Service
BLS	Basic Life Support
CMC	Complaint Management Committee
CME	Continued Medical Education
CNIC	Computerized National Identity Card
CQI	Continuous Quality Improvement
CT	Computerized Tomography
DHIS	District Health Information System
DoB	Date of Birth
DRAP	Drug Regulatory Authority of Pakistan
ED	Emergency Department
EDL	Essential Drug List
EMR	Electronic Medical Record
EMS	Emergency Medical Services
EQA	External Quality Assessment
FMS	Facility Management and Safety
HCP	Healthcare Provider
HIC	Hospital Infection Control
HMIS	Health Management Information System
IC	Infection Control
ICC	Infection Control Committee
ICT	Information and Communication Technology
ICT	Infection Control Team
IEC	Information, Education and Communication
IMS	Information Management Systems

IQA	Internal Quality Assurance
JD	Job Description
KCl	Potassium Chloride
LASA	Look-Alike, Sound-Alike
MER	Management of Equipment and Reagents
MIS	Management Information System
MLC	Medico-Legal Cases
MLR	Medico-Legal Report
MOM	Management of Medication
MSDS	Minimum Service Delivery Standards
NEQAS	National External Quality Assessment Service
NGO	Non-Government Organization
OEM	Original Equipment Manufacturer
PM&DC	Pakistan Medical & Dental Council
PNC	Pakistan Nursing Council
PPE	Personal Protective Equipment
PRE	Patient Rights and Education
QA	Quality Assurance
QC	Quality Control
QI	Quality Improvement
RBS	Random Blood Sugar
ROM	Responsibilities of Management
RRS	Recording and Reporting System
SMPs	Standard Medical Protocols
SOPs	Standard Operating Procedure
TAC	Technical Advisory Committee
WM	Waste Management

1. Introduction

The Government of Khyber Pakhtunkhwa promulgated the Khyber Pakhtunkhwa Health care Commission Act, 2015, to establish the Khyber Pakhtunkhwa Health Care Commission (KP HCC) as a regulatory body with the prime objective to improve the quality of healthcare services and ban quackery in Khyber Pakhtunkhwa in all its forms and manifestations. The KP HCC is legally mandated[1] to regulate all Health Care Establishments (HCEs) in the public and private sectors through registration and licensing. It is the responsibility of the HCEs throughout the province to get registered with KP HCC. Moreover, the KP HCC is ensuring to improve and maintain quality of healthcare through the implementation of Minimum Service Delivery Standards (MSDS). The HCEs are required to follow these standards in order to get license. No Health care Establishment can function legally without being registered and licensed by the Khyber Pakhtunkhwa Care Commission.

The KP HCC has adopted MSDS developed by the Punjab Healthcare Commission (PHC) for the three recognized systems of treatment; Allopathy, Homeopathy, and Tibb. These Minimum Service Delivery Standards include hospitals (Up to 15 beds, 16 to 30 beds, 31 to 49 beds, 50 and more beds), Basic Health Units, General Practitioners/Family Physicians/Specialist Clinics, Dental Clinics, Clinical Laboratories and Collection Points, Radiological/Imaging Diagnostic Centers, Homeopathic Clinics, Tibb Clinics.

1.1 Service Delivery Standards

Setting service delivery standards and indicators is an established practice for continually improving the provision of quality services in the health sector. Joint Commission International (JCI) in the USA is one such organisation that sets standards to improve the quality of health services. Likewise, the Quality Care Commission in the UK ensures clinical governance with the help of a system of setting standard and facilitating compliance. The Indian Public Health Standards' were introduced in 2005 and since then the Quality Council of India expanded their scope with the launching of 'Standards for the Health and Wellness Industry in 2008. The Australian Council on Healthcare Standards was initiated in 1974 that has facilitated the development of the New Zealand and Singapore Councils. Accreditation Canada (formerly the Canadian Council on Health Services Accreditation) became independent from the Joint Commission for Accreditation of Hospitals (JCAH) in 1953. The Quality Holistic Accreditation (QHA) Trent Accreditation Scheme is based in the UK and Europe and has serviced hospitals in Asia. Internationally accredited hospitals can be found in Pakistan, India, Bangladesh, Kazakhstan, China and Iran.

Standardization of healthcare services by implementing Minimum Service Delivery Standards is however, a newer concept in Pakistan, and Khyber Pakhtunkhwa province has taken the initiative by establishing the Khyber Pakhtunkhwa Health Care Commission.

1.2 Reference Manual for Clinical Laboratories

In order to meet its legal obligations towards all recognized systems of healthcare, the Commission has developed the Minimum Service Delivery Standards and Indicators for implementation by clinical laboratories. The document comprises 37 standards with 118 associated indicators grouped

[1] Khyber Pakhtunkhwa Health Care Commission Act, 2015

in 10 Functional Areas for such services along with Reference Material and Assessment Scoring Matrix. Keeping in view the ground realities, these standards have been kept **dynamic** and subject to evidence based improvement. All aspects of implementation, assessment and scoring have been included in this single document to better facilitate the implementers at HCEs as well as the surveyors involved in inspections.

A **Color Coding** scheme has been included to facilitate the clinical laboratory/HCE staff responsible to implement and assess implementation status at their own level before formal Assessment by KP HCC. The RED indicators are required to be fully implemented and have been ascribed 100% weightage while in case of YELLOW, partial compliance at least to the extent of 80% is acceptable to qualify for a license from KP HCC and accordingly these indicators have been ascribed 80% weightage. Following scoring scale shall be used for self-assessment by the HCE staff as well as by the KP HCC assessors:

Lowest			**Shades of Levels of Implementation**							**Highest**
0	1	2	3	4	5	6	7	8	9	10

97 indicators require full compliance and have ascribed 100% weightage while 21 are acceptable even at partial compliance at least to the extent of 80% (ascribed 80% weightage). The HCE staff is advised to have self-assessment to ensure complete implementation, before the KP HCC assessors carry out formal assessment and score the HCE for licensing on the basis of criteria described above.

An Implementation Assessment Scoring Matrix has been given at the end of each Standard and set of Indicators for self-assessment practice by the HCE Staff, whereas additional details are provided for the assessors. It is highly desirable to achieve 100% scoring in all areas as these standards are already minimum. Summary Scoring Matrix is given at **Annexure A**.

PART 2
STANDARDS, INDICATORS AND ASSESSMENT SCORING MATRIX

2. STANDARDS, INDICATORS AND ASSESSMENT SCORING MATRIX

2.1 Responsibilities of Management (ROM)

03 Standards & 13 Indicators

The standards under the functional area of responsibilities of management (ROM) provide the structure to help managers effectively work together to enhance organizational performance. To meet their obligations, leaders/managers must collaborate as a team to achieve a common objective. The leaders/managers are responsible to develop the mission, vision and goals of the organization, and encourage honest and open communication and address conflicts of interest so that good relationships can thrive and enable the achievement of the stated goals.

The bigger establishments of clinical laboratories, like hospitals, generally have three tiers of leadership, including the governing body, senior managers, pathologists and technical staff who work together to deliver safe and quality care. The standards related to the responsibilities of management entail creating a culture that fosters safety as a priority, planning and providing services that meet patients' needs and ensuring availability of physical, financial and human resources necessary to provide the services. The management is also responsible to engage all managers, pathologists and technologists in performance improvement. The standards make clear that performing management functions is the direct responsibility of all leaders and that a coherent working relationship amongst different tiers enhances the quality of care/services provided to the patients. In the small scale practices/laboratories however, the scope of management functions/responsibility of management will be according to the scale of services provided at a particular HCE and can be performed by the pathologist overall incharge of the laboratory.

Standard 1. ROM-1: The laboratory is easily identifiable

Indicators (1-5):

Ind 1. The laboratory is identifiable with name on a sign board

Survey Process:

The essence of the indicator is to ascertain that any one approaching the laboratory is able to identify the location of the laboratory with the help of a board on which name of the lab is clearly written. Surveyors are required to make an assessment while approaching the laboratory from a reasonable distance. The sign board should clearly specify whether it is a main laboratory or a collection center.

Compliance Requirements:

- ✓ Sign board clearly displaying the name of the laboratory or the collection center, as the case may be.
- ✓ Sign board(s) placed appropriately for clear visibility.

Scoring:

- If there is a sign board which clearly identifies and specifies whether it is a laboratory or a collection center, then score as **fully met.**
- If there is no sign board to clearly identify the laboratory as above, then score as **not met.**

Ind 2. The laboratory sign board conforms to the prescribed local legal standards

Survey Process:

This requires surveyor knowledge about the local laws which prescribe the specifications/standards for the sign boards regarding their size, place of fixation and the type and strength of fixation. This is required to ensure safety and stability to withstand the wind pressures.

Compliance Requirements:

- ✓ Sign board size should conform to the local legal standards.
- ✓ Sign board fixation should conform to the local legal/technical/safety standards.

Scoring:

- If the sign board conforms to the local legal standards as above, then score as **fully met.**
- If the sign board has no-conformity to the local legal standards, then score as **not met.**

Ind 3. The laboratory is registered/licensed with the KP HCC

Survey Process:

The surveyor is required to check the following in original before proceeding any further with the assessment/inspection:

- ✓ Registration Certificate/License/Provisional Licence under the KP HCC Act.

Compliance Requirements:

- ✓ KP HCC Registration/License number clearly displayed on the sign board/separately.
- ✓ Registration Certificate/Licence with the KP HCC displayed at a prominent place inside the laboratory.

Scoring:

- If the laboratory has displayed Registration Certificate or valid Provisional Licence/ Full Licence issued by the KP HCC, then score as **fully met.**
- If the Registration Certificate is displayed and a Licence with the KP HCC is under process, then score as **partially met.**
- If none of the above is available, then score as **not met.**

Ind 4. Associated collection centers are reflected in the Registration Certificate/Licence issued by the KP HCC

Survey Process:

The list of the collection centers attached with a particular clinical laboratory are required to be reflected in the application for Registration/Licence. The surveyors are required to check the following:

Compliance Requirements:

- ✓ Evidence of reflecting the list of collection centers of the laboratory, if any, in the application for Registration/Licence with the KP HCC.
- ✓ Registration Certificate/Licence of the laboratory under KP HCC Act, accordingly having Licence/Provisional Licence number linked with serial number(s) of the collection center(s) (clinical laboratory Registration number/collection center serial number in the list) e.g. (CL#/CC#).
- ✓ Evidence of having applied for licensure in case it is not licensed.

Scoring:

- If the status of the collection center(s) is reflected in the application by the laboratory for Registration/Licence with the KP HCC and the KP HCC Registration Certificate/License reflects the status of collection centers as required, then score as **fully met.**
- If the application by the laboratory reflects the status of collection centers but the KP HCC Registration/Licence has not been received, then score as **partially met.**

- If the application does not reflect the status of collection centers, then score as **not met.**

Ind 5. Signed valid MOU, showing linkage with any other laboratory or organization for referral of specialized tests, exists[2]

Survey Process:

NOTE: This indicator does not apply to all laboratories and should be scored for laboratories referring tests to other organizations/labs. Otherwise mark as NOT APPLICABLE. A majority of the laboratories do not perform all the test/full range of lab tests. Therefore, some laboratories send samples to other relevant laboratories for getting specific tests performed. Linkages should demonstrate that the laboratory management has facilitated patients by limiting patient's visits and providing services at one facility for different tests. Look for a documented memorandum of understanding (MOU) with other laboratories, duly signed by both parties for specialized tests, such as polymerase chain reaction (PCR), and other specialized techniques, etc.

Compliance Requirements:

✓ Written and valid MOU with referral laboratory which fulfills the above requirements.

Scoring:

- If a signed and valid MOU/documented system of referral with other laboratories exists, then score as **fully met.**
- If no such evidence of a referral system exists, then score as **not met.**

GUIDELINES

Identification

The sign board should clearly specify if it is a laboratory or collection center, ensuring visibility, readability, notice-ability and legibility in accordance with local legal standards.

Registration and Licensing

Registration and licensing forms, along with the detailed processes, are provided on the KP HCC website. A Registration Certificate is issued to a HCE upon submission of an application on Registration Form prescribed by the KP HCC with all the necessary details. Laboratories are required to display the Registration Number and Registration Certificate appropriately and prominently, along with 'Scope of Services' duly portrayed. The main board/boards are appropriately placed to display the Registration Number and scope, whereas the Registration Number can be displayed in or outside the director's room or at the reception, etc.

Outsourcing Specialized Tests

Specialized tests not performed in the lab are referred to contracted laboratories. The laboratory director/incharge shall select the reference laboratory to which specimens are dispatched for test/analysis and reporting. The laboratory director/incharge shall also develop and implement

[2] Where applicable.

SOPs for dispatch of specimen, receipt and issuance of reports. When results are received from the referral laboratory, the original report is always forwarded to the requesting clinician. The list of the referral laboratories currently contracted and details of tests performed by the respective labs should be displayed. Laboratory management, in consultation with the technical experts as appropriate, shall establish a procedure(s) for the referral of specimens to other laboratories and to consultants for providing second opinions, which shall include inter-alia the following:

1. Evaluating and selecting referral laboratories and consultants in terms of competence to perform the requested examinations and ensuring that there are no Conflicts of Interests (COIs).
2. Maintaining a record of all referral laboratories.
3. Maintaining a record of all specimens referred.
4. Recording regarding dispatch dates.
5. Maintaining a record of reports.
6. Monitoring the receipt of reports from the referral laboratory or referral consultant.
7. Defining the respective responsibilities for the interpretation and reporting of referred examinations.
8. Periodic review of the arrangements with referral laboratories to ensure that requirements including terms of external quality assurance (EQA), performance and turnaround times are continually met.

   Note: Referral laboratories should be compliant of the KP HCC regulatory requirement and, or be, accredited by some accreditation body as applicable for ensuring that the quality management systems meet the requirements of good practices of quality assurance.

A memorandum of understanding (MOU) is a formal agreement between two or more laboratories (parties) signed to establish referral/outsourcing partnerships. Although the MOUs do not confer any legal binding, they reflect a degree of seriousness, define responsibilities and mutual respect amongst the parties.

Table 1: Sample Memorandum of Understanding Template

Sample Memorandum of Understanding Template
Memorandum of Understanding Between (Partner-1) and (Partner-2) This memorandum of understanding (MOU) sets for the terms and understanding between the (partner-1) and the (partner-2) to _____ (insert activity). **Background** (Why the partnership is important) **Purpose** This MOU will (purpose/goals of partnership) The above goals will be accomplished by undertaking the following activities: (List and describe the activities that are covered under the partnership and who will do what) **Reporting** (Record who will evaluate effectiveness and adherence to the agreement and when evaluation will happen)

Funding
(Specify that this MOU is not a commitment of funds)

Duration
This MOU is at-will and may be modified by mutual consent of authorized representatives from (list partners). This MOU shall become effective upon signature by the authorized representatives from the (list partners) and will remain effective until modified or terminated by any one of the partners with mutual consent. In the absence of mutual agreement by the authorized representatives from (list partners) this MOU shall end on (end date of partnership).

Contact Information
Partner 1

1. Name
2. Authorized representative
3. Position
4. Address
5. Telephone
6. Fax
7. E-mail

Partner 2

1. Name
2. Authorized representative
3. Position
4. Address
5. Telephone
6. Fax
7. E-mail

_____ Date: _____
(Partner 1 signature)
(Partner name, organization, position) _____

_____ Date: _____
(Partner 2 signature)
(Partner name, organization, position) _____

Assessment Scoring Matrix

Standard 1. ROM. 1: The laboratory is easily identifiable.

Indicator 1-5		Max Score	Weightage (Percentage)	Score Obtained
Ind 1.	**The laboratory is identifiable with name on a sign board.**	10	**100%**	
Ind 2.	**The laboratory sign board conforms to the prescribed local legal standards.**	10	**100%**	
Ind 3.	**The laboratory is registered/licensed with the KP HCC.**	10	**80%**	
Ind 4.	**Associated collection centers are reflected in the Registration Certificate/License issued by the KP HCC.**	10	**80%**	
Ind 5.	**Signed valid MOU, showing linkage with any other laboratory or organization for referral of specialized tests, exists.**	10	**100%**	
Total		50		

Standard 2. ROM-2: A technically qualified and experienced individual heads the laboratory

Indicators (6-6):

Ind 6. The individual heading the laboratory has requisite and appropriate technical qualification and experience

Survey Process:

The director/individual heading the laboratory is responsible for the overall operation and administration. Although he/she has the option to delegate some of the responsibilities, he/she remains ultimately responsible and must ensure that all the duties are properly performed and applicable regulatory requirements are duly complied. Review the job description[3] of the laboratory head/director and determine if the individual has the technically appropriate qualification and experience[4] to manage the laboratory according to the stated mission. The JD should also include the binding clauses regarding physical presence of the laboratory head/director in the laboratory on daily basis to ensure required supervision and reporting.[5]

Compliance Requirements:

- ✓ The technical head of the lab is a qualified pathologist having valid PM&DC Registration.
- ✓ The qualification of the pathologist is commensurate with the scope of service of the laboratory.
- ✓ The JD of the head of the laboratory, in addition to other duties, includes the binding clause regarding the physical presence of a pathologist for the time required in line with the scope of services.

Scoring:

- If the qualification and experience of the director/individual heading the laboratory meets the technical requirements, then score as **fully met.**
- If the qualification and experience of director/individual heading the laboratory is deficient, then score as **not met.**

GUIDELINES

The lab director will be the person responsible for the entire technical and managerial working of the laboratory. The following mandatory requirements, finalized after detailed deliberations with the pathologists working in the public and private sector in teaching and non-teaching settings and representing all regions of Khyber Pakhtunkhwa, are required to be complied:

1. The KP HCC may only register those clinical laboratories which have a full time/part time head or technical director having a post-graduate qualification in any branch of pathology recognized and registered with the PM&DC for personal supervision as technical incharge.

[3] Refer to Ind 25.
[4] Refer to Ind 26.
[5] Details in the guidelines.

2. The levels of recognized post-graduate qualifications of the technical head/lab director/section head for supervision viz a viz details regarding scope of work of the laboratory will be as under:

Table 2: Scope of Services

Category	Scope of Services/Type of Tests	Qualification of the Lab Director/Technical Head for Supervision
A	Immunology, PCR Histopathology, Genetic testing, Advanced Hematology, Enzyme / Hormone studies, Tissue typing, etc.	1. RMP with recognized post-graduation in any branch of pathology as technical head 2. Subject specialist pathologist or scientist as section heads 3. Full time director/technical head 4. Per shift section heads as per workload
B	Microbiology (C/S, etc.), Chemical pathology ELISA/ Immunoassay	1. RMP with recognized medium (M-Phil) degree in any branch of pathology as technical head 2. Technologist or scientist or pathologist as section heads as per work load
C	Routine clinical lab tests	1. RMP with recognized diploma/ equivalent PG qualification

3. Daily physical presence of a pathologist, full or part time, depending upon the lab category, level of complexity and magnitude of work is essential:
4. Full time means 7 hours daily presence.
5. Part time means minimum 4 hours daily presence.
6. One full time pathologist may opt to supervise another lab located at such a distance that he/she can remain physically present for the minimum time required to ensure quality of work of the 2nd lab without compromising the quality of work at the primary job.
7. Timing of actual availability of pathologist in the lab shall be displayed.
8. The labs not complying with the above may function only as collection centers for the qualified labs under a documented arrangement till they become compliant in terms of qualified HR.
9. Computer generated report should bear name of the pathologist who actually authenticated the test provided the lab has a demonstrable ICT set up and computer signature logging.
10. Provisional/emergency report issued in the absence of a pathologist must be followed by confirmatory report duly signed by the pathologist.
11. Technical head/director lab shall be solely responsible for QA of all processes and test reports.

Physical Presence of the Laboratory Head/Director:

Physical presence of the laboratory head/director daily in the laboratory is essential on a **full time/part time basis,** depending upon the scope of the laboratory services. For a laboratory providing high end services, a full time head in addition to section heads is mandatory. For laboratories having a limited scope of service, and/or performing fewer number of tests, the presence of a laboratory head/director for a minimum 4-5 hours daily is mandatory. Classification of laboratories into A, B, and C types depending on the scope of work/range of tests performed is

recommended. A pathologist may also practice at a second laboratory provided he/she can ensure physical presence for 4-5 hours daily at the 2nd lab and further provided that:

1. He/she bears the responsibility of overall technical supervision at both labs.
2. All processes/ test analyses in his/her absence are performed by the duly qualified technical staff.
3. The quality of work assigned at the primary place of work, which usually requires 6-7 hours' presence at a major HCE, does not suffer.

The correctness/quality assurance of all the processes and preparation of test results is the ultimate responsibility of the laboratory head/director through laboratory technicians/specialists/section heads whereas the authentication of reporting is the direct responsibility of the laboratory head/director. There may be situations where another pathologist/histopathologist/ microbiologist /chemical pathologist, etc. is also authorised to authenticate the test reports. The mode of authentication of test report may be by personally signing the reports or by clearing on the computer systems which endorses an electronic stamp of the signing expert.

Eligibility of the Laboratory Head/Director

1. Medical graduate with post graduate qualification/s in any one or more branches of pathology.
2. Past experience of working in a clinical laboratory preferred.

Job Summary

The director is the overall in charge of the laboratory functioning and exercises substantive/allocated administrative and financial powers, ensures best possible diagnostic services within the available resources, evolves strategies to improve technical capacity and optimizes functioning of the laboratory for quality testing and patient satisfaction.

Duties/Responsibilities

1. Achieves the goals by planning, budgeting, organizing, staffing, directing, coordinating, delegating, monitoring, controlling and regulating various functions.
2. Allocates and approves budget and resources for various activities.
3. Ensures the quality of testing in all diagnostic facilities provided by the laboratory.
4. Supports research activities.
5. Develops the laboratory strategic plan in consultation with other stakeholders.
6. Remains physically present for the required time commensurate with the scope of the services of the concerned laboratory.

Managerial

1. Oversees all technical and managerial functions.
2. Selects and appoints section heads.
3. Coordinates in preparation and implementation of an annual operational plan.
4. Provides worker's safety and rights.
5. Sanctions leave of the officers/officials.
6. Constitutes relevant committees to execute lab functions and improve systems.
7. Ensures periodic preventive maintenance and prompts repair of all the laboratory equipment.

8. Takes appropriate actions for redressing the grievances of the public.
9. Delegates responsibilities to the relevant staff as required.
10. Prepares a Disaster Management Plan and ensures its implementation through regular drills and revisions.
11. Undertakes periodic/regular review of the laboratory services to identify lapses and takes measures for improvement.
12. Holds regular staff meetings for appraisal of the services and mitigation of issues.
13. Ensures implementation of the SOPs for infection control.
14. Heads the Waste Disposal Committee to ensure proper disposal of human tissues, and other wastes etc. in accordance with the standard operating procedures (SOPs) developed under Khyber Pakhtunkhwa Hospital Waste Management Rules (KPHWMR) 2018.
15. Ensures enforcement of bio risk and biosafety management regulations.
16. Ensures implementation of SOPs for internal and external quality assurance (IQA and EQA).
17. Ensures regular calibration of the laboratory equipment as per OEM Guidelines.
18. Develops/adapts broader policies/protocols/SOPs to meet the contextual laboratory requirements and ensures that every employee is conversant with those.
19. Responsible for recruitment, promotion and transfer of staff.
20. Takes disciplinary actions or submits the disciplinary cases to the appropriate authority.
21. Identifies the deficiencies in performance of the staff and takes/recommends corrective measures.
22. Reviews the management information system (MIS)/reporting system and ensures required actions.
23. Issues job descriptions (JDs) to each employee under their signatures and maintains that record.
24. Ensures implementation of performance appraisal system for the laboratory staff.
25. Ensures that laboratory protocols and procedures are amended from time to time as per requirement/institutional instructions.
26. Performs any other professional duty assigned by the relevant higher authority.

Financial

1. Ensures timely preparation of annual budget proposal and availability of required financial resources.
2. Ensures optimal utilization of the budget/resources in accordance with the policy/prevailing judiciary laws.

Logistics

1. Monitors the procurement and distribution of logistics and supplies (kits, reagents, consumables, equipment, etc.)

Trainings

1. Develops and ensures CME and CPD for the staff.

Assessment Scoring Matrix

Standard 2. ROM. 2: A technically qualified and experienced individual heads the laboratory.

Indicator 6		Max Score	Weightage (Percentage)	Score Obtained
Ind 6.	**The individual heading the laboratory has requisite and appropriate technical qualification and experience.**	10	**100%**	
Total		10		

Standard 3. ROM-3: Responsibilities of management are defined

Indicators (7-13):

Ind 7. Those responsible for lab management lay down the laboratory's mission statement

Survey Process:

The mission statement of a clinical laboratory is a statement of core purpose and focus that normally remains unchanged over time and hence, is required to be prepared by the top management. Check if the mission statement is laid down. Review that the laboratory's mission statement should specify the type and quality of services which the laboratory can provide to patients.

Compliance Requirements:

- ✓ Documented mission statement that fulfills the above requirements.
- ✓ Mission statement is displayed for the staff and patients to view.

Scoring:

- If there is a documented mission statement and it is displayed, then score as **fully met.**
- If there is a documented mission statement but not displayed, then score as **partially met.**
- If there is no documented mission statement, then score as **not met.**

Ind 8. Those responsible for management lay down a detailed laboratory Standard Operating procedures (SOPs)

Survey Process:

The management of clinical laboratories must develop, implement and maintain lab-specific processes and procedures/SOPs. The SOPs can be developed indigenously based on the policy or by adapting available resource material such as reference books, manuals, etc. The surveyors should look for the written record of policy and SOPs, etc.

Compliance Requirements:

- ✓ Written laboratory SOPs available.
- ✓ Staff is aware of the laboratory SOPs.

Scoring:

- If the laboratory are documented and staff is aware of it, then score as **fully met.**
- If there are either no SOPs or the staff is not aware of it then score as **not met.**

Ind 9. Those responsible for management lay down an emergency Standard Operating Procedures (SOPs)

Survey Process:

Check laboratory SOPs for emergency situations like accidents, natural calamities, epidemics, etc. See if the emergency SOPs are documented and staff is aware of it.

Compliance Requirements:

- ✓ Written laboratory emergency SOPs covering the above requirements.
- ✓ The staff is aware of the emergency SOPs.

Scoring:

- If the emergency SOPs are available and staff is aware of it, then score as **fully met.**
- If the emergency SOPs are available but about 20% of the staff is not aware of those, then score as **partially met.**
- If there are no emergency SOPs, then score as **not met.**

Ind 10. Those responsible for management approve sufficient laboratory budget and allocate the resources required to accomplish the mission.

Survey Process:

Review any documentary evidence for lack of resources (kits, etc.). Evidence is available in the form of delayed reporting or refusal of tests to the patients, etc. because of non-availability of kits, equipment, staff consumables etc.

Compliance Requirements:

- ✓ The premises of the laboratory has adequate space suitable for the required activities.
- ✓ The staff, equipment and consumables remain available to support the scope of laboratory services as evidenced from the stock register and incumbency record/duty roster.
- ✓ No evidence of delay in reporting the test results on account of non-availability of equipment, kits/reagents or the concerned staff.

Scoring:

- If there is no evidence of lack of resources, then score as **fully met.**
- If there is evidence of lack of resources, then score as **not met.**

Ind 11. Those responsible for management establish the laboratory's organogram

Survey Process:

An organizational chart/organogram shows the structure/plan of the laboratory that gives the job titles of all the staff, showing how they are connected/reporting to each other. Review the

documents that define the laboratory's organizational structure and check that it is displayed.

Compliance Requirements:

- ✓ The organogram prepared as above is documented.
- ✓ The organogram is displayed for patients and the staff.

Scoring:

- If there is an updated organizational chart ('organogram') which is displayed, then score as **fully met.**
- If there is an updated organizational chart ('organogram'), but it is not displayed, then score as **partially met.**
- If there is none, then score as **not met.**

Ind 12. Those responsible for management appoint the section heads in the laboratory

Survey Process:

The laboratory section head is responsible for the overall functioning of a particular section according to the laid down policy. Review the process for appointment of the laboratory's section heads/lead experts.

Compliance Requirements:

- ✓ The section heads are appointed.
- ✓ Evidence of adopting due process for appointing section heads, i.e. under the signatures of the technical head of the laboratory.

Scoring:

- If there is a clearly defined process for appointment of the section heads/lead experts, then score as **fully met.**
- If the process is limited to the laboratory's director/in charge only, then score as **partially met.**
- If there is no formal process, then score as **not met.**

Ind 13. Those responsible for management support research activities [6]

Survey Process:

Note: This indicator applies to laboratories conducting research. Otherwise mention NOT APPLICABLE.

All research must be formally approved by the laboratory director in consultation with other team members. Review any research reports approved by the management team and support extended for research. For the setups not conducting research on their own, this may include sharing disease

[6] Where applicable.

related data with relevant authorities /research organizations, while ensuring patient confidentiality.

Compliance Requirements:

- ✓ Research approved by the management and its printed report OR
- ✓ Record of sharing disease related data with relevant authorities/research organizations while ensuring patient confidentiality.

Scoring:

- If there is documented evidence of research activities, then score as **fully met.**
- If there is no research of any kind conducted or underway, then score as **not met.**

GUIDELINES

Responsibility of Laying Down the Mission statement
Prototype mission statements are given below:

MISSION STATEMENT (Sample 1)
_____ ABC Laboratory is committed to providing patient focused, high quality services with state of the art technology to our customers and physicians in a safe and supportive environment. We advance patient care through research in compliance with the best laboratory practices.

MISSION STATEMENT (Sample 2)
The mission of ABC Laboratory is to provide superior, cost-effective testing and state of the art customer service in an environment that promotes compassionate care and contributes to coworkers' satisfaction. We strive to meet these goals by continuing to grow and adapt in order to consistently meet the needs of our community, patients, clients and health system.

MISSION STATEMENT (Sample 3)
To accomplish our vision, the mission of the Clinical Laboratory Program is to prepare professionals to demonstrate the highest quality of technical and clinical competence in serving their patients and the laboratory profession.

MISSION STATEMENT (Sample 4)
ABC Laboratory's mission is to TRANSFORM HEALTH AND HEALING by providing high quality, cost-effective, innovative laboratory services, which enhance patient health. The Laboratory supports clinical care, education, and research by demonstrating the core values of:
EXCELLENCE: in technology and consultative services,
CARING: by staff for those we serve, and
INTEGRITY: in our interactions with customers, colleagues, and ourselves.

SOP Template and Components
Each template contains a header, body and footer. Within the body of the template there are eight sections; Purpose, Scope, Policy, Definitions, Roles and Responsibilities, Procedures, References, and Appendices. Most sections either require, or provide the option to enter information specific to the organization/laboratory/section that will own the SOPs.
Emergency policies and SOPs should be aligned to the national policies announced during natural

calamities and outbreaks.

Header Information

The header information in the SOPs template is crucial to the identification and tracking of SOPs. These items must be completed and must follow the SOP identification and versioning practices utilized by the organization/laboratory/section which owns the SOP.

The header contains the organization name, SOP title, SOP identifier, and SOP version. Subsequent pages within each SOP will automatically be populated with header information once this section has been completed.

SOP Organization

The organization/laboratory name is the group that 'owns' the SOP. The owner can be thought of as the group with the authority to mandate the use of the SOP.

SOP Identifier (SOP ID)

The SOP identifier generally consists of a meaningful combination of letters and numbers. For example, MS06-SOP-001 might be the identifier used for Minimum Standards For Laboratories SOP #001.

SOP Version

In order to ensure that the most recent, approved document of a SOP is being used, the document must follow a numeric version control policy. Enter the current version (e.g. 1.0 0, 1.10, etc.)

Effective Date

The meaning of the term 'effective date' must be defined by the SOP owner.

Developing Laboratory Policy and Guidelines

The approach to establishing an effective health laboratory service requires addressing essential services at each level, including clinical health needs, required resources, staffing, equipment, and supplies.

Characteristics of SOPs

Sample Header

[Insert the name of the Organization, Department or Project which owns the SOP, the SOP identifier and the SOP Version below]

Organization:			
SOP Title:	Development, Implementation & Maintenance of Standard Operating Procedures (SOPs)		
SOP ID:		SOP Version:	

Section 1: Purpose

The purpose section contains standard, non-editable language.

Development, Implementation and Maintenance of Standard Operating Procedures (SOPs)

1. PURPOSE

The purpose of this document is to establish a uniform process for the preparation, review, implementation, and retirement of a standard operating procedure (SOP).

Section 2: Scope

The scope section contains standard, non-editable language with the option to include additional language that pertains to the scope.

2. SCOPE

This standard operating procedure applies to the development and maintenance of all laboratory SOPs and related appendices. The following procedures apply to all SOPs and associated documents, developed or revised after this SOP's effective date. [Optional: Insert any additional details necessary to further define the scope of this SOP

Section 3: Standard Operating Procedures

The policy section contains standard, non-editable language with the option to include additional policy statements.

3. STANDARD OPERATING PROCEDURES

This standard operating procedures comply with the MSDS prescribed by the KP HCC and is in line with the good clinical practices/OEM guidelines.

Refer to the relevant laws/regulations/rules/standards, as the case may be.

Section 4: Definitions

The definitions section contains standard, non-editable language with the option to include additional definitions.

4. DEFINITIONS

APPENDIX: Supplemental document providing information to support the requirements of a standard operating procedure.

Approval Date: The date on which the SOP is approved for use.

DEVIATION: Formally documented, unplanned departure from an SOP.

[Optional: Insert any additional definitions for technical or special terms used within this standard operating procedure that may not be familiar to the lay reader.]

Section 5: Roles and Responsibilities

The roles and responsibilities section contains standard, non-editable language with the option to add with new responsibilities to an existing role.

Adding responsibilities to an existing role:

5. ROLES AND RESPONSIBILITIES

All members of the organization are responsible for regularly reviewing the SOPs relevant to their job title and for completing any related, required training. In addition, any individual affected by the SOP may bring forward recommendations for the addition, revision or retirement of an SOP.

SOP Administrator(s)/Developer/Controller

An individual filling the SOP Administrator role is accountable for the creation, implementation and management of standard operating procedures. The Administrator or Designee shall be responsible for the following activities:

1. Ensures all routine operations and activities are documented by SOPs.
2. Initiates and/or approves proposals for SOP creation, revision and/or retirement.
3. Approves SOPs and associated documents.
4. Reviews SOP waivers and deviations.
5. Identifies roles/job titles within the organization for which a SOP is applicable.
6. Ensures that employees regularly review relevant SOPs and receive training as needed.
7. Documents and tracks SOP revisions and approvals.

[Optional: Insert any additional details regarding the responsibilities of the Administrator/Developer

To create additional responsibilities for an existing role, type the information in the new box.
Adding a new role and related responsibilities:

In this case, a single text box will hold the title of the new role and the responsibilities associated with the new role as under;

Additional Roles and Responsibilities

[Optional: Insert any additional roles and responsibilities that apply to this SOP]

Section 6: Procedure

The procedure section contains standard, non-editable category titles for a set of activities that must be addressed in the SOP.

6. PROCEDURE

Steps involved in the completion of all related procedures/tasks to be written in numbered form:

i.

ii.

iii. etc.

Archival Communication Plan

[Describe the process that is used to confirm a project is ready for archival, how that information is communicated and to whom (e.g. study, sponsor, IRB, etc.)]

Section 7: References

The references section contains standard, non-editable language with the option to include additional references.

7. REFERENCES

MSDS Code, standard/indicator to which SOP relates/complies

[Optional: Insert any additional SOP references]

Section 8: APPENDICES

The appendices section contains standard, non-editable language with the option to include additional language that pertains to any new appendices developed. To create additional appendices, type the information in the new box.

8. APPENDICES

[Optional: Insert any appendices properly numbered/referred to the context to enhance facilitation in implementation]

Sample Footer

_____	_____	_____
Approver Name	Approver Signature	Effective Date

Objectives of the Laboratory

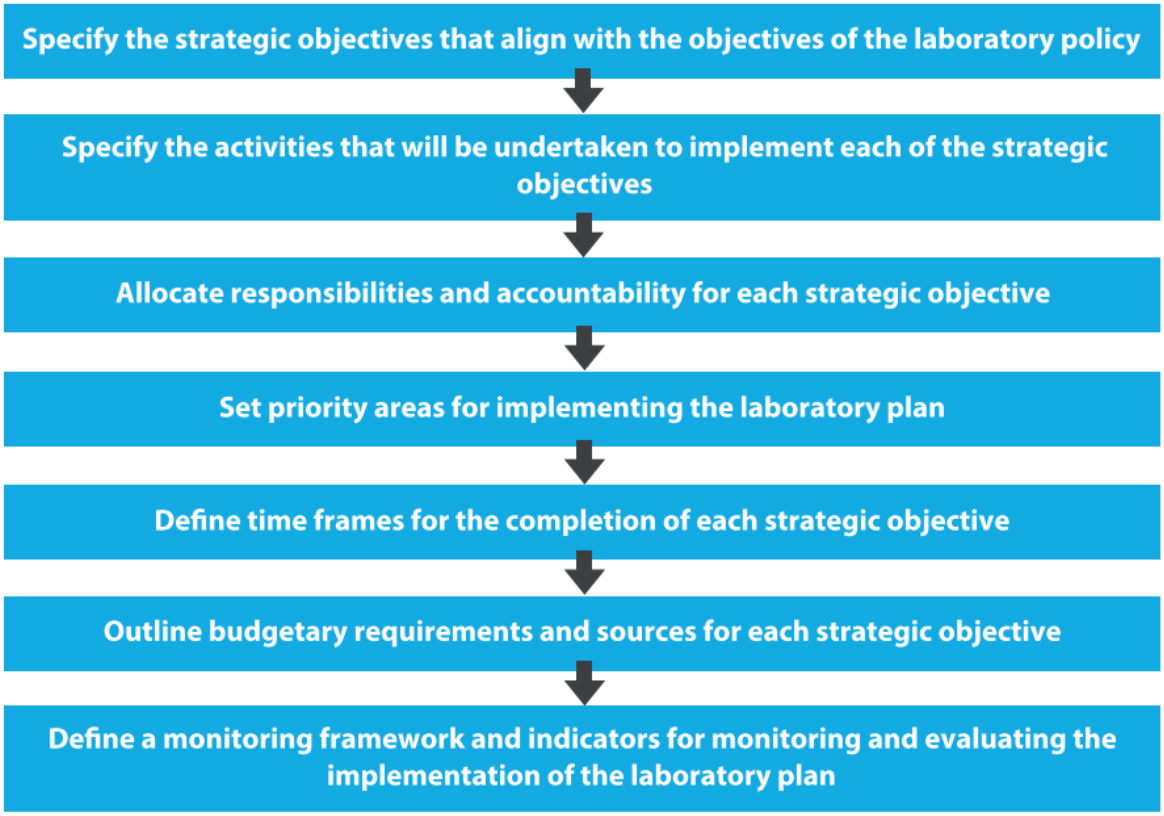
1. To affirm commitment and support for the organization and management of efficient, cost-effective and sustainable laboratory services.
2. To strengthen laboratory services for supporting diagnosis, treatment, surveillance, prevention, and control of diseases.
3. To establish standards for laboratory quality systems.
4. To ensure the quality of the laboratory services through an established QA system.
5. To empower the establishment, implementation and monitoring of the laboratory plan.
6. To ensure adequate financial and human resources to meet the requirements of the laboratory services.
7. To commit to ethical values in laboratory practice, including patient confidentiality, adherence to professional codes of conduct and ethical research practices.
8. To encourage research and collaboration to inform and improve the quality of laboratory services.
9. To monitor the implementation of the bio-risk, bio-safety management and mitigation plan.

Developing a Laboratory Plan

The laboratory plan should be carefully designed, realistic and practical, and include a time frame for implementation with the necessary indicators, budgetary allocations and designated partners. A step-wise approach to development is more likely to be sustainable and capable of contributing to the achievement of health system goals.

The process of developing a laboratory plan should include the following steps:

Figure 1: Process of Developing a Laboratory Plan



Standard Operating Procedures

Laboratories must have written standard operating procedures (SOPs). All lab personnel, who perform operations, need to document that they have read and understand all SOPs relevant to their work. New employees should be given hands-on training which should include all relevant SOPs.

The Benefits of SOPs

1. Important for training new staff
2. Efficient workflow
3. Address safety concerns
4. Minimize chances of miscommunication
5. Minimize variability in test results
6. Minimize failed test runs
7. Serve as a vital part of a laboratory quality assurance program

Budget Allocation

Budget formulation, including forecasting and finalizing the budget, is the responsibility of the senior management.

Budgeting refers to the allocation of capital and setting the expenditure with respect to the laboratory's core functions to achieve the set or designated targets. The budget needs to be focused and prepared to cover all of the financial requirements and to cover any of the future investment plan(s). The routine and daily expenses will have appropriate allocation so that the future investments do not affect the scheduled existing expenses of the laboratory.

A budget process refers to the process by which organizations create and approve a budget, ensuring that these remain aligned with the rules and regulations, which is as follows:

1. The Finance Department of the lab prepares worksheets to assist the section in-charges for preparation of sectional budget estimates.
2. The Director calls a meeting of the section incharges and they present and discuss plans for the following year's projected level of activity.
3. The section incharge can work with the Finance Department, or work alone to prepare an estimate for their sections for the coming year.
4. The completed budgets are presented by the section incharges to their Directors/HODs for review and approval.

Budgeting Technique

Most organizations/institutions produce incremental budgets (i.e. using historic budgets and adding effect for inflation). Although this kind of budgeting is timely and less-costly to prepare, it might mean that unnecessary activities in the past will still be carried out. Zero-based budgeting (ZBB) can detect inflated budgets by eliminating wasteful and obsolete operations/activities, since every line of the budget has to be justified in order to align it with the overall strategic goal. Every item is reviewed and approved on a need- basis rather than history. This can also increase coordination and communication in the laboratory, as well as aligning staff with strategic goals.

Steps of Budgeting Process

The six key-steps to internal budgeting are:

1. **Objectives**
   Defining objectives, process outline, expected results.

2. **Preparation**
   Finding actual operational statistics of every department/section. For example, the number of tests performed in different sections of the laboratory, kits/chemicals and other consumables issued from stores, deciding budget statistics, establishing costs and understanding the nature of work.

3. **Authorization**
   Head of Finance Section, Accounts Officer, Department Manager.

4. **Implementation**
   Allocation of funds, creating a guideline, limiting expenditure.

5. **Monitoring and reporting**
   Comparing budgeted costs and revenue with the actual, reporting any variance.

6. **Review**
   Investigating any variance, controllable or non-controllable (e.g. maintenance, utilities, etc.)

Monthly Statement of Expenditure (SOE)

The SOE is a reconciled statement of expenditure prepared monthly by the official/officers managing the finances, usually by the date defined by the organization and submitted to the next

higher office.

Organizational Chart (Organogram)

An organizational chart (often called an Organogram) is a diagram that shows the structure of an organization and the relationships and relative ranks of its departments and positions/jobs. An organizational chart gives a clear line of authority showing where subordinates are accountable to their immediate supervisors.

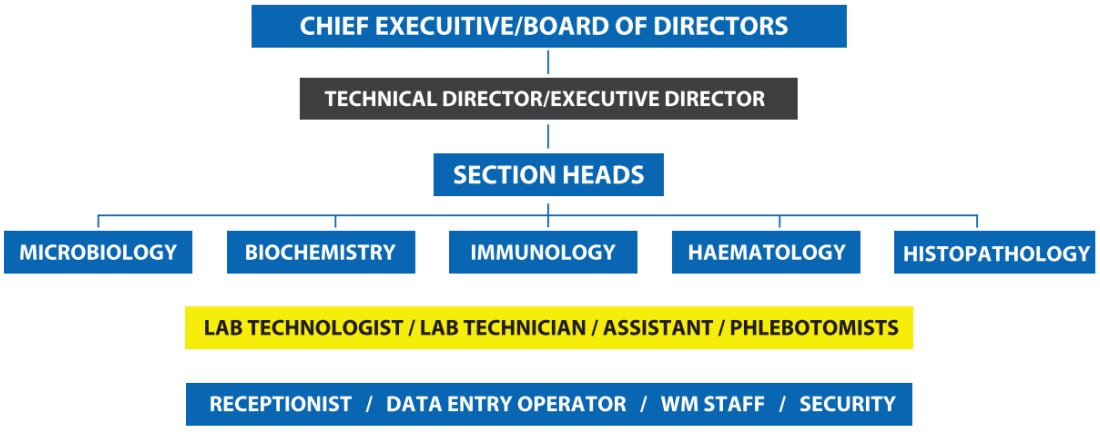
An organizational structure determines the manner and extent to which roles, responsibilities and power are delegated, controlled, and coordinated, and how information flows between various levels of management.

The organizational chart has been described as looking like a tree, with the roots representing the management (directors) while the branches symbolize various sections and the leaves depict the staff workers. A good organizational chart of a laboratory should clearly depict:

1. Functions/Services
2. Relationships
3. Responsibilities
4. Authorities
5. Communications
6. Span of control

Laboratories should have a policy for regularly reviewing (annually) and updating the organogram in terms of changes in positions. The organogram should be displayed at all relevant places and be available with the pertinent staff.

Figure 2: Sample Laboratory Organogram



Laboratory section heads bring together their knowledge and skills of laboratory procedures and safety to ensure that each section of the laboratory operate smoothly.

A person to be appointed as **laboratory section incharge** should be properly qualified and experienced. The person should have post-graduation qualification relevant to the level/scope of services and should have at least 3 years of experience in the relevant field.

These professionals complete an array of duties which mainly include:

1. Overseeing technical procedures.
2. Scheduling staff.
3. Re-ordering supplies.
4. Monitoring of laboratory standards and controls.

5. Train laboratory technicians and assistants on the correct procedures and use of laboratory equipment, in addition to mentoring and disciplining lab staff.
6. Section incharge also makes sure that employees follow standards and safety regulation and incorporate discussions into lab group meetings for continuous improvement of best laboratory practices.

Research in laboratory is a process of gathering information, gaining knowledge about disease diagnosis for the purpose of initiating and modifying diagnostic criteria for continually raising the standards of the laboratory. All research, including the protocols, must be formally approved by the senior management of the laboratory. Research reports are submitted to the director/section Incharge that document the research activities. It also needs to be verified that those responsible are providing guidance, resources and budget, fulfilling all legal and ethical requirements of research. It is important that laboratories undertake research which is relevant to improvement in healthcare services and medical education by analyzing the available data. The written research methodology must conform to the approved national/international guidelines.

Those who are not directly conducting the research activities should at least provide the disease related data to concerned higher authorities for epidemiological studies.

Assessment Scoring Matrix

Standard 3. ROM. 3: Responsibilities of management are defined.

Indicator 7-13		Max Score	Weightage (Percentage)	Score Obtained
Ind 7.	**Those responsible for lab management lay down the laboratory's mission statement.**	10	**80%**	
Ind 8.	**Those responsible for management lay down a detailed laboratory policy and standard operating procedures (SOPs).**	10	**100%**	
Ind 9.	**Those responsible for management lay down an emergency policy and standard operating procedures (SOPs).**	10	**80%**	
Ind 10.	**Those responsible for management approve sufficient laboratory budget and allocate the resources required to accomplish the mission.**	10	**100%**	
Ind 11.	**Those responsible for management establish the laboratory's organogram.**	10	**80%**	
Ind 12.	**Those responsible for management appoint the section heads in the laboratory.**	10	**80%**	
Ind 13.	**Those responsible for management support research activities.**	10	**100%**	
Total		70		

2.2 Facility Management and Safety (FMS)

03 Standards & 11 Indicators

A clinical laboratory not only serves the medical needs of the society but also generates revenues for the organization that are utilized in meeting expenses and further expansions. A well-managed facility therefore, will not only provide quality services to the patients and clinicians, but will also produce better revenue for the laboratory. Since the patient outcome is largely dependent on the precise diagnosis on the basis of laboratory test/analyses reports, there is a rising need to have excellence in services in the clinical laboratories and hospitals. It is therefore, highly desirable that clinical laboratories meet at least the minimum acceptable working standards and all the equipment meets the required precision level. It is imperative that qualified professionals handle and maintain these facilities in accordance with the relevant standards as the reliability of the results, professionalism and repute of the laboratory depends on these services and facilities.

It is incumbent on the clinical laboratory management to maintain a clean and healthy lab environment and keeping the facility running in an orderly manner. Laboratories can use financial management software for maintaining a balance in the revenue and expenses and tracking the amount spent on purchase/maintenance of expensive testing equipment, on the maintenance of building and power generation, etc. to efficiently manage costs. The management needs to respond quickly and efficiently to service and preventive maintenance by setting up schedules in order to provide uninterrupted services in a clean and healthy environment.

Standard 4. FMS-1: The management is aware of and complies with the relevant laws, bylaws, rules and regulations, and facility inspection requirements under the relevant building and associated codes applicable to laboratories

Indicators (14-16):

Ind 14. The management is conversant with the relevant laws and regulations and knows their applicability to the laboratory

Survey Process:

The surveyor may demand copies of the relevant laws and regulations which should include building, fire safety, and safety requirements for lifts/elevators, as and where applicable. Through observation and discussion, confirm the awareness of the management and staff about laws, regulations and rules and how these are applicable to the laboratory.

Compliance Requirements:

- ✓ Copies of current/updated relevant laws, regulations and rules available **(Annexure B)**.
- ✓ Laboratory staff is aware of the relevant laws, regulations and rules and knows how those relate to their functioning.
- ✓ Compliance of relevant laws, regulations and rules is observable.

Scoring:

- If copies of relevant laws and regulations are available and there is clear evidence of compliance with fire safety and other building code specifications, relevant laws and regulations and the operational staff are aware of the requirements, then score as **fully met.**
- If there is awareness of the requirements of the applicable laws and regulations but incomplete compliance up to 80%, then score as **partially met.**
- If copies of rules and regulations are not available in the laboratory, then score as **not met.**

Ind 15. The management regularly updates any amendments in the prevailing relevant laws and rules

Survey Process:

Surveyors are required to check for evidence of routinely updated laws, rules and regulations. This needs an updated copy/amendment done accordingly, duly signed for authenticity of record.

Compliance Requirements:

✓ Evidence that a process to keep the relevant laws, regulations and rules properly updated is adopted.

Scoring:

- If updated versions of relevant laws and regulations are available, then score as **fully met.**
- If updated versions of relevant laws and regulations are not available, then score as **not met.**

Ind 16. The management ensures implementation of the laws and regulations

Survey Process:

The general requirements listed in various rules and regulations illustrate some of the basic health and safety elements to be implemented in all new and remodeled buildings to be used as laboratories. Check to see if documentation supports implementation and that this is confirmed with observable examples.

Compliance Requirements:

✓ Evidence that the relevant laws, regulations and rules are properly implemented, for example:

- Implementation of Khyber Pakhtunkhwa Hospital Waste Management Rules, 2018, in such a way that all key requirements are clearly observable.
- Compliance of the building, fire safety, and safety requirements for lifts/elevators.

Scoring:

- If there is evidence of implementation of all prevailing laws and regulations, then score as **fully met.**
- If there is up to 80% compliance, then score as **partially met.**
- If there is less than 80% compliance, then score as **not met.**

GUIDELINES

Applicability of Laws and Regulations to the HCE

The basic design of a clinical laboratory is ideally required to support its functions, e.g.:

1. Reception and waiting areas
2. Incharge lab office
3. Sample collection areas
4. Lab diagnostic sections
5. Record section
6. Storage, supply and other support/back up services
7. Civic services
8. Parking areas

The legal aspect is one of the most significant considerations in planning and designing a building. Architects, engineers, planners, and those in allied professions, need to have working knowledge

of the applicable laws, rules and regulations and relevant codes.

In the public sector, the **Communication and Works Department (C&W)**, having an architect section headed by the Chief Architect, is the main governmental body responsible for planning and designing hospital/laboratory/related buildings.

In the private sector hospital/laboratory buildings are designed by the architectural firms and the designs are approved by the local government authorities, as per the applicable codes. In either case, designing and planning of the laboratory should be done in accordance with the relevant laws/regulations and codes, including the following:

1. Zoning Regulations with the land-use map (Guidelines for Development and Operations), ensure that the site selected is located in the area appropriate for the intended use. A planner/designer who designs a site plan must consider the following aspects of the project while remaining within zoning restrictions of the law pertaining to the locality:
   i. Access and accessibility
   ii. Catchment area population to be served
   iii. Volumetric dimensional limits of the building in terms of site coverage
   iv. Building height
   v. Distance of other facilities and utilities required
   vi. Easements and rights of way, if any
   vii. Sources of materials and of local skilled and unskilled labor

Although such regulations constrain design, they also establish the criteria that help to evolve a design which is consistent with the overall plan for the community, without disturbing the local ethics and environment while ensuring safety.

2. The building code is prescribed to achieve maximum safety in building construction to ensure that it can withstand powerful earthquakes and other calamities and cover the following:
   i. Classification and general requirements for laboratory by use or occupancy
   ii. Types of construction
   iii. Light and ventilation
   iv. Labor safety and welfare during construction and Sanitation
   v. Electrical and mechanical regulations
   vi. Design, keeping in view the history of incidence of earthquakes, cyclones and other disasters/calamities
   vii. Protection from hazardous material
   viii. Permits and inspection requirements
   ix. Any other code prescribed by the state

3. The fire safety code is provided by the Directorate of Civil Defense and adheres to the following provisions in order to minimize injury, death, and loss to the staff, patients and families, and also to curtail damage to the laboratory infrastructure:
   i. General precautions against fire
   ii. Principles of fire safety in buildings/structures
   iii. Fire protection appliances
   iv. Maintenance of fire exits
   v. Purpose specific design of high-rise buildings
   vi. Suppression control in hazardous areas

vii. Specifying smoking areas as per provisions of relevant law/rules
viii. Management and use of combustible materials

4. Movement of Patients, Attendants and Visitors
   i. Patients should be requested not to leave or go beyond patient waiting or sample collection areas.
   ii. Children should have an attendant, preferably a female.
   iii. All visitors should enter and leave the laboratory only through the main entrance.

Other relevant bylaws, regulations and codes include **sanitation codes, environmental protection laws and water codes.** These vary in form and content according to the requirements and need of the laboratory.

The following international standards can be consulted while designing the laboratory:

1. Facility Guideline Institute (FGI) Guidelines for Design and Construction of Laboratories and Health Care Facilities
2. International Building Code (IBC)
3. National Fire Protection Agency (NFPA)
4. The Americans with Disabilities Act (ADA)
5. Occupational Safety and Health Administration (OSHA)
6. **Inspection of Laboratory Design.** The lab administration can hire some professional private construction company for inspection of the building design in addition to the indigenous systems of inspection. During inspection, application of national/international building codes, where necessary, may be checked in addition to the following parameters:
   i. The land or site upon which the laboratory is being constructed
   ii. Design or structure of the laboratory
   iii. Use of standardized raw material and its consumption
   iv. Methods of construction or workmanship
   v. Sanitation codes, environmental protection laws and water codes
   vi. Minimum standards for the width/size of the doors, aisles, passageways, stairways, or other means of exit
   vii. Structural strength or the stability of the building to withstand any damages by fire, earthquake, wind, flood, or by any other cause

Compliance with Legislation and Regulations

HCEs/Labs are required to abide by the relevant laws like waste management, infection control, building codes, etc. to ensure the safety and comfort of patients and care providers. It is the responsibility of the senior management to be familiar with these laws/rules/regulations, any amendment thereto and ensure the same by other relevant staff for implementation.

Risk Management

Every organization, depending on its size, is required to assign one or more individual/s to provide an oversight for planning and implementation of the requirements of all aspects of the risk management program, including the following features, in a consistent and continuous manner:

1. Planning all aspects of the program
2. Implementing the program
3. Educating the staff

4. Testing and monitoring the program
5. Periodical review and revision
6. Annual reports to the governing body/board on the effectiveness of the program
7. Providing consistent and continuous management support

This is particularly important during the construction or renovation of a facility for which qualified engineering services should be mandatory.

Assessment Scoring Matrix

Standard 4. FMS. 1: The management is aware of and complies with the relevant laws, by laws, rules and regulations, and facility inspection requirements under the relevant building and associated codes applicable to laboratories.

Indicator 14-16		Max Score	Weightage (Percentage)	Score Obtained
Ind 14.	**The management is conversant with the relevant laws and regulations and knows their applicability to the laboratory.**	10	**80%**	
Ind 15.	**The management regularly updates any amendments in the prevailing relevant laws and rules.**	10	**100%**	
Ind 16.	**The management ensures implementation of these requirements.**	10	**80%**	
Total		30		

Standard 5. FMS-2: Facility work flow design conforms to the scope of services

Indicators (17-18):

Ind 17. Space allocation and effective separation between administrative and technical laboratory areas

Survey Process:

The primary objective in laboratory design is to provide a safe and facilitative environment for laboratory personnel to conduct their work. There should be sufficient separation/demarcation between administrative and technical areas. The administrative area has offices, reception/patient waiting area, etc., whereas the technical area includes sample collection, sample processing/testing and reporting areas which should have unidirectional work flow. Physically check the laboratory layout for sufficient separation and space allocation for each area and different sections of the laboratory.

Compliance Requirements:

- ✓ Laboratory design/layout that ensures:
  - Safe environment for patients and the staff
  - Clear separation of technical areas and administrative/patient waiting areas.

Scoring:

- If there is sufficient space and clear separation of different administrative and technical areas, then score as **fully met.**
- If there is insufficient space and separation between administrative and technical areas, then score as **not met.**

Ind 18. Measures are taken to restrict movement of the technical staff working in different sections of the laboratory

Survey Process:

The surveyors are required to have knowledge regarding the risk of transmission of infections to the patients/clients or other persons which may be present in the reception/waiting areas and the required biosafety measures. The staff working in different lab sections may exit from the working area only after ensuring that their hands, gloves, aprons, cloths or foot wear etc, are not contaminated with specimens/chemicals. The surveyors should look for the measures adopted by the laboratory to ensure the same. The laboratory staff on duty should be identifiable and follow the written directions regarding controlling their movements and direct interaction with patients/clients.

Compliance Requirements:

- ✓ Staff wears the ID badges during duty.
- ✓ Written SOPs for the staff regarding exiting the workplace for any interaction with patient/client available.
- ✓ Display of the SOPs prominently at the exit/entry point of each section.
- ✓ Staff awareness about the SOPs.

Scoring:

- If all of the above requirements are complied with, then score as **fully met.**
- If any one of the above requirements is not complied with or surveyors have reasons to believe that there is non-compliance of the above, then score as **not met.**

GUIDELINES

The primary objective in laboratory design is to provide an environment to facilitate the laboratory personnel to conduct their work and at the same time, ensure the safety of patients/clients and the environment. There should be clear demarcation between administrative and technical areas. The administrative area may include offices, reception and patient waiting area etc. whereas the technical area includes sample collection, sample processing and testing sections. For effective separation of technical areas from the administrative areas and for fulfilling the biosafety requirements, a combination of the following measures needs to be taken:

1. Control the entry of patients/clients into the technical working areas by employing usual administrative controls e.g. by keeping the doors closed.
2. Controlling the exit of the technical staff working in the lab sections to directly interact with the patients/clients to minimize chances of transferring any contamination/ infection.
3. Taking due precautions when such interaction is essential.
4. Laboratory staff should wear ID cards bearing employee's ID picture, name and designation.
5. Lab staff to follow the dress code.
6. Properly manning the entry and exit gates.

Assessment Scoring Matrix

Standard 5. FMS-2: Facility work flow design conforms to the scope of services.

Indicator 17-18		Max Score	Weightage (Percentage)	Score Obtained
Ind 17.	**Space allocation and effective separation between administrative and technical laboratory areas.**	10	**100%**	
Ind 18.	**Measures are taken to restrict movement of the technical staff working in different sections of the laboratory.**	10	**100%**	
Total		20		

Standard 6. FMS-3: The laboratory has plans for fire and non-fire emergencies within the sections

Indicators (19-24):

Ind 19. Plans and provisions for early detection of fire and non-fire emergencies exist[7]

Survey Process:

Review the plan to ensure that it addresses the requirement of detection of fire and non-fire emergency situations. Then, by observation, review of documentation and interview, determine if the requirements are in the knowledge of all staff.

Compliance Requirements:

- ✓ Plan for fire and non-fire emergencies.
- ✓ The plan addresses the requirement of early detection of fire and non-fire emergencies.
- ✓ The provisions to detect the above emergency situations at an early stage as laid out in the plan, e.g.:
  - Smoke detector/s.
  - Monitoring through CCTV cameras.
  - Trained staff physically deployed to ensure the required outcome.
- ✓ The staff is aware of the plan.

Scoring:

- If the plan and provisions to detect the above emergency situations at an early stage exist and staff is aware of it, then score as **fully met.**
- If the emergency plan does not exist, then score as **not met.**

Ind 20. Provisions for abatement of fire and non-fire emergencies exist

Survey Process:

Review the plan to ensure that it addresses the requirement of abatement of fire and non-fire emergencies. Then, by observation, review of documentation and interview, determine if the requirement(s) have been implemented.

Compliance Requirements:

- ✓ A plan providing for an environment which has lesser chances of occurrence of fire and non-fire emergencies viz:
  - There is no loose electric wiring to cause short circuiting.

[7] Applicability to be explained in the RM.

- No loose plugs and sockets which can spark.
- No power cord(s) that is/are worn out to cause electrocution.
- Ramps, if they exist, are non-slippery.
- Stairs have supporting rails, etc.
- Building meets the local construction standards.

Scoring:

- If the plan includes the requirements and there is evidence that these are implemented, then score as **fully met.**
- Since this is an important patient safety issue, if the requirement is not included in the plan, or if not clearly implemented, then score as **not met.**

Ind 21. Provisions for containment of fire emergencies exist

Survey Process:

Provision of emergency containment resources should be checked by the surveyors e.g. water, sand buckets, fire extinguishers, etc.

Compliance Requirements:

- ✓ Water source/buckets
- ✓ Sand buckets
- ✓ Shovel
- ✓ Fire extinguisher(s)
- ✓ Fire blankets

Scoring:

- If all above arrangements are present, then score as **fully met.**
- If there is non-availability of any of the above fire emergency containment resources, then score as **not met.**

Ind 22. Displayed safe exit points in case of fire and non-fire emergencies exist

Survey Process:

The surveyor is required to observe availability of displayed safe exit points. Physically check emergency exits and also make sure that there are no obstructions in front of emergency exits. Awareness of staff is checked through interviews regarding emergency evacuation points.

Compliance Requirements:

- ✓ Emergency exit points 24/7 illuminated sign board(s) displayed as required.
- ✓ No obstructions at any time on the emergency exits.
- ✓ Staff is aware of the emergency exits.

Scoring:

- If the safe exit points are displayed and staff is aware, then score as **fully met.**
- If the safe exit points are not displayed and/or staff is not aware, then score as **not met.**

Ind 23. Mock drills are held at least once in a year

Survey Process:

Regular 'mock' drills should be conducted in different shifts and sections of the laboratory. The drills should be fully documented, noting the staff involved, major observations and any subsequent changes to the system including the structures, provisions and plans (as applicable). Look for documented evidence that 'mock' drills are conducted at least once a year. This survey team may physically observe the mock drill by giving an unannounced emergency alarm where the record confirms that all staff was subjected to the mock drill.

Compliance Requirements:

- ✓ Record of mock drills/attendance.
- ✓ Record confirms that all staff was subjected to the mock drill.
- ✓ Record of corrective actions taken after mock drills.

Scoring:

- If there is documented evidence that mock drills were held at least once in the past one year and that they involved the staff in different sections and shifts, then score as **fully met.**
- If no mock drill is conducted or there is/are non-conformities with the above, then score as **not met.**

Ind 24. Staff members are trained for their role in case of such emergencies

Survey Process:

Staff members are trained for dealing with fire emergencies. They are to be imparted certified trainings preferably by Rescue 1122/Civil Defense/any other recognized body. Look for documentation/certificates of the trainings which include at least key personnel in every duty shift.

Compliance Requirements:

- ✓ Record that confirms participation of at least the key staff from each shift.

Scoring:

- If there is documented evidence of training of staff from every duty shift, then score as **fully met.**
- If trained personnel are not available in every duty shift, then score as **partially met.**
- If no training is imparted, then score as **not met.**

GUIDELINES

Emergency Plans

The organization shall:

1. Have a fire plan covering fire arising out of burning of inflammable items, explosion, electric short circuiting or acts of negligence or due to incompetence of the staff on duty.
2. Deploy adequate and qualified personnel for implementation of the plan.
3. Acquire adequate firefighting equipment and ensure that records are kept up to date.
4. Have an adequate training program.
5. Have schedules for, and conduct, mock fire drills.
6. Maintain mock drill records.
7. Explicitly display exit plans.
8. Have an alarm and dedicated emergency illumination system, which come into effect in case of fire.

Necessary Items and Equipment

1. Fire-proof blanket
2. Safety shower
3. Buckets with sand
4. Portable fire extinguishers are essentially of two types; Carbon Di-oxide (CO2) and Bromo-chloride-fluoromethane (BCF, halon, halogenated hydrocarbons) and can be used without causing damage to electrical equipment. The extinguishing power of halon is about 6 times that of CO2. Water has the disadvantage that it conducts electricity, whereas powder extinguishers (containing salts) cause damage to instruments.

Actions

1. When fire is detected, stay calm, try to oversee the situation and watch out for danger. Then the following actions should be taken in this order:
   i. Close windows and doors.
   ii. Give fire alarm (shouting, telephone, fire alarm).
   iii. Rescue people (and animals if present).
   iv. Switch off electricity and/or gas supply.
   v. Fight fire, if possible, with at least two persons.
2. Persons with burning clothing should be wrapped in a blanket on the floor, sprayed with water or be pulled under a safety shower. A CO_2 fire extinguisher can also be used, but do not spray on the face.
3. When using fire extinguishers, it is important that the fire is fought at the seat of the fire i.e. at the bottom of the flames, not in the middle of the flames.
4. If gas cylinders are present, there is the danger of explosion by overheating. If they cannot be removed, take cover and try to cool them with a fire-hose. When the situation looks hopeless, evacuate the building. Let everybody assemble outside and check that no one is missing. To practice this, a regular mock fire drill (once a year), should be held.

   The following things should be present in lab premises to address emergency situations:
   i. Fire extinguishers
   ii. Sand buckets

iii. Emergency exits
iv. Displayed emergency contact numbers
v. Trained human resource

Emergency Exit Plan

All workplaces should have adequate exits and unobstructed escape routes in case of fire. The number of exits required for all employees to exit safely depends on several factors, including whether the facility uses substances that are at a high risk for combustion, the layout of the building and the type of construction materials used. Fire exit signs must also be posted.

All hospitals/laboratories must have at least two clearly marked exits, so if one is blocked during a fire, the other may be used and obstructions must be kept away from exits at all times.

The organization shall take care of non-fire emergency situations by identifying those and deciding appropriate course of action. These may include:

1. Earthquakes
2. Civil disorders effecting the HCE
3. Terrorist attacks
4. Invasion of swarms of insects and pests
5. Invasion of stray animals
6. Hysteric fits of patients and/or relatives
7. Anti-social behavior by patients/relatives
8. Temperamental disorders of staff causing deterioration in patient care
9. Spillage of hazardous (acids, mercury, etc.), infected materials (used gloves, syringes, tubing, sharps, etc.) and medical wastes (blood, pus, amniotic fluid, vomits, etc.)
10. Building or structural collapse
11. Fall or slips or collision of personnel in the corridors
12. Fall of patient from the bed/stretcher
13. Bursting of pipelines
14. Sudden flooding of areas like basements due to clogging in pipelines or heavy rains
15. Sudden breakdown in the supply of electricity, gas, vacuum, etc.
16. Bursting of boilers and/or autoclaves

The HCE shall prepare and act according to the specific instructions of the Health Department regarding allocation of beds, calling staff on emergency duty and ensuring uninterrupted supplies, etc. in case of war related emergencies.

The HCE shall establish liaison with civil and police authorities, Rescue 1122 and the fire brigade, as required by law for enlisting their help and support in case of an emergency.

Emergency Exit System

1. The floors of beams of egress shall be illuminated at all points including angles and intersections of corridors and passageways, landings of stairs and exit doors with bulbs of not less than one thousandth (0.001) lumens per square centimeter.
2. Lighting source is of reasonably assessed reliability, such as public utility electric service.
3. Emergency lighting facilities maintain the specified degree of illumination in the event of failure of the normal lighting for a period of at least one hour.
4. Illuminated "EXIT" signs – distinctive in color, reliable source – 5000th lumens $(0.005)/cm^2$.
5. Size of signs – plainly legible letters not less than fifteen centimeters high with the principal

strokes of letters not less than nineteen millimeters wide.

6. Provide luminous directional exit signs located one foot or below floor level.
7. There should be separate ingress and egress routes.
8. Corridors, hallways and aisles must be 2.4 meters in width.
9. Use of ramps as access to second and higher floors.
10. Stairways with safe and adequately secured railings.
11. Stairway must be at least 112 cm. wide and made of concrete.
12. Any opening in any wall shall be protected by fire doors or fixed wire glass windows. It must have protection for vertical openings also.

Any door in a stairway, ramp, elevator shaft, stairway enclosure or light and ventilation shaft or chute, shall be self-closing, and shall normally be kept closed.

Simulation Exercises/Mock Drills

The following actions should be taken to comply with the standards:

1. **Simulation exercises/mock drills are conducted on all shifts in all buildings.**
   Simulation exercises are conducted in all locations on each shift. For the hospital, drills on top and network floors are conducted so that the area of fire origination is evaluated along with the floor above and below. All drills are reviewed for the purpose of identifying deficiencies and for improvement. Unless specifically arranged, all mock drills are unannounced.
2. **At least 50% of the required drills are unannounced.**
   Management maintains a schedule of drills which is designed to cover all areas of the facility. The designated Fire Safety Manager reviews the schedule and makes adjustments based upon drill performance and real events.
3. **All simulation exercises/mock drills are critiqued to identify deficiencies and opportunities for improvement.**
   Health and Fire Safety staff coordinates fire drills, which includes critiques. Designated fire wardens observe staff reaction and participation. After the drill, the lead fire warden conducts a debriefing with the nurse in charge and/or the fire warden, advising of any problems or areas for improvements. A report of the drill is maintained identifying what went well and opportunities for improvements and tracks their progress.
4. **The effectiveness of the fire response training according to the fire plan is evaluated at least annually.**
   The health and safety committee completes an annual evaluation of the environment of care. A score is utilized to rate compliance to the main elements of the standards.
5. **During fire drills, staff knowledge is evaluated, including the following:**
   i. When and how to sound fire alarms (where such alarms are available).
   ii. When and how to transmit for offsite fire responders.
   iii. Containment of smoke and fire.
   iv. Transfer of patients to areas of refuge.
   v. Fire extinguishment.
   vi. Specific fire response duties.
   vii. Preparation for building evacuation.

Table 3: Sample Format of a Fire Drill Report Fire Alarm/Fire Drill Report

Sample Format of a Fire Drill Report Fire Alarm/Fire Drill Report

To be completed after every alarm or drill by the designated fire safety officer

Date: _____ Time: _____

Location of alarm/fire sign: _____

Name of person triggering the alarm: _____

1) Rounds of floors made by:

1st Floor: _____2nd Floor: _____

Doors closed: _____

Hallways cleared: _____

Visitors/Patients instructed appropriately: _____

Staff knows how and when to turn off the electric and gas supply:

_____

Fire extinguishers on proper location: _____

Staff was aware of the location of the fire and prepared to evacuate through appropriate exits:

_____

Staff from departments other than nursing at appropriate posts: _____

Staff co-operation:_____

2) Reason for alarm (if not a planned drill):

3) Communication to switchboard:

4) Additional comments:

5) Problems identified/recommendations:

Signed: _____ Position: _____

Training in Emergency Situation Handling

The training shall include various classes of fire, information and demonstration on how to use a fire extinguisher and the procedure to be followed in case of fire and non-fire emergencies.

1. All laboratory staff, including technical and managerial, are required to attend a training on fire fighting.
2. Specific roles and responsibilities of staff and volunteers at a fire's point of origin regarding raising of alarm in their area.
3. Specific roles and responsibilities of staff and volunteers away from a point of origin of fire. The staff is trained to be on standby for further instructions and prepare the area in case an evacuation is necessary. At a minimum, keep patients and visitors calm and informed, close doors in the department to limit the spread of smoke from a fire and clear corridors to ensure a clear evacuation route. In off-site facilities, staff, patients, and visitors exit to the exterior of the building, no matter where the fire is located.
4. Specific roles and responsibilities of staff and volunteers in preparing for building evacuation. In the event of a total building evacuation, it is the responsibility of each area's director/manager/ supervisor to ensure that the staff is trained and responsible to first evacuate patients from the immediate fire area and that patients are accounted for. This normally includes the room that is on fire, rooms on either side or the room directly across the hall, closing all other room doors for temporary protection. They will then proceed with full compartment evacuation to the adjacent safe compartment.

Assessment Scoring Matrix

Standard 6. FMS-3: The laboratory has plans for fire and non-fire emergencies within the sections.

Indicator 19-24		Max Score	Weightage (Percentage)	Score Obtained
Ind 19.	**Plans and provisions for early detection of fire and non-fire emergencies exist.**	10	**100%**	
Ind 20.	**Provisions for abatement of fire and non-fire emergencies exist.**	10	**100%**	
Ind 21.	**Provisions for containment of fire emergencies exist.**	10	**100%**	
Ind 22.	**Displayed safe exit points in case of fire and non-fire emergencies exist.**	10	**100%**	
Ind 23.	**Mock drills are held at least once in a year.**	10	**100%**	
Ind 24.	**Staff members are trained for their role in case of such emergencies.**	10	**80%**	
Total		60		

2.3 Human Resource Management (HRM)

06 Standards & 16 Indicators

The standards under Human Resource (HR) are intended to ensure that the clinical laboratory determines the qualifications and competencies for staff positions that match the organization's mission and workload. The laboratory management must provide the right number of qualified staff to meet the routine workload and emergency requirements. To meet this goal, the standards require the laboratory to plan for staffing, conduct orientation to educate and train staff, assess, maintain, and improve staff capability and promote self- development and learning. There may be a well-organized HR section or HR management department as per workload of laboratory. The major functions of the HR section include not merely hiring and firing of the staff, but in fact also to develop the HR pool as an important asset for the laboratory itself in particular and for other organizations in general.

Standard 7. HRM-1: Staff deployment is in accordance with the scope of laboratory work

Indicators (25-27):

Ind 25. Job description for every post is identified and documented

Survey Process:

A Job Description (JD) is a listed description that a person uses to define tasks or functions and responsibilities of a position. A JD is usually developed by conducting a job analysis, which includes examining the tasks and sequences of tasks necessary to perform the job. It will be determined and documented for every post.

Compliance Requirements:

- ✓ Documented individual JDs.
- ✓ Every JD bears the signatures of the employer and the concerned employee.

Scoring:

- If all posts have a documented JD, then score as **fully met.**
- If there is no JD or there are non-compliances, then score as **not met.**

Ind 26. Eligibility criteria regarding qualification and experience for each job is available

Survey Process:

Eligibility criteria are the requirements in terms of qualification and experience that must be met by an individual to be appointed against a post. Check that the eligibility criteria for every post is available in documented form.

Compliance Requirements:

- ✓ As per the criteria prescribed on the basis of PM&DC Ordinance 1962 and the (Amendment Ordinance) 2012, a medical graduate having qualification/s registered with the PM&DC is eligible to manage the laboratory of corresponding category, as detailed in the guidelines summarized as under:
  - Higher level specialization like FCPS/FRC Path/PhD/ equivalent, etc. in the discipline of pathology for heading a laboratory which portrays broader scope of diagnostic services.
  - A mid-level specialization like MPhil for a Category-B laboratory.
  - Diploma/Equivalent in clinical pathology as a minimum for Category-C laboratories.
  - A respectively qualified technologist to be the section head.

Scoring:

- If there are written eligibility criteria for every post, then score as **fully met.**
- If there are no eligibility criteria or it is deficient, then score as **not met.**

Ind 27. Recruitments are made according to laid down eligibility criteria

Survey Process:

Eligibility criteria regarding the employee's qualification, disciplinary background and experience should be strictly followed for quality recruitments. Personal files of every employee containing all relevant documents regarding qualification and experience are maintained for future reference. Randomly review personnel files of 5-10 employees. In case the laboratory has less than five employees, review all files and match their qualification and experience against laid down eligibility criteria for a particular post.

Compliance Requirements:

- ✓ All appointments are according to eligibility criteria.

Scoring:

- If all reviewed files have relevant qualification and experience certificates/documents and are according to eligibility criteria, then score as **fully met.**
- If documented record is not according to eligibility criteria or there is no record, then score as **not met.**

GUIDELINES

For quality recruitments, eligibility criteria regarding the employee's qualification, disciplinary background and experience should be strictly followed. A personal file of every employee, containing all relevant documents for qualification and experience, should be maintained for future reference. Eligibility criteria for every post should be available in documented form, which includes the following:

1. Qualification in terms of degrees/diplomas in order of preference
2. Relevant experience
3. Age

A JD is a list that a person uses for tasks or functions and responsibilities of a position. A JD is usually developed by conducting a job analysis, which includes examining the tasks and sequences of tasks necessary to perform the job. It will be determined and documented for every post, against which eligibility criteria is identified. It documents the requirements in terms of qualification and experience that must be met by an individual to be appointed against a post. Following are sample JDs:

JD for Pathologist/Director Laboratory is provided in the Guidelines under Ind. 6 along with eligibility criteria to head the laboratory offering a specific scope of service.

Sample JD for Job Titled Pathologist/Section Head	
Job Code	
Qualification & Experience	M.B.B.S. and FCPS (if person possessing FCPS is not available then MCPS/DCP or other equivalent qualification recognized by the PMDC)

Position Type:	Full Time:	Dress Code:
Reports to	Laboratory Head/Technical Director	

Job Summary

May be designated as in-charge of the Pathology Laboratory in addition to his/her section duty in the absence of incumbent, for deliverance of optimal standard of investigations. The extent of the work is to read the slides and critical tests as the case may be, supervise the working of the Lab Technicians & Technologists and conduct/participate in internal and external QA activities.

Duties / Responsibilities

Technical

1. Discusses with the Primary Physician in charge of the case to facilitate investigation of the complicated patients.
2. Reviews referrals by Primary Physician/Specialists and from the lower-level practices to establish diagnosis.
3. Performs procedures for investigation purposes e.g. bone marrow biopsy etc.
4. Ensures readiness of all reports / findings for delivery/communication to the requesting clinicians/patients/attendants within stipulated time as per SOPs.
5. Conducts complicated tests and checks slides as the case may be.

Preventive / Promotive

1. Ensures compliance of SOPs particularly on Infection Control and Waste Management etc. in the laboratory.
2. Ensures that instruments/equipment being used in procedures is properly sterilized.
3. Ensures that all staff performing tests or participating in the procedures is physically well protected by using PPE e.g. wearing proper dress i.e. gowns, masks, caps, gloves and shoes etc.

Teaching / Supervision

1. Trains and supervises Medical and Paramedical staff as per requirements/Protocols and work instructions of the laboratory.

General

1. Remains on call after working hours.
2. Checks the punctuality of the staff attached to his section.
3. Checks the cleanliness and up keep of the section.
4. Ensures that responsible staff regularly upkeeps & maintains electro-medical equipment of the laboratory to ensure their functionality at all the time.
5. Ensures that the supplies of chemicals/kits/reagents & consumables etc. are regularly replenished.
6. Ensures the preparation and implementation of the duty roster for his section.
7. Provides technical assistance to the management for purchase of new equipment/instruments needed from time-to-time for the unit.
8. Checks that the subordinate staff performs their duties as per JDs, SOPs & SMPs.
9. Writes Performance Evaluation Reports of subordinate staff.

10. Performs any other professional duty assigned by the in charge.

(I have read and accept the job description)

Signature of the incumbent:

Sample JD for Job Titled Technologist/Scientist/Section Head		
Job Code		
Qualification & Experience	BSc/MSc/MPhil/PhD in the related field.	
Position Type:	Full Time:	Dress Code:
Reports to	Laboratory Head/Technical Director	

Job Summary

May be designated as in-charge of the particular section of the Laboratory, in addition to his/her section duty. The extent of the work is to perform the difficult tests or when there is a doubt in any result for QA and supervise the working of the Lab Technicians & other Technologists in his area of responsibility. Conducts/participates in internal and external QA activities.

Duties / Responsibilities

Technical

1. Discusses and facilitates requested investigations with the Primary Physician of the case as required and conducts complicated tests for QA.
2. Ensures readiness of all reports/findings for the reporting pathologist within stipulated time.
3. Communicates the reports to the reporting pathologist/in charge as soon as ready.
4. Provides urgent reports to patients/attendant/physicians as per policy.

Preventive / Promotive

1. Ensures compliance of SOPs particularly on Infection Control, Waste Management etc.
2. Ensures that equipment being used are clean/sterilized.
3. Ensures that all staff performing tests or participating in the procedures is physically well protected by using PPE e.g. wearing proper dress i.e. gowns, masks, caps, gloves and shoes etc.

Teaching / Supervision

1. Trains and supervises the subordinate staff for compliance of work related SOPs / Protocols / instructions.

General

1. Remains on call after working hours.
2. Checks the punctuality & performance of the subordinate staff as per JDs, SOPs & SMPs.
3. Ensures that responsible staff regularly upkeeps/cleans the section & maintains electro-medical equipment to ensure their functionality at all the time.
4. Ensures that the supplies of chemicals/kits/reagents & consumables etc. are regularly

replenished.

5. Ensures the preparation and implementation of the duty roster for his unit.
6. Provides technical assistance to the management for procuring equipment/kits as needed.
7. Writes Performance Evaluation Reports of subordinate staff.
8. Performs any other professional duty assigned by the in charge.

(I have read and accept the job description)

Signature of the incumbent:

Sample JD for Job Titled Laboratory Technician		
Job Code		
Qualification & Experience	Matric preferably F.Sc. + Diploma in Lab Tech from PMF or equivalent qualification recognized by PMF. One year relevant experience preferable.	
Position Type:	Full Time:	Dress Code:
Reports to	Section in charge Technologist/Pathologist	

Job Summary

Accomplishes duties under the guidance of Incharge. Draws blood samples, performs laboratory tests assigned and provide results to the patients/requesting physicians as per policy. Assists the section head/in charge in accomplishing IQA and EQA.

Duties / Responsibilities

Technical

1. Draws / receives samples and Investigation Request Forms from the referring physician/walk in patients, carefully checks/cross checks the particulars of the patients on the sample and its requisition.
2. Performs the tests accurately by following the SOPs, ensuring the readiness of results in time.
3. Prepares slides for histopathology and hematology etc. and performs tests as assigned/according to scope of having been trained.

General

1. Ensures that all instruments, equipment are in working order and Chemicals/Reagents are kept in sufficient quantity to meet the laboratory needs.
2. Maintains the stock register/inventory for equipment, instruments, reagents and the daily investigation record and daily expense of the reagents/kits etc.
3. Ensures delivery of reports to different units / clients.
4. Supervises duties of Laboratory Assistant.
5. Maintains orderliness and cleanliness of the allocated section himself and through relevant staff.
6. Performs any other professional duty assigned by the in charge.

(I have read and accept the job description)

Signature of the incumbent:

Assessment Scoring Matrix

Standard 7. HRM-1: Staff deployment is in accordance with the scope of laboratory work.

Indicator 25-27		Max Score	Weightage (Percentage)	Score Obtained
Ind 25.	**Job description for every post is identified and documented.**	10	**100%**	
Ind 26.	**Eligibility criteria regarding qualification and experience for each job is available.**	10	**100%**	
Ind 27.	**Recruitments are made according to laid down eligibility criteria.**	10	**100%**	
Total		30		

Standard 8. HRM-2: The staff members joining the laboratory are oriented to the laboratory environment, the laboratory sections and their individual jobs

Indicators (28-31):

Ind 28. An appropriate orientation plan exists for newly inducted employees

Survey Process:

Orientation should be on general laboratory working, safety, biosafety, quality assurance, standard operating procedures and on specific techniques/tasks assigned to the employee. The content of each level of the orientation plan should be in written form to ensure the provision of uniform and standardized orientation on different topics. Check if the written orientation plan is available with the management.

Compliance Requirements:

- ✓ Written orientation plan covering the following:
  - General laboratory working
  - Safety
  - Biosafety
  - Quality assurance
  - SOPs
  - Specific techniques/tasks assigned to the individual employees

Scoring:

- If there is a written orientation plan covering all of the above-mentioned topics, then score as **fully met.**
- If there is a written orientation plan covering at least 80% of the above mentioned topics, then score as **partially met.**
- If there is no orientation plan or non-conformance is more than 20%, then score as **not met.**

Ind 29. Each staff member is made aware of laboratory wide procedures as well as section/unit/service/programme specific procedures

Survey Process:

Assess the knowledge of the staff regarding the laboratory SOPs, by evaluating against the contents of the orientation plan.

Compliance Requirements:

✓ Written record of level specific orientation sessions conducted for all staff covering:
- Laboratory wide procedures (general SOPs).
- Section/Unit/Service/Program specific procedures.

Scoring:

- If the staff is aware of general and specific procedures, then score as **fully met.**
- If there is no orientation/awareness on procedures, then score as **not met.**

Ind 30. Each staff member is made aware of his/her rights and responsibilities

Survey Process:

This would require that each staff member has a written job contract that defines specific responsibilities and employee rights as per the KP HCC Charters/labor laws and is shared with the staff member at the time of induction.

Compliance Requirements:

✓ Written job contract having clear description of employee rights and responsibilities.
✓ JD duly signed by the employee and the employer.

Scoring:

- If each staff member has a written job contract as above, then score as **fully met.**
- If any staff member does not have a written job contract or if there is no formal way to let the member know of their rights and responsibilities, then score as **not met.**

Ind 31. All employees are educated with regard to patients' rights and responsibilities

Survey Process:

During the general laboratory orientation program, employees are educated about patient rights and responsibilities. Interview the staff to assess their awareness about patient rights and responsibilities.

Compliance Requirements:

✓ Written record of orientation sessions conducted for all staff regarding patient rights and responsibilities.

Scoring:

- If there is documented evidence that all staff members have been so educated and they are aware of it, then score as **fully met.**
- If less than 80% of staff have been educated, then score as **partially met.**

- If there is no evidence that this education has been imparted, then score as **not met.**

GUIDELINES

General Orientation

Upon selection, new employees must be oriented in order to make them realize that they are productive contributors. Orientation improves the ability of the employee to perform their job and to satisfy their personal desire and feeling that they are an important part of the organization. The section incharge and the human resource (HR) department complete the orientation by introducing the new employee to the co- workers. Every section should recognize that its success depends upon the capacities of its staff and shall design a comprehensive induction orientation program for all employees. The induction orientation processes will be an integral capacity building program and will provide information, guidance and support to the staff to undertake their organizational responsibilities and succeed in their new role. This will familiarize the new staff with the laboratory's policies, systems, procedures, management structure and encourage commitment to the vision, mission and values of the organization.

Policy

The aim of the policy is to specify a program to introduce new joiners to the organization, its culture and environment and the coworkers. The induction orientation program designed by the HR department, should include the following:

1. The vision, mission, values, objectives and policies of the HCE.
2. Overview of the organizational structure, systems and key processes.
3. Brief on key processes of the relevant department.
4. Description of the HCE's specialty/s and target population.

Procedure

At the time of joining the HCE/lab, the employee will submit photocopies of past credentials to the HR department. The HR department will complete the necessary documentation, including the following, and will get signatures of the employee where necessary:

1. Appointment letter.
2. Joining report **(Annexure C)**.
3. Statement of ethics **(Annexure D)**.
4. Confidentiality agreement **(Annexure E)**.
5. Reference forms for at least two referees (who should not be blood relations) to be filled by the employee **(Annexure F)**.
6. Employee's health questionnaire form **(Annexure G)**.

The designated HR person, after briefing the employee about the laboratory's vision, mission, values, objectives and policies, will issue him/her the Employee Handbook in order to provide all the policies in detail. The employee will also be introduced to all the colleagues through a physical tour of the laboratory.

Ideally, an **Employee Handbook** should contain:

1. Mission statement, values and goals of the laboratory.
2. Standards of conduct to follow (towards a client, for communication, teamwork, maintaining sense of accountability, appearance, etc.).
3. Expectations from employees and their responsibilities, such as to keep personal business to a

minimum, reporting procedures and personnel and disciplinary action to be taken in various situations.

4. Policies and procedures to follow in the respective departments and in emergency situations.
5. Efficient and safe use of equipment with regards to health and safety standards.
6. Information regarding employee benefits schemes, special recognition/appreciation criteria, etc.

The HR representative will then provide an **Orientation Checklist** to be filled by the employee and give his/her feedback about the orientation **(Annexure H).** The checklist will be filed into the employee file and feedback will be used for required improvements in the orientation program.

Staff Rights and Responsibilities

This standard would require that a copy of the written JD, defining the responsibilities, should be provided to every staff member for reference and to understand their duties.

1. Responsibilities

The HR department must have well-defined JDs for each category of staff which will be duly signed by the employee/s and made part of the respective personal file.

2. Rights

The HR Department will maintain an employee manual, describing in detail the rights of the staff members, which should also be shared with the employee/s.

3. Patients' Rights

The rights and responsibilities of the patients are available as Patient Charters as covered in Section 2.9 of the MSDS and also published on the KP HCC website **(Annexure I).**

The following points regarding the rights and responsibilities of employees are to be considered:

1. Staff members may have cultural, religious or personal preferences/conflicts concerning their involvement with specific components in the care or treatment of patients. The laboratory management shall provide a mechanism for employees to submit their requests for review of work assignments by their Head of Department (HoD)/section heads. However, the continuum of patient care services shall be ensured at all levels.
2. Staff members will make their requests known to their HoD, manager or supervisor in writing.
3. Examples of procedures, which may conflict with some staff members' beliefs include, blood administration, therapeutic abortion, circumcision, sterilization procedures, etc.
4. The HoD, manager or supervisor shall make every effort to accommodate the request and maintain the duties referenced in the employees' JD.
5. The HoD, manager or supervisor shall reassign duties, if reasonable and possible, to accommodate the request and meet the needs of the patient.
6. Responses to all requests for reassignment of duties, whether approved or denied will be provided in writing to the employee.
7. A record of all requests and actions taken shall be maintained in the employee's departmental file.
8. If the request of the staff member cannot be granted, the employee may appeal to the next higher authority to review the request. The decision of the HR department shall be final to the

extent of the respective request.

Similarly, the staff is to be apprised about the Rights and Responsibilities of the patients and the laboratory staff.

1. The general orientation on patient's charter should also document how all the employees are educated about patient rights and responsibilities.
2. Staff should be aware of patient rights and responsibilities

Assessment Scoring Matrix

Standard 8. HRM-2: The staff members joining the laboratory are oriented to the laboratory environment, the laboratory sections and their individual jobs.

Indicator 28-31		Max Score	Weightage (Percentage)	Score Obtained
Ind 28.	**An appropriate orientation plan exists for newly inducted employees**	10	**80%**	
Ind 29.	**Each staff member is made aware of laboratory wide policies and procedures as well as section/unit/service/program specific policies and procedures.**	10	**100%**	
Ind 30.	**Each staff member is made aware of his/her rights and responsibilities.**	10	**100%**	
Ind 31.	**All employees are educated with regard to patients' rights and responsibilities.**	10	**80%**	
Total		40		

Standard 9. HRM-3: An appraisal system for evaluating the performance of employees exists as an integral part of the human resource management process

Indicators (32-35):

Ind 32. Well-documented performance appraisal tools exist in the laboratory

Survey Process:
Review the appraisal system tools and assess if it evaluates actual performance targets and not just administrative factors.

Compliance Requirements:

- ✓ Written performance appraisal tools (reporting format).
- ✓ Evidence that the tools can assess actual performance targets.

Scoring:

- If the written performance appraisal reporting format is available as above, then score as **fully met.**
- If the written performance appraisal / reporting format is not available, then score as **not met.**

Ind 33. All of the employees/consultants/students/voluntary workers are made aware of the performance appraisal tools at the time of induction

Survey Process:
This should be part of the initial orientation and there should be documented evidence (such as the employee's signature on the JD) confirming that the employee understood how they would be evaluated. Randomly check the knowledge of a representative sample of employees regarding the appraisal system.

Compliance Requirements:

- ✓ Documentation that all employees are made aware of the performance evaluation/appraisal tools at the time of induction.
- ✓ Awareness of the staff performance evaluation/appraisal tools is confirmed by interviewing.

Scoring:

- If employees are aware of appraisal system tools, then score as **fully met.**
- If employees are not aware of it, then score as **not met.**

Ind 34. The appraisal is used as a tool for further development

Survey Process:

Based upon the appraisal reports, gaps will be identified in the employee's performance, which will be helpful in identifying development plans. The appraisal system is used as a tool for further professional development of employees (such as more experience, trainings, and a different job assignment). This may not be required for every appraisal – only if the appraisal indicates the gaps and needs suggestions to bridge the gaps. The survey team should check for documented gap identification and recommended actions for improvement in the appraisal forms and evidence of actions taken for improvement of gaps.

Compliance Requirements:

- ✓ Identified gaps in the performance of employees.
- ✓ Evidence of corrective actions in accordance with the identified gaps.

Scoring:

- If there is documented evidence of gap identification, recommended actions for improvement and evidence of actions taken, then score as **fully met.**
- If there is evidence of gap identification and recommended actions for improvement in the appraisal tools, but documented evidence of actions taken for improvement is missing, then score as **partially met.**
- If the appraisal tool does not provide gap identification, then score as **not met.**

Ind 35. Performance appraisal is carried out at pre-defined intervals and is documented

Survey Process:

The laboratory should have defined the frequency of performance appraisals. Customarily, this is done within the first 3-4 months for a new employee/probationer, and at least annually for all other employees. The surveyors should evaluate if the laboratory has defined and documented frequency of employee appraisal. Check dates of appraisal reports of a representative sample of new and old employees. Review 5-10 files of the employees to determine if the appraisal is documented and present in their files. In case of less than five, employees review all files.

Compliance Requirements:

- ✓ Notified predefined intervals for carrying out the performance appraisals.
- ✓ Evidence to support the compliance of the above.

Scoring:

- If the laboratory has defined the frequency of employee appraisal and there is documentation (dates on appraisal reports) that all reviewed employees have received timely appraisals, then score as **fully met.**

- If the laboratory has defined the frequency of employee appraisal, but only about 80 percent of reviewed employees had their appraisal on time, then score as **partially met.**
- If the laboratory does not have a schedule for periodic employee appraisal or if less than 80 percent of the employees received their appraisal on time, then score as **not met.**

GUIDELINES

Performance Appraisal

A performance appraisal, employee appraisal, performance review or career development discussion is a method by which the job performance of an employee is evaluated (generally in terms of quality, quantity, cost, and time) typically by the corresponding section incharge.

A performance appraisal is a part of guiding and managing career development and is a process of obtaining, analyzing, and recording information about the relative worth of an employee to the organization. It is an analysis of an employee's recent successes and failures, personal strengths and weaknesses, and suitability for promotion or further training. It is also the judgment of an employee's performance in a job based on considerations other than productivity alone.

The comprehensive appraisal system shall evaluate actual performance against given targets and not just administrative factors. The appraisal shall document and include an appraisal of the employees' actual performance and an agreed plan for staff development to address any performance issues.

In the public sector, performance of employees is evaluated through an Annual Confidential Report (ACR) written by the supervisor (reporting officer)/second reporting officer. The ACR generally covers the evaluation of the respective employee against the JD assigned to the position and covering strengths and areas of improvement. In the private sector, the employee is asked to give written key performance indicators (KPIs) relevant to the assignment and in line with the JDs to be evaluated at the time of performance appraisal. The employee and concerned manager should have a copy of the KPIs for the performance evaluation.

Orientation of Performance Appraisal

As an integral part of the initial orientation, the employee should be briefed about the performance appraisal system in practice at the HCE/lab. There should be documented evidence (such as the employee's signature on the JD) that confirms that the employee understands about the evaluation. Also link with **Indicator No. 32.**

Career Development

There should be documented evidence (when appropriate to the employee's appraisal) that the appraisal system is used as a tool for further development (such as more experience, more training, and a different job assignment). This may not be required for every appraisal – only if the appraisal indicated the need.

A performance appraisal is a part of guiding and managing career development. It is the process of obtaining, analyzing, and recording information about the relative worth of an employee to the organization.

Frequency of Performance Appraisals

The HCE/lab should have defined the frequency of performance appraisals. Customarily this is

within the first 3-4 months (probation period) for new employees and at least annually for ALL other employees.

Assessment Scoring Matrix

Standard 9. HRM-3: An appraisal system for evaluating the performance of employees exists as an integral part of the human resource management process.

Indicator 32 - 35		Max Score	Weightage (Percentage)	Score Obtained
Ind 32.	**Well-documented performance appraisal tools exist in the laboratory.**	10	**100**	
Ind 33.	**All of the employees/consultants/students/ voluntary workers are made aware of the performance appraisal tools at the time of induction.**	10	**100**	
Ind 34.	**The appraisal is used as a tool for further development.**	10	**80**	
Ind 35.	**Performance appraisal is carried out at pre-defined intervals and is documented.**	10	**80**	
Total		40		

Standard 10. HRM-4: Documented personal record for each staff member exists

Indicators (36-36):

Ind 36. Personal files are maintained in respect of all full time/part time employees

Survey Process:

Randomly select 5-10 employees (either from a list of all employees or by name, as identified during visits to laboratory sections). Ascertain if ALL have a human resource/personal file having documented information regarding the employment contracts, qualification including copies of diplomas/transcripts, laboratory personnel licenses (where required), training and experience, records of radiation exposure (if applicable), records of continuing education, job description, date of employment, disciplinary background, evaluation reports, health status, etc.

Compliance Requirements:

✓ HR/Personal files of all employees having the following information are maintained:

- Employees' contracts showing date of employment
- Copies of qualifications like degrees/diplomas/transcripts
- Laboratory personnel licenses (registration where required)
- Training and experience
- Records of continuing education
- Job description
- Disciplinary background
- Evaluation reports
- Health status

Scoring:

- If all reviewed files have documented information as applicable as above, then score as **fully met.**
- If any of the reviewed files do not contain all the required information, then score as **not met.**

GUIDELINES

Personal Files

The purpose of maintaining personal files is to keep an updated record of employees. The personal files of employees should be maintained because:

1. It makes good business sense to have accurate information handy and organized when you want to use it for an official purpose.
2. Immediate supervisors will eventually encounter the need to produce documentation about employee performance and work history.

3. Some employee records are required by federal or provincial government/other agencies and must be kept in the personal files. Organizing the record of employees in a proper manner makes access easy.

The personal file of each employee is very confidential and access to the file is only allowed after the approval from a competent authority. Access to information about employees should be strictly limited to those people in the HCE who need to use it for official purposes. Since unauthorized access to personal files can result in severe repercussions, any breach in this connection should make the responsible person liable to severe penalties. It should be ensured that personal files (hard and soft copies) are stored in a secure physical location and are not left unattended even during working hours. When asked by the people outside the organization to provide 'verification' of certain employment information about the employee/s of the HCE, it should be ensured that only the information which has been authorized by the employee/s is released. Employment verifications are usually required to support such things as mortgage applications, credit applications, etc. Employee authorization should be in writing and specify the information they wish you to reveal. Tell your employee the policy is designed for his/her protection.

Contents of Personal Files

The human resource (HR) departments in good organizations customarily maintain the following documents in the personal file of each employee in a standard manner:

1. Curriculum vitae
2. Offer letter
3. Contract copy and JD
4. Joining report
5. Photograph (two, blue background, passport size)
6. CNIC copy
7. Copies of documents pertaining to all academic and professional qualifications
8. Copies of training/certifications
9. Salary slip/certificate (previous employer)
10. Experience certificate
11. Official email account issuance form
12. Reference form/background check
13. Medical/personal information form
14. Information for employee/business card
15. Leave forms (if any)
16. Notice (if any)
17. Performance evaluation form
18. In-service training
19. Salary increment/promotion
20. Resignation/termination letter (whichever is received in the HR departments)
21. Exit interview form (whenever the employee leaves the office)

Review the Personal Files and check that he following are maintained:

1. Qualifications of the staff member
2. Record of in-service education/training

3. JD as applicable
4. Work history/disciplinary background
5. Results of evaluations
6. Record of health status of employees

Assessment Scoring Matrix

Standard 10. HRM-4: Documented personal record for each staff member exists.

Indicator 36 - 36		Max Score	Weightage (Percentage)	Score Obtained
Ind 36.	**Personal files are maintained in respect of all full time/part time employees.**	10	**100**	
Total		10		

Standard 11. HRM-5: In-service staff capacity building record is documented

Indicators (37-38):

Ind 37. In-service training plan for staff members is available

Survey Process:
Review the plans for capacity building of staff of various categories and confirm that they were imparted the required training.

Compliance Requirements:

- ✓ Documented plan showing listing of staff including all categories for in-service trainings/capacity building.

Scoring:

- If the in-service training plan exists and staff is trained, then score as **fully met.**
- If there is in-service training plan and up to 80% staff is trained, then score as **partially met.**
- If there is either no training plan or less than 80% staff is trained, then score as **not met**

Ind 38. All records of in-service training and education are contained in the personal files

Survey Process:
Review the representative sample of personal files for in-service training record.

Compliance Requirements:

- ✓ Record of attendance to support that in-service training was actually conducted.

Scoring:

- If all the reviewed files contain documentation of in-service education/trainings (when relevant to the individual) and the employee's education, then score as **fully met.**
- If any file does not document relevant in-service training, or does not document the employee's education, then score as **not met.**

GUIDELINES

The plans for capacity building of staff of various categories should be present in written form. Every employee should be provided the opportunity to participate in various capacity building programs according to the plan.

In-Service Training and Education Record

The HR department will be responsible for maintaining the following documents in the personnel file of each employee of the laboratory:

1. Curriculum vitae
2. Photograph (two, blue background, passport size)
3. CNIC copy
4. Copies of documents pertaining to all academic and professional qualifications
5. Copies of trainings/certifications
6. Salary slip/certificate (previous employer)
7. Experience certificate
8. Offer letter
9. Contract copy and JD
10. Joining report
11. Official email account issuance form
12. Reference form/background check
13. Medical/personal information form
14. Information for employee/business card
15. Leave forms (if any)
16. Notice (if any)
17. Performance evaluation form
18. In-service trainings
19. Salary increment/promotion
20. Resignation/termination letter (whichever is received in the HR department)
21. Exit interview form (whenever the employee leaves the office)

Assessment Scoring Matrix

Standard 11. HRM-5: In-service staff capacity building record is documented.

Indicator 37 - 38		Max Score	Weightage (Percentage)	Score Obtained
Ind 37.	**In-service training plan for staff members is available.**	10	**80**	
Ind 38.	**ALL records of in-service training and education are contained in the personal files.**	10	**100**	
Total		20		

Standard 12. HRM-6: There is a process for collecting, verifying and evaluating the credentials (education, registration, training and experience) of laboratory professionals, including doctors, technologists and others

Indicators (39-40):

Ind 39. A system for the verification of documents and certificates of employees exists in the laboratory

Survey Process:

The assessor has to look for the way the laboratory validates that its staff has the appropriate and required documents that demonstrate that they are legally permitted to perform the duty for which they are appointed. There should be a process to validate the accuracy of these documents (there are multiple examples internationally of fraudulent 'credentials'). The lab should have verified the documents with the primary source – such as the university or the training organization. Professional qualifications should be currently registered with the respective professional council or body.

Compliance Requirements:

- ✓ Existence of a process for verification of documents with the primary source – such as the university or the training organization or the professional councils.
- ✓ Evidence that the professional qualifications are currently registered with the respective professional council or body.

Scoring:

- If there is a clearly defined process to validate the credentials' of ALL staff members, then score as **fully met.**
- Since this is an important legal as well as a patient safety issue, if there is no recognized process to validate the credentials', then score as **not met.**

Ind 40. Verification of credentials/documents is done in the laboratory for any newly added qualification/training certificate

Survey Process:

Randomly select the human resource/personal files of a representative sample of technical and others staff and review these files to determine if all newly added certificates are validated.

Compliance Requirements:

- ✓ Existence of a process for verification of newly added documents with the primary source.
- ✓ All newly added documents are either found verified or are in the process of verification.

Scoring:

- If ALL reviewed new certificates are verified, then score as **fully met.**
- If verification of newly added certificates is not documented, then score as **not met.**

GUIDELINES

Verification of Licensure/Certification

There should be a process to validate the accuracy of these documents (there are multiple examples of fraudulent 'credentials' internationally). The lab should have verified the documents with the primary source such as the college/university/authority or the training organization, as the case may be, as follows:

1. Current licensure/certification or registration is verified with the primary source at the time of hiring and at renewal prior to expiry of validity.
2. Primary source verification will be obtained through a secure electronic communication. If a licensing board/agency/authority cannot provide this type of verification, a letter in that respect must be obtained from it.
3. In the event that an employee is hired against a position that requires a license, certification or registration, and the same has been revoked, suspended or rendered invalid, the HCE may terminate the concerned employee on these grounds.
4. Practitioners should have current/valid registration with the respective professional council or body e.g. PM&DC for doctors, Pharmacy Council for pharmacists, Pakistan Nursing Council (PNC) for nurses and Khyber Pakhtunkhwa Medical Faculty for paramedics.
5. It is the employee's responsibility to provide proof of license, certification and/or registration, and to notify their manager and HR immediately of any change in the status of the license, certification, and/or registration.

Periodical Updating and Verification of Credentials

The HR department should update and verify the file at least once in a year or more frequently, if required. The employee should intimate the HR Department about any change in the credentials immediately/soon after its occurrence.

The HR department shall maintain/place copies of credentials of all employees of the HCE in their respective personal files which shall include at least:

1. Educational degrees/diplomas, both undergraduate and postgraduate.
2. Registration with registering/licensing body.
3. Pre-service and In-service trainings.
4. Related experience; local or foreign.

Assessment Scoring Matrix

Standard 12. HRM-6: There is a process for collecting, verifying and evaluating the credentials (education, registration, training and experience) of laboratory professionals, including doctors, technologists and others.

Indicator 39 - 40		Max Score	Weightage (Percentage)	Score Obtained
Ind 39.	**A system for the verification of documents and certificates of employees exists in the laboratory.**	10	**100**	
Ind 40.	**Verification of credentials/documents is done in the laboratory for any newly added qualification/training certificate.**	10	**100**	
Total		20		

2.4 Management of Equipment and Reagents (MER)

03 Standards & 13 Indicators

Laboratory result errors due to faulty equipment, poor quality chemicals/reagent/kits are one of the most common healthcare issues, which require due care and attention for their prevention. Such errors are among the most frequently reported adverse events. Standards under the management of equipment and reagents (MER) help laboratories to sustain and improve the quality of lab results by creating a system for selecting, ordering, procuring, storing, preparing, labeling, dispensing, and monitoring proper use of equipment and chemicals/reagents/kits. The standards are designed to reduce practice variations, errors and misuse; through monitoring the efficiency, quality and safety of reagent management processes; promote the use of evidence-based good practices; and standardize processes in the laboratories.

Standard 13. MER-1: Ensure quality of equipment and reagents through standardized procurement procedures

Indicators (41-44):

Ind 41. The procurement procedure of the laboratory is laid down

Survey Process:

Procurement of quality laboratory equipment and reagents is ensured in accordance with the Drug Regulatory Authority of Pakistan (DRAP) Act 2012 and the Medical Devices Rules 2015 framed under the Act and as amended from time to time. The assessor should ask for updated laboratory procurement SOPs.

Compliance Requirements:

- ✓ Documented procurement SOPs to comply with the rules/regulations.

Scoring:

- If the procurement SOPs are present, then score as **fully met.**
- If there are no SOPs, then score as **not met.**

Ind 42. Specifications for all the equipment and reagents/kits/consumables to be purchased are documented

Survey Process:

There should be documented specifications of all equipment and reagents being used in the laboratory and procurement done against the same. Look for a list of specifications for equipment and reagents. Compare the specifications of 20% of the reagents and equipment procured in the last one year with the list of specifications.

Compliance Requirements:

- ✓ A register/file/computer record of specifications.

Scoring:

- If the specifications of all the equipment and reagents are documented and available and procurement is made in accordance with them, then score as **fully met.**
- If specifications are not documented, or procurements are not in accordance with the specifications, then score as **not met.**

Ind 43. Procurement orders are clear, dated and signed

Survey Process:

While reviewing procurement records, determine if orders are clear, dated and signed. Review 20% of procurement orders of the last one year for dates and signatures.

Compliance Requirements:

✓ Availability of record as above.

Scoring:

- If all reviewed orders are dated and signed, then score as **fully met.**
- If all orders are not dated and signed, then score as **not met.**

Ind 44. Procured items are regularly entered into stock registers

Survey Process:

Review stock registers and randomly check 20% of each category of procured items, including equipment, kits, reagents, disposables, etc., to ascertain that they are entered into the stock register.

Compliance Requirements:

✓ Stock registers are maintained.

Scoring:

- If all reviewed items are entered in the stock register, then score as **fully met.**
- If any of the reviewed items is not entered in the stock register, then score as **not met.**

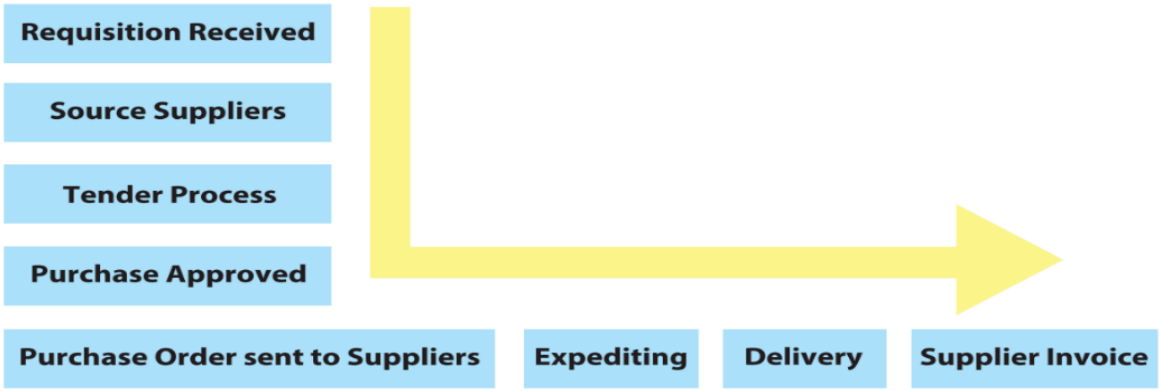
GUIDELINES

The procurement process includes the following:

1. Prepare technical specifications
2. Prepare tender documents
3. Solicit bids from vendors/suppliers
4. Evaluate bids
5. Award and contract
6. Compile delivery, installation and commissioning program

STANDARD PURCHASING PROCESS

Figure 3: Standard Purchasing Process



It is important to consider minimum specifications and requirements before starting the procurement process of medical/laboratory devices. The standardized specifications allow procurement of medical devices of high quality, safety and efficacy, as well as adequate planning of the financial, infrastructure and human resources for the implementation, functioning and commissioning of the devices.

The following points are to be considered while laying down technical specifications:

1. Technical specifications should be tailored appropriately by users according to the specific situation, especially:
   i. Local standards and legislation; local regulations and conditions;
   ii. Installation conditions, technological levels, electrical range, capacities, utility environment, procedures, personnel (users) experience and other local specific conditions.
2. Technical characteristics of technical specifications indicate basic, appropriate, standard equipment for low and middle income countries. If you are interested in purchasing more advanced equipment, you should consider optional functions depending on your needs.
3. The number of accessories, consumables, spare parts and other components indicates the usual and/or ideal number and is not a mandatory quantity. The user can determine this quantity according to a product's characteristics and frequency of use in your laboratory.
4. For tender purposes, you should consider not only medical equipment itself, but also related services in order to be able to use the equipment.

   Procurement/Purchase orders are documents sent from a buyer to a supplier with a request for an order. The type of item, the quantity and agreed upon price are generally (should be!) printed on the purchase order – the more specific the order, the more details included, the more effective the purchase order will be. It should also be properly dated, timed and duly signed.

   When a seller (supplier, vendor, etc.) accepts a purchase order, a legally binding contract is formed between the two parties. In addition, the buyer should always clearly and explicitly communicate their properly timed and dated requests to the seller so there is no confusion when the purchase order is received.

   Also, in the event that buyer refuses payment, the seller is protected because the purchase order is a binding contract between both parties.

Sample Stock Register Page:

The stock register is a record showing the entry of an item in the store after purchase, and later, its issue to the relevant sections and consumption. Purchase of equipment is verified through entry into stock register, which is made by the store keeper.

Table 4: Purchase Order Format

Purchase Order Format			
HCE/Laboratory Name		To, Supplier/Vendor Name	
Street Address		Address	
Email		Email	
Phone		Phone	
Delivery Method		Date Supply Required	

Item/s-Codes	**Description**	**Unit Price**	**Total**
Totals			

General Conditions:		
Specific Instructions:		
Authorized By:	**Name:**	**Signatures:**
	Designation:	**Stamp:**
	Employee ID Code:	**Date:**

Assessment Scoring Matrix

Standard 13. MER-1: Ensure quality of equipment and reagents through standardized procurement procedures.

Indicator 41-44		Max Score	Weightage (Percentage)	Score Obtained
Ind 41.	**The procurement procedure of the laboratory is laid down.**	10	**100**	
Ind 42.	**Specifications for all the equipment and reagents/kits/ consumables to be purchased are documented.**	10	**100**	
Ind 43.	**Procurement orders are clear, dated and signed.**	10	**100**	
Ind 44.	**Procured items are regularly entered into stock registers.**	10	**100**	
Total		40		

Standard 14. MER-2: Safe handling and storage of laboratory reagents

Indicators (45-48):

Ind 45. Documented procedures guide the safe storage and use of reagents

Survey Process:

Documented SOPs providing for safe storage at a proper place, and periodical issue on demand to various sections, should be available. As reagents and kits are sensitive, their storage should be under controlled temperature, light and humidity conditions, as directed by the manufacturers. Physically inspect tidiness and temperature controlled storage space.

Compliance Requirements:

- ✓ Written SOPs which guide safe storage and use of reagents.
- ✓ Issuance and use as per SOPs.

Scoring:

- If SOPs for storage in tidy, temperature, light and humidity controlled places and issuance and use of the reagents/kits are documented, then score as **fully met.**
- If there are no SOPs for proper storage, issuance and use as described above, then score as **not met.**

Ind 46. Inventory of reagents is maintained

Survey Process:

While visiting the laboratory, review the record of stored items and check if quantities of reagents/kits are mentioned in the record. Also check if the record is regularly updated after issuance of any reagent.

Compliance Requirements:

- ✓ Up-dated inventory of stored reagents.

Scoring:

- If the inventory of stored reagents is properly maintained and it is regularly updated, then score as **fully met.**
- If the inventory of stored reagents is not properly maintained, then score as **not met.**

Ind 47. The SOPs of reagent management include a procedure of alert for near expiry reagents

Survey Process:

While visiting the storage area in the laboratory, review the procedure for near expiry (one month) reagent alerts. Look for marking of all near expiry reagents in red. Issue and use of near expiry reagents should be earlier than others.

Compliance Requirements:

✓ Availability of written SOPs for creating an alert about any item which has an expiry date of one month.

Scoring:

- If there is a procedure for creating an alert of near expiry reagents and marking in red and early use, then score as **fully met.**
- If there is no procedure for creating an alert of near expiry reagents, red marking and early use/disposal of such reagents, then score as **not met.**

Ind 48. Labeling of reagents is as per SOPs

Survey Process:

To ensure that the nature of chemicals/reagents is properly understood and evaluated by all personnel who can come into contact with those, proper labeling is mandatory. Also make sure that there are no orphan (unlabeled) containers left in the laboratory.

Compliance Requirements:

✓ The labels must bear the following:

- Full name of the chemical/reagent
- Concentration (strength)
- Date of manufacturing/issuing (as applicable)
- Date of expiry

Scoring:

- If all issued reagent bottles are appropriately labeled, then score as **fully met.**
- If any issued reagent bottle is not completely labeled, then score as **not met.**

GUIDELINES

General Considerations for safe Storage and Use of Reagents

1. **Minimize or restrict** the quantities stored and avoid over-ordering, which is usually false economy as disposal can cost more than purchase.
2. **Authorize** purchases and maintain records of location, keeper and quantities.
3. **Hazard Information** may be obtained and kept available on the materials purchased. Check

that the existing information is up to date. Company's labels and signs are to be read carefully before storing any chemical.

4. **Segregation** must be considered before storage. Do not store unsegregated checmicals in alphabetical order or incompatible chemicals in close proximity to each other. The amount of space that can be placed between different chemical classes depends on the amount of storage area available in the lab. Store dry reagents, liquids reagents and solutions in separate areas. Within each of these chemical forms, segregate into hazard classes.

   Segregate dry reagents as follows:

   i. Oxidizing solids
   ii. Flammable solids
   iii. Water reactive solids
   iv. All others solids

   Segregate liquid reagents and solutions as follows:

   i. Acid liquids
   ii. Caustic liquids
   iii. Oxidizing liquids
   iv. Per-chloric acid solutions
   v. Flammable or combustible liquids
   vi. All other liquids

Once separated into hazard classes, chemicals may be stored alphabetically.

1. **Disposal** of old, expired chemicals is to be done promptly. Regular disposal of waste or unwanted/unused chemicals will reduce the quantities stored and release valuable storage space.
2. **Tidiness of storage** - breakages and spillages are far more likely if storage arrangements are cramped, overcrowded or there is limited visibility.

Maintain an **inventory/stock register** of chemicals stored in any laboratory. Chemical inventory management systems can also be maintained electronically, on which chemicals can be checked in at delivery/receipt and even create bar code labels. Manual/electronic inventory systems can be used to record each use, the location of chemicals and allow for re-ordering when stocks are low.
Near expiry reagents should be issued and consumed first. System for alerts generation for near expiry chemicals (one month) should be devised manually or electronically.
Put **labels and signs** on bottles showing:

1. Full chemical/reagent name
2. Concentration (strength)
3. Date of dispensing
4. Date of expiry

Assessment Scoring Matrix

Standard 14. MER-2: Safe handling and storage of laboratory reagents.

Indicator 45 - 48		Max Score	Weightage (Percentage)	Score Obtained
Ind 45.	**Documented policies and procedures guide the safe storage and use of reagents.**	10	**100**	
Ind 46.	**Inventory of reagents is maintained.**	10	**100**	
Ind 47.	**The policies of reagent management include a procedure of alert for near expiry reagents.**	10	**100**	
Ind 48.	**Labeling of reagents is as per SOPs.**	10	**100**	
Total		40		

Standard 15. MER-3: Comprehensive procedures for equipment management and maintenance exist in the laboratory

Indicators (49-53):

Ind 49. Log books of all equipment are available

Survey Process:
A log book of every equipment is available in the laboratory which is updated on a regular basis. The assessor should review the availability of logbooks of all equipment.

Compliance Requirements:
- ✓ Availability of updated log books.

Scoring:
- If log books of all equipment are available, then score as **fully met.**
- If a log book of any of the equipment is not available, then score as **not met.**

Ind 50. Regular periodic maintenance and calibration record of all the equipment is available in the log books

Survey Process:
Any breakdowns, repairs and maintenance is required to be endorsed in the log books prepared from the date of the commissioning of the equipment. Existing labs are to ensure compliance with effect from notification of these standards if already not being practiced. The survey team should look for a record accordingly, clearly showing regular periodic maintenance and repair service and calibration record of every equipment. The record should also include due date of maintenance and recalibration.

Compliance Requirements:
- ✓ The log books contain record of any breakdowns, repairs and maintenance.

Scoring:
- If a complete record of periodic maintenance and calibration exists as above then, score as **fully met.**
- If there is any non-conformity, then score as **not met.**

Ind 51. Documented and relevant log sheet is displayed on each equipment

Survey Process:
For a majority of the equipment, maintenance needs are dependent on the hours of use. Log sheets

reveal regular record of every run. The lab is required to maintain, save and link the log sheets with log books for maintenance, as per their work load and policy. The survey team should physically inspect all the equipment for displayed log sheets.

Compliance Requirements:

✓ The log sheets are displayed on the equipment.

Scoring:

- If every equipment has a displayed log sheet, then score as **fully met.**
- If up to 80% of equipment have displayed log sheets, then score as **partially met.**
- If there are log sheets on less than 80% of the equipment, then score as **not met.**

Ind 52. Emergency contact number(s) is/are displayed on all equipment

Survey Process:

The survey team should physically inspect all equipment for displayed emergency contact numbers for emergency management of equipment breakdown.

Compliance Requirements:

✓ Availability of emergency contact number of the technician or the firm for emergency management of equipment breakdown.

Scoring:

- If emergency contact numbers in respect of all equipment are displayed, then score as **fully met.**
- If less than 20% of equipment do not have emergency contact numbers, then score as **partially met.**
- If more than 80% of equipment do not have emergency contact numbers, then score as **not met.**

Ind 53. Equipment inventory is maintained

Survey Process:

The survey team should review the documented inventory clearly showing the date of purchase, commissioning, calibration and the source.

Compliance Requirements:

✓ Availability of equipment inventory showing:

- Date of purchase
- Its source (manufacturer/importer/distributor/vendor)
- Date of commissioning (date of first operationalization)
- Date(s) of calibration

Scoring:

- If updated inventory is available, then score as **fully met.**
- If there is no inventory or if it is not updated, then score as **not met.**

GUIDELINES

Table 5: Equipment Maintenance Log

Name of equipment:				Manufacturer's contact details:		
Label:				Manufacturer's contact details:		
Serial number:				Person responsible for equipment:		
Manufacturer:				Date put into service:		
Date	**Maintenance description**	**Maintenance performed by**	**Date of validation before put into service**	**Validation performed by**	**Next maintenance planned on (date)**	**Remarks**

Preventive Maintenance Plan

The HCE shall ensure that the staff operating the equipment is trained in handling the equipment as per the manufacturer's instruction manual. There shall be a documented preventive maintenance plan for all equipment and machinery including DG sets, etc., using a log book/tracker.

The organization shall develop a schedule of weekly/monthly/annual inspection and calibration of equipment which shall involve measurement in accordance with Original Equipment Manufacturer (OEM) guidelines. These services can be provided through an in house arrangement or alternatively through outsourcing. The organization shall ensure that calibration and conformance testing of the equipment has been done prior to commissioning.

The HCEs shall ensure that the record regarding purchase and maintenance of equipment and machinery is properly documented and maintained. The facilities shall ensure that no equipment is non-functional/out of use merely for want of minor repairs, preventive maintenance, lack of essential spares, electrical faults, etc. Important factors resulting into gross equipment wastage may also include the following:

1. Mishandling of equipment
2. Untrained and unskilled manpower
3. Purchase of highly sophisticated equipment without competent personnel to handle it
4. Purchase of excess equipment without a justifiable demand

This calls for an efficient system for equipment management in the form of carrying out the equipment audit. In other words, there is a need for periodic evaluation of the quality of performance of the equipment in a HCE. Some of the advantages of equipment audit include:

1. Helps in standardization of the equipment
2. Concurrently evaluates performance and utility
3. Provides a satisfactory mechanism to assist phasing out/condemnation
4. The equipment audit reports provide an objective method for procurement of equipment in the future

5. Identify inadequacies and recommend remedial measures
6. Cost per reportable result and cost effectiveness can be evaluated

Defining Equipment Audit

1. "A retrospective evaluation of the quality of performance of the equipment in a hospital by an Equipment Audit Committee based on documented records of the equipment at the time of purchase and its subsequent maintenance." OR
2. "Equipment audit is the periodic evaluation of the quality of the performance of the hospital equipment."

Equipment Audit Committee

The Equipment Audit Committee may comprise of:

1. Health facility incharge
2. User HoD or representative
3. Head of hospital maintenance workshop
4. The matron or representative

The Equipment Audit Committee shall meet once in three months and select its chairperson and secretary from among the members in the first equipment performance audit. Maintenance of the history sheet and its subsequent write-up is sine-qua-non for performance of the equipment audit by the committee. A format of the history sheet and log book is given on the following page.

Table 6: Equipment History Sheet

S/No.	Description
1.	Name of Equipment
2.	Date of Purchase
3.	Cost of Equipment
4.	Name and Address of Supplier
5.	Date of Manufacture
6.	Date of Installation
7.	Department where Installed
8.	Environmental Control*
9.	Spare Parts Inventory
10.	Technical Manual/Circuit Diagrams/Literature
11.	After Sale Service Arrangement
12.	Warranty Period
13.	Life of Equipment
14.	Depreciation per year
15.	Charges of Tests**
16.	Use Coefficient***
17.	Down-time/up time
18.	Cost of Maintenance
19.	Date of Condemnation
20.	Date of Replacement
21	Other Relevant Remarks

*Proper environment control in terms of temperature, lighting, and ventilation should be ensured and recorded, wherever applicable.

**Wherever applicable, charges of tests must be specified.
***Should be applied to assess the utilization of equipment.

Table 7: Equipment Log Book

Log Book							
S/no.	Description						
	Name of Equipment	Warranty period	Validity period of maintenance contract	Date of breakdown	Date of repair	Cost incurred	Details of preventive maintenance
1.							
2.							
3.							

The various parameters to be considered in the equipment audit procedure are as follows:

Procurement

The following need consideration:

1. Need assessment – was the equipment required? What was the use coefficient of the equipment?
2. Were the technical specifications worked out and provided by the user department?
3. Were the same specified in the tender notification?
4. Was the receipt of equipment as per the specifications of the supply order?
5. Was the availability of spares ensured, after services contract specified and training arranged?

Performance

The history sheet and log book may be gainfully utilized for this. It is essential that a periodic scientific evaluation of the quality of the performance of the equipment is carried out. The process of equipment audit will also prove to be an indispensable tool in formulating standards/specifications of medical equipment and in establishment of bench marking for medical equipment.

Maintenance or 'planned preventive maintenance' is regular and repetitive work done to keep equipment in good working order and to optimize its efficiency and accuracy. This activity involves regular, routine cleaning, lubricating, testing, calibrating and adjusting, checking for wear and tear and eventually replacing components to avoid breakdown. Productive preventive maintenance refers to the proper selection of equipment to be included in planned preventive maintenance. Decisions must be made on what to include and to reduce costs (consideration is cost-effectiveness).

An important aspect of planned preventive maintenance is the participation and commitment of the user (planned preventive maintenance). Preventive maintenance should start with users, and the bulk of the work should be their responsibility. The task must be performed daily, with joint activities involving the user and a technician engineer at the end of the week. Highly technical repairs, which are the engineer's responsibility, may be scheduled every six months or on a need basis.

Setting Up a Planned Preventive Maintenance System

In order to establish an effective, efficient planned preventive maintenance system, a Registry Filing System is needed. The manufacturer's manual for preventive maintenance of the equipment can be supplemented by computer packages in setting up such a system; if a computer is not available, a manual file can be set up. The planned preventive maintenance administrative system requires the following:

1. **Equipment Inventory**

   All relevant information about the equipment must be entered, including its location, records of repair and maintenance, and the manufacturer.

   A reference number is given and written on a printed paper label, which is attached to each item. This number is recorded in a ledger of equipment with full identifying details.

   All equipment in the hospital/laboratory that is in the care of the hospital service workshop should be recorded on registers or cards, as shown in the format ahead.

Table 8: Sample Equipment Service History Form

Sample Equipment Service History Form									
Name of facility						EQUIPMENT FUNCTION			
Location									
Department									
Name of equipment:				Approved by:		Date installed:			
Manufacturer:						Manuals:			
Distributor:				Power:_____v _____a no. of wires:		Freq. of P.M:			
Model number:				Type of enclosure:		Remarks:			
Serial number:				Type of plugs:					
Date	C/P	W.O N.O.	LEAKAGE		WORK DONE	Work By	Total labour hours	Parts cost	Remarks
			GRD	O.GRD					
C=Curativerepair P=Preventiverepair Leakage= Leakage current									

2. **Establishing a 'Maintenance Schedule'**

   After determining what is to be done, the frequency of the task must be decided. A heavily used item must be cleaned and checked more frequently than one, which is used less often; however, minimum frequency must be set. The frequency suggested in the manufacturer's manual can be used as a guide, but the actual usage should determine the maintenance

procedure required.

The schedules presented here are meant to serve only as guidelines; modifications may be introduced to conform to the manufacturers' specifications. An outline record card will be included with each schedule for recording measurements. The engineer should also note on the record card any item that needs to be replaced, if work is to be carried out later, and whether or not the same engineer is to carry out the work.

For several types of equipment, the maintenance needs are dependent on the hours of use. Log sheets should be displayed on every equipment and reveals regular record of every run.

Table 9: Instrument/Equipment Logbook

Instrument/Equipment Logbook								**Instrument Code No.:**
Date	**Name of Instrument /Equipment**	**Starting Time**	**End Time**	**Total Time Used**	**Status**	**Operator Sign**	**Checked By**	**Remarks, if any**
Verified By : (Date)				**Remarks / Comments / Suggestion by Verifier**				

Emergency contact number for emergency management of equipment breakdown should be displayed on every equipment.

Assessment Scoring Matrix

Standard 15. MER-3: Comprehensive procedures for equipment management and maintenance exist in the laboratory.

Indicator 49 - 53		Max Score	Weightage (Percentage)	Score Obtained
Ind 49.	**Log books of all equipment are available.**	10	**100**	
Ind 50.	**Regular periodic maintenance and calibration record of all the equipment is available in the log books.**	10	**100**	
Ind 51.	**Documented and relevant log sheet is displayed on each equipment.**	10	**80**	
Ind 52.	**Emergency contact number(s) is/are displayed on all equipment.**	10	**80**	
Ind 53.	**Equipment inventory is maintained.**	10	**100**	
Total		50		

2.5 Recording and Reporting System (RRS)

03 Standards & 9 Indicators

The RRS standards highlight that correct and timely generation of lab reports contribute significantly in facilitating the physicians towards precise diagnosis and patient care and that the clinical staff must be facilitated by timely and accurate information from the labs to provide coordinated and integrated care. In addition, it is important to protect the privacy of the data collected and to limit unauthorized access to the patients' information.

Clinical laboratory and medical records support patient care. Currently, there is major drive to computerize laboratory data and medical records, but without improvement in the quality of data/paper records and data entry, perceived benefits of computerization cannot be realized. Structuring the laboratory record can bring direct benefits to patients by improving patient outcomes and doctor performance and the onus for improving records lies with individual health professionals.

Standard 16. RRS-1: The laboratory has a complete and accurate laboratory record for every patient[8]

Indicators (54-58):

Ind 54. Electronic record of every patient is maintained

Survey Process:

A well-kept laboratory record provides a source of reliable future reference and base of validated reporting. Identify that each laboratory record is completely computerized. The laboratory record is required to be maintained for a minimum period of 3 years. "Weeding of Old Record" and period for maintaining various types of record is given at **Annexure J.** The reviewer should randomly check computerized records.

Compliance Requirements:

✓ Computerized laboratory record of all tests conducted.

Scoring:

- If there is computerized record as required above, then score as **fully met.**
- If there is no computerized record as required above, then score as **not met.**

Ind 55. Every laboratory record has a unique identifier

Survey Process:

Identify that each laboratory record has a unique identifier which can be the CNIC number or mobile number or lab/computer specific number. The importance of this indicator is that there may be more than one record for a patient or that there is a possibility that two or more patients have the same name and parentage information, so laboratory results might be placed into the wrong laboratory record. The reviewer should check records with associated identifier.

Compliance Requirements:

✓ Use of unique identifier numbers for each patient.

Scoring:

- If there is a clear mechanism to positively identify each patient's laboratory record associated with a specific identifier, then score as **fully met.**
- If there is no clear mechanism to positively identify each patient's laboratory record with a specific identifier, then score as **not met.**

[8] Downtime policy describing how the records will be available, is required to available.

Ind 56. The record provides an up-to-date and chronological account of each patient's record of tests

Survey Process:

A complete record of every patient is available in chronological order. Randomly review the record of 15-20 patients to determine if the laboratory adequately records the results for all tests. Check the availability of records in chronological order.

Compliance Requirements:

✓ The patient record is chronological.

Scoring:

- If the laboratory record shows chronological order of each patient's tests done in the laboratory, then score as **fully met.**
- If the laboratory record does not show chronological order of each patient's tests done in the laboratory, then score as **not met.**

Ind 57. Only authorized person make entries in the laboratory record

Survey Process:

Only authorized individuals can make entries into the laboratory records. The reviewer should confirm documented evidence of notified names of authorized persons who can make entries into the laboratory record.

Compliance Requirements:

✓ Written authorization of particular staff who can perform data entry.

Scoring:

- If all entries into the laboratory record are made by authorized persons, then score as **fully met.**
- If there is any entry made by an unauthorized person, then score as **not met.**

Ind 58. Every laboratory record entry is dated, timed and the person making entries can be identified

Survey Process:

Assessors must focus attention on checking the entries for date, time and name of data entry operator during the review of randomly selected 10-20 of the reports in the last one year.

Compliance Requirements:

✓ The lab records are dated, timed and the person making the data entries can be identified.

Scoring:

- If entries are made as above, then score as **fully met.**
- If there is inconsistency in the record to above description and entries are not made as above, then score as **not met.**

GUIDELINES

Electronic Medical Record[9]

Maintaining an electronic medical record (computerized medical record) serves as the most convenient, reliable and cost effective central repository for planning patient care and documenting communication amongst the patient and healthcare service providers/professionals contributing to patient care. In addition to facilitating provision of high quality patient care, an appropriately documented medical record also serves as a legal document to verify the services provided.

Maintaining electronic records is the best method for lab records due to the speed with which the reports can be replicated and communicated to the care providers/patients/clients. All clinical labs are therefore required to computerize their record. Laboratory computerization can range from a simple computer data entry for printing reports to a sophisticated software based intercommunicating system on which the section/lab incharge can view the report for verification before it is released. It is also important for the lab staff to be generally familiar with the ways patient record is maintained in HCEs for ease of inter communication.

The following are general minimum aspects of patients records at any HCE, whereas specialized services, such as emergency services or surgical services, shall contain such additional documentation as required for those services;

1. Outpatient Records. Medical records for outpatients shall contain at least the following:
   i. A unique identifying number and a patient identification form.
   ii. Name, address, DoB, gender and person to be notified in an emergency.
   iii. Diagnosis of the patient's condition.
   iv. The name of the physician ordering treatment or procedures.
   v. Patient allergies.
   vi. Physician's orders or orders from another practitioner authorized by law to give medical or treatment orders as applicable.
   vii. Documentation of informed consent providing information about the procedures for which consent is required by law/regulations.
   viii. Reports from any diagnostic testing.
   ix. Sufficient information to justify any treatment or procedure provided, report of outcome of the treatment, progress notes and the disposition of the patient after treatment.
2. Inpatient Records. Medical records for inpatients shall contain at least the following:
   i. A unique identifying number and a patient identification form.
   ii. Name, address, DoB, gender and person to be notified in an emergency.
   iii. The date and time of the admission.
   iv. The admitting diagnosis and clinical symptoms.

[9] Authority O.C.G.A. Sec. 31-7-2.1. History. Original Rule entitled “Medical Records” adopted. F. Nov. 22, 2002; eff. Dec. 12, 2002.

v. Name of the attending physician.
vi. Any patient allergies.
vii. Documentation regarding advanced directives.
viii. Report from the history and physical examination.
ix. Report of the nursing assessment performed after admission.
x. Laboratory, radiological, electrocardiogram, and other diagnostic assessment data or reports as indicated.
xi. Reports from any consultations.
xii. The patient's plan of care.
xiii. Physician's orders or orders from another practitioner authorized by law to give medical or treatment orders.
xiv. Progress notes from staff members involved in the patient's care, which describe the patient's response to medications, treatment, procedures, anesthesia, and surgeries.
xv. Data or summary data where appropriate, from routine or special monitoring.
xvi. Medication, anesthesia, surgical, and treatment records.
xvii. Documentation that the patient has been offered the opportunity to consent to procedures for which consent is required.
xviii. Date and time of discharge.
xix. Description of condition, final diagnosis, and disposition on discharge or transfer.
xx. Discharge summary with a summary of the hospitalization and results of treatment.
xxi. If applicable, the report of autopsy results.

Unique Patient Identifiers

All documents of a patient must be consistently labeled with at least 1 unique identifier so that it can be verified that documents correspond to the particular patient. Computer generated unique ID number is the easiest and correct identification method. Since the patient's medical record becomes a focal point in cases where there is a question regarding the care and treatment rendered; it is therefore important that the medical record is kept accurately and timely. The medical record serves three primary purposes: i. to ensure quality of patient care; ii. to provide documentary evidence of the patient's course of illness and treatment; and iii. to facilitate review.

Medical record is often considered as a means of protecting the HCE by providing a defense in a medical malpractice action. However, the purpose of the medical record is not to provide a defense only, but is also to preserve the truth. A complete and accurate medical record will protect the legal interests of the patient, the HCE and the responsible practitioner. The medical record will provide a justifiable defense, or will indict the responsible party if there is no justifiable defense.

Accurate identification of a patient is the backbone of an effective and efficient medical record system. Correct identification is needed to positively identify the patient and ensure that each patient has one medical record number and one medical record with no more duplicates. In order to identify patients, we need a UNIQUE PATIENT CHARACTERISTIC, the type and number of which will change from one setting to another. Some useful unique patient characteristics include the following:

1. Client/Patient full name
2. Gender
3. Date of Birth (DoB)

4. Computerized National Identification (CNIC) number
5. Mother's first name
6. Father's first name
7. Social security number
8. Health insurance number
9. In the case of a new-born, physical/anatomical characteristic, e.g. fingerprint or footprint

The following are NOT considered as unique characteristics:

1. Where a person lives is NOT a unique patient characteristic because it can change.
2. A person's age is NOT a unique patient characteristic because it DOES change.
3. A patient's birthplace, although it does not change, is NOT used as a unique character because it is often identified by most people as being the place where they 'come from' as opposed to the place where they were actually born. Similarly, many people are born at the same place/city/ hospital/town etc.

Up-to-date Chronological Record

Information documented during or immediately after providing care or about an event when it occurs, is considered to be more reliable and accurate record of care than information recorded later, based on memory.

Chronological entries present a clear picture of the sequence of care provided/of events over time and facilitates better communication amongst care providers. It is imperative that record of tests of every patient/client be maintained sequentially and in chronological order. It means that all tests done at a particular lab should be available in a date wise sequence.

Access to Medical Record

Lab management should authorize in writing, the person/s who can enter the data pertaining to tests for reporting and due verification/signing before the reports are released to patients/clients.

The medical record may be used to validate the site of the service, medical necessity and appropriateness of the diagnostic and/or therapeutic services provided, and that the services have been reported accurately. HCE policy identifies and authorizes the personnel who can access the patient's record to ensure confidentiality of patient information.

Recording of Date and Time of the lab record starts from the time a sample is received in the lab or when patients report for sampling, with recording the particulars of the person making the entry. Similarly, it is important to record date and time when the report is generated and then released to the concerned person with particulars of the person doing so. Recording accurate date and time is important whenever there is a need to produce the documentation as a proof of certain action having been taken on time. It is a valuable source of data for coding and health research, as well as an evidence and rationale for funding and resource management. Laboratory authorities shall ensure implementation of this requirement.

Assessment Scoring Matrix

Standard 16. RRS-1: The laboratory has a complete and accurate laboratory record for every patient.

Indicator 54 - 58		Max Score	Weightage (Percentage)	Score Obtained
Ind 54.	**Electronic record of every patient is maintained.**	10	**100**	
Ind 55.	**Every laboratory record has a unique identifier.**	10	**100**	
Ind 56.	**The record provides an up-to-date and chronological account of each patient's record of tests.**	10	**100**	
Ind 57.	**Only authorized person to make entries in the laboratory record.**	10	**100**	
Ind 58.	**Every laboratory record entry is dated, timed and the person making entries can be identified.**	10	**100**	
Total		50		

Standard 17. RRS-2: A comprehensive reporting system exists in the laboratory

Indicators (59-60):

Ind 59. A computerized reporting system is available[10]

Survey Process:

The laboratory should have a computerized reporting system. The reports should be duly signed by the section incharge/any authorized person. The assessor should review 10-20 computerized reports of the patients/clients who reported to the laboratory in the last one year. Also check if reports are digitally/manually signed.

Compliance Requirements:

- ✓ Availability of a computerized reporting system.
- ✓ All reports to bear digital/manual signatures/name of the authenticating pathologist.

Scoring:

- If all of the reviewed reports are computerized and duly signed, then score as **fully met.**
- If any report is not computerized, then score as **not met.**

Ind 60. Critical results and notifiable diseases are reported

Survey Process:

Critical results and notifiable diseases are required to be immediately reported to relevant persons/authorities as the case may be. Check the submission of critical results and reports of notifiable diseases to relevant persons/authorities.

Compliance Requirements:

- ✓ Critical results are reported to the concerned consultant/client immediately.
- ✓ All notifiable disease reports are submitted to concerned authorities.

Scoring:

- If the critical result/s and notifiable disease/s are reported to the concerned person/authority as applicable, then score as **fully met.**
- If the reporting system does not exist or there is no evidence of compliance, then score as **not met.**

[10] Format of the checklist provided in the Guidelines.

GUIDELINES

A Laboratory Information Management System (LIMS) is a software based laboratory and information management system used for patient's reporting, with features that support a modern laboratory's operations. LIMS tends to have a base set of functionality which includes:

1. The reception and log in of a sample and its customer data
2. Tracking of a sample

SOPs for Reporting Critical Laboratory Results

1. Critical test results are defined as any values/interpretations for which delays in reporting can result in serious adverse outcomes for patient care. These values should be defined by the laboratory director, in consultation with the concerned clinicians. The scope includes laboratory, cardiology, radiology, and other diagnostic tests in the inpatient, emergency, and ambulatory settings[11].
2. All critical reports are verbally informed to the concerned person/client/consultant immediately by the pathologist. The laboratory should have procedures for immediate notification when results of certain tests fall within established 'alert' or 'critical' ranges.
3. As soon as the technical validity of the results has been established by a senior technician/technologist/pathologist, the requesting doctor must be contacted without delay. If the identity of the requesting doctor is not obvious from the request form, his/her identity must be ascertained from the client. If this fails, urgent results can be phoned to the ward or clinic sister or the most senior nurse on duty or the patient/client as the case may be.
4. When results are transmitted verbally, in all cases the request form must be signed to indicate when and to whom and by whom the results are communicated provisionally. This must always be followed by a report duly signed by the pathologist.
5. Such results will be telephoned to any patient-care unit lacking a computer terminal. A written record of test results telephoned to patient care areas must be made by the physician, nurse or other individual who receives the report.
6. The process developed by the organization for managing the critical results of diagnostic tests must include a definition of critical tests and critical values for each type of test, by whom and to whom the critical test results are reported, the established time frames for reporting and follow-up and an established method for monitoring compliance.
7. Advanced technologies and innovations may be used for prompt reporting/communication of results to the requesting clinicians. However, blood group results should not be communicated on telephone.

SOP for Reporting Notifiable Disease Results

It is the responsibility of the laboratory management to be aware of the notifiable diseases and intimate detection of any of those to the concerned authority.

[11] Joint Commission on Accreditation of Healthcare Organization (JCAHO) Standards.

Assessment Scoring Matrix

Standard 17. RRS-2: A comprehensive reporting system exists in the laboratory.

Indicator 59 - 60		Max Score	Weightage (Percentage)	Score Obtained
Ind 59.	**A computerized reporting system is available.**	10	**100**	
Ind 60.	**Critical results and notifiable diseases are reported.**	10	**100**	
Total		20		

Standard 18. RRS-3: The laboratory record supports continuity of patient care

Indicators (61-62):

Ind 61. Minimum reporting time for every test is documented

Survey Process:

The minimum reporting time for every test is documented so that the patient can access his/her reports after that specified time. Review the documented minimum reporting time for every test. Check the time of availability of reports of tests done in the last one week and match their reporting time with the specified minimum reporting time.

Compliance Requirements:

- ✓ The minimum reporting time for every test is documented and displayed for the information of patients/clients.

Scoring:

- If computerized reports are electronically or otherwise accessible after the minimum reporting time, then score as **fully met.**
- If there is no access to reports electronically or otherwise after the minimum reporting time, then score as **not met.**

Ind 62. Reports are accessible to individual patients through a specific code

Survey Process:

NOTE: If the computerized system is online, otherwise mark as NOT APPLICABLE.

The laboratory test record is accessible to patients electronically through a specific code number given on receipt to a particular patient if they so require. Review receipt copies to check if the code number is available.

Compliance Requirements:

- ✓ The patients/clients/doctor can access the reports online through a given code.

Scoring:

- If computerized reports are electronically accessible through the given code number, then score as **fully met.**
- If no access to reports through codes electronically is available, then score as **not met.**

GUIDELINES

Timely Reporting of Laboratory Results

1. The laboratories define the time frame for reporting test results based on patient needs, services offered, and clinical staff requirements. The time frame also includes emergency tests and after- hours and weekend testing needs. Results of the urgent tests, such as those from the emergency department, operating theatres, and intensive care units are given special attention due to their critical importance in planning and monitoring the patient care. In cases where laboratory services are contracted with an outside organization, the test results must also be reported timely as per the time frame set forth by organizational policy or specified in the contract.
2. Turnaround time is the period of time from receipt of the specimen in the laboratory to release of the result. Results of routine tests requested are generally available on the following day. In some cases, a longer turnaround time may be indicated depending on the complexity of the test or when the test is not performed on daily basis.
3. The head of the laboratory must establish liaison with the clinicians requesting for the tests to ensure that specimens are delivered to the laboratory as per the defined time frame and that there is no delay in receipt of the reports once these are released from the laboratory. Any delays, must be investigated to find out the reasons and remedial action to avoid reoccurrence in the future. The HCE/laboratory shall ensure availability of adequate staff, material and equipment to make the laboratory results available within a defined time line.

Electronic Accessibility of Reports to Patients

Computerization of lab record facilitates the patients/clients/concerned care providers to access the electronic reports and for taking actions related to the management of the patients. It is therefore required that a code/password is provided to the concerned person at the time the request for test and the sample is received in the lab to access/download the report, if an online computerized system is available.

Assessment Scoring Matrix

Standard 18. RRS-3: The laboratory record supports continuity of patient care.

Indicator 61 - 62		Max Score	Weightage (Percentage)	Score Obtained
Ind 61.	**Minimum reporting time for every test is documented.**	10	**100**	
Ind 62.	**Reports are accessible to individual patients through a specific code.**	10	**100**	
Total		20		

2.6 Quality Assurance (QA)

04 Standards & 16 Indicators

The processes of Quality Assurance (QA) and Continuous Quality Improvement (CQI) are employed to ensure precision in the functioning of the lab systems to deliver authentic and reliable tests results. QA includes the Internal Quality Assurance (IQA) and External Quality Assurance (EQA). The basic techniques involved are observation of a phenomenon, subjecting to a panel of tests, rechecking the test results, isolating and taking action. If desired results are obtained after implementation of Quality Improvement (QI), continue with the change and look for the next area to improve. If the results are adverse, discard those and try some other technique. Continue to observe the results until a pattern of foreseeable positive results emerges from performing certain actions. QI is easy for healthcare professionals to learn since it is based on the basic scientific model of discovery. As healthcare professionals learn the concepts and strategies behind QI, they will infuse their background scientific and experience into the program. Innovative measures and positive results which include higher quality of service delivered and validated results follow quickly. These standards under the functional area of QA/CQI are a set of procedures and protocols to be persistently followed to achieve the expected quality in the reports (QA) and a systematic approach of using data to measure, assess and improve current performance i.e. QI. This continuous process focuses on outcomes of care, and must include reducing actual and potential risks to patient safety. The standards emphasize documentation of processes, systems and individual behaviors that reduce the likelihood of unanticipated adverse events.

Standard 19. QA-1: The laboratory has a comprehensive and documented Quality Assurance (QA) program

Indicators (63-65):

Ind 63. The laboratory has Quality Assurance (QA) SOPs

Survey Process:
Written SOPs for laboratory QA, covering both IQA and EQA components, are necessary to ensure validity of laboratory results and continuous improvement. Check the availability of QA SOPs and review the SOPs to ascertain that these cover both EQA and IQA.

Compliance Requirements:
✓ Written SOPs on laboratory QA covering both IQA and EQA components.

Scoring:
- If there are QA SOPs covering both IQA and EQA components, then score as **fully met.**
- If there are QA SOPs but do not contain both IQA and EQA components, then score as **partially met.**
- If there are no QA SOPs, then score as **not met.**

Ind 64. There is a designated focal person responsible for Quality Assurance (QA) activities in the laboratory

Survey Process:
QA activities in the laboratory are monitored by a focal person who is responsible for all coordination, reporting and implementation of QA. Check documented evidence of a designated focal person for QA activities.

Compliance Requirements:
✓ Designation of focal person with clear responsibilities regarding QA in the laboratory.

Scoring:
- If there is designated focal person for QA activities, then score as **fully met.**
- If there is no designated focal person for QA activities, then score as **not met.**

Ind 65. Quality Assurance (QA) SOPs are communicated and coordinated among the staff

Survey Process:
QA SOPs are disseminated and awareness is imparted to all staff members. Roles and responsibilities

for various QA activities are assigned and documented. Randomly check the knowledge of 5-10 employees regarding QA SOPs.

Compliance Requirements:

- ✓ Written SOPs on laboratory QA covering both IQA and EQA components.
- ✓ Documentary evidence of staff orientation on SOPs.
- ✓ Interview the staff.

Scoring:

- If there is evidence of dissemination of SOPs among the staff and the knowledge of staff regarding QA SOPs is up to the mark, then score as **fully met.**
- If there is deficient knowledge of staff regarding QA SOPs, then score as **not met.**

GUIDELINES

Comprehensive Quality Assurance Program of Lab

Quality assurance (QA) is an ongoing, comprehensive program which analyzes every aspect of an entire operation; it involves determining a quality goal, deciding whether the goal has been achieved or not, and ensuring corrective actions accordingly.

In the laboratory, QA involves the entire testing process: pre-analytical, analytical (testing), and post- analytical processes.

The QA program must:

1. Assess the effectiveness of the lab's policies and procedures.
2. Identify and correct problems.
3. Assure the accurate, reliable, and prompt reporting of test results.
4. Assure the adequacy and competency of the staff.

The lab must also initiate corrective actions when problems occur and document all QA activities.

Quality assurance in clinical laboratories incorporates all the factors that may influence achieving the reliable results and comprises of two key components. First, the internal quality control (IQC) that includes appropriate measures taken during day-to-day activities to control all possible variables that can influence the outcome of laboratory results. This is a continuous process that operates concurrently with analysis. Second, external quality assurance (EQA), entailing provision of blind samples to the laboratory by the external agency contracted for testing and reporting, which is necessary to conduct comparability of results among laboratories.

Quality Control

Quality control procedures are used in each assay to assure that a test run is valid and the results are reliable those include:

1. Kit controls
2. Quality control samples

There are many procedures and processes that are performed in the laboratory, and each of these must be carried out correctly in order to assure accuracy and reliability of testing. An error in any part of the cycle can produce a poor laboratory result. For assuring the quality, a method of detecting errors at each phase of testing is needed.

The entire set of operations that occur in testing is called the path of workflow which begins with

the patient and ends in reporting and results interpretation. The concept of the path of workflow is a key to the quality control and must be considered when developing quality practices. For example, a sample that is damaged or altered as a result of improper collection or transport cannot provide a reliable result.

The complexity of the laboratory system requires that many factors, including the following, must be addressed to assure quality in the laboratory:

1. The laboratory environment
2. Quality control procedures
3. Communications
4. Record keeping
5. Competent and knowledgeable staff
6. Good-quality reagents and equipment.

Assuring accuracy and reliability throughout the path of workflow depends on good management of all of the essentials of quality.

1. Organization

In order to have a functioning quality management system, the structure and management of the laboratory must be organized so that quality policies can be established and implemented. There must be a strong supporting organizational structure as the management commitment is crucial and there must be a mechanism for implementation and monitoring.

2. Personnel

The most important laboratory resource is competent, motivated and committed staff. The quality management system addresses many elements of personnel management and oversight, and reminds of the importance of encouragement and motivation.

3. Equipment

Each piece of equipment used in the laboratory must be functioning properly. Choosing the right equipment, installing it correctly, ensuring that new equipment works properly, and having a system for maintenance are important components of the equipment management program in a quality management system.

4. Purchasing and Inventory

Proper management of purchasing and inventory of reagents and supplies in the laboratory is a challenging task and can produce cost savings, in addition to ensuring that supplies and reagents are available when needed. The procedures that are a part of management of purchasing and inventory are designed to ensure that all reagents and supplies are of good quality, and that they are used and stored in a manner that preserves quality and reliability.

5. Process Control

Process control comprises of several factors that are important in ensuring the quality of the laboratory testing processes. These factors include quality control for testing, appropriate management of the sample, including collection and handling, and method verification and validation. The elements of process control are very familiar to laboratory staff; quality control was one of the first quality practices to be used in the laboratory and continues to

play a vital role in ensuring the accuracy of testing.

6. **Information Management**
   The output of the laboratory is the information (data), primarily in the form of test reporting and needs to be carefully managed to ensure accuracy and confidentiality, as well as accessibility to the laboratory staff and to the health care providers. Information may be managed and conveyed either using paper systems or with computers.

7. **Error Management**
   An 'occurrence' is an error or an event that should not have happened. A system is needed to detect these problems or occurrences, to handle them properly, and to learn from mistakes and take action so that they do not reoccur.

8. **Assessment**
   The process of assessment is a tool for examining laboratory performance and comparing it to standards, benchmarks or the performance of other laboratories. Assessment may be internal (performed within the laboratory using its own staff) or external (conducted by a group or agency from outside the laboratory). Laboratory quality standards are an important part of the assessment process, serving as benchmarks for the laboratory.

9. **Process Improvement**
   The primary goal in a quality management system is continuous improvement of the laboratory processes, and this must be done in a systematic manner. There are a number of tools that are useful for process improvement.

10. **Customer Services**
    Work space and facilities must be such that the workload can be performed without compromising the quality of work and the safety of the laboratory staff, other health care personnel, patients and the community.

A quality control focal person is responsible for the following:

1. Develop a complete and thorough description of QA SOPs. The focal person also ensures that all laboratory personnel are trained in their specific duties when new activities or techniques are introduced into the laboratory.
2. Develop QA tools and train laboratory personnel on these tools.
3. Know how to perform an extensive assessment when developing new activities in the laboratory.
4. Conduct laboratory QA audits, identify errors and plan corrective actions.

Every employee entering a career in analytical clinical laboratory will have to abide by QA SOPs. QA/QC SOPs are communicated to the laboratory staff through a structured program. The training course includes the key components of QA/QC which will help the employees to understand the need to produce sound and authentic laboratory test results by using appropriate standards, controls, written SOPs and method validation.

Assessment Scoring Matrix

Standard 19. QA-1: The laboratory has a comprehensive and documented Quality Assurance (QA) program.

Indicator 63 – 65		Max Score	Weightage (Percentage)	Score Obtained
Ind 63.	**The laboratory has Quality Assurance (QA) SOPs.**	10	**80**	
Ind 64.	**There is designated focal person responsible for Quality Assurance (QA) activities in laboratory.**	10	**100**	
Ind 65.	**Quality Assurance (QA) SOPs are communicated and coordinated among the staff.**	10	**100**	
Total		30		

Standard 20. QA-2: External Quality Assurance (EQA) compliance procedures and tools are available in the laboratory

Indicators (66-67):

Ind 66. External Quality Assurance (EQA) of the laboratory is ensured through external assessment by nationally/internationally recognized bodies

Survey Process:

For implementing an efficient QA system in the laboratory, EQA certification is required from any recognized institute/body which is authorized to do so. For ensuring EQA, at least one certificate from any other recognized institute issued in the last one year is required. Institutes authorized to issue such certificates include NEQAS/Armed Forces Institute of Pathology (AFIP). Check for an EQA certificate issued from NEQAS/AFIP.

Compliance Requirements:

- ✓ EQA certification from NEQAS/AFIP any other recognized institute issued during the last one year.

Scoring:

- If there is availability of at least one EQA certificate in the last one year, then score as **fully met.**
- If there is no EQA certificate in the last one year, then score as **not met.**

Ind 67. Record of External Quality Assurance (EQA) reports are maintained

Survey Process:

EQA reports received from authorized assessment bodies/institutes are maintained by the laboratory. Check for the availability of EQA reports at least for the last one year.

Compliance Requirements:

- ✓ EQA reports from NEQAS/AFIP/any other recognized institute issued in the last one year.

Scoring:

- If the record of EQA reports of the last one year is available, then score as **fully met.**
- If there is no record of EQA reports or the record is deficient, then score as **not met.**

GUIDELINES

Following sample format may be adopted/adapted and used for assessment of quality assurance practices in the laboratory:

Table 10: Assessment of Quality Assurance Practices in Laboratory

Sr. No.	Sample Quality System	Evaluation				Remarks
		Y	P	N	NA	
1.	The laboratory shall define and document its policies and procedures for selection and use of purchased external services, equipment, and consumable supplies that affect the quality of its services. There shall be procedures and criteria for inspection, acceptance/rejection, and storage of consumable materials.					
2.	The laboratory shall participate in inter-laboratory comparisons, such as those organized by external quality assessment schemes.					
3.	The laboratory management shall monitor the results of external quality assessment and participate in the implementation of corrective actions when control criteria are not fulfilled.					
4.	Management review shall take account of follow-up of previous management reviews, status of corrective and required preventive action, the outcome of recent internal audits, assessment by external body, outcome of external quality assessment, quality indicators, non-conformities, monitoring of turnaround time, results of continuous improvement processes and evaluation of suppliers.					

* Y = Yes, P = Partial, N = No, NA = Not Applicable

Assessment Scoring Matrix

Standard 20. QA-2: External quality assurance (EQA) compliance procedures and tools are available in the laboratory.

Indicator 66 - 67		Max Score	Weightage (Percentage)	Score Obtained
Ind 66.	**External Quality Assurance (EQA) of the laboratory is ensured through external assessment by nationally/internationally recognized bodies.**	10	**100**	
Ind 67.	**Record of External Quality Assurance (EQA) reports are maintained.**	10	**100**	
Total		20		

Standard 21. QA-3: Internal Quality Assurance (IQA) is ensured through standardized laboratory practices

Indicators (68-75):

Ind 68. Policies and procedures guide the safe collection of specimens

Survey Process:
Review the laboratory policy and procedure manual to validate that it covers the SOPs for safe collection of specimens.

Compliance Requirements:
- ✓ SOPs for safe collection of specimens available.
- ✓ Evidence that the SOPs for safe collection of specimens are being implemented.

Scoring:
- If the SOPs for safe collection of specimens are available and being implemented, then score as **fully met.**
- If the SOPs for safe collection of specimens are not being implemented, then score as **not met.**

Ind 69. Policies and procedures guide the identification and proper labeling of specimens

Survey Process:
Review the laboratory policy and procedure manual to validate that it covers the SOPs for identification of specimens. Then, by observation, check for example how a patient whose blood is being drawn was positively identified and how the specimen was labeled as these actions are taken simultaneously and have great significance for patient safety (misidentified patient and mislabeled specimens are a common source of laboratory errors).

Compliance Requirements:
- ✓ SOPs for patient identification and labeling of specimens available.
- ✓ SOPs for patient identification and labeling of specimens being implemented.

Scoring:
- If the SOPs for specimen identification are available and being implemented, then score as **fully met.**
- If the SOPs for sample identification and proper labeling are not being implemented, then score as **not met.**

Ind 70. Policies and procedures guide the safe handling of specimens

Survey Process:

Review the laboratory policy and procedure manual to validate that it covers the SOPs for safe handling of specimens. Then, by observation, check how the specimen is handled safely.

Compliance Requirements:

- ✓ SOPs for safe handling of specimens available.
- ✓ SOPs for safe handling of specimens being practiced.

Scoring:

- If the SOPs for safe handling of specimens are available and being implemented, then score as **fully met.**
- If the SOPs for safe handling of specimens are missing or not being practiced, then score as **not met.**

Ind 71. Policies and procedures guide the safe transportation of specimens

Survey Process:

Review the laboratory policy and procedure manual to validate that it covers the SOPs for safe transportation of specimens. Then, by observation, check for example, how the specimen was safely sent to the relevant section of the laboratory, or to a referral laboratory, as mishandling of specimens during transportation is a common source of laboratory errors.

Compliance Requirements:

- ✓ SOPs for safe internal and external transportation of specimens available.
- ✓ SOPs for safe transportation of specimens being practiced.

Scoring:

- If the SOPs for safe transportation of specimens are available and being implemented, then score as **fully met.**
- If the SOPs for safe transportation of specimens are not being implemented, then score as **not met.**

Ind 72. Policies and procedures guide the safe processing of specimens

Survey Process:

Review the laboratory policy and procedure manual to validate that it covers the SOPs for safe processing of the specimens. Then, by observation, check for example, how a specimen was processed.

Compliance Requirements:

- ✓ SOPs for safe processing of specimens available.

✓ SOPs for safe processing being practiced.

Scoring:

- If the SOPs for safe processing of specimens are available and being implemented, then score as **fully met.**
- If the SOPs for processing of specimens are not being implemented, then score as **not met.**

Ind 73. Policies and procedures guide the safe disposal of specimens

Survey Process:

Review the laboratory policy and procedure manual to validate that it covers the SOPs for safe disposal of specimens and general waste. Laboratory specimen disposal should be in accordance with the Hospital Waste Management Rules 2018, as amended from time to time, based on the EPA Act. Safe disposal has great significance for the safety of laboratory staff, the patients and the environment, and in containing the spread of infections.

Compliance Requirements:

✓ SOPs for safe disposal of specimens available.
✓ SOPs for safe disposal of specimens being practiced.

Scoring:

- If SOPs for the safe disposal of specimens are available and being implemented, then score as **fully met.**
- If SOPs for the safe disposal of specimens are not being implemented, then score as **not met.**

Ind 74. Availability of controls for Internal Quality Assurance (IQA) is ensured

Survey Process:

Controls are the materials incorporated in or added to a reaction, which has predetermined results, and are required to validate efficient working of kits, procedures and equipment. Check the availability of controls for every test and review documented evidence for use of controls.

Compliance Requirements:

✓ Controls are available for IQA.
✓ Controls are used for IQA as per technical instructions.

Scoring:

- If there is availability of controls that are used properly in tests, then score as **fully met.**
- If there are no controls being used in tests, then score as **not met.**

Ind 75. Process cycle records are maintained

Survey Process:

It is important that the process cycle records for each equipment are maintained properly. Surveyors are required to check the record accordingly.

Compliance Requirements:

✓ Every process cycle record, having the following information, is maintained:

- Date of process.
- Process start and end time.
- Sample identity.
- Total samples in each process.
- Signatures of the person authorized to operate the machine on each process cycle record.

Scoring:

- If there is availability of process cycle record fulfilling the above requirements, then score as **fully met.**
- If there is no process cycle record or it has deficient information, then score as **not met.**

GUIDELINES

SOPs for Handling of Specimens

Sample Collection

Specimen collection is the first phase of interaction between the patient and the laboratory. Appropriate counseling should be done before specimen collection, and consent taken whenever needed. Attention should be paid to the patient's sensibilities during the entire process. Any error in specimen collection can lead to erroneous results. It is therefore considered an important step of good clinical laboratory practice and is referred to as **'pre-analytic control'**.

1. A phlebotomist/laboratory technician will be responsible for collecting the sample.
2. Specimen collection can be done at the patient's bedside, in the laboratory or in the field.
3. Trained manpower should be employed for specimen collection.
4. A laboratory should have a 'Primary Specimen Collection Manual', containing information on patient preparation before specimen collection (if any), and the exact methodology of specimen collection, labeling, handling, transportation and storage of the specimens. In addition, the laboratory should provide adequate and appropriate information/instructions to patients wherever necessary. All pre- analytical factors that may influence the test results should be identified. This manual should be available for reference and should be used for the training of staff engaged in specimen collection.

Guidelines for obtaining/collecting specimens:

1. Collect the material from the site in which the etiologic agent will most likely be found.
2. Collect the specimen at the optimum time (e.g., early morning sputum for acid-fast bacillus [AFB].
3. Obtain cultures prior to administration of antibiotics whenever possible.

4. Collect adequate volume of material. Inadequate amounts of specimen may yield false negative results.
5. Collect the specimen in a manner that minimizes or eliminates contamination from indigenous flora as much as possible, to ensure that the sample will be representative of the infected site.
6. Use appropriate collection devices, transport media and sterile, leak proof containers.
7. Use sterile equipment and aseptic technique to collect the specimen, to prevent the introduction of microorganisms during invasive procedures.
8. Clearly label the specimen including specific information regarding the site of collection (e.g., blood obtained via blue lumen of right subclavian central catheter) and complete the ordering process.
9. Identify the specimen source and/or specific site correctly so that proper processing methods and culture media will be selected by the laboratory personnel.
10. If the specimen is collected through intact skin, cleanse the skin first with 70% alcohol followed by an iodine solution (e.g. povidone-iodine) or chlorxidine/alcohol combination. If iodine is used, remove excess iodine after the specimen has been collected.
11. Provide clear instructions to patients if they are collecting their own specimen (e.g., clean catch urine or stool) in order to obtain the best quality specimen and allay their fears.
12. Deliver the specimen promptly to the laboratory. Delay in transport may compromise the specimen.
13. As with all patient contact episodes, consistent attention must be given to hand hygiene and use of appropriate Personal Protective Equipment (PPE).
14. Use appropriate safety devices to minimize risk of accidental needle stick, cut or puncture. It is advisable to make sure the user is knowledgeable about how the safety device works prior to its use.

Every laboratory should make a Lab Safety Manual according to the following guidelines:

Laboratory Safety Procedures

1. General

i. Work carefully and cautiously in the laboratory, using common sense and good judgment at all times.
ii. EATING, DRINKING AND SMOKING IS PROHIBITED in the laboratory and in the laboratory space of a combined lecture/laboratory room.
iii. Long hair must be tied back during laboratory sessions.
iv. Open toed shoes are prohibited.
v. No sleeveless tops are permitted. Thighs and midriffs must be covered with protective clothing while working in the laboratory. Lab coats must be worn when directed by the instructor.
vi. Identify the location of all exits from the laboratory and from the building.
vii. Be familiar with the location and proper use of fire extinguishers, fire blankets, first aid kits, spill response kits and eye wash stations in each laboratory.
viii. Note the location of the red phones (if available) that provide direct access to the office of the management. In the event of an emergency, pick up the red receiver and state the location and the nature of the emergency. Identify the location of the nearest desk phones.
ix. Report all injuries, spills, breakage of glass or other items, unsafe conditions, and

accidents of any kind, no matter how minor, to the instructor immediately.

x. Keep sinks free of paper or any debris that could interfere with drainage.
xi. Lab tables must be clear of all items that are not necessary for the lab exercise.
xii. Wash hands and the lab tables with the appropriate cleaning agents before and after every laboratory session.

2. Open Flames - Fire Hazard

i. Identify and be familiar with the use of dry chemical fire extinguishers that are located in the hallways and laboratory rooms.
ii. Flames are only to be used under the supervision of the instructor.

3. Sharp Objects and Broken Glass

i. Pointed dissection probes, scalpels, razor blades, scissors, and microtome knives must be used with great care, and placed in a safe position when not in use.
ii. Containers designated for the disposal of sharps (scalpel blades, razor blades, needles, dissection pins, etc.) and containers designated for broken glass are present in each laboratory. Never dispose of any sharp object in the regular trash containers.
iii. Report all cuts, no matter how minor, to the senior.
iv. All labs and the preparation room house a first aid kit containing antiseptics, bandages, band-aids and gloves to care for minor cuts.
v. Do not touch the broken glass with bare hands. Put on gloves and use a broom and dustpan to clean up glass. Dispose of ALL broken glass in the specific container marked for glass. Do not place broken glass in the regular trash.
vi. When cutting with a scalpel or other sharp instrument, forceps may be used to help hold the specimen. Never use fingers to hold a part of the specimen while cutting.
vii. Scalpels and other sharp instruments are only to be used to make cuts in the specimen, never as a probe or a pointer.

4. Noxious Chemicals

i. Material Safety Data Sheets should be available in a yellow binder mounted on the door of the laboratory. In case of a spill, an accident or a safety question, staff can find chemical safety information in the Data Sheets.
ii. The lab should be equipped with a portable safety exhaust hood for the handling of noxious fumes.
iii. Chemical spill clean-up kits should be available in every lab.

5. Instrument and Equipment

Care must be used when handling any equipment in the laboratory. The staff is responsible for being familiar with and following correct safety practices for all instruments and equipment used in the laboratory.

i. Microscope Handling

a. Microscopes must be carried upright, with one hand supporting the arm of the microscope and the other hand supporting the base. Nothing else should be carried at the same time.
b. Microscopes must be positioned safely on the table, NOT near the edge.

c. After plugging the microscope into the electrical outlet, the cord should be draped carefully up onto the table and never allowed to dangle dangerously to the floor.
d. The coarse adjustment must NEVER be used to focus a specimen when the 40x or oil immersion lens is in place.
e. When finished with the microscope, the cord should be carefully wrapped/secured before returning it to the cabinet.
f. The microscope must be placed upright and in the appropriate numbered slot in the cabinet.
g. All prepared microscope glass slides are to be returned to their appropriate slide trays; wet mount preparations are to be disposed of properly.
h. Malfunctioning microscopes should be reported to the instructor.

ii. Hot Plates and Water Baths

a. The instructor will regulate the temperature of hot plates and water baths with a thermometer.
b. This equipment must be placed in a safe place.
c. Use insulated gloves or tongs to move beakers or test tubes in and out of the water baths.
d. Use care when working near hot plates and water baths, as they may still be hot even after being turned off.

6. Preserved Specimens

i. Gloves (latex and non-latex) are provided to handle preserved specimens.
ii. When larger specimens are being dissected, the part of the specimen that is not being dissected should be kept enclosed in the plastic bag.
iii. When dissecting smaller specimens, seal the bag after removing the specimen, so as to confine the preservative in the specimen bag.
iv. Notify the instructor if there is a spill of preservative.
v. Body parts or scraps of the specimen are NOT to be disposed of in the sink.
vi. Dispose of dissecting pins or other sharp objects in the red sharps containers, NOT in the regular trash.
vii. Specimens are to be clearly labeled and stored in designated containers or cabinets when not in use.
viii. Follow the directions of the instructor concerning the proper disposal of preserved specimens after they are finished being used.

7. Body Fluids

Special precautions are to be followed in all laboratories using any body fluids, such as blood, saliva, and urine because of the potential to transmit disease-causing organisms.
Follow all instructions carefully.

i. Use gloves and goggles in all laboratory experiments that involve the use of body fluids.
ii. All contaminated material, such as slides, cover slips, toothpicks, lancets, alcohol swabs, etc., must be placed in a biohazard bag for proper disposal and should never be reused.
iii. No samples of body fluids are to be brought into the laboratory from outside sources

Histology and Cytology Laboratory Safety Procedures

The following laboratory safety guidelines for histology and cytology are in addition to the laboratory safety procedures to be followed for all sorts of laboratories:

1. Students are only permitted to work on the preparation of histology slides (including infiltration and embedding, sectioning, and staining) during the scheduled class time and under the guidance of the instructor.
2. Staff should wear protective gloves when handling fixatives, embedding solutions, and staining solutions.
3. Only water is to be poured down the sinks; all chemical solutions should be collected in labeled waste containers.
4. Xylene must be used under the hood.
5. Any spills should be reported immediately to the instructor or laboratory technician.
6. Staff must use forceps to transfer slides from one coplin jar to the next.
7. All lids on the coplin jars must be secured except when transferring slides from one jar to the next.
8. All sharp instruments (e.g., razor blades and microtome blades) must be handled with extreme care and disposed of in designated sharps containers.
9. Before removing a paraffin block from the microtome, the microtome wheel must be locked in position and the microtome blade must be removed from the blade holder.
10. All scraps of paraffin must be swept from the floor and the microtome table, using a dustpan and brush.
11. Microtomes must be covered when not in use.
12. The specimen should be secured properly so that there is no leakage, spillage or contamination. A biohazard symbol should be used on the containers during transportation. Appropriate specimen transportation kits (such as use of dry ice, etc.) should be used wherever required. The specimen should be sent to the laboratory along with the requisition form.

There is clearly a difference between the hazards posed by packages sent to a specialist or reference laboratory and those to a routine diagnostic laboratory. The former are likely to contain cultures or concentrates of infectious agents whereas the bulk of the latter is not particularly infectious. It is advisable that cultures and such specialized materials are unpacked in the laboratory by professional staff. There is concern over the use of clerical staff for receiving and documenting specimens. It is not unusual to see food and drink being consumed by clerical staff near the specimens. The disturbingly large numbers of untrained staff who acquire infections in the laboratory undoubtedly include clerical and reception staff.

Therefore, it is essential that clerical staff handling specimens should be given some form of training in the safe handling of specimens (Fig-1). Any specimen in a plastic bag which carries a 'Danger of Infection' label should not be removed from that bag. The accession number can be put on the outside of that bag. Leaking or broken specimens should not be touched. Provision should be made for a member of the professional staff to deal with such samples. These specimens should not be allowed to be moved to other parts of the room.

Figure 4: Protective Measures

SOPs for Safe Handling and Proper Labeling of Specimens

Identification and Labeling

A properly labeled sample is essential so that the results of the test match the patient. The key elements in labeling are:

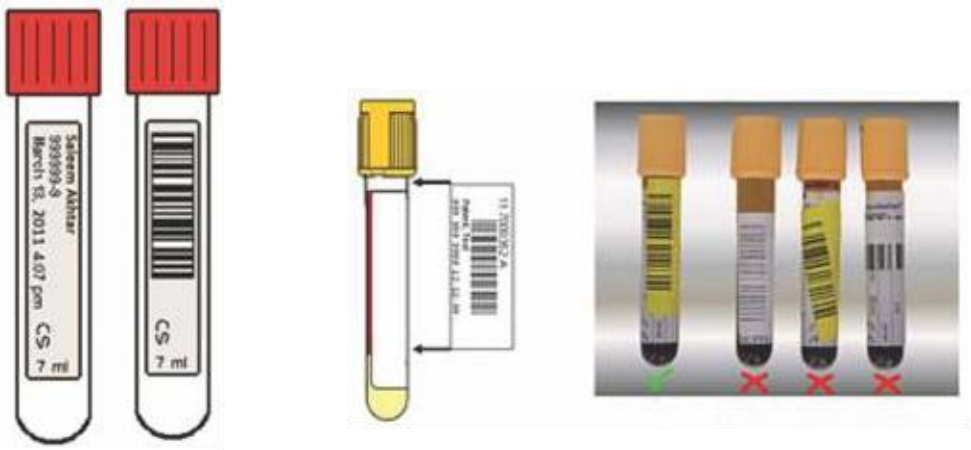
1. Patient's surname, first and middle.
2. Patient's ID number.
   NOTE: Both of the above MUST match the same on the requisition form.
3. Date, time and initials of the sample collector must be on the label of EACH tube.
4. Automated systems may include labels with bar codes.

The date and signature/initials of the collector must be recorded after the specimen has been collected and after verifying that the patient's name and ID on the label agrees with that on the test requisition. This is the single most important factor in preventing errors in a patient's specimen identification. Use of a request form wrapped around the container is not acceptable as a specimen label (Fig-2). Specimens will not be accepted if the information on the specimen label does not match the information on the accompanying requisition.

Figure 5: Labeling Sample Tube

Examples of labeled collection tubes are shown below:

Figure 6: Labeling Sample Tubes



SOPs for Safe Transportation of Specimens Safe Transportation

Figure 7: Safe Transportation

Transport Within Hospitals and to Referral Labs

All employees are required to take reasonable care of their own health and safety as well as that of all other persons who may be affected by their acts or omissions at work. Responsibility for the safe collection and packaging of clinical samples shall rest entirely upon the sender. It is therefore imperative that all areas where clinical materials are generated remain conversant with up to date safety codes of practice.

All laboratory Specimens are Potentially Hazardous.

It is important that care is taken when collecting and handling clinical samples to ensure that the risk of infection to staff is kept to an absolute minimum. These rules must be observed at all times and never allowed to lapse at busy periods or because of a failure to maintain adequate supplies of bags or containers. Members of staff employed within the laboratory must not be put at risk because of ignorance, negligence or bad technique.

Note: Never leave samples unattended in a public area.

Transport of Samples using Courier Services

1. Samples must always be carried in closed boxes, which are clearly marked as 'Biological Substance'.
2. Samples must be individually bagged, placed in a secondary bag containing absorbent material, sealed and carefully placed in the transport container.
3. Two storage boxes will be provided for each surgery or clinic, one for holding blood specimens and one for non-blood specimens.
4. On collection by the couriers, the samples will be transferred by the couriers into two separate transport boxes, one for blood, and one for non-blood, lined with a clear plastic bag containing absorbent material and which can be secured with a cable tie when full.
    i. Where a patient's pathology request requires both blood and non-blood samples, these should be placed in the non-blood containers.
    ii. Blood and tissue slides should be regarded as sharps and placed in an appropriate plastic slide transport box before packaging.
    iii. Handle specimen containers gently at all times.
    iv. Samples must never be carried unprotected in the open hand or given to other members of staff in this way.
    v. Samples must not be left unattended when not secured in the van.
5. The patient's confidentiality must be preserved at all times.
6. In the event of a vehicle breakdown or a road traffic accident, do not allow persons other than courier or laboratory staff to handle specimens.
    i. Any spillage must be reported immediately to a designated senior member of the department concerned.
    ii. Decontamination materials shall be carried in each vehicle to enable small spillages to be contained. In the event of major contamination, the pathology support services must be contacted before any material is touched.
7. The response by the pathology laboratory staff will depend upon the size and extent of the spillage and upon the level of contamination.
8. All decontamination shall be in accordance with the Pathology Safety Policy which should be available as SOPs. Always wash hands thoroughly before rest breaks and at the end of a work period.

Sample Processing

1. Collect the required amount of specimen. While small amounts of blood are now used for many automated tests, there are minimum requirements. Optimum collection volumes allow for the test to be repeated and verified, if necessary.
2. Minimum volumes are to be used for patients where unnecessary blood loss may affect the patient's status.
3. When difficulties are encountered with blood volumes, consult the laboratory. Avoid hemolysis, which can elevate certain analytes (e.g., LDH, K, AST).
4. Follow specific specimen processing instructions. The laboratory should develop its SOPs in this regard.
5. A Quality Control Manual should be developed by each laboratory.
6. Instrument and method of testing for each test should be defined.
7. Periodic calibration of equipment as per laboratory/manufacturer guidelines should be

conducted and records should be documented.

8. Never decant or aliquot the specimen from one type of container to another.
9. Unusual specimens (lipemic, icteric, hemolyzed) may require a repeat specimen.
10. When using tubes with anticoagulants, especially for coagulation tests, a sufficient fill volume is required to ensure the appropriate specimen dilution.
11. Use the proper container and mix all specimens containing anticoagulant or preservative by gentle inversion 8 to 10 times.
12. Reference ranges and critical values should be defined for each test.

Figure 8: A View of a Laboratory

Sample Disposal

Make an inventory of toxic compounds in the laboratory and prepare a protocol for their collection and disposal.

Waste sample remains should never be disposed of by washing down a drain. Use proper receptacles for this purpose. Nevertheless, sinks and gullies should be fitted with removable SILT TRAPS which should be emptied regularly. In certain cases, heavily polluted samples may have to be treated as toxic chemical waste.

Figure 9: Hazardous Materials Warning Signs

General guidelines for hazardous materials disposal are given on the following page.

1. INFECTIOUS WASTE

i. General

a. Infectious waste must be disposed of in a carefully controlled manner in accordance with National Guidelines on Hospital Management.

b. Infectious waste has been defined to include biological waste, cultures and stocks, pathological waste, and sharps.

c. Infectious waste must either be incinerated or treated prior to disposal.

d. The term infectious waste is synonymous with biohazard; it does NOT include chemical agents, such as carcinogens, which affect living organisms through chemical means.

ii. Definitions

a. Biological Waste

- Includes blood and blood products, excretions, exudates, secretions, suctions and other body fluids that cannot be directly discarded into the municipal sewer system.
- EXCLUDES articles contaminated with fully absorbed or dried blood.
- Biological waste must either be incinerated or sterilized with steam in a dedicated autoclave.
- After treatment, biological waste may be treated as normal refuse.

b. Cultures and Stocks

- Includes etiologic agents and associated biologicals, including specimen cultures and dishes and devices used to transfer, inoculate and mix cultures.
- Includes wastes from the production of biologicals, serums, and discarded live or attenuated vaccines.
- Cultures and stocks must be treated in the same way as biological waste.

c. Pathological Waste

- Includes biopsy materials, all human tissues and anatomical parts from surgery and other procedures.
- Includes carcasses and bedding from animals exposed to pathogens in research, but does NOT include teeth or preservative agents such as formaldehyde.
- Pathological waste must be incinerated.

d. Sharps

- Includes needles, scalpel blades, lancets and syringes that have been removed from their original sterile containers.
- Sharps must be incinerated.
- The definition DOES NOT EXEMPT needles or syringes used for non-infectious materials, such as transferring chemical solutions.

iii. Disposal

a. Waste which is to be incinerated must be collected and taken to an infectious waste incinerator.
b. Waste which may be disposed in the ordinary trash should be clearly marked "NON¬INFECTIOUS" or "STERILE" and put inside outer packaging which is NOT red or orange in color.
c. Autoclaves used for infectious waste treatment must be designated and tested.
d. Autoclave users must develop written operating procedures to keep records with detailed parameters for treatment, methods for monitoring, methods for indicating adequate sterilization conditions during each treatment, and monthly tests of sterilization conditions using a specified biological indicator.

iv. Storage

a. Infectious waste should be segregated from other wastes by puffing it in separate containers at the point of generation.

b. Locate containers to minimize access by unauthorized persons and clearly identify as containing infectious waste.
c. Except for sharps, store infectious waste in red plastic bags OR containers made of other materials impervious to moisture and strong enough to prevent tearing under normal use conditions.
d. Pathological, biological and culture/stock wastes should be treated or disposed within 7 days of generation, or within 30 days if refrigerated or frozen.
e. If a generator (laboratory or department) produces less than 50 pounds of waste in a calendar month, the 7 day storage limitation does not apply.
f. Sharps should be contained in leak proof, rigid, puncture resistant RED containers which have tight lids or are taped closed.
g. There is no limit on the length of storage for sharps.

2. CHEMICAL WASTE

i. General

a. Prior to disposal of any chemical waste, a designated person must perform an official hazardous waste determination to see if the waste is hazardous.
b. A short list of non-hazardous chemicals can be notified; all others should be considered hazardous until the determination has been made.
c. Hazardous waste is incinerated, at off-site locations, whenever possible. Departments are encouraged to employ waste reduction procedures to limit costs. Use these guidelines to prepare and request disposal of hazardous chemical waste.

ii. Hazardous chemical waste refers to any material substance that is;

a. CORROSIVE (pH<2 or pH>12)
b. REACTIVE (oxidizers, water reactive)
c. FLAMMABLE (flash point <140 F)
d. TOXIC

iii. Containers

a. All waste must be in appropriate NON-LEAKING containers with lids that are non-leaking, tight fitting and are not cracked, broken, or chemically damaged.
b. The container size should match the amount of waste.
c. Containers must be compatible with the waste contained.
d. Liquid containers must be less than 5 gallons and weigh less than 45 pounds.
e. Paper or cardboard primary containers should be put into sealed plastic bags.
f. Except for common solvents which can be bulked together, waste disposal charges are related to container volume rather than solely a weight basis; a partially full container may cost the same as a full one.

iv. Labels

a. All unused chemicals in original non-leaking containers with the manufacturer's label will be accepted as it is.
b. All other waste requires a hazardous waste label. The labels must be completed and attached to each waste container, except for very small containers.
c. Labels should be affixed in a manner that does not cover existing labels or markings.
d. Solvent labels should preferably be put onto string tags attached to containers.
e. Complete the LOWER part of the label with your name, building, room number,

department, and identification of contents. Include total weight or volume and percent ranges for all constituents.

v. Packing

a. Generators should find cardboard boxes and make them available to the designated staff at the time of waste removal.
b. DO NOT pack waste in boxes, since waste containers will be examined by visual inspection.
c. Sanitary staff will pack waste in boxes according to compatibility.
d. Boxes should be sealable when necessary, and sturdy enough to transport the material.
e. Boxes exceeding 45 pounds or 18 inches on a side cannot be safely handled by one person, and will not be picked up.

3. EMERGENCIES

i. **HAZARDOUS MATERIAL SPILLS** are an inevitable part of most work environments. To effectively combat spills, it is necessary to prepare for them beforehand. Whenever employees work with a substance, they should be aware of its characteristics, and should have formulated plans of what to do in case of a spill, including what steps to take, who to call for assistance, what PPE is necessary, and what material is appropriate to contend with a spill, and where to find appropriate spill-response equipment. Departments are encouraged to have spill response kits at strategic locations.

ii. **GENERAL GUIDELINES** The first step in dealing with any chemical spill is to assess the magnitude of spilled material and the associated level of hazard. No one should attempt to deal with a spill until properly equipped with adequate PPE and spill treatment materials. Risk assessment is successful only if personnel are familiar with the hazardous properties of the material they are handling and have developed methods to follow in the event of a spill.

iii. **PROCEDURES** If the risk assessment suggests you can safely and properly clean up the spill:

a. **Get personal protective equipment.** Do not attempt spill response until you have put on PPE appropriate for the situation. Available equipment may include respiratory protection, goggles, gloves, impervious shoes/boots, and body protection. All equipment will not be necessary for every situation, but should be available. If you are unsure about your ability to control a spill, get assistance. Any spill for which respiratory protection is needed must not be conducted without backup personnel equipped in the same manner.
b. **Get spill control equipment** from your department's spill kit. Spill control materials are sold in two general forms: loose materials (vermiculite, cat litter) and spill control pillows, which are produced in various shapes and contain different types of absorbents. Spill control pillows are preferred because they are much easier to pick up when finished. Also available are materials designed for specific types of chemical spills such as acids or solvents. In general, spilled liquids present more danger than solids, and quick response is therefore critical. For flammable liquids, special attention should be paid to potential ignition sources in the vicinity.
c. Absorb the spill. If there is danger the spill may spread, dike the perimeter with

absorbent, then absorb. "Floor chemistry" should not be attempted. If you desire to perform simple neutralization/treatment schemes, first absorb and contain the material.

d. Collect the contaminated absorbent and put into a sturdy leak proof container. Close the container if there are volatile substances which may continue to pose a threat.
e. Dispose of the contaminated absorbent in the same manner you would dispose of the substance that was spilled. If the spilled chemical is hazardous, do not put the clean-up residue in the dumpster. If hazardous, contact professionals to dispose.

4. EMPTY CONTAINERS AND GLASS

i. Empty Containers

a. Containers that have held hazardous substances are empty by definition when one of two following conditions is met. For one group of materials, a container is empty when all contents have been removed by techniques ordinarily used for that type of material (e.g., pouring for liquids), and the container has less than 3% of the original contents. For another group, a container is only empty when it has been triple rinsed with a solvent capable of removing the remaining contents. Contact the manufacturer for specific discussions of which group a material falls into.
b. In all cases, remove as much of the contents as possible before disposal (including recycling). For liquids, this would be turning the container upside down and letting it drain until no more drops will come out. For low viscosity liquids such as aqueous solutions, let drip no less than 60 seconds.

ii. Non-Hazardous Chemicals

a. A designated person must perform an official hazardous waste determination for disposal of all chemicals.
b. Collect solids in disposable, non-leaking containers, labelled with contents, clearly marked as non-hazardous, and prepared for disposal.
c. Solutions containing only non-hazardous, water miscible liquid materials, with pH between 6 and 9.5, can be disposed through the sewer system.
d. Remember: "hazardous" includes flammable liquids even if water soluble.
   The items listed below are considered NON-hazardous:
   - Acetates: Ca, K, Na, K, Mg, NH4
   - Naturally occurring amino acids and salts
   - Citric acid and salts of Na, K, Mg, NH4, Ca
   - Bicarbonates: Na, K
   - Borates: Na, K, Mg, Ca
   - Bromides: Na, K, NH4
   - Carbonates: Na, K, Mg, Ca, NH4
   - Chlorides: Na, K, Mg, Ca, NH4
   - Formates: Na, K, Mg, Ca, NH4
   - Lactic acid and salts of Na, K, Mg, NH4, Ca
   - Sugars and sugar alcohols
   - Starch
   - Iodides: Na, K, Ca

- Oxides: B, Mg, Ca, Al, Si, Fe, Zn
- Phosphates: Na, K, Mg, Ca, NH4
- Silicates: Na, K, Mg, Ca
- Sulfates: Na, K, Mg, Ca, NH4

Caution: Chemicals and chemical products should not be given or sold to the general public or offered as surplus property. Commercial chemical products may be offered as surplus property if reasonable cautions are followed.

iii. Treatment

a. Elementary neutralization can be performed on wastes which are hazardous only because they are corrosive (acids, bases).
b. A neutralized solution should have a final pH value between 6 and 9. Corrosive waste should not be discharged through the sewer system.
c. Treatment of other materials to lessen the hazard or amount of waste can be included as part of the SOPs in laboratories.
d. Such procedures should be written and made a part of specific experimental protocol.

5. RADIOACTIVE WASTE DISPOSAL

i. General Procedures

a. Only containers available from authorized departments shall be used.
b. Each radioactive waste container must have a record of materials in the container which is kept up-to-date.
c. Mark each container with a "Caution-Radioactive Material" label.
d. Package the waste according to the instructions given for each waste type below.
e. Segregate waste according to half-life:
    - less than 91 days = short-lived
    - greater than 90 days = long-lived
f. When the container is full, complete a Radioactive Waste Disposal tag. Instructions are on the back of the tag.
g. Attach the tag to the outer surface of the container.

ii. Solids

a. Segregate by half-life.
b. Place dry waste in drums, marked "Dry Radioactive Waste Only."
c. Place all solid radioactive waste (filter papers, gloves, bottle caps, empty scintillation vials, etc.) into the innermost plastic liner.
d. When full, tape the plastic liner shut; do not overfill.
e. Do not put unabsorbed liquid in dry waste drums.
f. Do not put contaminated equipment or radioactive powders in dry waste drums.
g. Contain sharps in a separate rigid red plastic container to prevent puncture injuries.

iii. Liquids

a. Aqueous wastes

- Segregate aqueous waste by half-life.
- Must be placed in carboys with secure screw tops.
- Must have a "Caution - Radioactive Material" label attached.
- Keep containers closed during storage.

- Supply secondary containment able to contain the liquid in case of breakage.
- Segregate LSC fluid, aqueous, and other liquids.

b. Scintillation vials with counting fluid

- Must be placed in a container supplied by the duly authorized firm.
- Mark container "Scintillation Vials Only".
- Carefully place UNOPENED vials into the inner plastic liner. When full, tape the plastic liner shut; do not overfill.
- Dispose of bulk liquid scintillation counting fluid by emptying into properly labelled liquid waste jugs and treating as liquid waste.
- Segregate scintillation fluid from other liquid wastes.
- Empty scintillation vials may be washed and reused, or may be disposed as dry waste if they contain NO residual scintillation fluid.

iv. Mixed Waste

Mixed waste is any waste material, other than LSC fluid, that contains radioisotopes and possesses other hazardous properties; i.e. the waste is:

a. Flammable or explosive
b. Toxic
c. Corrosive (pH greater than 12.5 or less than 2)
d. Reactive
e. Persistent (halogenated hydrocarbons and polycyclic aromatic hydrocarbons with more than three and less than seven rings)
f. Carcinogenic
g. Mixed waste must be characterized for isotope as well as hazardous components and concentrations (% by weight or volume)
h. Common examples of mixed waste include:
    - Radio-labelled carcinogens
    - Solvents containing radioisotopes
    - Contaminated lead
i. There is a disposal option for liquid scintillation cocktail containing radioisotopes

v. Waste Storage

The storage of hazardous materials must be in compliance with National Guidelines on Hospital Management. Your methods of handling waste are subject to unannounced inspections by regulatory inspectors.

a. All containers need to have a label at all times indicating the contents. For waste materials, this could be a simple label such as "WASTE SOLVENT" or "USED ACETONE".
b. Put the label on the container BEFORE ADDING WASTE.
c. All containers need a lid at all times when not actively adding or removing waste. Evaporation in a hood is not a legal disposal method. Funnels do not count as lids.
d. Secondary containment is advised for liquid containers.
e. Storage limits and locations are the same for waste as for new materials. For example, storage of flammable liquids in excess of 10 gallons requires a flammable liquid storage cabinet. Glass bottles may not be stored on the floor because they can easily be broken by accidental kicking.

Figure 10: Safe Packing for Disposal

Storage of Specimens and Blood in the Wards, Labs and in other Departments

It is the responsibility of the laboratory staff that:

1. Specimens should be stored in wards or labs, for a limited time period, and arrangements should be made for processing or disposal as early as feasible.
2. Proper storage facility should be provided in the wards and labs (storage cabinets, freezers etc.).
3. Ensure the appropriate labelling of the specimen container and the pathology request form if the patient is known or suspected of having a disease considered as "high risk".
4. Ensure that the specimen is packaged and stored in a suitable and safe manner.
5. Routine Histology specimens must be placed directly into formalin and can be stored at room temperature until transported to the Histology Laboratory.
6. Frozen Section specimens must be sent dry, directly to the Histology Laboratory.
7. FNA slides for Cytology Referral should be stored at room temperature until transported to the Histology Laboratory.

Controls

1. A control is used in all chemistry tests to prove that the independent variable (test result) is the correct change reflecting the dependent variable (sample being tested). In our context, these controls are mediums usually in fluid form having a known standard value, are placed with each chemical test batch to ensure that the test readings produced by the machines are correct up to the required/expected standard. These controls are used for example, for ensuring the accuracy of Glucometer, Spectrophotometer, and the particular test control solutions, e.g. glucose test, Cholesterol test, etc.
2. Commercially prepared positive and negative controls at least once per 24 hours and on opening of a new bottle or when a question of validity of any test arises. The readings should closely conform to the provided/published standard values.

Table 11: Process Cycle Record/Chart

Process Cycle Record/Chart*			
Process/Test Name:			**Summary** Man Machine**
Machine Name:			Duty Duration:
Tech (Man) Name / No.:			Cycle Time:
Supervisor Name:			Idle Time:
Date: dd/mm/yy	Start Time: 00:00	EndTime:00:00	Utilization Ratio:
Additional info if any:			

Sheet No.@		**Kit: Name, Code etc.**			
S/#	Sample Unique ID #	Patient Name	S/#	Patient Unique ID #	Patient Name
1.			2.		
3.			4.		
5.			6.		
7.			8.		
9.			10.		
11.			12.		
13.			14.		

Legend:*One Chart per Cycle, ** All inclusive, @ Extra sheet may be used with other particulars remain constant

Assessment Scoring Matrix

Standard 21. QA-3: Internal Quality Assurance (IQA) is ensured through standardized laboratory practices.

Indicator 68 – 75		Max Score	Weightage (Percentage)	Score Obtained
Ind 68.	**Policies and procedures guide the safe collection of specimens.**	10	**100**	
Ind 69.	**Policies and procedures guide the identification and proper labeling of specimens.**	10	**100**	
Ind 70.	**Policies and procedures guide the safe handling of specimens.**	10	**100**	
Ind 71.	**Policies and procedures guide the safe transportation of specimens.**	10	**100**	
Ind 72.	**Policies and procedures guide the safe processing of specimens.**	10	**100**	
Ind 73.	**Policies and procedures guide the safe disposal of specimens.**	10	**100**	
Ind 74.	**Availability of control for Internal Quality Assurance (IQA) is ensured.**	10	**100**	
Ind 75.	**Process cycle records are maintained.**	10	**100**	
Total		80		

Standard 22. QA-4: Continuous laboratory improvement is documented

Indicators (76-78):

Ind 76. Gaps are identified through QA reports and used as tools for improvement

Survey Process:

NOTE: In case QA reports are satisfactory and there are no gaps, mark as NOT APPLICABLE.

Through EQA and IQA reports, gaps in procedures and processes are identified. These gaps are used as tools for further development.

Compliance Requirements:

- ✓ EQA and IQA reports identifying gaps in procedures and processes.
- ✓ Evidence that identified gaps are used as tools for improvement.

Scoring:

- If gaps are identified through QA reports and those are used as tools for improvement, then score as **fully met.**
- If gaps are identified through QA reports, but not used as tools for improvement, then score as **not met.**

Ind 77. Corrective actions are implemented upon identification of gaps

Survey Process:

QA reports should suggest corrective actions for identified gaps. Check documented evidence for implementation of corrective actions.

Compliance Requirements:

- ✓ EQA and IQA reports suggest corrective actions for the identified gaps.
- ✓ Record confirms that suggested corrective actions are implemented.

Scoring:

- If corrective actions are suggested and implemented, then score as **fully met.**
- If corrective actions are not suggested/taken, then score as **not met.**

Ind 78. Measures are taken to minimize recurrence of errors

Survey Process:

Gaps once identified and rectified are to be avoided in future. Review documented evidence for

measures to minimize recurrence of errors.

Compliance Requirements:

✓ Documented evidence for measures taken to minimize recurrence of errors.

Scoring:

- If there are documented measures to minimize recurrence of errors, then score as **fully met.**
- If there are no measures taken for minimizing recurrence of errors, then score as **not met.**

GUIDELINES

Figure 11: Quality Improvement Process

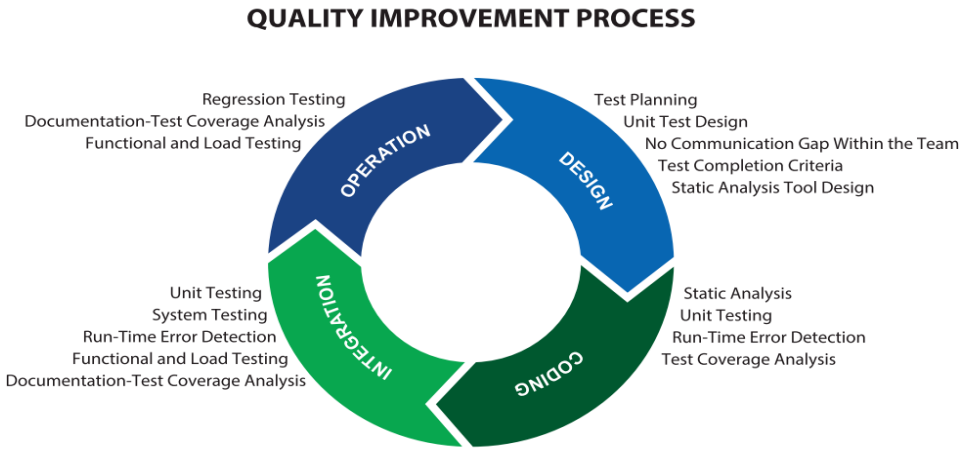


Table 12: Pre-Analytical Errors

PRE-ANALYTICAL ERRORS	
PATIENT PREPARATION	
TYPE OF ERROR	**PREVENTIVE ACTION**
Wrong patient preparation	Enquiry before sample collection
SAMPLE COLLECTION	
TYPE OF ERROR	**PREVENTIVE ACTION**
Wrong container of collection	Appropriate container is selected
Wrong order of draw	Follow proper order of draw
Mixing error	Blood samples are mixed properly
Hemolysis	Care is taken during blood collection
Wrong labeling	Patient's name with laboratory no.

With data readily available, laboratory management can view all of their test results and not only identify errors but also retrace their root cause, delivering actionable information to monitor and improve QA processes. Subsequently, this improves the quality of laboratory measurements and enables management to verify that all processes are operating to set standards of performance. Daily management with a laboratory analytics system and an engaged leadership team are essential components in monitoring quality assurance and reducing lab errors. When laboratory data is managed daily, dramatic improvements can be made and errors can be eliminated, resulting in improved specimen quality, utilization, instrument performance, and patient safety.

Assessment Scoring Matrix

Standard 22. QA-4: Continuous laboratory improvement is documented.

Indicator 76 – 78		Max Score	Weightage (Percentage)	Score Obtained
Ind 76.	**Gaps are identified through QA reports and used as tools for improvement.**	10	**100**	
Ind 77.	**Corrective actions are implemented upon identification of gaps.**	10	**100**	
Ind 78.	**Measures are taken to minimize recurrence of errors.**	10	**100**	
Total		30		

2.7 Biosafety and Biosecurity (BSBS)

06 Standards & 18 Indicators

Prevention of Healthcare Associated Infections (HAIs) is one of the major safety initiatives a clinical laboratory is required to undertake. A large number of infected specimens of human origin are brought to the laboratory for testing and reporting. Therefore, the laboratory staff is likely to come in contact with any of such samples accidentally and can acquire the infection, sometimes with serious consequences. Necessary measures adopted for reducing the risk of unintentional exposure to pathogens and toxins or their accidental release for reducing the risk of infections/disease, is referred to as biosafety.

The patient samples are subject to security risks as misuse of the stored samples can be a potential source of biohazard at the national and international level. Due protection and security of such sources of biohazards is mandatory responsibility of every laboratory. Measures adopted for reducing the risk of unauthorized access, loss, theft, misuse, diversion or intentional release of such samples for any such acts, is referred to as biosecurity.

These standards provide the biosafety and biosecurity framework for clinical laboratories and require the development and implementation of plans to prevent and control microbial infections and hazards by using an integrated approach across all programs, services and settings.

Standard 23. BSBS-1: The laboratory has a comprehensive and coordinated biosafety program

Indicators (79-82):

Ind 79. Availability of laboratory biosafety SOPs

Survey Process:

Written laboratory biosafety SOPs should cover all activities necessary for infection control, including at least safe handling of specimens, isolation procedures, safe sample storage, hand hygiene procedures and disposal of the specimens, etc. Review biosafety SOPs for infection control.

Compliance Requirements:

- ✓ Documented laboratory biosafety SOPs available.

Scoring:

- If there are documented biosafety SOPs that includes at least all of the above, then score as **fully met.**
- If there are no documented biosafety SOPs, then score as **not met.**

Ind 80. Biosafety SOPs are communicated to the laboratory employees

Survey Process:

Check from the record that written biosafety SOPs are disseminated to all staff and that they are aware of the same. Assess knowledge of the representative sample of the laboratory staff on biosafety SOPs.

Compliance Requirements:

- ✓ Record confirms that copies of written biosafety SOPs are provided to the laboratory employees.
- ✓ Record confirms that the staff was trained to implement these SOPs.
- ✓ Staff are aware of these SOPs.

Scoring:

- If the biosafety SOPs are available with laboratory staff and they are aware of the same and these are implemented, then score as **fully met.**
- If the biosafety SOPs are not available with laboratory staff or they are not aware of the same, or if these are not implemented, then score as **not met.**

Ind 81. The laboratory has a designated qualified technician for ensuring biosafety activities

Survey Process:

Review if there is any designated and trained person for ensuring implementation of biosafety SOPs.

Compliance Requirements:

✓ Designation of a qualified technician for ensuring biosafety activities.

Scoring:

- If a person is designated for the above activities, then score as **fully met.**
- If no person is designated for the above activities, then score as **not met.**

Ind 82. Regular biosafety monitoring reports are generated in the laboratory

Survey Process:

Regular biosafety reports are required to be generated by a designated technician on a monthly basis. Review monthly biosafety reports produced and reported.

Compliance Requirements:

✓ Record of monthly biosafety monitoring reports prepared by the designated technician.

✓ These reports are submitted to the laboratory head on a regular basis.

Scoring:

- If monthly biosafety monitoring reports are available in the laboratory, then score as **fully met.**
- If there are no reports on biosafety, then score as **not met.**

GUIDELINES

SOPs on biosafety should cover the following topics:

1. Introduction to General Safety and Training for the Biosafety Level (BSL) (number) Laboratory
    i. Required Training
    ii. Administrative Procedures
    iii. Description of Laboratory
    iv. General Laboratory Safety
    v. Biosafety Cabinet Safety
    vi. General Accident Procedures
2. Standard Operating Procedures
    i. Containment Requirements
        a. Laboratory Entry/Exit
        b. Specimen Transport
        c. Work within the Laboratory
    ii. Proper Use and Maintenance of Equipment
        a. Biological Safety Cabinets
        b. Incubators
        c. Centrifuges
        d. Autoclave

e. Emergency Equipment
f. Repair and Service

iii. Operational Procedures
a. Inventory Control System
b. Working inside the Biosafety Cabinet
c. Working outside the Biosafety Cabinet
d. Removal of Equipment, Vable samples, and Autoclavable Aastes from the Biosafety Cabinet
e. Internal Clean-up, Decontamination and Waste Disposal
f. Maintenance of Laboratory (insert room number)
g. Recording of Data

iv. Experimental Procedures
a. Safety Checks and Emergency Procedures
b. Training and Orientation
c. Personal Protective Equipment
d. Waste Removal from lab
e. Management of Spills
f. Management of Accidental Exposures
g. Medical Surveillance
h. Emergency Phone Numbers and Procedures
i. Emergency Phone Numbers
j. General Emergency Procedures
k. Responding to Specific Emergencies

Required Training

Training and Orientation (describe your lab requirements)

All employees will attend the courses in laboratory safety training, biological safety training, and fire safety/fire prevention (respiratory protection training and radiation safety training as needed), and annual refreshers. Training record should be present in personal files.

The minimum requirements for qualification to work in the BSL2 lab are:

1. Trainings including biosafety, lab safety, and fire safety and prevention
2. Specimen handling and processing
3. Use of PPE

Laboratory personnel shall demonstrate the following:

1. Willingness to follow established laboratory safety guidelines and these standard operating procedures.
2. The lab manager/head will provide information and arrange for training at the time of an individual's initial assignment to the lab. He/she will arrange for refresher training at least annually and when there are any changes in processes or procedures.

Administrative Procedures

It is the responsibility of each employee to carefully consider every action taken in the BSL 2 lab and its potential impact on possible exposure or contamination, and to follow established standard operating procedures (SOPs) and protocols diligently and without variance.

1. All employees will read and adhere to the Biosafety Manual and to the SOP Manual for the

laboratory. All employees will use pertinent sections in this Biosafety Manual as a guideline and reference.

2. All employees will attend the training courses in Laboratory Safety training, Biological Safety training, Respiratory Protection training, and Fire Safety/Fire Prevention. Records of certification will be kept in the human resources files.
3. All employees working in the lab will be will be provided vaccination.
4. No employee will be trained to work in the lab without the express permission of the lab manager/head.
5. New SOPs and protocols must be approved by the lab manager/chair before initiation.
6. Current SOPs and protocols will be reviewed and/or revised by the laboratory manager every 6 months.

A scientist, trained and knowledgeable in appropriate laboratory techniques, safety procedures, and hazards associated with handling infectious agents must be responsible for the conduct of work with any infectious agents or materials. He/she will be ultimately responsible for ensuring implementation of a comprehensive biological safety program for all laboratories under their charge. This individual should also consult other health and safety professionals with regard to risk assessment.

Responsibilities of the Biosafety Focal Person

1. Development of a complete biosafety program
2. Cooperation and interaction between the following entities:
    i. Responsible for the health and safety of those working with biological materials and/or select agents and toxins in his/her laboratory;
    ii. Ensures proper training and instruction for laboratory personnel in safe practices and protocols, including, at a minimum, training in aseptic techniques and biology of the organism(s) used;
    iii. Ensures that laboratory personnel receive any necessary medical surveillance;
    iv. Ensures that biosafety cabinets are certified as needed;
    v. Ensures that personal protective equipment is provided and used; and
    vi. Ensures compliance by laboratory personnel with relevant regulations, guidelines, and policies.

A **biosafety level** is a set of biocontainment precautions required to isolate dangerous biological agents in an enclosed laboratory facility. The levels of containment range from the lowest biosafety level 1 (BSL-1) to the highest at level 4 (BSL-4).

Biosafety Level 1 is suitable for work involving well-characterized agents not known to consistently cause disease in immunocompetent adult humans, and present minimal potential hazard to laboratory personnel and the environment. BSL-1 laboratories are not necessarily separated from the general traffic patterns in the building. Work is typically conducted on open bench tops using standard microbiological practices. Special containment equipment or facility design is not required but may be used as determined by appropriate risk assessment. Laboratory personnel must have specific training in the procedures conducted in the laboratory and must be supervised by a scientist with training in microbiology or a related science.

Biosafety Level 2 builds upon BSL-1 and is suitable for work involving agents that pose moderate hazards to personnel and the environment. It differs from BSL-1 in that: i. laboratory personnel have specific training in handling pathogenic agents and are supervised by scientists competent in

handling infectious agents and associated procedures; ii. access to the laboratory is restricted when work is being conducted; and iii. all procedures in which infectious aerosols or splashes may be created are conducted in Biosafety Cabinets (BSCs) or other physical containment equipment.

Biosafety Level 3 is applicable to clinical, diagnostic, teaching, research, or production facilities where work is performed with indigenous or exotic agents that may cause serious or potentially lethal disease through the inhalation route of exposure. Laboratory personnel must receive specific training in handling pathogenic and potentially lethal agents, and must be supervised by scientists competent in handling infectious agents and associated procedures. All procedures involving the manipulation of infectious materials must be conducted within BSCs or other physical containment devices. A BSL-3 laboratory has special engineering and design features.

Biosafety Level 4 is required for work with dangerous and exotic agents that pose a high individual risk of aerosol-transmitted laboratory infections and life-threatening disease that is frequently fatal, for which there are no vaccines or treatments. Agents with a close or identical antigenic relationship to agents requiring BSL-4 containment must be handled at this level until sufficient data are obtained either to confirm continued work at this level, or re-designate the level. Laboratory staff must have specific and thorough training in handling extremely hazardous infectious agents. Laboratory staff must understand the primary and secondary containment functions of standard and special practices, containment equipment, and laboratory design characteristics. All laboratory staff and supervisors must be competent in handling agents and procedures requiring BSL-4 containment. The laboratory supervisor in accordance with institutional policies controls access to the laboratory.

(For further details refer to Biosafety in Microbiological and Biomedical Laboratories - CDC)

Table 13: Biosafety Level One Laboratory Inspection Sample Report

Biosafety Level One Laboratory Inspection Sample Report		Name of HCE Institutional Biosafety Committee	
Lab P.I./Contact Person:	Inspection Date:	Inspected By:	
Lab Location (Bldg/Rm - one room per report):	College/Department:	Campus Phone #/ (or Mail Stop):	
List of agents that will be used/stored in lab (list recombinant DNA, bacterial, viral, fungal, parasitic, prion, toxic, or other agents):			
INSPECTION CHECKLIST (Citation numbers refer to Biosafety in Microbiological and Biological Laboratory sections in the BSL-1 criteria)			

LABORATORY FACILITIES AND EQUIPMENT		**Y**	**N**	**NA**
A.3	Food must be stored outside the laboratory area.			
A.3.a	Needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal.			
A.3.b	Used, disposable, sharps must be carefully placed in conveniently located puncture-resistant containers used for sharps disposal.			
A.3.c	Non-disposable sharps must be placed in a hard walled container for transport to a processing area for decontamination, preferably by autoclaving.			

A.3.d	Broken glassware must not be handled directly. Plastic ware should be substituted for glassware whenever possible.			
A.6	Perform all procedures to minimize the creation of splashes and/or aerosols.			
A.7	Decontaminate work surfaces after completion of work and after any spill or splash of potentially infectious material with appropriate disinfectant.			
A.8	Decontaminate all cultures, stocks, and other potentially infectious materials before disposal using an effective method.			
A.8.a	Materials to be decontaminated outside of the immediate laboratory must be placed in a durable, leak proof container and secured for transport.			
A.9	A sign incorporating the universal biohazard symbol must be posted at the entrance to the laboratory when infectious agents are present.			
A.10	An effective integrated pest management program is required.			
LABORATORY FACILITIES AND EQUIPMENT		**Y**	**N**	**NA**
A.11	The laboratory supervisor must ensure that laboratory personnel receive appropriate training regarding their duties, the necessary precautions to prevent exposures, and exposure evaluation procedures. Personnel must receive annual updates or additional training when procedural or policy changes occur.			
C.2	Protective laboratory coats, gowns, or uniforms are recommended.			
C.3	Wear protective eyewear when conducting procedures that have the potential to create splashes.			
C.4	Gloves must be worn to protect hands from exposure to hazardous materials.			
C.4.b	Remove gloves and wash hands when work with hazardous materials has been completed and before leaving the laboratory.			
D.1	Laboratories should have doors for access control.			
D.2	Laboratories must have a sink for hand washing.			
D.3	The laboratory should be designed so that it can be easily cleaned. Carpets and rugs in laboratories are not appropriate.			
D.4	Laboratory furniture must be capable of supporting anticipated loads and uses. Spaces between benches, cabinets, and equipment should be accessible for cleaning.			
D.4.a	Bench tops must be impervious to water and resistant to heat, organic solvents, acids, alkalis, and other chemicals.			
D.4.b	Chairs used in laboratory work must be covered with a non-porous material that can be easily cleaned and decontaminated with appropriate disinfectant.			
D.5	Laboratories windows that open to the exterior should be fitted with screens.			

INSPECTION FINDINGS

Checklist Number	Deficiencies Recommended	Status of Corrective Actions

Institutional Biosafety Committee (IBC) Disposition: Approved for work at BSL-1		Provisionally approved for work at BSL-1
Comments:		
Signature of Reviewer:		Date:

Assessment Scoring Matrix

Standard 23. BSBS-1: The laboratory has a comprehensive and coordinated biosafety program.

Indicator 79 - 82		Max Score	Weightage (Percentage)	Score Obtained
Ind 79.	**Availability of laboratory biosafety SOPs.**	10	**100**	
Ind 80.	**Biosafety SOPs are communicated to the laboratory employees.**	10	**100**	
Ind 81.	**The laboratory has a designated qualified technician for ensuring biosafety activities.**	10	**100**	
Ind 82.	**Regular biosafety monitoring reports are generated in the laboratory.**	10	**100**	
Total		40		

Standard 24. BSBS-2: Continuous staff biosafety measures are ensured and documented

Indicators (83-85):

Ind 83. The laboratory has appropriate consumables, equipment and facilities to ensure biosafety

Survey Process:

To avoid any biohazard risk to the employees, at least Personal Protective Equipment (PPE) should be available in the laboratory. Check the stock registers for the availability of all necessary items. Physically check some of the PPE items.

Compliance Requirements:

✓ Availability of required PPE.

Scoring:

- If the PPE items are available in the laboratory, then score as **fully met.**
- If PPE items are not available in the laboratory, then score as **not met.**

Ind 84. All staff involved in the handling and disposal of laboratory waste shall receive regular vaccination

Survey Process:

Check the record for appropriate vaccination of staff involved in handling of biohazardous laboratory material. Also check if complete doses are given.

Compliance Requirements:

✓ Record of vaccination of staff at risk against hepatitis B, etc.

Scoring:

- If there is evidence that proper vaccination with complete doses is provided to the staff at risk, then score as **fully met.**
- If there is no vaccination or incomplete vaccination, then score as ***not met.***

Ind 85. Annual medical check-up of all staff is documented

Survey Process:

Check the record for appropriate annual medical checkup of all staff involved in handling of biohazardous laboratory material.

Compliance Requirements:

- ✓ Record of annual medical checkup of all staff involved in handling of biohazardous laboratory material.

Scoring:

- If there is evidence that there is a proper annual medical checkup of all staff involved in handling biohazardous laboratory material is done, then score as **fully met.**
- If there is no evidence of annual medical checkup of the staff, then score as **not met.**

GUIDELINES

Proper Use of Equipment

Biological Safety Cabinets

1. To assure sterility inside the cabinet and establish proper air flow for containment, the blower should be turned on at least ten minutes before infectious materials are to be put into the biosafety cabinet.
2. Biosafety cabinets must be certified prior to use. A qualified outside contractor must certify these cabinets annually. Check the certification sticker on the front of the unit to verify your biosafety cabinet's condition.
3. The biosafety cabinet air flow and Magnehelic gauge should be checked (reading is equal to approximately 0.5 inches) to assure proper operation of the cabinet before placing any materials into it. Readings indicate relative pressure drop across the High Efficiency Particulate Air (HEPA) filter. Higher readings may, therefore, indicate filter clogging. Zero readings may indicate loss of filter integrity. In either of these cases, notify the laboratory manager.
4. NEVER place anything over the front or rear grill of a biosafety cabinet.
5. Disrupting the airflow into the front grill allows contaminated air from inside the cabinet to blow into the lab or directly at the person sitting at the cabinet. It also allows non-sterile air from the room to blow into the biosafety cabinet over the experiments.
6. Materials should be placed in the cabinet so as not to block air flow into the rear grill. Leave a few inches for air to flow around objects. Any disruption of the air flow in the cabinet decreases its effectiveness.
7. Before manipulating infectious materials, make sure that you have everything you need in the cabinet. The fewer times you pull your hands out of the cabinet, the less disruption of the air flow.
8. Work should be performed in the center of the work surface of the cabinet whenever possible. Work outward progressing from clean to dirty (contaminated). However, infectious agents should not be placed directly adjacent to, or directly on, the intake grills.
9. After manipulating infectious agents, make sure all containers are tightly closed.
10. All waste and disposable items generated by work in the cabinet should be left (describe where it should be stored) until properly decontaminated or contained for transport to the autoclave
11. After the cabinet has been emptied, wipe inner surfaces with (name of disinfectant), followed by 70% ethanol. Do not shut down the blower. These instructions must be written to accommodate your lab practices).

12. The bleach in the vacuum traps must be changed after one week of use or when the flask is half full.

    NOTE: No biological agent-containing material should be allowed into any drain connected to the sanitary sewer system (e.g., from a sink) unless the method of inactivation has been pre- approved by the Department of Health. Please contact_____ to obtain pre-approval.
13. The vacuum filters must be replaced if clogged or if liquid makes contact with the filter. Used filters should be placed in the waste to be autoclaved.

NOTE: Though Class IIB cabinets are hard-ducted (so that all air is removed from the room), Class IIA cabinets recirculate about 70% of the air inside themselves and exhaust the remainder to the lab. Any use of volatile solvents, such as absolute ethanol, should be kept to a minimum or done elsewhere. Dangerously high levels of volatile vapors can accumulate inside the cabinet and pose a threat of fire or explosion.

Incubators

1. Upright Incubators (these must be written specific to your lab)
    i. Incubators are normally set at 37o C.
    ii. Temperature should be checked each day by all users.
    iii. Operation manuals are located (describe where these are).
    iv. Fan alarm is sounding, check the panel for the identifying blinking light.
        a. If there is no obvious reason for the alarm, contact the lab manager.
        b. The'CO2 Low' (or High) message indicates a deviation from 5% CO2. Check the hose from the wall to the unit.
        c. The 'tank farm' must be checked for empty tanks once/week.
        d. Decontaminate incubators at least every (insert length of time).

Water Bath

The water bath should be monitored for water level, and filled with distilled water only. To prevent growth of any organisms, water should be treated with (name of disinfectant).

Centrifuges

(Describe procedures)

Autoclave

(Describe procedures)

(Add similar lists for each type of equipment, such as floor shakers, microplate reader, etc.)

Emergency Equipment

1. Fire Extinguisher, located [location(s) of fire extinguisher(s)].
    i. Operation
        a. Fire extinguishers should be used only if the fire is small and confined to one small area! USE JUDGEMENT IN THIS! DO NOT CREATE A LIFE-THREATENING SITUATION WHILETRYINGTO EXTINGUISH A FIRE!
        b. To operate, pull the pin to release the handle.
        c. Stand at a safe distance from the fire (as directed on the fire extinguisher).

d. Aim the nozzle at the base of the fire, squeeze the handle to discharge the agent, and sweep completely left and right until a few seconds after seeing no fire.

ii. Maintenance

Fire extinguishers are inspected annually by EH&S. Check the gauge periodically to ensure operational status. Call EH&S at 965-1823 if you have any questions.

2. Telephones are located (describe locations).

Staff Biosafety

Lab staff should have medical checkups and vaccinations.

1. Following vaccinations should be provided:
   i. Hepatitis B vaccination
   ii. Typhoid vaccination
2. Annual medical checkup of lab staff includes:
   i. Blood complete examination
   ii. Urine complete examination
   iii. Anti-HCV
   iv. HBs Antigen
   v. HIV
   vi. X-ray chest

Assessment Scoring Matrix

Standard 24. BSBS-2: Continuous staff biosafety measures are ensured and documented.

Indicator 83 - 85		Max Score	Weightage (Percentage)	Score Obtained
Ind 83.	**The laboratory has appropriate consumables, equipment and facilities to ensure biosafety.**	10	**100**	
Ind 84.	**All staff involved in the handling and disposal of laboratory waste shall receive regular vaccination.**	10	**100**	
Ind 85.	**Annual medical check-up of all staff is documented.**	10	**100**	
Total		30		

Standard 25. BSBS-3: Patient biosafety is ensured and documented

Indicators (86-87):

Ind 86. Proper ventilated waiting areas for patients are available

Survey Process:
Check the waiting area for patients to see that it is properly ventilated.

Compliance Requirements:
- ✓ Effective ventilation either naturally or by means of exhaust fan(s).

Scoring:
- If the waiting area for patients is well ventilated, then score as **fully met.**
- If the patient waiting area is not properly ventilated, then score as **not met.**

Ind 87. Patients are not allowed inside the laboratory working area

Survey Process:
Check for access control of patients to the laboratory working area. Check for the connection between the patient waiting area and the laboratory working area.

Compliance Requirements:
- ✓ Evidence of controlled entry into the laboratory working area.

Scoring:
- If there is no free patient access to the lab working area and proper checks are available in between, then score as **fully met.**
- If there is unchecked patient access to the laboratory working area, then score as **not met.**

GUIDELINES

Ventilated Waiting Areas
1. The patient waiting area should be airy, with a minimum of one window, at least 5x6 feet in size.
2. Air from the laboratory working areas is not allowed to mix with the room air of the waiting areas. This needs careful consideration regarding the fixing of exhaust fans at both the places and provision of openings for air suction as well as blowing out by the exhaust fans.

Control of Access into Working Areas
Access inside the lab can be controlled by:

1. Placing/caution boards so that patients/relatives do not use it as a thoroughfare
   i. No Thoroughfare.
   ii. Entry Only For Authorized Staff Only.
2. Keeping the connecting door closed.
3. Checking at the connecting entrance of the working area of laboratory by a guard/orderly.
4. Affixing an automatically closing and locking door, which can only be operated by the authorized persons biometrically or by the swipe cards.

Assessment Scoring Matrix

Standard 25. BSBS-3: Patient biosafety is ensured and documented.

Indicator 86 - 87		Max Score	Weightage (Percentage)	Score Obtained
Ind 86.	**Proper ventilated waiting areas for patients are available.**	10	**100**	
Ind 87.	**Patients are not allowed inside the laboratory working area.**	10	**100**	
Total		20		

Standard 26. BSBS-4: There is a documented procedure of bio risk management

Indicators (88-89):

Ind 88. All incident reports are documented

Survey Process:
Review records for proper reporting of incidents which breach laboratory biosafety. Check documented record of action(s) taken on occurrence of the same.

Compliance Requirements:
- ✓ Record of reporting the incidents which breached laboratory biosafety.
- ✓ Record of action(s) taken on occurrence of the same.

Scoring:
- If documented evidence of incident reporting and proper actions taken is available, then score as **fully met.**
- If no incident record is available, then score as **not met.**

Ind 89. Required disinfectants/spill kits are available in the laboratory

Survey Process:
Check stock registers for purchase and regular consumption of standard disinfectants/spill kits.[12]

Compliance Requirements:
- ✓ Availability of required disinfectants/spill kits in the laboratory.
- ✓ Record of regular use of the same.

Scoring:
- If evidence of use of disinfectants/spill kits is available, then score as **fully met.**
- If disinfectants/spill kits are not available in the laboratory, then score as **not met.**

GUIDELINES
1. An Incident Report is appropriate for 'near misses', i.e. incidents not resulting in personal harm or property damage, but which might have, under slightly different circumstances. 2. The Incident Report requires responses from i. the person involved, ii. any witnesses to the incident, and iii. the Principal Investigator/Supervisor. Attach additional pages if necessary to complete the report. **Reports that are not signed by the Principal Investigator/Supervisor will be returned for completion.** The committees require input from the supervisor. See completed

[12] Staff should be trained to manage the spill and use the spill kit. Check for expiry dates where applicable.

example following the instructions.

3. Commonly, there are multiple causes in any given incident-all of which should be identified. Provide a complete and detailed response to each question, making a serious attempt to identify all 'root cause(s).' The contributing factors were probably evident, but overlooked or unrecognized previously. These factors become more distinctly identifiable in light of the specifics of the incident. A well-planned work process will include multiple layers of safeguards. Once causes are identified at all levels, consider safeguards and procedures that might be changed to prevent future incidents.
4. Complete the attached Lab Incident Report Form within 48 hours of the incident. An incident is defined as any unplanned and unwanted event that occurred during the performance of work activities and that resulted in or could have led to injury or material damage to property. Incident repercussions range from minor (e.g., a broken mercury thermometer) to significant (e.g., a 5-gallon bottle of sulfuric acid dropped in a heavy-traffic hallway).
5. This report is not intended to assign blame; it should be used as a tool to foster recommendations for procedural improvement. A well-prepared report will identify all work systems that need to be redesigned to compensate for foreseeable human errors. These reports will also be used to improve safety policies.

Table 14: Incident Report

Incident Report

Please be as accurate as possible. We encourage reporting of all incidents.

Date:_____Time of accident: _____

Name of person reporting incident (Please print): _____

Street address: _____

City: _____ Province:_____Phone#: _____

COMPLETE THIS SECTION IF THERE WAS AN INJURY:

Type of bodily injury (if any): _____

Status of injured person (s): Employee _____Student _____ Client _____Other_____

Location of the accident: _____

No. of persons injured: _____

Name(s) of person(s) injured:_____

_____

_____ 4.

_____

Describe exactly what happened: _____

Emergency medical treatment given?_____Yes_____No

To whom?_____ By whom? _____

Describe procedure(s): _____

Person(s) taken to hospital?_____Yes_____No Name(s): _____

Name of hospital: _____

Were police called to the scene? _____Yes_____No

Name of police station: _____

Official reported: _____

Signatures:(Investigator/Supervisor/Technical Director) _____ID: _____

Absorbents

1. Universal Spill Absorbent – universal spill pillow or absorbent pads in commercial spill kits. Alternatively, a 1:1:1 mixture of Flor-Dri (or unscented kitty litter), sodium bicarbonate, and sand. This all-purpose absorbent is good for most chemical spills including solvents, acids (NOT for hydrofluoric acid), and bases.
2. Hydrofluoric Acid - HF compatible spill pillow or liquid 'HF acid eater'
3. Solvents/Organic Liquid Absorbent - Inert absorbents such as vermiculite, clay, sand, FlorDri, and Oil-Dri.

Neutralizers

1. Acid Spill Neutralizer - sodium bicarbonate, sodium carbonate, or calcium carbonate.
2. Alkali (Base) Neutralizer - sodium bisulfate.
3. Bromine Neutralizer - 5% solution of sodium thiosulfate and inert absorbent.

Personal Protective Equipment (PPE)

1. Goggles and face shield
2. Heavy neoprene gloves
3. Disposable lab coat and corrosive apron
4. Plastic vinyl booties

Tools for Clean-up

1. Plastic dust pan and scoop
2. Plastic bags (30 Gallon, 3 mm thickness) for contaminated PPE
3. One plastic bucket (5 Gallon Polyethylene) with lid for spill and absorbent residues

Others

1. For HF: calcium gluconate gel (always check expiration date)
2. For mercury: aspirator bulb and mercury decontaminating powder
3. For alkali metals: dry sand or a class 'D' fire extinguisher
4. For acid chlorides - Oil Dri, Zorb-All or dry sand

Spill clean-up Procedure

1. The absorbent material is applied to the spill from the outer edge to the center in order to prevent spreading the spilled material. This applies whether you are using dry pourable

absorbents such as clay litter, or using spill pillows or paper towels. Clean up the spill by working from the exterior to the interior of the spill in a circular pattern, not back and forth in a grid pattern as this will spread the spill. Put the used up absorbent material in the plastic bag of the category/color code and dispose accordingly. Commercially available spill kits provide complete guidelines for use.

Assessment Scoring Matrix

Standard 26. BSBS-4: There is a documented procedure of bio-risk management.

Indicator 88 - 89		Max Score	Weightage (Percentage)	Score Obtained
Ind 88.	**All incident reports are documented.**	10	**100**	
Ind 89.	**Required disinfectants/spill kits are available in the laboratory.**	10	**100**	
Total		20		

Standard 27. BSBS-5: Measures to ensure biosecurity in the laboratory are practiced

Indicators (90-91):

Ind 90. Only authorized persons are permitted to enter the sample storage area

Survey Process:

Check documents showing evidence that only authorized laboratory staff can access the sample storage area. Authorized persons should also wear proper ID.

Compliance Requirements:

- ✓ Only authorized persons are permitted to go to the sample storage area.
- ✓ Persons so authorized are identifiable through IDs being worn.

Scoring:

- If only authorized persons, identifiable through IDs being worn are only permitted to go to the sample storage area, then score as **fully met.**
- If there is free access to the sample storage area, then score as **not met.**

Ind 91. Any transportation of samples is properly recorded

Survey Process:

NOTE: In case transportation of samples is not involved, mark as NOT APPLICABLE.

Check the availability of records/logbook for transportation of samples to any other laboratory.

Compliance Requirements:

- ✓ Record of samples transported to other labs, if any is available.

Scoring:

- If sample transportation log book is available, then score as **fully met.**
- If no sample transportation log book is available, then score as **not met.**

GUIDELINES

Sample storage areas are designated as controlled areas within the laboratory and need additional protective measures to ensure the integrity of the security interest involved. For these controlled areas, the following additional protective measures are provided:

1. Access is limited to only those authorized employees who need access in the performance of their official duties.
2. Entrances are secured at all times or monitored by an authorized employee or security guard.

3. Doors are equipped with high security locks or card readers with alarm contacts. High security locks are keyed ‘separately’ from the building master key system. Card readers are keyed ‘alike’.
4. Controlled areas are cleaned only during normal working hours and under the supervision of an authorized employee or security guard.
5. Locks, or their combinations, are changed if the key or combination has been compromised, if the area has been discovered unsecured or unattended, or when an employee no longer needs access due to transfer, termination, retirement, etc.

A sample movement record must be kept for two years and must include the following details:

1. Sample name/description
2. Name of the person completing the record
3. Location details of the place from which the sample is being moved from
4. Location details of the place the sample is being moved to
5. Date of the movement

Assessment Scoring Matrix

Standard 27. BSBS-5: Measures to ensure biosecurity in the laboratory are practiced.

Indicator 90 - 91		Max Score	Weightage (Percentage)	Score Obtained
Ind 90.	**Only authorized persons are permitted to enter the sample storage area.**	10	**100**	
Ind 91.	**Any transportation of samples is properly recorded.**	10	**100**	
Total		20		

Standard 28. BSBS-6: The laboratory has a well-designed, comprehensive and coordinated waste management plan

Indicators (92-96):

Ind 92. Written laboratory waste management SOPs are available

Survey Process:
Surveyors should check the availability of laboratory waste management SOPs.

Compliance Requirements:
- ✓ Written laboratory waste management SOPs available.

Scoring:
- If laboratory waste management SOPs are available, then score as **fully met.**
- If the laboratory waste management SOPs are not available, then score as **not met.**

Ind 93. Waste management SOPs are communicated to the laboratory employees

Survey Process:
Assess the knowledge of the laboratory staff regarding waste management SOPs.

Compliance Requirements:
- ✓ Copies of the lab waste management SOPs are provided to the laboratory employees.
- ✓ Laboratory employees are conversant with the lab waste management SOPs.

Scoring:
- If the laboratory staff has good knowledge of waste management SOPs, then score as **fully met.**
- If the laboratory staff has deficient knowledge of waste management SOPs, then score as **not met.**

Ind 94. The laboratory has appropriate consumables, collection and handling systems and equipment for waste management

Survey Process:
Surveyors should check for the availability of sufficient and appropriate consumables, collection and handling systems and equipment for waste management in the laboratory.

Compliance Requirements:
- ✓ Sufficient and appropriate quantity of the following is available:

- Color coded waste collection bins as given at **Annexure K**
- Color coded bags for waste segregation
- Color coded waste trolleys
- Storage area for hazardous waste

✓ Waste disposal mechanism is available

Scoring:

- If all of the above resources are present, then score as **fully met.**
- If any one of the above requirements is deficient, then score as **not met.**

Ind 95. Contracts with waste disposal service organizations are available

Survey Process:

Check the availability of a contract with a waste disposal agency/company for final disposal of hazardous waste. If the lab disposes off entire waste itself, and has the facility for the same, then a contract/MOU is not required.

Compliance Requirements:

✓ Written contract with waste disposal services if the lab does not dispose of the hazardous waste through an onsite mechanism.

Scoring:

- If a contract as above, or evidence of onsite disposal by the lab itself is available, then score as **fully met.**
- If there is no such contract or on site disposal arrangement, then score as **not met.**

Ind 96. Waste transported from collection centers for final disposal is recorded[13]

Survey Process:

In case of offsite waste disposal from collection centers, check the record of waste transportation to the site of final disposal.

Compliance Requirements:

✓ Record in terms of weight, time and date, of risk waste for offsite final disposal.

Scoring:

- If a record of waste transportation from collection centers is available, then score as **fully met.**
- If there is no record of waste transportation from collection centers, then score as **not met.**

[13] Where applicable.

GUIDELINES

The details in SOP standardize the process and provide step-by-step instructions that enable anyone within the system to perform the task/procedure in a consistent and correct manner. The SOP also serves as an instructional and reference resource. The step-by-step written procedure furthermore contributes to the concept of accountability because staff expectations and health care facility procedures are documented and activities can be measured against the SOP. Communicating procedures that anyone in the system can follow with consistent results will ensure that the health care facility continually provides a minimum quality of service.

SOPs of the following waste management steps should be present:

1. Identification, segregation, packaging
2. Handling of packaged health care risk waste
3. Waste storage
4. On site transport
5. Waste quantification
6. Decontamination of general surfaces
7. Spillage management
8. Waste management
9. Worker health and safety

For checking knowledge of laboratory staff, review available SOPs. From the SOPs, ask 10 questions from each relevant staff. If at least 8 questions are correctly answered, then score it as good knowledge (Fig-8).

Figure 12: Waste Collection Trolley

Waste Storage

A storage location for healthcare waste should be designated inside the healthcare establishment or research facility. The waste, in bags or containers, should be stored in a separate area, room, or building of a size appropriate to the quantities of waste produced and the frequency of collection.

Recommendations for storage facilities for healthcare waste are as follows:

1. The storage area should have an impermeable, hard-standing floor with good drainage; it should be easy to clean and disinfect.
2. There should be a water supply for cleaning purposes.
3. The storage area should afford easy access for staff in charge of handling the waste.
4. It should be possible to lock the store to prevent access by unauthorized persons.
5. Easy access for waste-collection vehicles is essential.
6. There should be protection from the sun.
7. The storage area should be inaccessible for animals, insects, and birds.

8. There should be good lighting and at least passive ventilation.
9. The storage area should not be situated in the proximity of fresh food stores or food preparation areas.
10. A supply of cleaning equipment, protective clothing, and waste bags or containers should be located conveniently close to the storage area.
11. Unless a refrigerated storage room is available, storage times for healthcare waste (i.e. the delay between production and treatment) should not exceed the following:
    i. Temperate climate: 72 hours in winter, 48 hours in summer
    ii. Warm climate: 48 hours during the cool season, 24 hours during the hot season

Waste Disposal

As per waste management rules either or a combination of the following methods are applicable for waste disposal:

1. Dumping
2. Incineration
3. Treatment and disposal in municipal waste:
    i. Waste disposal can be done through indigenous arrangements or can be contracted out. The contract should be valid and categorically mention the outsourced services and also specify the method of disposal.

Record should be maintained in registers as under:

Table 15: Daily Waste Disposal Record Register Format

Daily Waste Disposal Record (Register Format)										
Date	Time	No. of Yellow Bags	Wt. of Yellow Bags	Labeling	No. of Sharps Containers	Wt. of Sharps Containers	Labeling	Handed Over By	Vehicle No.	Receivers Signature

Assessment Scoring Matrix

Standard 28. BSBS-6: The laboratory has a well-designed, comprehensive and coordinated waste management plan.

Indicator 92 - 96		Max Score	Weightage (Percentage)	Score Obtained
Ind 92.	**Written laboratory waste management SOPs are available.**	10	**100**	
Ind 93.	**Waste management SOPs are communicated to the laboratory employees.**	10	**100**	
Ind 94.	**The laboratory has appropriate consumables, collection and handling systems and equipment for waste management.**	10	**100**	
Ind 95.	**Contracts with waste disposal service organizations are available.**	10	**100**	
Ind 96.	**Waste transported from collection centers for final disposal is recorded.**	10	**100**	
Total		50		

2.8 Access, Assessment, and Continuity of Care (AAC)

03 Standards & 9 Indicators

Temporal access alone is a major factor which plays a pivotal role in the utilization of services provided by a clinical laboratory. If one cannot easily reach the laboratory location, there is a great likelihood that it will either be dropped or diverted to anyone facility which may not be of a similar standard.

A clinical laboratory should consider the service it provides as part of an integrated system of healthcare delivery, healthcare practitioners and professionals, and levels of care, which make up a continuum of care. The goal is to correctly match the patient's healthcare needs with the services available, to coordinate the services to be provided to the patients individually and in other healthcare settings, and to facilitate their recovery from ailments, then discharge and follow-up. The result is improved patient care outcomes and more efficient use of available resources.

Standard 29. AAC-1: Laboratory services are easily accessible

Indicators (97-102):

Ind 97. The laboratory is easily accessible

Survey Process:
This indicator clearly demands the ease with which one can reach the laboratory premises using any commonly available/affordable transport at any time of day or night. The clinical laboratory location should not be in a narrow street which does not allow free flow of traffic.

Compliance Requirements:
✓ Laboratory is easily accessible around the clock.

Scoring:
- If the laboratory is easily accessible fulfilling the above requirements, then score as **fully met.**
- If the laboratory does not comply with the above conditions and is not easily accessible, then score as **not met.**

Ind 98. Basic facilities are available in the laboratory

Survey Process:
Surveyors should look for the availability of basic facilities for the patients.

Compliance Requirements:
✓ The following should be available at the least:
- Clean water supply
- Power supply with backup
- Sufficient parking place

Scoring:
- If the survey team agrees that the basic facilities are accessible, then score as **fully met.**
- If basic facilities are inaccessible, then score as **not met.**

Ind 99. There are clean toilets/washrooms with bolts, preferably separate for males and females

Survey Process:
There should be clean toilets with bolts for privacy, preferably separate for male and female patients. This is essential to cater for having fresh urine samples in addition to normal usage.

Compliance Requirements:

- ✓ Onsite toilets preferably separate for males and females available.
- ✓ Cleanliness ensured.
- ✓ Privacy ensured.

Scoring:

- If separate and clean toilets with bolts are available, then score as **fully met.**
- If a clean toilet with bolts is available but it is common for males and females, then score as **partially met.**
- If the toilet is not available, then score as **not met.**

Ind 100. Facilitated toilets for disabled patients are available in the laboratory

Survey Process:

Check if facilitated toilets having side supports for the disabled, or having enough space for a wheel chair, are available in the laboratory premises.

Compliance Requirements:

- ✓ Facilitated toilets for disabled patients available in labs with wider scope of services.

Scoring:

- If facilitated toilets for the disabled patients are available in the laboratory, then score as **fully met.**
- If there are no facilitated toilets for the disabled patients in the laboratory, then score as **not met.**

Ind 101. Disabled patients are facilitated for phlebotomy

Survey Process:

Check if there is enough space for the wheel chair of a disabled person to reach the reception of the laboratory or the point where the blood sample can be taken comfortably, or alternatively the phlebotomist can reach out to the patient.

Compliance Requirements:

- ✓ Disabled persons can easily reach the phlebotomist.

Scoring:

- If the disabled patients are facilitated as above, then score as **fully met.**
- If the disabled patients are not facilitated as above, then score as **not met.**

Ind 102. Directional arrows pointing towards various important areas for patients are displayed in the laboratory

Survey Process:

Directional arrows make important areas of laboratories easily accessible.
Check for directional arrows pointing towards at least sample collection area, report collection area and toilets.

Compliance Requirements:

✓ Directional arrows pointing towards at least the following:

- Sample collection area
- Report collection area
- Toilets

Scoring:

- If required directional arrows are present, then score as **fully met.**
- If no such directional arrows are displayed, then score as **not met.**

GUIDELINES

Universal health coverage has been considered a pillar of sustainable development and global security. Thus, health related facilities should be universally available, accessible, acceptable, appropriate, and of good quality (AAAQ framework). In public health, there is a direct link between the distance patients travel to access health and the reduction of ill health and suffering in a country. Patients tend to use health facilities more if they are located close to them than if they are far way. The issue of distance of the patients to the centers is seen as one of the main determinants of the use of health services. In third world countries, the distance covered by patients is usually greater than in developed world countries, in which healthcare facilities are more accessible. This has an important impact on the quality of life in these countries. Accessibility to healthcare is the capability of a population to obtain a specified set of healthcare services. Reflecting the equilibrium between characteristics and expectations of the providers and the clients, quality care has been conceptualized in four dimensions of access:

1. geographic accessibility – the physical distance or travel time to the potential user;
2. availability – having the adequate type of care for who is needing it;
3. financial accessibility – willingness and ability of users to pay for services; and
4. acceptability – response of the health service providers to the social and cultural individual expectations and communities in general. Identifying different levels of spatial accessibility to healthcare services in a certain area allows decision makers to understand the impacts of opening, closing, changing location or modifying the services offered by existing facilities.

Currently, several advanced methodological approaches are used to estimate health accessibility, such as gravity, kernel density, and catchment area models. However, the conventional and most common techniques used to calculate accessibility in public health research are still the Euclidean and network distance. Euclidean distance techniques describe a location's relationship to a source or a set of sources based on the straight-line distance. Networked distance is the physical travel

path or road to reach the destination. The constraint of the Euclidian distance is that it does not take into account physical barriers to movements and transportation routes, thereby underestimating the real travel distance.

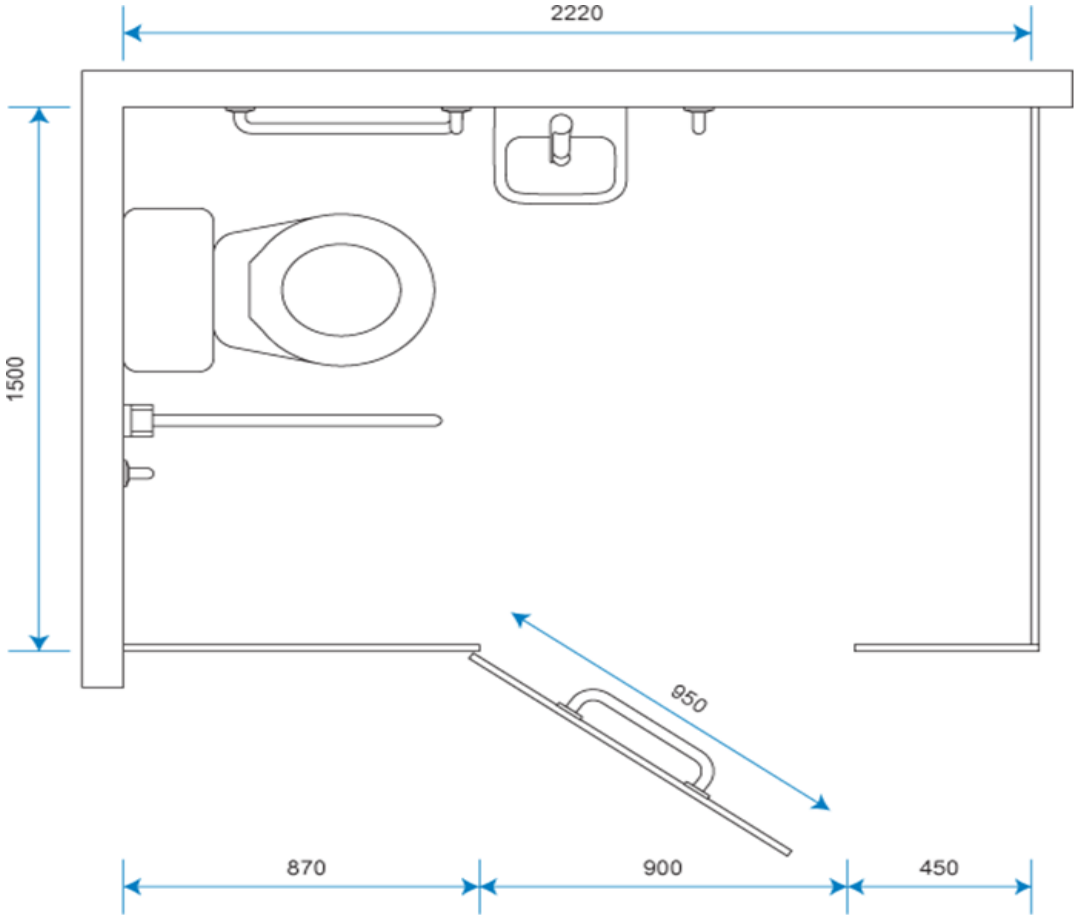
Arrows guiding the basic facility areas must be displayed.
Cubical separate toilets for males and females with the following facilities:

1. Water supply and electricity
2. Water closet with muslim shower
3. Hand wash sink with soap
4. Paper hand towels/air driers
5. Dust bins

Doors, especially toilet doors, should have a clear width of 90 cm.

1. If not sliding doors, doors should open outward. If not, it cannot close once the wheelchair is in.
2. It should have a door-pull handle at the hinge side for easy reach and closure for those in wheelchairs (see illustration).
3. Doors shall be designed to open easily with lever handles for persons with no hand or grip function.
4. Doors should be opened by a single effort requiring less than 2.3 kg of force.

Figure 13: Toilets dimensions



This indicator can be evaluated by checking the presence of the following:

1. Wheel chairs
2. Ramps for wheel chairs for easy access to sample collection area

Directional arrows should point towards important areas from a patient's perspective. Such areas are:

1. Reception
2. Waiting area
3. Sample collection area
4. Report collection counters
5. Toilets

Assessment Scoring Matrix

Standard 29. AAC-1: Laboratory services are easily accessible.

Indicator 97 - 102		Max Score	Weightage (Percentage)	Score Obtained
Ind 97.	**The laboratory's location is easily accessible.**	10	**100**	
Ind 98.	**Basic facilities are accessible in the laboratory.**	10	**100**	
Ind 99.	**There are clean toilets/washrooms with bolts, preferably separate for males and females.**	10	**80**	
Ind 100.	**Facilitated toilets for disabled patients are available in the laboratory.**	10	**100**	
Ind 101.	**Disabled patients are facilitated for phlebotomy.**	10	**100**	
Ind 102.	**Directional arrows pointing towards various important areas for patients are displayed in the laboratory.**	10	**100**	
Total		60		

Standard 30. AAC-2: Laboratory services are provided as portrayed/claimed

Indicators (103-103):

Ind 103. Laboratory services being provided are displayed

Survey Process:

This will require knowledge of the surveyors and staff regarding the full scope of services which a clinical laboratory can provide and what types of tests are carried out in a particular section, e.g. biochemistry, microbiology, histopathology, hematology, etc. Surveyors may also check the documentation/list of diagnostic facilities provided.

Compliance Requirements:

- ✓ Menu of services (types of tests which can be done) displayed.
- ✓ List of tests which can be done is available.

Scoring:

- If the services provided are listed and displayed, then score as **fully met.**
- If the services provided are listed but not displayed, then score as **partially met.**
- If the services provided are neither listed nor displayed, then score as **not met.**

GUIDELINES

Services of each section should be mentioned. Broadly, laboratory services can be divided into the following groups:

1. Histopathology
2. Microbiology
3. Haematology
4. Chemical pathology
5. Serology

Assessment Scoring Matrix

Standard 30. AAC-2: Laboratory services are provided as portrayed/claimed.

Indicator 103-103		Max Score	Weightage (Percentage)	Score Obtained
Ind 103.	**Laboratory services being provided are displayed.**	10	**80**	
Total		10		

Standard 31. AAC-3: A comprehensive audit system for laboratory performance assessment exists in the laboratory

Indicators (104-105):

Ind 104. There is a system to monitor and measure the performance of the laboratory biannually

Survey Process:

Review the documentation, such as minutes of meetings of the senior management, etc. These should reflect that the performance of the laboratory is reviewed with the objective measures/indicators.

Compliance Requirements:

- ✓ System to monitor and measure the performance of the laboratory biannually.

Scoring:

- If there is documentation of monitoring of the progress toward the laboratory's strategic and operational objectives, then score as **fully met.**
- If there is no documentation of monitoring, then score as **not met.**

Ind 105. Procured kits and their consumption are compared with tests performed during laboratory performance audit

Survey Process:

Review stock registers regarding documentation of purchased kits and compare their stated capacity with the number of tests conducted. This check will help in controlling the likelihood of generating results without actually running a test.

Compliance Requirements:

- ✓ Audit of kits procured with the number of tests conducted with each.
- ✓ Action taken in case of disparity.

Scoring:

- If kits procured and numbers of tests conducted are comparable, then score as **fully met.**
- If there is disparity in kits procured and the number of tests conducted, then score as **not met.**

GUIDELINES
Laboratory performance monitoring reports must include: 1. Number of quality tests performed

2. Number of new latest tests added
3. Equipment available
4. Latest technology added
5. Number of trained human resource in each section
6. Average turn-around time of reports
7. Number of errors reported and corrective actions taken

Confirm number of kits purchased from purchase orders and stock register.

Number of tests can be verified from the record of tests performed.

Assessment Scoring Matrix

Standard 31. AAC-3: A comprehensive audit system for laboratory performance assessment exists in the laboratory

Indicator 104-105		Max Score	Weightage (Percentage)	Score Obtained
Ind 104.	**There is a system to monitor and measure the performance of the laboratory biannually against the stated mission.**	10	**100**	
Ind 105.	**Procured kits and their consumption are compared with tests performed during laboratory performance audit**	10	**100**	
Total		20		

2.9 Care of Patients (COP)

03 Standards & 6 Indicators

The process of patient care includes planning of emergency care, providing emergency care, evaluating the patient's response to care and planning follow-up in case of referral. This section demands availability of written SOPs and staff knowledge for the management of such untoward events.

In case of some emergency condition developed during taking the sample or if a patient or relative otherwise suffers a medical emergency while in the premises of the laboratory, immediate required care should be provided.

Standard 32. COP-1: Emergency handling of patients is guided by protocols

Indicators (106-107):

Ind 106. Protocols for providing first aid/emergency care to the patients are documented

Survey Process:

Review the policies and procedures, which should cover the SOPs for providing first aid to the patients who develop some emergency condition, e.g. sudden fall of BP and collapse during taking the specimen or while otherwise present in the laboratory premises. Observe and interview the staff to check that they are aware of SOPs for providing first aid and required arrangements.

Compliance Requirements:

- ✓ SOPs to manage emergency conditions as mentioned above.
- ✓ Staff conversant with the SOPs.
- ✓ Arrangements for providing first aid.

Scoring:

- If there are SOPs as well as arrangements for providing first aid and staff members are aware of those, then score as **fully met.**
- If there are no SOPs or the arrangements for providing first aid are deficient, then score as **not met.**

Ind 107. Relevant contact numbers for emergency evacuation/referral are available in the laboratory

Survey Process:

Review the availability of emergency contact numbers like ambulance services and a list and contact numbers of nearby hospitals which should be contacted for facilitating patient emergency care and referral. Check if all emergency numbers are displayed in the laboratory. Assess if staff is aware of the emergency contact numbers.

Compliance Requirements:

- ✓ List of contact numbers of the following for use in emergency is displayed:
  - Nearest referral hospitals/clinics
  - Rescue 1122
  - Other ambulance services
  - Police Station
  - Fire Brigade

Scoring:

- If emergency contact numbers for patient emergency care are available, displayed in the laboratory and staff is aware of it, then score as **fully met.**
- If emergency contact numbers are available in the laboratory and in the knowledge of the staff but not displayed, then score as **partially met.**
- If neither emergency contact numbers exist nor is staff aware of it, then score as **not met.**

GUIDELINES

Policies and Procedures

Each laboratory should have well thought out and documented policies and procedures for emergency care, in line with statutory requirements. These policies and procedures, developed in the light of applicable laws, shall guide and encourage patient safety as the overall principle for providing healthcare services to patients. These documents include SOPs/protocols to provide care for common emergencies as it may occur with any one at any place/time, e.g. syncopy, cardiac arrest, choking, acute bronchospasm, bleeding, fracture, etc. and shall address both adult and pediatric patients. The procedure shall incorporate at least identification, assessment and provision of appropriate care followed by referral if required. The policy/SOPs should spell out and ensure availability of all the necessary equipment in working order during the operational time of the laboratory. Some of the SOPs/SMPs are as under:

SMPs For Medical Emergencies in the Laboratories [14]

Introduction

One cannot be certain that medical emergencies will not occur in a laboratory, therefore be prepared to manage such an occurrence. HCPs must have basic knowledge of the signs and symptoms of these emergency situations to act quickly, efficiently and effectively. If you are uncertain, please call (shout if required to) for help from a senior clinician or colleagues. Most of the emergencies can be dealt with satisfactorily if more than one HCP is competent to attend to the situation. The basic guidelines to manage such an emergency are given below.

Preparatory SOPs

Following are the FIVE steps to prepare and manage a medical emergency:

1. Medical history including history of allergy and drug history
2. Assessment of patient's condition
3. Resuscitation knowledge, training and practice
4. Proficiency in the use of emergency medications and devices
5. Calling for medical assistance

ANAPHYLACTIC REACTION

Note history of any allergy from the medical history form and if not mentioned, ask about the details before withdrawing the blood sample.

If an anaphylaxis is suspected in an adult with the following:

1. Angioedema

[14] To be taken as Guidelines and be updated as per advancements.

2. Urticaria
3. Hypotension
4. Abdominal pain
5. Conjunctivitis
6. Erythema
7. Pruritus
8. Vomiting
9. Rhinitis

Take the following actions:

1. CALL THE NUMBER 1122 and ask for an ambulance service and brief the person at the other end with the situation and try to answer all their questions.
2. Administer oxygen by mask @10L/min.
3. Give IM Adrenaline on the lateral aspect of thigh (0.5ml of 1 in 1000) (1mg/m1).
4. If there is NO response AFTER 5 minutes, REPEAT STEP 3.
5. If the patient loses consciousness, give basic life support (CPR), continue treatment until ambulance or other medical assistance is available.

CARDIAC ARREST

If a cardiac arrest is suspected in an adult with the following presentation:

1. Loss of consciousness
2. No breathing
3. No pulse

Take the following actions:

1. CALL THE NUMBER 1122 and ask for an ambulance service and brief them with the situation. Try to answer all their questions.
2. Institute basic life support (CPR).
3. Use automated defibrillator.
4. Maintain the above until help arrives.

EPILEPTIC SEIZURE

1. The safety of the patient and those attending the patient are important during a seizure attack. The seizure may present as:
2. Sudden loss of consciousness
3. Temporary apnea and cyanosis
4. Tonic and clonic jerking movements
5. May become incontinent
6. Tongue biting

Take the following actions:

1. Stop the sample withdrawal and clear the surroundings.
2. Avoid and/or prevent patient falling.
3. Avoid and/or prevent patient injuring herself/himself.
4. Avoid restraining the patient unless essential to prevent injury.

5. Call 1122 if seizure persists for more than a few minutes.

If the seizure subsides, ensure the following:

1. Protection of patient in 'recovery position'.
2. Monitor consciousness state (responding to commands).
3. Maintain airway.
4. Remove vomitus (if any) from the oral cavity by suction.
5. Keep under observation for 30 minutes.
6. Instruct the patient to report to his/her doctor about the incident and let the patient go home.

STROKE

If a patient shows signs of 'stroke', follow the steps below:

1. CALL RESCUE 1122 for an ambulance.
2. Stop the sample withdrawal.
3. Administer oxygen.
4. Maintain airway.

ASTHMA

Most asthma-related deaths occur outside the hospital.

Management:

1. Assess severity:

i. **Acute severe —** patient unable to speak in complete sentences, pulse rate greater than 110 per minute, respiratory rate greater than 45 per minute.

ii. **Life threatening asthma —** 'silent chest', cyanosis, sweating, hypercarbic flush, bradycardia/ hypertension, confusion, and agitation.

iii. If more than one feature is severe, or if any feature is life-threatening, arrange hospital transfer.

DIABETES

The most common diabetic emergencies are:

1. Low blood sugar — hypoglycaemia in patients on anti-diabetic medications.
2. High blood sugar — hyperglycaemia, particularly diabetic ketoacidosis.

Hyperglycaemia:

Clinical symptoms include:

1. Thirst
2. Increased urine output and dehydration
3. A progressive reduction in level of consciousness ensues with hypotension, coma and cessation of urine output in severe cases.

Management:

1. Primary assessment and resuscitation (DRS-ABC) to secure the airway, breathing and circulation.
2. Transport to a hospital facility.

Hypoglycaemia:

Clinical symptoms of hypoglycemia include:

1. Sweating
2. Hunger
3. Tremor
4. Agitation
5. Progressively drowsiness, confusion and coma
6. Assume that any diabetic with impaired consciousness has hypoglycaemia until proven otherwise

Management:

1. Conscious patients can usually be treated with rapid acting oral carbohydrates, e.g. fruit juice, packets of granulated sugar, glucose powder as such or dissolved in water.
2. After ten minutes this short acting carbohydrate should be followed up with food which contains longer acting carbohydrate.
3. It is important that the victim is not left alone until the danger of hypoglycaemia has passed.
4. If the patient is unconscious, attend to the airway, breathing and circulation.
5. Protect the victim from injury.
6. Call Rescue 1122 ambulance.

CHEST PAIN/MYOCARDIAL INFARCTION

Victims usually begin with varying degrees of atheromatous coronary occlusion. Myocardial infarction (MI) is usually initiated by rupture or erosion of a thin cap which overlies these atheromatous plaques. Platelet adhesion and aggregation then occurs over the ruptured surface. The haemodynamic effects of this thrombus formation may lead to prolonged ischaemic symptoms and pain at rest. If the clot occludes the coronary artery, a MI occurs.

Symptoms and Signs:

1. Persisting central chest pain, with possible radiation to the left or right arms, jaw, or neck
2. Pain is no longer improved with Glyceryl Trinitrate (GTN)
3. Nausea, vomiting
4. A sense of impending doom
5. Restlessness
6. Shortness of breath
7. Pallor, cold sweaty skin
8. Pump failure: hypotension, raised venous pressure, tachycardia and possibly pulmonary oedema

Management:

If acute MI is suspected:

1. Give reassurance, and keep the patient warm.
2. Sit the patient up if breathless.
3. Lay the patient flat if he or she feels faint.
4. If the patient has GTN tablets or spray, give one tablet to be chewed or one spray under the

tongue.

5. Repeat in five minutes; if pain is unrelieved, call an ambulance (dial 111).
6. If the patient is not allergic to aspirin, give 300mg aspirin chewed or sucked.
7. Continue monitoring level of consciousness and be prepared to initiate adult collapse guidelines if patient becomes unconscious.

VASOVAGAL SYNCOPE

It is a transient loss of consciousness due to cerebral ischemia caused by a reduction in blood supply to the brain. Vasodilatation causes pooling of blood in the peripheries and vagal stimulation causes slowing of the heart. This combination causes a dramatic fall in blood pressure.

Presentation:

1. Patient feels light headed or dizzy, possibly nauseous, uncomfortable or agitated.
2. Appears pale and sweaty with a thready, slow pulse and hypotension.

Management of vasovagal syncope in a FIT, healthy young patient:

1. Lay the patient flat.
2. Relieve any compression on the neck and maintain an airway.
3. Raise patient's legs.
4. Ensure the patient has access to fresh air.
5. Keep patient supine and reassured on regaining consciousness.
6. Slowly raise patient to a seated position after pulse and blood pressure recover.
7. Transfer the patient to a hospital for further assessment as indicated when there are significant medical problems, or when syncope is prolonged or complicated by seizure.

HYPERVENTILATION

Prolonged rapid deep breathing often in very anxious patients can lead to profound metabolic changes that may result in loss of consciousness. A fall in arterial carbon dioxide concentration causes cerebral vasoconstriction and respiratory alkalosis.

Presentation:

1. The patient may notice tingling of the fingers or lips.
2. Tetanic spasm of the peripheries.
3. Dizziness.
4. These symptoms tend to increase anxiety and respiratory rate and depth.
5. Eventually the patient will become unconscious due to a relative cerebral hypoxia.
6. The patient is apnoeic for a period due to reduced respiratory drive with low arterial carbon dioxide concentration.
7. As the arterial carbon dioxide level rises and cerebral vasoconstriction reverses, the patient starts breathing again and regains consciousness.
8. Hyperventilation recommences, and the cycle continues, with further loss of consciousness.

Management:

1. Reassure the patient.

2. If the patient is conscious, encourage re-breathing into a paper bag to increase inspired carbon dioxide.
3. If the patient is unconscious, maintain airway until consciousness is regained.
4. Place in the recovery position and give reassurance, while the patient continues re-breathing into a paper bag.

Assessment Scoring Matrix

Standard 32. COP-1: Emergency handling of patients is guided by protocols.

Indicator 106-107		Max Score	Weightage (Percentage)	Score Obtained
Ind 106.	**Protocols for providing first aid/emergency care to the patients are documented**	10	**100**	
Ind 107.	**Relevant contact numbers for emergency evacuation/referral are available in the laboratory.**	10	**80**	
Total		20		

Standard 33. COP-2: Sentinel events are intensively analyzed

Indicators (108-109):

Ind 108. The laboratory has defined sentinel events

Survey Process:
Review the written definition of a sentinel event. At a minimum this should include: i. all unexpected deaths, ii. any anaphylactic reaction/collapsing of a patient during obtaining of sample (blood sample), iii. wrong reporting carrying a potential life risk, iv. patient violence against staff, v. staff violence against patients. vi. loss of a precious sample. Look to see if the system analyses the root cause and associated factors that contributed to the event.

Compliance Requirements:
- ✓ Laboratory has defined sentinel events and a written definition is available.
- ✓ List of possible sentinel events is available.

Scoring:
- If there exists a definition of sentinel events and the possible sentinel events are listed, then score as **fully met.**
- If there is no definition and list, or if the list is not adequately comprehensive, then score as **not met.**

Ind 109. Sentinel events are intensively analyzed when they occur

Survey Process:
Ask for any documentation of intense analysis of any sentinel event that has occurred in the past 12 months. (It is highly unlikely that none have occurred. If none were reported, the surveyors should explore the reporting process). Determine the corrective actions taken as a result of the analysis such as a change in policy and operating procedures and training of staff.

Compliance Requirements:
- ✓ Record of a sentinel event/s that occurred and was intensively analyzed.
- ✓ Corrective actions to avoid recurrence

Scoring:
- If there was a reported sentinel event and it was intensively analyzed, including corrective action to prevent or reduce the likelihood of reoccurrence, then score as **fully met** **OR** If no sentinel event was reported, but the survey team is comfortable that if one occurred it would be reported and analyzed, then also score as **fully met.**
- If there was a sentinel event, but there was either no analysis or the analysis was 'superficial'

such as limited to assigning blame to an individual, then score as **not met.**

GUIDELINES

Sentinel events include “unexpected occurrences involving death or serious physical or psychological injury, or the risk thereof” and all of the following, even if the outcome was not death or major permanent loss of function, e.g. rape or suicide attempt.

A **sentinel event** is defined by The Joint Commission as any unanticipated event in a healthcare setting resulting in death or serious physical or psychological injury to a patient or patients, not related to the natural course of the patient's illness. Sentinel events specifically include loss of a limb or gross motor function, and any event for which a recurrence would carry a risk of a serious adverse outcome. Sentinel events are identified under The Joint Commission accreditation policies to help aid in root cause analysis and to assist in the development of preventative measures. The Joint Commission tracks events in a database to ensure events are adequately analyzed and undesirable trends or decreases in performance are caught early and mitigated.

Causal factors are analyzed, focusing on systems and processes, not individual performance. Potential improvements, called an ‘action plan’, are identified and implemented to decrease the likelihood of such events in the future. However, the organization is expected to prepare a root cause analysis and action plan within 45 calendar days of the event.

Assessment Scoring Matrix

Standard 33. COP-2: Sentinel events are intensively analysed.

Indicator 108-109		Max Score	Weightage (Percentage)	Score Obtained
Ind 108.	**The laboratory has defined sentinel events.**	10	**100**	
Ind 109.	**Sentinel events are intensively analyzed when they occur.**	10	**100**	
Total		20		

Standard 34. COP-3: The laboratory policies and procedures support domiciliary services to the patients (where applicable/ claimed)

Indicators (110-111):

Ind 110. The laboratory is equipped with means of communication and transport services for home based patient sample collection

Survey Process:

NOTE: If home service is claimed by the laboratory, otherwise mark as NOT APPLICABLE.

Physically check the availability of a communication system and any means of mobility for the phlebotomist for home based patient sample collection (motor cycles, etc.). Review the record of domiciliary services provided to the patients in the last one year.

Compliance Requirements:

- ✓ Availability of functional means of communication.
- ✓ Availability of transport viz: two wheeler/four wheeler as suited.
- ✓ Record available for review.

Scoring:

- If there are communication and mobility services for the phlebotomists and record of domiciliary services are available for review, then score as **fully met.**
- If there are communication and mobility services for the phlebotomists but no record of domiciliary services available for review, then score as **partially met.**
- If there are no communication and mobility services for the phlebotomists and no record of domiciliary services are available for review, then score as **not met.**

Ind 111. The laboratory has appropriate means of collection and transportation of home based samples

Survey Process:

NOTE: If home service is claimed by the laboratory, otherwise mark as NOT APPLICABLE.

Physically check the availability of boxes for safe sample transportation to the laboratory. These boxes should contain all required items for collection of sample from the home based patient.

Compliance Requirements:

- ✓ Availability of items for phlebotomy viz tourniquet, alcohol swabs, disposable syringes with appropriately gauged needles.
- ✓ Containers for samples of blood, sputum, urine, etc.
- ✓ A suitable box to contain all of the above and safe transportation of the sample to the

laboratory.

Scoring:

- If sample transportation boxes equipped with all necessary phlebotomy items are available in the laboratory, then score as **fully met.**
- If sample transportation boxes equipped with all necessary phlebotomy items are not available in the laboratory, then score as **not met.**

GUIDELINES

Means of mobility for phlebotomists includes motorcycles. Service record should include name of the patient with complete home address and valid contact number.

Old age or disabled individuals afraid of spending hours in queues at hospitals/diagnostic labs and facing difficulties in commuting can prevent such patients from coming to HCE and thus compromising their health. Keeping the need of people in consideration, good labs can offer the facility of home sample collection. For providing quality service to the patients, trained human resource and means of sample collection and transportation should be ensured (Fig-9). Means of sample collection and transportation includes blood transportation boxes (picture given below).

Figure 14: Transportation Box

Assessment Scoring Matrix

Standard 34. COP-3: The laboratory policies and procedures support domiciliary services to the patients (where applicable/claimed).

Indicator 110-111		Max Score	Weightage (Percentage)	Score Obtained
Ind 110.	**The laboratory is equipped with means of communication and transport services for home based patient sample collection.**	10	**80**	
Ind 111.	**The laboratory has appropriate means of collection and transportation of home based samples.**	10	**100**	
Total		20		

2.10 Patient Rights and Education (PRE)

03 Standards & 7 Indicators

The healthcare establishment/lab shall define patient and family rights and responsibilities as per the guidelines/charters provided by the KP HCC. The staff is aware of these and is trained to protect patients' rights. Patients are informed of their rights and educated about their responsibilities at the time of accessing services. They are informed about the process, the possible outcomes and are involved in decision making. The costs are explained in a clear manner to the patient and/or family. Patients are educated about the mechanisms available for addressing grievances.

Standard 35. PRE-1: A system exists for obtaining consent when it is required

Indicators (112-113):

Ind 112. The laboratory has listed those situations where specific informed consent is required

Survey Process:
Review any written policy or list. Then review 10 laboratory records of patients who should have (by laboratory policy) a specific informed consent to validate. This would include consent related to procedures to be done in the lab for obtaining the specimens, if any.

Compliance Requirements:

✓ List of situations requiring informed consent.

Scoring:

- If ALL relevant records document an informed consent, then score as **fully met.**
- Since this may have a medico-legal significance, if ANY relevant records do not document consent, then score as **not met.**

Ind 113. The policy describes who can give consent when a patient is incapable of independent decision-making

Survey Process:
Review the policy to determine who is identified as being able to give consent in addition to the patient.

Compliance Requirements:

✓ Written directions as to who can give consent when a patient is incapable of independent decision- making for providing informed consent.

Scoring:

- If there is a policy describing who, other than the patient, may give informed consent, then score as **fully met.**
- If there is no such policy, then score as **not met.**

GUIDELINES

Scope of Informed Consent
Although the client's/patient's general consent is obtained for the proposed care or treatment, a written consent is mandatory for any invasive procedures.

The client's informed consent is a prerequisite to carry out any diagnostic invasive procedure and the patient has the right to refuse or to halt any such procedure.

In different situations of health care provision or involvement of the client in any research activity, the mode of consent and action will be:

1. When a patient is unable to express his or her will and a medical intervention is urgently needed, the consent of the patient may be presumed, unless it is obvious from a previous declared 'Expression of Will' that consent would be refused in the situation.
2. When the consent of a legal representative is required and the proposed intervention is urgently needed, that intervention may be made if it is not possible to obtain the representative's consent in time.
3. When the consent of a legal representative is required, patients (whether minor or adult) must nevertheless be involved in the decision-making process to the fullest extent which their capacity allows.
4. If a legal representative refuses to give consent and the physician or other provider is of the opinion that the intervention is in the interest of the patient, then in case of a non-emergency situation, the decision must be referred to a court or some form of arbitration.
5. In all other situations where the patient is unable to give informed consent and where there is no legal representative or representative designated by the patient for this purpose, appropriate measures should be taken to provide for a substitute decision making process, taking into account what is known and, to the greatest extent possible, what may be presumed about the wishes of the patient.
6. The consent of the patient is required for the preservation and use of all substances of the human body. Consent may be presumed when the substances/body part are to be used in the current course of diagnosis, treatment and care of that patient.
7. The informed consent of the patient is needed for participation in clinical teaching.
8. The informed consent of the patient is a prerequisite for participation in scientific research. All protocols must be submitted to a proper ethical review committee. Such research should not be carried out on those who are unable to express their will, unless the consent of a legal representative has been obtained and the research would likely be in the interest of the patient.

As an exception to the requirement of involvement being in the interest of the patient, an incapacitated person may be involved in observational research which is not of direct benefit to his or her health provided that, that person offers no objection, that the risk and for burden is minimal, that the research is of significant value and that no alternative methods and other research subjects are available.

Policy Regarding Consent for Incapacitated Patient

The HCE shall take into consideration the statutory norms. This would include taking of consent from next of kin/legal guardian. The order of preference is; spouse, son, daughter, brother, sister, parents. However, in case of unconscious/unaccompanied patients, the treating doctor can take a decision in life-saving circumstances.

Assessment Scoring Matrix

Standard 35. PRE-1: A system exists for obtaining consent when it is required.

Indicator 112-113		Max Score	Weightage (Percentage)	Score Obtained
Ind 112.	**The laboratory has listed those situations where specific informed consent is required.**	10	**100**	
Ind 113.	**The policy describes who can give consent when a patient is incapable of independent decision-making.**	10	**100**	
Total		20		

Standard 36. PRE-2: Patients and families have a right to information on expected costs

Indicators (114-115):

Ind 114. The tariff list is available to patients

Survey Process:
Review the tariff list and then ask how it is made available to the patients/ families. Customarily, this is only upon the patient's request.

Compliance Requirements:
- ✓ Tariff list available for showing on demand.
- ✓ Patients/clients informed about the rates of their required tests.

Scoring:
- If there is evidence that the tariff list is readily available to patients on demand, then score as **fully met.**
- If there is no procedure to make it available to patients, then score as **not met.**

Ind 115. Patients/families are informed about the additional reports which are generated/included in the report with the same sample and cost

Survey Process:
Review the process used to inform the patient/relative about the cost effective package with additional reports with the same sample and cost. Also determine if this is done by someone who is knowledgeable, e.g. a qualified lab tech who is notified to do so or a doctor or pathologist incharge.

Compliance Requirements:
- ✓ Clients informed about the additional reports possible in a cost effective package.
- ✓ Above information provided by a doctor or a qualified and authorized lab technician.

Scoring:
- If there is a process to inform the patient/relative as above and it is done by a knowledgeable person, then score as **fully met.**
- If there is no process, then score as **not met.**

GUIDELINES
Tariff List The HCE shall ensure that there exists a tariff list and the same is communicated to the patients with a clear and justified explanation. Tariff rates should be uniform and transparent.

The reception area/account section and various laboratory sections display/contain information about the tariff policy of the HCE which shall include:

1. The rights of the clients/patients
2. Services and facilities available in the laboratory
3. Costs of services
4. Feedback and complaints pathways

Tests related to a specific system are grouped under various names like renal function tests, liver function tests, lipid profile, blood complete examination, urine complete examination, etc. Names of parameters included in each broader category must be enlisted and provided to the patient at the time of testing. In case, if any of the parameters/tests are missed during reporting, the patient should recognize it and bring it to the knowledge of authorities.

Assessment Scoring Matrix

Standard 36. PRE-2: Patients and families have a right to information on expected costs.

Indicator 114-115		Max Score	Weightage (Percentage)	Score Obtained
Ind 114.	**The tariff list is available to patients.**	10	**100**	
Ind 115.	**Patients/families are informed about the additional reports which are generated/ included in the report with the same sample and cost.**	10	**100**	
Total		20		

Standard 37. PRE-3: Patient rights for appeals, complaints and confidentiality

Indicators (116-118):

Ind 116. Patient's complaints are accepted by the laboratory and properly registered

Survey Process:
Copies of any patient complaint filed with the laboratory are kept in record. Check the register of complaints and review it thoroughly.

Compliance Requirements:
- ✓ A complaint register/record is maintained.
- ✓ A complaint box is affixed in the patient waiting area.

Scoring:
- If the complaint box and register are present and complaints are properly recorded, then score as **fully met.**
- If there is no complaint box and/or register, then score as **not met.**

Ind 117. Proper actions and remedial measures are taken in response to patient's complaints

Survey Process:
Patients' complaints can help promote safety from risks in several ways. Complaints provide information and suggestions about unsafe systems and providers. Appropriate remedial measures improve safety and reduce risk. Check if remedial measures are well documented.

Compliance Requirements:
- ✓ Record of actions taken on the complaint

Scoring:
- If the proper actions are taken and properly documented, then score as **fully met.**
- If there is no action taken against patients' complaints, then score as **not met.**

Ind 118. Confidentiality of patient record is maintained

Survey Process:
Laboratory workers have a responsibility to protect patient data from unauthorized access. Only

authorized persons may have access to the electronic database having patient related information.[15] Check the accessibility of computerized reports.

Compliance Requirements:

- ✓ Only the authorized persons have access to patient related information

Scoring:

- If computerized reports are not directly accessible, then score as **fully met.**
- If the patient record is freely accessible, then score as **not met.**

GUIDELINES

Right to Express Concern or Complain

An institutionalized, accessible and transparent grievance redress mechanism must be in place. The information as how to lodge a complaint must be clearly displayed in the local language at prominent places.

A complaint is an expression of client dissatisfaction and a way of feedback on the quality of care which needs a response. Every healthcare facility should inform the clients/patients about their right to complain and the complaint handling procedures. A complaint may be written or verbal and be lodged by the patient, his/her attendants or a legally authorized person. Various ways should be adopted, for example:

1. Display the message clearly in the local language at prominent places in the facility, such as the registration desk, waiting area, OPDs, main entrance, private rooms, etc.
2. Pertinent information may be made available in the form of leaflets/brochures at appropriate places.
3. Client feedback/satisfaction must be sought on a prescribed but simple format at the time of discharge (format attached at **Annexure L**).

Complaint Management Procedure

To become a quality driven service, a facility should encourage the clients and their family members to freely raise and discuss their views, concerns or complaints with the concerned staff. These dialogues help and serve as opportunities for improvement. Every HCE must have a documented grievance redressal procedure, entailing collecting, prioritizing, investigating, resolving and reporting complaints. A proposed format for the Complaint Management Procedure is attached at **Annexure M**. The complaints against service providers that carry a client's perspective should be handled first by the manager/concerned section incharge. For example, the section incharge should tackle the complaints, verbal or written, related to the laboratory and should take remedial action there and then. In case actions are beyond his/her mandate, he/she, must refer it to the Complaint Cell.

A Complaint Cell should be established at every HCE and resourced properly. The Cell shall essentially comprise of a core staff and be headed by a manager appointed by the HCE and be supported by a team of experts (Complaint Management Committee-CMC). The

[15] The authorized person is required to be aware and compliant of legal & safety requirements regarding release of such information to persons/authorities other than patient when required.

department/specialist against whom a complaint is received/under investigation will not be part of the committee for that particular case. The CMC may co- opt an expert for assistance. Every complaint must be thoroughly investigated and documented. The complaint cell will maintain department wise records of complaints investigated and actions taken. A record of the Complaint Register must lie in the office of the MS or Incharge of the health facility, with the complete number and details of complaints received and actions taken.

The detailed policy of the HCE for documentation of the processes should define a credible and transparent mechanism for receiving and handling complaints against the functioning of the HCE and the practice of its staff. This mechanism should be used fairly and timely for collecting, prioritizing, reporting, and investigating complaints. To ensure that measures for patient complaint system are effective and efficient, they should be well-targeted and focused to address the identified problems.

Information about Progress of the Investigation and Outcome

It is important that the client/patient is informed of the level at which the complaint can be handled. This duty should be clearly entrusted to a designated staff member of the complaint cell/department of the HCE. The client should be kept informed about the progress of the investigation at regular intervals, in case these are prolonged, and also of the outcome. This will help to build the credibility of the process/facility.

Patient's data is privacy sensitive and must be protected from unauthorized access to remain confidential. To that end, all laboratory staff members must promise to keep patient data confidential in word and in writing.

In addition to that, access to the computerized reports of patients must be limited. If computer based patient record system is breached and results in harm to the patient's privacy, it amounts to liability on the care provider. Liability can also arise if a system is not protected from hacker access and breaches of patient confidential results or records are made/destroyed or altered. Fortunately, it is possible to protect the patient privacy and confidentiality in the computer system through several security measures. Security of the system can be enhanced through authentication with login procedures that require users to enter their passwords and user IDs to serve as a minimum security procedure on most of the systems. Higher levels of authentication, such as biometrics and smart cards grant access when a user produces a card with an authorized pass word, finger print recognition or voice recognition.

Assessment Scoring Matrix

Standard 37. PRE-3: Patient rights for appeals, complaints and confidentiality.

Indicator 116-118		Max Score	Weightage (Percentage)	Score Obtained
Ind 116.	**Patient's complaints are accepted by the laboratory and properly registered.**	10	**100**	
Ind 117.	**Proper actions and remedial measures are taken in response to patients' complaints.**	10	**100**	
Ind 118.	**Confidentiality of patient record is maintained.**	10	**100**	
Total		30		

PART 3
ANNEXURES

3. Annexures

ANNEXURE A: Summary Assessment Scoring Matrix

Functional Area		Max Score	Required Score	Score Obtained
2.1	**Responsibilities of Management (ROM)**	130	118	
2.2	**Facility Management and Safety (FMS)**	110	104	
2.3	**Human Resource Management (HRM)**	160	150	
2.4	**Management of Equipment & Reagents (MER)**	130	126	
2.5	**Recording & Reporting System (RSS)**	90	90	
2.6	**Quality Assurance (QA)**	160	160	
2.7	**Biosafety and Biosecurity**	180	180	
2.8	**Access, Assessment, and Continuity of Care (AAC)**	90	86	
2.9	**Care of Patients (COP)**	60	56	
2.10	**Patient Rights and Education (PRE)**	70	70	
Total		**1,180**	**1,140**	

ANNEXURE B: Health Related Laws in Khyber Pakhtunkhwa

No.	Health Related Laws
1.	Pakistan Medical Commission Act, 2020
2.	Khyber Pakhtunkhwa Food Safety & Halal Food Authority Act, 2014
3.	The Khyber Pakhtunkhwa Healthcare Commission Act, 2015
4.	The Khyber Pakhtunkhwa Public Procurement Regulatory Authority Act 2012
5.	The Khyber Pakhtunkhwa Consumer Protection (Amendment) Act, 2017
6.	The Khyber Pakhtunkhwa Blood Transfusion Safety Authority Act, 2016
7.	The Khyber Pakhtunkhwa Environmental Protection Act, 2014
8.	Pakistan Nursing Council (Amendment) Act, 2021
9.	Allopathic System (Prevention of Misuse) Rules, 1968
10.	Pharmacy Act, 1967
11.	The Unani Ayurvedic And Homoeopathic Practitioners Act, 1965
12.	The Allopathic System (Prevention of Misuse) Ordinance, 1962
13.	Khyber Pakhtunkhwa Hospital Waste Management Rules, 2018
14.	Injured Persons Act, 2004
15.	Khyber Pakhtunkhwa Injured Persons and Emergency (Medical Aid) Act, 2014

ANNEXURE C: Joining Report - Format

EMPLOYEE DETAILS	
Name	
Phone Number Home:	**Mobile Number:**
Email ID:	
Residential Address:	
Date of Joining	

EMPLOYEE'S JOINING CONFIRMATION
I _____ do hereby confirm that I have accepted your offered job as _____ in_____Department and have accordingly joined with effect from _____. **(Employee Signature) (Date)**

EMPLOYEE'S JOINING VERIFICATION
The date of joining mentioned above is correct. **Verified By:** **Name: _____ Designation: _____** **Signature: _____ Date: _____** **Note: Submission of this REPORT is mandatory. A copy of this report will be sent to the Accounts Department.**

ANNEXURE D: Statement of Ethics

Guideline 1	We do not make misleading claims for our services or criticize our competitors before clients. We only believe in servicing our client's needs to the best of our efforts.
Guideline 2	We perform our work according to the specified quality standards.
Guideline 3	We avoid conflicts of interest either of a financial or personal nature; these could compromise the objectivity and integrity of our work.
Guideline 4	We exercise our professional judgment impartially while taking any decisions related to work, keeping all pertinent facts, relevant experience and the advice of our management in mind.
Guideline 5	We hold the affairs of our clients in the strictest confidence. We do not disclose propriety information obtained in the course of work or derive benefit from using information outside the company.
Guideline 6	We act with courtesy and consideration towards all with whom we come into contact in the course of our professional work.
Guideline 7	We do not accept any favors, gifts or inducements, including undue hospitality and entertainment, from the clients. The only expectations would be if the gifts are of promotional nature (diaries, calendars, etc.) or of a nominal value, the indulgence of which would not damage the company's reputation.
Guideline 8	We are fully committed to the principle of equality and non-discrimination on the grounds of disability, sex, age, race, color, ethnicity, origin or marital status. We do not indulge in any intimidation and harassment of any sort at work.
Guideline 9	We will communicate with our clients and its representative in an effective and timely manner.
Guideline 10	We would be perceived by clients and other thought leaders as setting the standards in client focus and client service among professional service companies.

Declaration

I have read and understood the **"Statements of Ethics"** and stand committed to it.

Signature: _____

Name: _____

Date of Joining: _____

ANNEXURE E: Confidentiality Agreement

In the course of your work at _____ Laboratory you are likely to receive, from time to time, information which is not in the public domain. You are reminded that such information must be kept confidential and release of such information could lead to termination of employment, civil or criminal prosecution.

All memoranda, notes, reports and other documents will remain part of the Laboratory's confidential records. Such confidential information must at all times be kept in a secure place on the Laboratory's premises and disclosed to others only in accordance with our duties as an employee of _____.

Inventions, copyrights and other intellectual property, when conceived, developed or made during employment by the Laboratory, or within one year thereafter, shall be regarded as made by employee solely and exclusively for the benefit of the Laboratory. These shall not be disclosed to others without the Laboratory's written consent, and shall be the sole and exclusive property of the Laboratory.

The employee agrees to make prompt and full written disclosure of such inventions, copyrights and other intellectual property, and when requested by the Hospital to do so, either during or after employment.

By signing this agreement you confirm that you will comply with these requirements and you further undertake to preserve, even after you cease to be an employee, the confidentiality of information received by you during your employment at _____ .

I hereby confirm that I accept the set out above.

Signature: _____

Name: _____

Date of Joining: _____

ANNEXURE F: Reference Form

Kindly provide us the detail of at least 2 people, other than relatives, who have knowledge of your work experience and/or education.

Name of Candidate: _____ Position: _____

Reference 1	
Name:	Designation:
Company Name:	Address:
Telephone # (Home):	Telephone # (Office):
Mobile #:	Email:
Fax:	Other:

Reference 2	
Name:	Designation:
Company Name:	Address:
Telephone # (Home):	Telephone # (Office):
Mobile #:	Email:
Fax:	Other:

Reference 3	
Name:	Designation:
Company Name:	Address:
Telephone # (Home):	Telephone # (Office):
Mobile #:	Email:
Fax:	Other:

Reference 4	
Name:	Designation:
Company Name:	Address:
Telephone # (Home):	Telephone # (Office):
Mobile #:	Email:
Fax:	Other:

ANNEXURE G: Health Questionnaire Form

(To be filled by the employee)

Employee Name: _____ Designation: _____

Please read the following questions carefully and answer each question in Yes or No. If the answer to any question is "Yes", please give full detail.

No.	Question	Answer
1.	Have you ever been advised by a physician to have medical treatment or surgery/procedure/investigation for any of the following: 1. Heart disease 2. High blood pressure 3. Diabetes 4. Kidney disease 5. Cancer or brain tumor 6. Back pain including any muscular problem 7. Digestive problems 8. Liver disease including hepatitis B 9. AIDS	
2.	Do you have any health problem due to smoking	
3.	Are you currently taking any treatment or medication or awaiting medical investigations, laboratory test, treatment or surgery	
4.	Have you been absent from work due to medical reasons for a continuous period of a week or more during the last 2 years	
5.	Other (please specify)	

Please give detail of any "Yes" answer to the above questions in the following form.

Q#	Type of Disease	Date (from)	Date (to)	Treatment from (Name and address of Doctor)

DECLARATION:

I hereby declare that what has been stated above is true and complete to the best of my knowledge and if found that I have some health problem then I could be sent to the hospital, recommended by the HR Department, for complete checkup and test. In case of wrong information, I could be terminated from employment.

Signature: _____ Date of Joining: _____

ANNEXURE H: Orientation Checklist

Employee's Name: _____ Designation: _____

Department: _____ Date: _____

In order to avoid duplication of the instructions, the Information checked ( ) below has been given or explained to the employee by the HR department.

Introduction:		**Time Schedule:**	
Company Introduction	( )	Work Schedule/Lunch timings	( )
Mission & Vision	( )	Attendance & Punctuality	( )
Corporate Values	( )	Public Holidays	( )
Organizational Structure	( )	Leave	( )
Employment:		**Employee Relations:**	
Recruitment & Selection	( )	Violation of company rules	( )
Appointment Letter issued	( )	Disciplinary Policy	( )
Confidentiality Agreement signed	( )	Internal Communication	( )
Statements of Ethics signed	( )	Employee Records	( )
Probation & Confirmation	( )	Code of Conduct	( )
Resignation /Termination	( )		
Compensation & Benefits:		**Career Development:**	
Job Description issued	( )	Performance Management System	( )
Medical Facility	( )	Promotion/increments	( )
Parking Facility	( )	Training	( )
Provident Fund	( )		

Others:

Other Benefits	( )
Tour of the company	( )
Issuance of Employee Handbook	( )
Salary Administration:	
Salary Process	( )
Email address sent for addition	( )
Advance Salary	( )
Outstation Travel	( )

How satisfied are you with the orientation process?

a) Not Satisfied b) lmprovement Needed c)satisfied
1. Very Satisfied e) Outstanding

Additional Comments/Suggestions:

_____

_____

Orientation Conducted by:

Employee's Signature: _____

Supervisor's Signature: _____

ANNEXURE I: KP HCC Charters for Patients and HCEs

KP HCC CHARTER FOR PATIENTS & OTHERS

Part A: Rights of Patients and Others

A patient/client or his career, as the case may be, or any other person to whom healthcare services are being rendered, shall have a right to:

1. Health, well-being and safety;
2. Easy access to registration/help desk to get registered and be guided to the respective services as per requirement;
3. Special arrangements for elderly people and disabled to have easy access to required health services;
4. Be attended to, treated and cared for with due skill, and in a professional manner for the accepted standard of health in complete consonance with the principles of medical ethics;
5. Be made aware of the full identity and professional status of the Healthcare Service Provider(s) and other staff providing services;
6. Be given information to make informed choices about his healthcare and treatment options and/or to give informed consent, in terms and in a language that he understands;
7. Seek second opinion when making decisions about his healthcare, and may be assisted by the Healthcare Establishment/healthcare service provider in this regard;
8. Accept or refuse any treatment, examination, test or screening procedure that is advised to him, exceptions being in cases of emergencies and/or mental incapacity in accordance with the relevant law;
9. Personal health information to be kept secure and confidential;
10. Access his own medical records, including but not limited to, comprehensive medical history, Examination(s), investigation(s) and treatment along with the progress notes, and obtain copies thereof;
11. Not to be discriminated against because of age, disability, gender1, marriage, pregnancy, maternity, race, religion, cultural beliefs, color, caste and/or creed;
12. Expect that any care and/or treatment being received is provided by duly qualified and experienced staff;
13. Expect that the healthcare service provider or the Healthcare Establishment, as the case may be, has the capacity and required necessary equipment in order and working condition, for rendering the requisite services, including but not limited to treatment;
14. Receive emergency healthcare, unconditionally. However, once the emergency has been dealt with, he may be discharged or referred to another Healthcare Establishment [emergency requiring healthcare, is a situation threatening immediate danger tolife2 or severe irreversible disability, if healthcare is not provided urgently];
15. Be treated with respect, empathy and dignity irrespective of age, disability, gender, marriage, pregnancy, maternity, race, religion, socio -economic status, cultural beliefs, color, caste and/or creed;
16. Be treated in privacy and with dignity, and have his religious and cultural beliefs respected throughout the duration of care, including but not limited to, taking history, examination or adopting any other course of action;
17. Be made aware of procedures for complaints and resolution of disputes and conflicts;

18. File a written complaint to the concerned healthcare service provider, official of the Healthcare Establishment or such other organization/person, as the case may be and be associated throughout the progress of the complaint and its outcome;
19. Seek compensation if he has been harmed by, including but not limited to maladministration, malpractice, negligent treatment, or failure on the part of a healthcare service provider or any staff/employee or others rendering services at the Healthcare Establishment;
20. Be informed and to refuse to participate in research, or any project dealing with his disease, care and treatment;
21. Be accompanied by a family member or career, as the case may be, particularly in cases of children, females, elderly and disabled. The healthcare service provider and/or the Healthcare Establishment, as the case may be, are to ensure that in cases of children and females in the immediate post anesthesia phase, a female staff shall be present until a family member or career can join the patient/client, The healthcare service provider and/or the Healthcare Establishment, as the case may be, are also to ensure that in cases of children and females an authorized family member or a career or if not so possible, at least a female staff is present during physical examination and investigation procedures where physical contact and or exposure of body part(s) is required.
22. Expect that the Healthcare service provider, the Healthcare Establishment, and/or such other person rendering similar services, as the case may be, shall not misuse nor abuse their fiduciary position *vis-a-vis* him or his career(s) or family members, as the case may be, for undue favor(s) including but not limited to sexual favor(s) or any other undue or uncalled for reward or privileges in terms of professional fee or gifts etc.
23. Be informed as early as possible regarding cancellation and/or postponement of any appointment, surgery, procedure, treatment or meeting, as the case may be;
24. Be made aware of the costs, fee and/or expenses, prior to the consultation, treatment or other services, and/or operation/procedure, as the case may be, and receive payment receipt(s) for the same;
25. Be given written instructions regarding his treatment, including instructions at the time of discharge;
26. Examine and receive an explanation for the bill(s) regardless of the source of payment;
27. End of life care;

Nothing in this Charter prevents any organization/healthcare service provider/Healthcare Establishment from recognizing additional rights of the Patient/Client and/or the career, as the case may be. The purpose of this Charter is to inculcate and invigorate in the community the understanding and recognition of the fact that health, care and/or treatment is a right of an individual even when he is unborn and the same continues from his cradle to coffin.

This document will be reviewed annually or earlier, as deemed appropriate by the Khyber Pakhtunkhwa Healthcare Commission, in view of its experiences, through a consultative process involving patients, former patients, family members, related professionals, staff and other stakeholder groups.

Explanatory Notes

1. Gender includes male, female, transgender and intersex individuals.
2. Life, in the context of mental emergency, includes those of others.

3. End of Life Care includes healthcare, not only of patients in the final hours or days of their lives, but more broadly, care of all those with terminal illness or terminal condition that has become advanced, progressive and incurable. Accordingly, it may so happen that no treatment may be advisable and or given but the care should continue, keeping in view the ethics of the profession.

Part B: Responsibilities of Patients and Others

The patient/client or career, as the case may be, is responsible to the Healthcare Establishment, its staff or the Healthcare Service Provider for: -

1. Providing, accurate and complete information, to the best of his knowledge, regarding medical history, including but not limited to, present medical condition and complaints, medications, allergies and special needs, past illnesses, prior hospitalizations etc., as is required;
2. Reporting unexpected changes in his condition;
3. Adhering to the treatment plan prescribed to him;
4. Keeping appointments and when he is going to be late or is unable to do so for any reason, notify the concerned about the same, as soon as possible;
5. Taking responsibility for his actions if he refuses treatment or does not follow the given instructions;
6. Ensuring that the financial obligations of his care are fulfilled as promptly as possible;
7. Following the Healthcare Facilities' Rules and Regulations relating to patient care and conduct of others, including careers and or visitors;
8. Behaving in a courteous and polite manner which is non-threatening;
9. Refraining from conducting any illegal activity while he is at their premises;
10. Informing of any change of address and other requisite information.

KP HCC CHARTER FOR HEALTH CARE ESTABLISHMENTS

Part A: Rights of Healthcare Establishments/Healthcare Service Providers

The Healthcare Establishment or the Healthcare Service Provider, as the case may be, shall have the right to:

1. Collect accurate and complete information from the patient/client or career, to the best of his knowledge, regarding medical history including but not limited to, present medical condition and complaints, medications, allergies and special needs, past illnesses, prior hospitalizations etc., as is required;
2. Require the patient/client to follow treatment instructions, including the written instructions explained at the time of discharge;
3. Require all patients to abide by its rules and regulations regarding admission, treatment, safety, privacy and visiting schedules etc.;
4. Limit visiting hours and number of visitors in the best interest of the patient/client and that of the others in the Healthcare Establishment;
5. Limit number of careers in the best interest of the patient/client, and that of the others, while keeping in view the special needs of particular patients, for example, minor children, women, elderly and/or seriously ill patients;
6. Be timely notified by the patient/client regarding cancellation of appointment, consultation, procedure, surgery, etc. or delay in his arrival at the Healthcare Establishment;
7. Require the patient/client and/or career(s) to cooperate with Healthcare Establishment staff in carrying out assessments, prescribed investigations and treatment procedures.
8. Require from the patient/client or careers and visitors, as the case may be, to understand the role and dignity of the Healthcare Establishment, its staff and/or the Healthcare Service Provider, as the case may be, and treat them with due respect at all times;
9. Report and take legal action against the patient/client and/or his career(s), visitors, in case of harassment of its staff, damage to its property and disturbance to other patient(s), as the case may be;
10. Demand abstinence from the use of violent and disruptive behaviors or language abuse and take appropriate legal action in case of breach;
11. Prohibit smoking and/or substance/drug abuse on the premises and take appropriate legal action in case of breach;
12. Limit its liability for misplacement or theft of valuables and belongings of the patient/client, career and visitor;
13. Be paid for all services rendered to the patient/client, either personally or by the career or through the third party, e.g. insurance company.
14. Be notified of any change of contact, address and other details of the patient/client, as the case may be;
15. Ask for information from the patient/client regarding its services for the purposes of improving the healthcare services/systems within the Healthcare Establishment;
16. Maintain and utilize the data collected from the patient/client, subject to the principles and law relating to confidentiality, for the purposes of improving the healthcare services/systems within the Healthcare Establishment;

17. Ensure that while using the available facilities and equipment, due care and caution is taken by the patient/client and/or their careers and visitors, as the case may be.

The Khyber Pakhtunkhwa Healthcare Commission while recognizing the fact that each Healthcare Establishment is a "House of Hope" where advice and treatment, including other services, are rendered to the public at large, has developed this Charter of Rights for all Healthcare Establishments/Healthcare Service Providers in the Province of Khyber Pakhtunkhwa. All these rights are to be exercised with a view to make better services available to the masses.

The Khyber Pakhtunkhwa Healthcare Commission further assures that it stands committed to the cause of the Healthcare Establishments/Healthcare Service Providers in the exercise of these rights and shall always be ready and willing to support in the implementation and enforcement of the rights envisaged herein.

This document will be reviewed annually or earlier, as deemed appropriate by the Khyber Pakhtunkhwa Healthcare Commission, in view of its experiences, through a consultative process involving patients, former patients, family members, related professionals, Healthcare Establishments/Healthcare Service Providers, staff and other stakeholder groups.

Part B: Responsibilities of Healthcare Establishments/Healthcare Service Providers

The Healthcare Establishment or the Healthcare Service Provider, as the case may be, shall be responsible for:

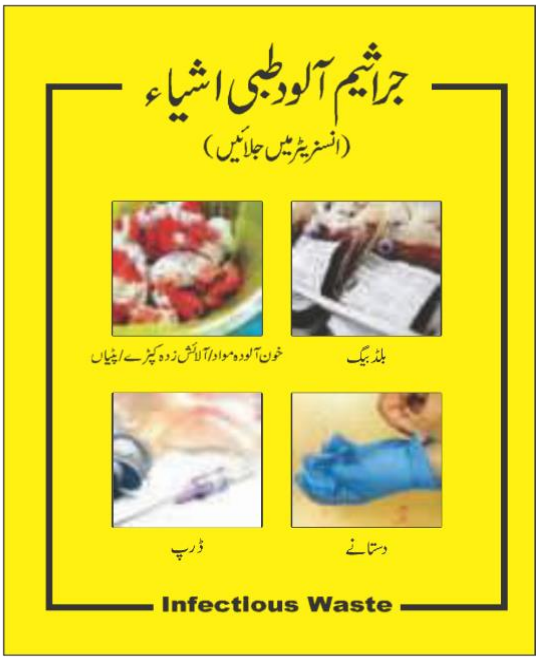
1. Ensuring the safety of patient/client.
2. Establishing such systems which enable easy access to services as are required by the patient/client.
3. Maintaining the services being provided through fully competent professionals.
4. Establishing systems to ensure that the rights of the patient/client and others are enforced and fully protected.
5. Adopting open policies regarding its procedures in relation to treatment of the patients/clients including but not limited to, their care and complaints etc.
6. Invigorating in their staff including but not limited to, Consultants and other professionals rendering services at the Healthcare Establishment, the importance and thorough practice of professional ethics.
7. Complying with all the governing laws, rules and regulations while operating, maintaining and rendering services.

ANNEXURE J: Weeding of Old Record

	Type of Record	**Period of retaining**
Official Record	Personal Files, Services books, Financial Record auditable and non-auditable, excisable/non-excisable record.	In accordance with the Government of Khyber Pakhtunkhwa Financial Rules or as per necessity, whichever is later.
Medical Record	Patient charts, Reports, X-Ray, CT Scan MRI, Pathology reports OPD Registers.	03 years or later as per necessity.
Medico-legal	Medico-Legal report/registers	12 years or later as per necessity.
Demographic Record	Birth and Death record	Birth and Death Registers to be kept forever.

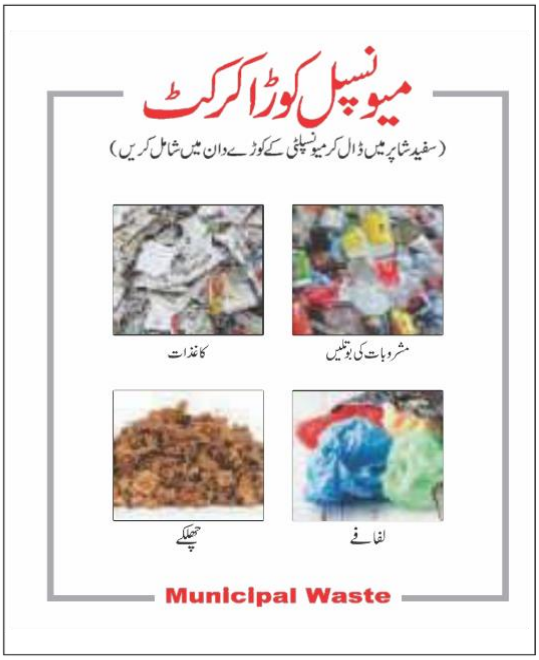
Annexure K: Segregation of Waste (both Clinical & Municipal) for Disposal

1. Yellow Colour

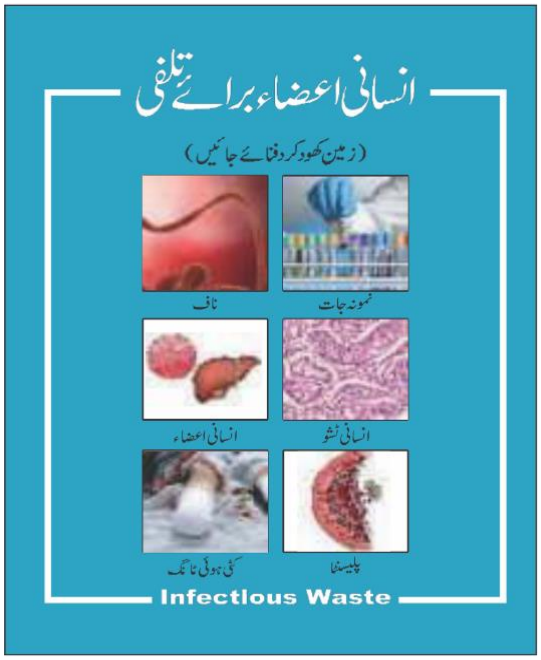


2. Red Colour

3. White Colour



4. Light Blue



ANNEXURE L: Template of Client Satisfaction Proforma

CLIENT SATISFACTION PROFORMA

No.	Questions	Response	
1	**Are you satisfied with the services, behavior of staff and environment at the laboratory ABC_____?**	Yes	No
2	**If YES, how? (You can circle more than one response and write below)**	1. Convenient to reach the facility. 2. Required guidance provided. 3. Services available as portrayed. 4. Services are affordable. 5. Staff is courteous. 6. Relevant staff is available. 7. Privacy is observed. 8. Female staff is available. 9. Test results provided in time. 10. Other(specify))	
3	**If NO, why? (You can circle more than one) response and write below)**	1. Issues of confidentiality. 2. Issues of privacy. 3. Lack of attention. 4. Inadequate guidance provided. 5. I was asked to come another time without taking the sample. 6. Tests/services are costly. 7. Waiting time is too long. 8. Staff is discourteous/unsatisfactory behavior. 9. Staff is not competent. 10. Relevant staff NOT available. 11. Female staff NOT available (gender issue). 12. Other (specify)	
	Signatures of patient/relative		
	Action by the person in charge with date:		

ANNEXURE M: HCE Complaints Management

1. OBJECTIVE

To ensure that complaints are handled in a standardized manner at all Healthcare Establishments (HCEs) in Khyber Pakhtunkhwa.

2. SCOPE

This document provides general guidelines to HCEs to develop or improve their Complaint Management Systems.

3. RESPONSIBILITY

The responsibility of complaints handling rests with the HCP; however, all staff members of the establishment are responsible for providing the necessary support.

4. DISPLAY OF INFORMATION

A. Inform the patient of his/her right to express his/her concern or complain either verbally or in writing.

B. This shall be done by clearly displaying the following information, in Urdu, at the entrance, help desk, every department and at the back of admission and discharge slips:

آپکو لیبارٹری کی سروس کے متعلق تحریری یا زبانی شکایات کرنے کا حق حاصل ہے۔ آپ اپنی شکایات لیبارٹری کے منتظم کو دفتر یا ٹیلی فون نمبر۔۔۔۔۔۔۔۔۔۔ پر کرسکتے ہیں یا استقبالیہ ہیلپ ڈیسک / ریسیپشن پر موجود شکایات رجسٹر میں اپنی شکایات درج کرسکتے ہیں۔

5. COMPLAINT HANDLING

A. Put into place a documented process for collecting, prioritizing, reporting and investigating complaints, which is fair and timely.

B. Registration

(i) A number of Complaint Registers shall be maintained by each HCE, one of which shall be available at istaqbaliah/help desk/reception, round the clock.

(ii) Each Complaint Register shall have:

- A 3" X 4" white chit pasted on the cover page with the following:

Complaint Register No. (Register No./Total number of Complaint Registers)
Opened on: **(Mention date as XX-XX-XXXX)**

- The following certificate on the inner side of the cover page:

"It is certified that this register contains _____ pages; each page has been numbered (at the top centre), stamped with the HCE seal (at top right corner) and initialed by me."

Date: XX-XX-XXXX (Signature and Name of Authorized Person)

- The following page format:

1	2	3	4	5	6	7	8	9	10
S / No.	Date	Complainant's Name	CNIC No.	Contact No.	Address	Detail of the Complaint	Signature/thumb impression of the complainant	Date seen & Signature Manager	Date seen & Signature CEO

Column 2-8 shall either be filled by the complainant or someone else (whom the complainant trusts) on his/her behalf.

- Every written or verbal complaint directly made to the HCE/Authorized Person shall be entered in the register within 24 hours.
- All complaints should be resolved expeditiously.
- Enter important points of the complaint in the register. Take notice of allegations and requests made.
- Investigate in an impartial manner.
- Keep the time factor in mind because any undue delay will reflect poorly on the management.

6. COMMUNICATION

A. Inform the complainant about the progress of the investigation at regular intervals and inform him/her about the outcome.
B. Stay in contact with the complainant and regularly update him/her about the progress made in investigation.
C. Record the outcome of the investigation and inform the complainant accordingly.
D. Don't indulge in argumentation. Be polite and empathetic.

7. QUALITY IMPROVEMENT

A. Use the results of the complaints investigation as part of the quality improvement process.
B. The registers should be perused by the Chief Executive of the establishment, at least once a month.
C. Make necessary changes in policy and procedures to improve the quality of healthcare services.

The Khyber Pakhtunkhwa Health Care Commission (KP HCC) has the legal mandate (Khyber Pakhtunkhwa Health Care Commission Act, 2015) to regulate the health care services in both public and private sectors in the province. The objective is to improve and maintain quality of healthcare, and ensure safety of patients and healthcare providers. The Health Care Establishments (HCEs) are assessed against set standards for this purpose. It is mandatory for the HCEs, including primary, secondary and tertiary levels to acquire license from the KP HCC through the implementation of the Minimum Service delivery Standards.

Khyber Pakhtunkhwa Health Care Commission

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