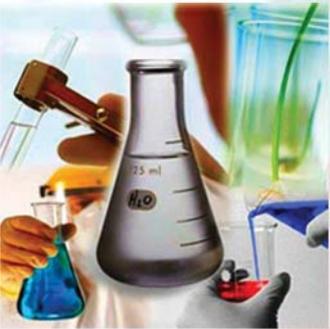


Health Regulation Department

Clinical Laboratory Regulation



2012

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Acknowledgment

Dubai Health Authority (DHA) is pleased to present the DHA Clinical Laboratory Regulation which represents a milestone towards fulfilling the DHA strategic objective in providing “A world class integrated health system that ensures excellence in health and healthcare for the Emirate of Dubai and promotes Dubai as a globally recognized destination for healthcare”.

The Clinical Laboratories’ Regulation places an emphasis on facility design and services criteria with a focus on quality of services and safety of professionals based on the local and federal laws in addition to international accreditation standards. Therefore, this document provides a base for the Health Regulation Department (HRD) to assess the Clinical Laboratories performance in Dubai and to ensure a safe and competent delivery of services. It will also assist Clinical Laboratories in developing their quality management systems and in assessing their own competence to ensure compliance with DHA regulatory requirements and the United Arab Emirates (UAE) federal laws.

This was developed by the HRD in collaboration with Subject Matter Experts whose contributions have been invaluable. The HRD would like to gratefully acknowledge those professionals and to thank them for their dedication to quality in health and their commitment in undertaking such a complex task.

The Health Regulation Department
Dubai Health Authority

I. Scope

This regulation specifies requirements for licensure, competence and safety particular to clinical laboratories subject to licensure under the Dubai Health Authority (DHA) establishment law, including governmental, semi governmental, private and clinical laboratories operating in free zone areas.

This Regulation may be amended from time to time at the discretion of DHA, and will be referred to as the Clinical Laboratory Regulation. The latest edition of the document shall be accessed through the DHA website www.dha.gov.ae

II. Purpose

The DHA is the sole responsible entity for regulating, licensing and monitoring all healthcare facilities and healthcare professionals in the Emirate of Dubai. Through the development, establishment, and enforcement of this regulation, which matches best practices for operating Clinical Laboratories, the DHA will ensure provision of the highest levels of quality of laboratory services at all times.

III. Definitions

Clinical Laboratory: shall mean a medical institution, building or place in which procedures for the examination of materials taken from or originating from the human body performed through testing by: chemistry, hematology microbiology, serology, cytology, pathology, immunohematology or other forms of examinations to obtain information for diagnosis, prophylaxis or treatment of humans.

Disabled People (also known as special needs) shall mean a personal condition or situation that could make it difficult for a patient to participate fully in their health care, which include disability (physical, intellectual or sensory disability), age affected (either elderly or very young), affected by trauma or affected by medications/drugs.

Fine Needle Aspiration (FNA) shall refer to a non-surgical procedure by which a sample of tissue can be obtained from virtually any palpable lump for diagnosing of lesions. Typically, FNAs are performed by endocrinologists, cytopathologists, or surgeons and interpreted by an experienced clinical cytopathologist. The procedure is fast, convenient, safe and well-tolerated by patients. No anaesthesia or hospitalization is required.

Healthcare professional shall mean healthcare personal working in healthcare facilities and required to be licensed as per the applicable laws in United Arab Emirates.

Health Care Worker (HCW) shall mean an individual employed by the health facility, whether directly or by contract with another entity, who provides direct or indirect patient care, this includes but not limited, healthcare professionals, medical and nursing students, administrative staff and contract employees who either work at or come to the health facility site.

Licensure shall mean issuing an official permission to operate a health facility to an individual, government, corporation, partnership, Limited Liability Company (LLC), or other form of business operation that is legally responsible for the facility's operation.

Medical Complaint shall mean expressions of dissatisfaction or concern about a health care service made by patients, or their relatives.

Panic Value shall refer to the laboratory findings (results) that are outside the normal range to a degree that may constitute an immediate health risk to the individual or require immediate action on the part of the ordering physician

Patient shall mean any individual who receives medical attention, care or treatment by any healthcare professional or admitted in a health facility.

Risk Management shall mean 'a logical and systematic method of establishing the context, identifying, analyzing, evaluating, treating, monitoring and communicating risks associated with any activity, function or process in a way that will enable organizations to minimize losses and maximize opportunities.

IV. Acronyms

DHA	:	Dubai Health Authority
DED	:	Department of Economic Development
FGI	:	Facility Guidelines Institute
HRD	:	Health Regulation Department
HVAC	:	Heating, Ventilation and Air Conditioning
LLC	:	Limited Liability Company
MEP	:	Mechanical Electrical Plumbing
MOH	:	Ministry of Health

CHAPTER ONE: LICENSURE AND ADMINISTRATIVE PROCEDURES

Clinical laboratory services can be provided in different settings. Either as an independent facility called “Clinical Laboratory” or as part of other health facility services such as Hospitals, Day Surgical Centres, Polyclinics or Specialty Clinics. A person or entity must obtain a license from Dubai Health Authority (DHA) to operate an independent Clinical Laboratory in the Emirate of Dubai. This applies to governmental, semi governmental, private laboratories and clinical laboratories operating in free zone areas.

1. Registration and Licensure Procedures

- 1.1 Health Regulation Department (HRD) shall receive applications to operate clinical laboratories in the Emirate of Dubai according to the applicable laws regarding this issue. *For further information [click here](#) to see article 4 and 5 of the Federal Law number 2/1996 concerning Private Health Facilities*
- 1.2 Application to operate a new independent Clinical Laboratory in a commercial villa or flat requires prior approval from Dubai Municipality (DM) for commercial use of the premises. The application to HRD shall include:
 - 1.2.1 Submission of the “new health facility licensure application form” which can be accessed through HRD licensing services www.dha.gov.ae
 - 1.2.2 The proposed general location with land plot number
 - 1.2.3 Schematic Designs (SD) showing the proposed floor layouts with each room numbered and labeled and a general cross section of the structure.
 - 1.2.4 The Clinical Laboratory functional program
- 1.3 In case of building a new independent Clinical Laboratory, the land plot allocated to the project shall be approved by DM for commercial use.
- 1.4 The applicant must ensure the facility design is compliant with “DHA Health Facility Guidelines: Planning, Design, Construction and Commissioning” published in DHA website www.dha.gov.ae
- 1.5 Upon receipt of a completed applicant's file, the HRD will conduct a detailed review of the submitted material to determine suitability for further processing.
- 1.6 The HRD shall issue an Initial Approval letter for a new Clinical Laboratory with defined services / restrictions particular to the applicant’s request.
- 1.7 This letter will be required to complete the Clinical Laboratory’s licensing procedures pertaining to issuing of the trade license by local authorities such as The Department of Economic Development (DED) in Dubai or equivalent licensing bodies (i.e. free zones authorities).
- 1.8 In case of Rejection of the application a detailed list of issues will be provided for corrective action and the Clinical Laboratory is required to re-submit the application with applicable fees.

For further details regarding the application form, ownership, licensure procedures, application fee and re-submission fee please [click here](#) or visit the HRD on the DHA website www.dha.gov.ae

2. Facility Name

- 2.1 During the initial registration process, the name of the Clinical Laboratory will be tentatively under the owner's name.
- 2.2 Each Clinical Laboratory shall be designated by a permanent and distinctive name which shall not be changed without prior notification of DHA.
- 2.3 The name of the health facility shall not tend in any way to mislead the public as to the type or extent of care provided by the facility.

3. Final inspection and issuing the License

- 3.1 A request for Final Inspection shall be submitted by the applicant, upon which an onsite pre-operational assessment will be conducted by HRD.
- 3.2 Applicant shall submit the detailed scope of services provided in the clinical laboratory along with final laboratory layout in AutoCad format prior to final inspection.
- 3.3 To obtain the DHA Independent Clinical Laboratory license, the applicant must meet the following:
 - 3.3.1 Appoint a Laboratory Medical Director (for the director qualifications please refer to Clinical Laboratory professional's licensure requirements document under Health Regulation on www.dha.gov.ae).
 - 3.3.2 Employ a sufficient number of qualified and DHA licensed clinical laboratory professionals to satisfy the facility's functional program and to meet patients' needs according to the scope of provided services.
 - 3.3.3 Install and operate clinical laboratory equipment required for provision of the scope of services and in accordance with the manufacturer's specifications and special requirements for height, space etc.
 - 3.3.4 Provide suitable infrastructure according to the services provided by the clinical laboratory. The basic infrastructure includes:
 - 3.3.4.1 Reception room/area.
 - 3.3.4.2 Specimen collection room/area, with nearby toilet.
 - 3.3.4.3 Specimen/Sample/slide storage facility including cold storage where applicable.
 - 3.3.4.4 Water supply suitable for analytical purposes.
 - 3.3.4.5 Adequate power supply.
 - 3.3.4.6 Analytical work area.
 - 3.3.4.7 Dedicated area for cleaning of glassware, sterilization/disinfection
 - 3.3.4.8 Designated areas for the collection of medical waste, general storage for supplies and equipment in addition to a storing area/cabinet for hazardous materials (shall be clearly labeled).
 - 3.3.4.9 Adequate ventilation, climate control and lighting arrangements
 - 3.3.4.10 Separate room/area for meetings/administrative work
 - 3.3.4.11 Separate facilities/area for staff for eating and storing food, drinks etc.

3.3.4.12 Communication facility with referral centers

3.3.4.13 Additional infrastructure facilities may be added for special tasks

For further details regarding design requirements please refer to [Chapter Two](#) of this document.

3.3.5 Provide a documented policy and procedure for the following:

3.3.5.1 Hazardous waste management

3.3.5.2 Laboratory reports management.

3.3.6 Provide analytical Standards Operating Procedures (SOPs) which may include:

3.3.6.1 List of tests performed in the clinical laboratory

3.3.6.2 Professional expertise required to perform the tests

3.3.6.3 The methodology for performing the tests,

3.3.6.4 Reference ranges and turnaround times.

3.3.7 The laboratory shall be accessible for disabled individuals.

3.3.8 The laboratory safety plan and design shall comply with the fire safety and other requirements by the Dubai Civil Defence Department.

3.3.9 Maintain Charter of Patients rights and responsibilities clearly posted on the facility premises in two languages one of which must be Arabic.

3.4 Based on the onsite assessment and after meeting the DHA requirements and recommendations, the HRD will issue a DHA license valid for one year.

3.5 Clinical Laboratory license shall be issued on three main categories¹:

3.5.1 General Clinical Laboratory (which can be referred to as a Reference laboratory).

3.5.2 Specialized Clinical Laboratory such as Genetic Laboratory.

3.5.3 Diagnostic Centre with two specialties (Clinical laboratory and diagnostic imaging services)

3.6 The license shall state the name and address of the Clinical Laboratory, the DED license number, the period of licensure validity as well as the specific service(s) that the facility is licensed to deliver with restrictions (if any).

3.7 The Clinical Laboratory license shall be clearly posted in the facility.

3.8 Clearly display the hours of operation of the facility as well as the types of available procedures

4. Management Responsibilities

Upon obtaining the independent Clinical Laboratory license or the approval for adding clinical laboratory service, the management of the Clinical Laboratory has certain licensure responsibilities they must fulfill, which include, but not limited to:

4.1 Comply with all federal and local laws and regulations.

¹ To be licensed as Diagnostic Centre with two specialties, the health facility shall meet the diagnostic imaging service requirements and criteria as per the DHA Diagnostic Imaging Service Regulation.

- 4.2 Take necessary measures to distribute new DHA circulars and announcements among all facility professionals.
- 4.3 Cooperate with HRD inspectors and/or any duly authorized representative and provide requested documentation or files.
- 4.4 Avoid giving misleading information and false statements which may lead to legal action against professionals or the health facility.
- 4.5 Settling of any violation fines related to professionals or the health facility.
- 4.6 Maintaining malpractice insurance for all licensed healthcare professionals as per article 25 and 26 of the UAE Federal Law number 10/2008 concerning Medical Liability.
- 4.7 Use the DHA Infectious Diseases Notification Service to report communicable disease required by the UAE Federal Law number 27/1981 concerning the Prevention of Communicable Diseases.
- 4.8 Submit to the Health Data and Information Analysis Department in DHA the required statistical data of the facility.
- 4.9 Obtain prior approval from the Ministry of Health (MOH) for media and advertisement materials, for further information regarding the media and advertisement materials approval procedures and requirements please visit the MOH website www.moh.gov.ae

5. Compliance Review

- 5.1 At any time and upon reasonable cause, HRD may conduct random inspections to audit the Clinical Laboratory to determine the facility compliance with the DHA regulation, and take appropriate action if required.
- 5.2 The HRD inspectors and/or any duly authorized representative may conduct regular onsite inspections to ensure compliance with the relevant DHA regulations.
- 5.3 The onsite inspections may be scheduled or un-announced.
- 5.4 After every inspection in which non-compliance to the DHA regulations has been identified, the authorized inspectors shall issue an onsite copy of the field inspection report followed by a letter stating the identified violations.
- 5.5 The clinical laboratory management shall submit to the HRD a written plan of correction of violations cited within fifteen days after receiving the noncompliance letter stating the identified violations.

6. Application for License Renewal

- 6.1 Application for renewal of the Clinical Laboratory license must be submitted not less than 30 days prior to expiration of the license and shall conform to all renewal requirements and applicable fees.
- 6.2 The applicant's failure to file the renewal licensing application within the given time shall result in expiration of the current license on its last effective date. In such cases, the facility shall be subjected to financial penalties and may lead to null and void of the facility license.
- 6.3 HRD will renew the facility license for a period of one year after fulfilling the DHA renewal requirements.

For further details regarding health facility license renewal procedures and requirements visit Health Regulation site on the DHA website www.dha.gov.ae

7. Temporary Suspension of the License

- 7.1 If the Clinical Laboratory operations or specific service(s) pose an imminent risk to the safety of patients or healthcare professionals working in the facility, the Director General of Dubai Health Authority may issue an order of revocation of the Clinical Laboratory services pending a final decision from an investigation committee.

8. Voluntary Cancellation of the License

- 8.1 Should a Clinical Laboratory wish to cease its services, a voluntary cancellation request shall be signed by the owner of the facility and must be submitted at least (30) days before closure of the facility.
- 8.2 The management of the facility shall comply with existing DHA regulations regarding cancellation of the health facility license

For further details regarding health facility license cessation procedures visit Health Regulation Department on DHA website www.dha.gov.ae

9. Null and Void License

- 9.1 As per the UAE Federal Law number 2/1996 concerning Health Facilities, the health facility license is considered null and void by force of law in the following conditions:
- 9.1.1 Transferring the health facility ownership to a different individual, corporation, Limited Liability Company (LLC), etc.
- 9.1.2 Closure of the facility for a period of six months without presenting valid and justified reason(s).
- 9.1.3 The health facility is not operating for a period of six consecutive months from the date of issuing the facility license.
- 9.1.4 Cancellation or liquidation of health Facility Corporation, partnership or LLC, etc.

10. Alterations and Additions to Clinical Laboratory Building

- 10.1 Any renovations that will result in change or addition to the premises shall require prior review and approval by the DHA and amendment of the Clinical Laboratory license.
- 10.2 The Clinical Laboratory management must submit an application file including both the preliminary and final architectural plans with specifications showing the proposed change or addition.
- 10.3 All construction, alterations or additions to an existing Clinical Laboratory building shall comply with the construction standards of the Dubai Municipality (DM) building code and meet the DHA Health Facilities Guidelines: Planning, Design, Construction and Commissioning.

For further information regarding the DHA Health Facilities Guidelines please [click here](#) or visit the Health Regulation site in DHA website www.dha.gov.ae

CHAPTER TWO: CLINICAL LABORATORY DESIGN REQUIREMENTS

11. General Design Considerations

Clinical Laboratory may be an independent laboratory or part of a health facility such as Hospital or Diagnostic Centre with two specialties, meanwhile, independent laboratory may also be freestanding purpose built or converted such as in villas, or in a multiple-use commercial building. The following general design considerations should be considered:

- 11.1 The location and access to any health facility shall be convenient both to people using public transportation and those using vehicles. Freestanding facilities may provide parking on the facility premises
- 11.2 Signage shall be provided to direct people unfamiliar with the Clinical Laboratory to the entrances and other areas in the laboratory.
- 11.3 The design, construction, renovation, expansion, equipment, and operation of all health facilities including clinical laboratories are subject to provisions of several local and federal laws for control of environmental pollution; this includes but not limited to hazardous waste materials storage handling, and disposal; medical waste storage and disposal; asbestos use in building materials, elimination of the use of Mercury and chlorofluorocarbons (CFCs) in health care, etc.
- 11.4 Special consideration should be given to the choice of fireproof construction for the buildings according to the building and design codes of Dubai Municipality (DM) and Civil Defense Department requirements.
- 11.5 Public corridors shall have a minimum width of 1.52 meters (5 feet). Items such as provisions for drinking water, vending machines, etc., shall not restrict corridor traffic or reduce the corridor width below the required minimum.
- 11.6 The minimum door opening width for patient use shall be 86.36 centimeters. If the facility serves patients confined to wheelchairs, the minimum width of door openings to rooms shall be 1.12 meters.
- 11.7 The minimum ceiling height shall be 2.39 meters (7 feet 10 inches)
- 11.8 Color contrast between walls, floors and doors shall be considered as it may reduce falling risk of blurred vision patients.

12. Reception and Waiting Area

- 12.1 In freestanding clinical laboratories a reception/information counter or desk shall be located to provide visual control of the entrance to the laboratory area and should be immediately apparent from that entrance.
- 12.2 Male and Female waiting area for patients may be provided or be shared with other adjacent departments. Escorts will be under staff control. Waiting area may be provided with provision of drinking water.
- 12.3 Toilet(s) for public use and for giving samples shall be conveniently accessible from the waiting area ensuring patient privacy. A hand-washing station shall be provided in the toilet room. The body fluid samples/stools should also be delivered to a sample collection point with acceptable proximity to the toilets.
- 12.4 Access to laboratory areas should be strictly limited to laboratory personnel. Members of the general public should get no further than the reception areas or waiting rooms.

13. Phlebotomy room/Specimen Collection Area:

- 13.1 Phlebotomy room shall have minimum space of 6 square meters (64.9 square feet), a seating space, a work counter, and a hand-washing station in the vicinity.
- 13.2 Phlebotomy room location, design and door swings should be oriented to provide patient privacy, a cubicle curtain or partial walls may be required to accomplish privacy.
- 13.3 Room shall be furnished with reclining chair or gurney for patients who become unsteady.

14. Laboratory Furniture Design and Exit Paths

- 14.1 Work benches shall be 75 cm wide
- 14.2 Aisle clearance between benches shall have a minimum of 60.96 centimeters.
- 14.3 Laboratory benches must not impede emergency access to an exit. This is also applicable to placement of other furniture and appliances such as chairs, stools, refrigerators, etc. A pathway clearance of 91.44 centimeter must be maintained at the face of the access/ exit door.
- 14.4 The space between adjacent workstations and laboratory benches should be 1.52 meter or greater to provide ease of access.
- 14.5 All furniture in the clinical laboratory must be sturdy and cleanable.

15. Laboratory Work/Testing area

- 15.1 Laboratory working area for basic clinical pathology tests shall have a minimum clear floor area of 15 square meters (161.4 square feet).
- 15.2 Laboratory work area shall have appropriate facilities for storage and refrigeration of blood, urine, and other specimens.
- 15.3 Work counters and equipment space shall be provided to accommodate all on-site tests identified in the functional program of the facility.
- 15.4 Work counters shall be sufficient to meet equipment specifications and according to manufacturer requirements. Extra space is required for advanced tests and equipment.
- 15.5 Work countertops should be made from monolithic, heat resistant, antimicrobial and impermeable material to moisture e.g. Corian, Epoxy resin or Trespa countertops. The floor and walls should be anti-static, heat resistant, anti-bacterial, anti-fungal and resistant to chemicals used for disinfection purposes.
- 15.6 Food items or cosmetics must not be stored in testing areas.
- 15.7 Documenting the specifics of each instrument and device is important for the architect or laboratory planner to determine square footage requirements and layout. The equipment list should include any instrument or device, no matter what size, that requires any utility, such as electricity. This is also very important for the engineers when determining the utility requirements and heat loads for the laboratory planner.
- 15.8 Each laboratory must contain a sink for hand washing. Taps for hand washing should be elbow operated/foot operated/sensor operated.
- 15.9 Laboratory sinks shall have lips that protect sink drains from spills. Sink lips or berms should be ≥ 0.25 inches and designed to completely separate the laboratory bench or fume hood work area from the sink drain.

16. Staff room

- 16.1 It is desirable that the design of the laboratory building should incorporate adequate additional facilities for food storage/consumption and personal hygiene task away from laboratory working area.
- 16.2 Laboratory professionals must have access to the following:
 - 16.2.1 Hand-washing stations and counter sink(s).
 - 16.2.2 Communication service such as telephone
 - 16.2.3 Electrical service
 - 16.2.4 Eye washing station shall be accessible within a maximum distance of 30.48 meters from the work area.
 - 16.2.5 Laboratory work area shall have appropriate facilities for storage and refrigeration of blood, urine, and other specimens.

17. Chemical/Waste Storage

- 17.1 Sufficient space or facilities (e.g., storage cabinets with partitions) shall be provided so that chemicals and reagents can be physically separated and stored.
- 17.2 Chemical storage shelves shall not be placed above laboratory sinks.

18. Flooring

- 18.1 Selected flooring surfaces shall be easy to maintain, readily cleanable, and appropriately wear-resistant.
- 18.2 The floor shall be non-pervious and with covings to the walls and cabinets to ensure that spills cannot penetrate underneath.
- 18.3 Tiles and wooden planks are not appropriate.
- 18.4 Joints for floor openings for pipes and ducts shall be tightly sealed.
- 18.5 Highly polished flooring, walling or finishes that create glare shall be avoided.
- 18.6 Slip-resistant flooring products shall be considered for flooring surfaces in wet areas such as the toilets and the work areas in the laboratory in addition to areas that include water for patient services.
- 18.7 Carpet cannot be used in phlebotomy rooms and working areas. However, if used in patient waiting areas and corridors carpet shall be glued or stretched tight and free of loose edges or wrinkles.

19. Walls

- 19.1 Wall finishes shall be washable, moisture-resistant and smooth.
- 19.2 Wall finish treatments shall not create ledges or crevices that can harbour dust and dirt
- 19.3 Color contrast between walls, floors and doors shall be considered as it may reduce falling risk of blurred vision patients.
- 19.4 In the vicinity of plumbing fixtures, wall finishes shall be smooth, scrubbable, and moisture-resistant and shall not create ledges or crevices that can harbor dust and dirt.

20. Lighting

- 20.1 Laboratory areas shall be provided adequate natural or artificial illumination to ensure sufficient visibility for operational safety.
- 20.2 Windows must be well sealed and provided with blinds.

21. Cleanability

- 21.1 The laboratory shall be designed so that it can be easily cleaned. Bench tops must be a seamless one-piece design to prevent contamination. Laminate bench tops are not suitable. Penetrations for electrical, plumbing, and other considerations must be completely and permanently sealed.
- 21.2 If the bench abuts a wall, it must be coved or have a backsplash against the wall. Walls should be painted with washable, hard non-porous paints.
- 21.3 Wooden and wood finish walls or floors and carpets are not appropriate because they can absorb hazardous and/or potentially infectious material, particularly liquids, making decontamination/remediation virtually impossible.
- 21.4 Spaces between benches, cabinets, and equipment must be accessible for cleaning and allow for servicing of equipment.
- 21.5 Laboratory furniture must have smooth, non-porous surfaces so as to resist the absorption of liquids and the harsh effects of disinfectants. Furniture must not be positioned in such a manner that makes it difficult to clean spilled liquids or conduct routine maintenance.

22. Autoclave and Sterilization Area

- 22.1 A method for decontaminating all laboratory wastes should be available in the facility. For maximum flexibility, autoclave space is recommended on each floor, or at a minimum in a convenient location in each lab facility, where microbiological testing is performed.
- 22.2 Autoclave space should be finished with epoxy coatings and should not have a suspended, acoustical ceiling. This area should be thoroughly sealed to promote cleanliness and reduce pest harborage.

23. Filing Cabinets and Storage

- 23.1 Filing cabinets and storage shall be provided for the safe and secure storage of patient's laboratory profiles with provisions for easy retrieval.
- 23.2 Filing cabinets and storage must be in safe location and must have restricted access.

24. Administrative Activities

- 24.1 Clinical Laboratory shall make provisions to support administrative activities, filing, and clerical work as appropriate. Such clerical space or room for typing and clerical work shall be separate from patients and public areas.

25. Equipment and Supply Storage

- 25.1 Dedicated waste collection and storage area
- 25.2 General storage facilities for supplies and equipment shall be provided based on the functional program facility.

25.3 Special storage for staff personal effects with locking drawers or cabinets shall be provided.

25.4 Storage areas for Non-clinical records, documents, and office supplies shall be provided

26. Fume hoods

26.1 Laboratory must have fume hoods if they deal with toxic or noxious hazardous fumes vapors or dust. The fume hoods shall meet the following general standards:

26.2 Average face velocity of 75 feet per minute (0.45 to 0.56 meters per second).

26.3 Connection to an exhaust system to the outside that is separate from the building exhaust system

26.4 Location of an exhaust fan at the discharge end of the system

26.5 Inclusion of an exhaust duct system of noncombustible corrosion-resistant material as needed to meet the planned usage of the hood

27. Fire Safety Design

27.1 Ensure the distribution of fire extinguishers is specified by fire code. For example, a fire extinguisher must be within 30 feet of a flammable liquid storage area.

27.2 Architects and engineers should consult with Fire Safety personnel regarding questions on the placement of fire extinguishers in laboratories.

27.3 Fire extinguishers should be conspicuously located where they will be readily accessible in the event of fire. They should be located close to the exits from an area and along normal paths of travel.

27.4 Fire protection and fire detection equipment should not be obstructed.

28. Special Standards for Use with Strong Oxidants

28.1 Fume hoods, and their associated equipment in the air stream intended for use with perchloric acid and other strong oxidants, shall be constructed of stainless steel or other materials consistent with special exposures.

28.2 These hoods and equipment shall be provided with a water wash and drain system to permit periodic flushing of duct and hood.

28.3 Electrical equipment intended for installation within such ducts shall be designed and constructed to resist penetration by water. Lubricants and seals shall not contain organic materials.

28.4 When perchloric acid or other strong oxidants are only transferred from one container to another, standard laboratory fume hoods and the associated equipment may be used in lieu of stainless steel construction.

29. Virology Laboratories or Laboratories Dealing With Radioactive Materials

In new construction or major renovation work, each hood used to process infectious or radioactive materials shall meet the following requirements:

- 29.1 Each hood shall have a minimum face velocity of 90 to 110 feet per minute (0.45 to 0.56 meters per second) with suitable pressure-independent air-modulating devices and alarms to alert staff of fan shutdown or loss of airflow.
- 29.2 Each hood shall have filters with a 99.97 percent efficiency (based on the DOP test method) in the exhaust stream, and be designed and equipped to permit the safe removal, disposal, and replacement of contaminated filters. Filters shall be located within 10 feet (3.05 meters) of the hood to minimize duct contamination.
- 29.3 Fume hoods intended for use with radioactive isotopes shall be constructed of stainless steel or other material suitable for the particular exposure and shall comply with local and federal standards.
- 29.4 Radioactive isotopes used for injections, etc., without probability of airborne particulates or gases may be processed in a clean-workbench-type hood where acceptable to the Federal Authority for Nuclear Regulation (FANR).

30. Bio-safety in Microbiological and Biomedical Laboratories:

- 30.1 Four levels of Bio-Safety Laboratories (BSL) - 1, 2, 3 and 4, have been designed for handling bio-hazardous material. Usually higher level of bio-safety is required while carrying out procedures using higher risk group organisms.
 - 30.1.1 **Bio-safety Level 1 (BSL-1)** represents a basic level of containment that relies on standard microbiological practices with no special physical barriers.
 - 30.1.2 **Bio-safety Level 2 (BSL-2)** represents a level of containment established by practices, equipment, and facility construction that is acceptable for clinical, diagnostic, teaching, and other laboratories working with indigenous agents that cause moderately severe illness and are usually found in the community. Many of the blood-borne pathogens (e.g., Hepatitis B virus, HIV, salmonella) can be safely manipulated in BSL-2 facilities. Primary containment barriers, include:
 - 30.1.2.1 Biological safety cabinets, safety centrifuge cups, etc., (used to minimize aerosol or high splash potential).
 - 30.1.2.2 Hand washing sinks.
 - 30.1.2.3 Autoclaves or other waste decontamination equipment.
 - 30.1.3 BSL- 2 design requirements include:
 - 30.1.3.1 Doors for access control (lockable door if housing restricted agents)
 - 30.1.3.2 Hand washing sink;
 - 30.1.3.3 Bench tops impervious to water and resistant to moderate heat and organic solvents, acids, alkalis, and chemicals used for surface decontamination;
 - 30.1.3.4 Sturdy laboratory furniture;
 - 30.1.3.5 Screens on windows if they are operable
 - 30.1.3.6 Bio-safety cabinets located so that fluctuations in air supply and exhaust or the operations of equipment do not alter the performance standard of the cabinet;
 - 30.1.3.7 Eyewash station readily available;

- 30.1.3.8 Autoclave available in the facility;
- 30.1.3.9 No fabrics or carpeting; and new facilities with inward airflow (negative pressurization) without recirculation of air outside the laboratory (100% outside exhaust).
- 30.1.4 **Bio-safety Level 3 (BSL-3)** applies to a level of containment suitable for working with indigenous or exotic pathogens that have a potential for transmission by the aerosol route and that may cause serious and potentially lethal infections. More emphasis is placed on primary and secondary barriers that apply to BSL 2 in addition to the following:
 - 30.1.4.1 Physical separation from access corridors
 - 30.1.4.2 Self-closing, double door access
 - 30.1.4.3 Exhausted air not re-circulated
 - 30.1.4.4 Entry through air lock or anteroom
 - 30.1.4.5 Hand washing sink near the laboratory exit
- 30.1.5 **Bio-safety Level 4 (BSL-4)** laboratories are designed and operated to provide maximum containment and protection from exposure to lethal pathogens. The basic means for accomplishing this is to conduct work inside Class III biological safety cabinets (glove boxes) or to place the worker inside a full-bodied positive pressure air-supplied suit. Either will provide maximum protection from these agents that pose a high individual risk of life-threatening disease, which may be transmitted via the aerosol route and for which there is no available vaccine or therapy. More emphasis is placed on primary and secondary barriers that apply to BSL 3 in addition to the following:
 - 30.1.5.1 Separate building or isolated zone
 - 30.1.5.2 Dedicated supply and exhaust, vacuum, and decontamination systems

CHAPTER THREE: CLINICAL LABORATORY OPERATIONAL STANDARDS

CLUSTER ONE: SPECIMEN HANDLING AND REPORTING

31. Requisition Form (Manual or Electronic)

- 31.1 The requisition form should be completed by a DHA licensed physician/licensed health professional requesting the tests and sent along with the specimen/patient to the laboratory.
- 31.2 It should contain the patient's identity, age, location, date of specimen collection and the investigations requested. The referring doctor should be encouraged to mention the provisional or working diagnosis and relevant clinical and treatment history in the space provided.
- 31.3 Licensed clinical laboratories may accept walk-in patients subject to internal policies and procedures of the laboratory

32. Specimen Collection

Specimen collection is the first phase of interaction between the patient and the laboratory.

- 32.1 Specimen collection can be done at the patient's bedside or in the laboratory phlebotomy room/specimen collection facilities depending on the type of specimen required for the test.
- 32.2 Appropriate counseling should be done before specimen collection. Attention should be paid to patient's sensibilities during the entire process. Any error in specimen collection can lead to erroneous results.
- 32.3 Trained phlebotomist shall be employed by the clinical laboratory for specimen collection.
- 32.4 Specimen collection can be performed also by physicians, nurses or medical laboratory technologist who must be trained periodically to ensure their competency.
- 32.5 Skilled DHA licensed Cytopathologists may perform Fine Needle Aspirations (FNA) on palpable lumps-in their labs- that do not require ultrasound guidance. However, the cytopathologist must obtain a written permission from the DHA prior to offering this service.
- 32.6 Clinical Laboratory may have a "primary specimen collection manual", containing information on patient preparation before specimen collection (if any), and exact methodology of specimen collection, labeling, handling, transportation and storage of the specimens.
- 32.7 These manuals should be available for reference and should be used for training of staff engaged in specimen collection.
- 32.8 The laboratory should provide adequate and appropriate information/instructions to patients wherever necessary.
- 32.9 Specimens should be secured properly to prevent leakage, spillage or contamination. It must be transported in biohazard bags and sent to the laboratory along with the completed laboratory requisition form in the absence of electronic data transfer.
- 32.10 A Biohazard symbol should be used on the containers during transportation.

- 32.11 Appropriate specimen transportation kit (such as use of dry ice, ice packs, etc.) shall be used wherever required.
- 32.12 Clinical laboratories shall have clear criteria for rejection of samples such as hemolyzed or lipemic samples.

33. Accession List

- 33.1 Accession list is a record of all the specimens received by the laboratory for analysis and is prepared by the laboratory at the time of specimen receipt.
- 33.2 The accession list must record: the patient's identity including name, age, sex, location in the hospital/ medical facility, name of referring physician, investigations requested, date and time of receipt of specimen and condition of the specimen at receipt.
- 33.3 The laboratory assigns a unique laboratory number to register each specimen received, which can be used to trace the specimen in the laboratory. The test results and remarks if any are also entered in the accession list.
- 33.4 In laboratories handling a very large number of specimens, the accession list may be computer generated and the condition of specimen at receipt may not be recorded unless it has been rejected.
- 33.5 Records of specimens referred to other laboratories for testing must be kept at the laboratory.

34. Reporting Test Results

- 34.1 Test results approved and signed by the designated DHA licensed laboratory staff should be made available to authorized person(s).
- 34.2 Results should be reported clearly, without any errors, specifying measurement procedure where appropriate and units of measurement.

35. Ethical Considerations

Provision of precise and accurate laboratory results optimizes patient's medical management. Inappropriate test selection, unnecessary investigations and incorrect test results not only have serious health implications but are also a financial burden to the individual and community.

- 35.1 Referring physicians are strictly prohibited from taking any commission for referring patient to specific clinical laboratory service provider.
- 35.2 Personnel working in clinical laboratories should be aware of their ethical responsibilities and comply with the ethical code of conduct which are governed by the principle of Patient centeredness where the patient is the center of all activities that the laboratory performs therefore they should at all times:
- 35.2.1 Maintain patient's information confidentiality at all times.
- 35.2.2 The technologists and professionals working in the clinical laboratory are held accountable for using expired reagents/kits that are not properly validated when performing laboratory investigation on patients' samples with the same reagents. Evidence of documented validation must be readily available for any inspection.

36. Outsourcing Clinical Laboratory Services

- 36.1 If Clinical Laboratory services are outsourced to another Clinical Laboratory facility (Reference Laboratory), it shall meet the outsourcing requirements.
- 36.2 Outsourcing requirements shall include, but not limited to:
- 36.2.1 The Reference laboratory must be accredited by a recognized agency such as the College of American Pathologists (CAP), ISO-15189, Clinical Pathology Accreditation of United Kingdom (CPA-UK), Joint Commission International Agency (JCIA) or equivalent for the specific discipline.
- 36.2.2 Primary sample collection and handling manual of the Reference laboratory which may be electronic.
- 36.2.3 Reference laboratory must have good facilities for the sample transport from the laboratory and fast turn-around time for the test.
- 36.2.4 Reports shall be received in a timely way that supports the continuity of care.

CLUSTER TWO: SAFETY

37. General Safety Considerations

Personnel working in laboratories may be exposed to risks from various chemicals, infectious materials, fire hazard, gas leak etc. The environment is also at risk of being contaminated by hazardous materials used and wastes generated in the laboratory. Safety in laboratories therefore includes protection of both the staff and the environment from hazardous materials. General Safety Measures include:

- 37.1 Documentation of Laboratory Safety Policies and Procedures.
- 37.2 All laboratory personnel should be aware about the laboratory safety policies and procedures and follow these at all times.
- 37.3 Eye wash facility should be available as "stand-alone" facility or attached to sink or portable. Sealed single use solution bottles may also be used.
- 37.4 Laboratories should ensure proper preservation and security of specimens.
- 37.5 Laboratory personnel should be thoroughly trained in managing emergencies such as biohazard spillage/large chemical spillage, gas leakage etc as applicable to the facility.
- 37.6 Periodic checking of all safety equipment and accessories should be ensured.
- 37.7 Laboratory personnel should follow safe hygienic practices which include hand washing, wearing protective clothing, gloves, eye protection etc.
- 37.8 Mouth pipetting is strictly prohibited. A rubber bulb, automatic pipette or, or other safety device must be used for all pipetting.
- 37.9 For reasons of both safety and security, personal belongings (coats, bags, pocketbooks, etc.) must not be kept in the work areas of the laboratories. Personal belongings must be secured in employees' lockers or staff designated areas.

38. Biohazard Materials

- 38.1 List of hazardous materials used in the laboratory should be prepared. All hazardous materials should be accounted for on a continuous basis.
- 38.2 Biohazard symbol should be used on all containers containing biohazard materials while being transported to the laboratory or disposed of.
- 38.3 Destruction/disposal of hazardous material should be authorized, supervised and handled according to standard procedures.
- 38.4 Solid biohazard waste disposal must be done through contracted DM approved companies.
- 38.5 Liquid Biohazard waste must be pre-treated and decontaminated using appropriate disinfectants prior to disposal.
- 38.6 All anatomic pathology wastes are placed in a biohazard waste container for incineration.
- 38.7 Biohazard spill kits and chemical spill kits must be available in the laboratory.

- 38.8 Accident/incident/injuries record of laboratory personnel should be maintained and reported to the designated authority. The report should include description of the event, factors contributing to the event and information on first aid or other health care provided. This information can be analyzed periodically towards effectively controlling and preventing future events. The records should be checked periodically by the laboratory safety officer even in the absence of fresh entries.

39. Handling Sharps

- 39.1 Two-handed recapping of needles is strictly prohibited. Contaminated needles or other sharps must not be sheared, bent, recapped, or removed from syringes or other devices unless it can be accomplished using a mechanical device (such as a hemostat) or by a one-handed technique
- 39.2 Sharps (i.e., needles, syringes with attached needles, scalpel blades) must be placed in a stable, rigid, puncture-resistant "sharps" container labeled with a biohazard warning label. Slides, coverslips, and capillary tubes may be placed in a rigid, puncture-resistant container or red-bagged biohazard waste container.
- 39.3 Sharps containers must not be overfilled. When a sharps container becomes two-thirds full, seal and discard it into a red-bagged biohazard waste container or into a red bag for incineration.

40. Fire Safety

Fire is a potential risk for all healthcare organizations, and is very critical where immobile patients are in locations that are difficult to evacuate. To respond to fire risk the clinical laboratory should:

- 40.1 Establish a fire safety plan for early detection, confining, extinguishment, rescue and alerting the Dubai Civil Defense
- 40.2 Assess the fire risks to the facility
- 40.3 Establish a No Smoking policy
- 40.4 Understand and manage risks associated with the facility's location and physical structures
- 40.5 Maintain and test fire protection and emergency communication systems
- 40.6 Train staff to respond to fire events on the premises
- 40.7 Monitor whether adequate numbers of suitably trained staff are distributed across all shifts to respond appropriately to a fire event

CLUSTER THREE: HEALTH INFORMATION MANAGEMENT

41. Laboratory Reports and Data Management

- 41.1 Laboratory data management includes recording details of the patient, findings of analysis, reporting of results and archiving the data for future reference.
- 41.2 The format of recording and reporting results should be described in the Standard Operating Procedures (SOPs).
- 41.3 Laboratories sending reports electronically should include electronic signature of the authorized signatory. Laboratories should be able to provide critical information required by a physician on telephone.
- 41.4 Provisions shall be made for securing Electronic laboratory reports.
- 41.5 Equipment maintenance reports must be kept for future reference.

42. Retention of Patient Result Records and Materials

- 42.1 Each clinical laboratory must maintain patient's result records in a manner that ensures accuracy, confidentiality and easy retrieval
- 42.2 An internal policy must be available concerning the time keeping of the patient laboratory reports either as hard copy or soft copy according to the clinical laboratory's internal policies. For further information regarding retention of patient result records and materials see *appendix 1*

CLUSTER FOUR: HUMAN RESOURCES AND MANAGEMENT

43. Medical Director

- 43.1 The Medical director in an independent Clinical Laboratory or laboratory in hospital setup shall be a full time DHA licensed pathologist (clinical pathologist or Histopathologist).
- 43.2 In case of a specialized laboratory a Clinical Laboratory Scientist (CLS) with Doctoral degree (in the specialized field) and appropriate training and experience may serve as the Laboratory Director for e.g. a genetics laboratory may be run by a CLS with Doctoral degree in genetics.
- 43.3 Medical director of a general clinical laboratory (not in hospital setting and without histopathology /cytopathology services) may be a full time Clinical Laboratory Scientist (general) holding Doctoral degree with appropriate training and experience.
- 43.4 In an Outpatient Care Facility the clinical laboratory may be run by a full time/part time pathologist.

For qualifications, training and experience requirements refer to the DHA Clinical Laboratory Professionals licensing requirements document under Health Regulation on www.dha.gov.ae.

44. Management Responsibilities

- 44.1 The clinical laboratory management shall decide on a **functional program** that defines vision, mission and service scope of the facility
- 44.2 The Clinical Laboratory management shall be responsible for directing the operation of the laboratory in accordance with the facility mission.
- 44.3 The clinical laboratory director shall be responsible for the quality of laboratory services and safe practice provision this include but not limited to the following:
 - 44.3.1 Developing clear strategic planning which include written values, vision and mission in a well articulated plan at the operational level to assist all staff in the organization to work towards achieving common goals.
 - 44.3.2 Developing organizational governance through devising a formal structure within the organization and make it known to all staff.
 - 44.3.3 Ensuring that all healthcare professionals working in the laboratory hold active and appropriate licensure by DHA and have necessary training and skills to deliver the services provided.
 - 44.3.4 Identifying which staff members may issue laboratory reports, those who are approved to perform tests, those who are qualified to interpret the results or to verify and report results, and those who direct or supervise the processes.
 - 44.3.5 Ensuring that the laboratory staff members shall have access to all regulations and clinical policies related to health services
 - 44.3.6 To take all appropriate and necessary actions to monitor and restore all local and federal regulatory requirements when compliance deficiencies are identified.
 - 44.3.7 Support Continuous Professional Development (CPD) of the staff members by allocation of time for these activities.

- 44.3.8 Support the development of policies and procedures to assist the laboratory to provide safe and quality care and appoint responsible staff for developing and reviewing the organization documents.
- 44.4 The laboratory director is responsible for assuring the consistent performance of contract and reference laboratory services.
- 44.5 The laboratory's director identifies key measures (indicators) to measure clinical and managerial structures, processes, and outcomes and quality improvement programs.
- 44.6 Maintain the recommended immunizations for health professionals working at the clinical laboratory. For further information refer to *Appendix 4*.
- 44.7 The management shall designate a qualified person(s) or a team to conduct:
- 44.7.1 Quality control.
- 44.7.2 Fire and safety review.
- 44.8 Documentation of ongoing assessment activities including corrective action effectiveness reviews, policy and procedure revisions made to prevent recurrence of a problem, discussion of assessment reviews with staff.

45. Healthcare Professionals Minimum Requirements

The management shall maintain accurate and complete personnel records for all staff, including personnel qualifications, training, experience, competency assessment, responsibilities and authority.

- 45.1 All healthcare professionals in the facility must hold an active DHA professional license and work within their scope of practice.
- 45.2 Appropriate and sufficient number of healthcare professionals are required to be on duty at all times.
- 45.3 The number of DHA licensed healthcare professionals assigned to each health service shall be determined by facility management and be consistent with type of services provided.
- 45.4 All healthcare professionals at a minimum **should** maintain valid training/certification in basic Cardiopulmonary Resuscitation (**CPR**) or Basic Life Support (**BLS**) or Advanced Cardiac Life Support (**ACLS**).

CLUSTER FIVE: FACILITY MANAGEMENT

46. Laboratory Equipment

- 46.1 Each laboratory should prepare an exhaustive list of equipment and consumables required of adequate capacity to meet work load requirement
- 46.2 All equipment should be in good working condition at all times. Periodic inspection, cleaning, maintenance of equipment should be done. An equipment log book should be maintained for all major equipment.
- 46.3 Laboratories should maintain necessary instructions for operation and maintenance of equipment in the form of Standard Operating Procedures (SOPs). A copy of SOP should be readily available to the clinical laboratory staff and to DHA inspectors if requested. User manual should be available readily for reference.

47. Standard Operating Procedures (SOPs)

- 47.1 Clinical Laboratories must develop detailed SOPs that cover both analytical and operational procedures according to the scope of services provided by the facility.
- 47.2 SOP should be simple and written in an easy language to understand.
- 47.3 The procedure described in the SOP must be followed exactly by all staff members to ensure high quality results
- 47.4 It is important for Analytical SOP documents to be readily available in the working area and may be referred to as laboratory work bench manual.
- 47.5 SOPs are controlled documents and can be changed only with approval of the laboratory quality manager and/or Medical Director of the laboratory.

For further information please refer to the *Appendix 2: Guidelines on Standard Operating Procedures*.

48. Quality Assurance:

- 48.1 Quality Assurance (QA) is the total process whereby the quality of laboratory reports can be guaranteed (*For further details on QA please refer to the Guidelines on Quality Assurance in Appendix 3*)
- 48.2 Quality Manager or designee or competent authorized person should review the quality control data and maintain record of evaluation.

49. Blood Bank

- 49.1 Blood bank as a part of the main laboratory is a section where approved blood or its components is typed, cross matched, and stored for future transfusion. This is the only scope allowed in a private hospital laboratory since no blood donation is permitted. The primary aim of the Blood Bank is to provide quality care to patients by dispensing safe and good quality blood and its components for transfusions. For further information please [click here](#) or visit www.dha.gov.ae.

Appendix 1: Retention of Patient Result Records and Materials

Material/Record	Period of Retention
General Laboratory	
Accession log	2 years
Maintenance/instrument maintenance records	2 years
Quality control records	2 years
Surgical Pathology (including bone marrows)	
Wet tissue	2 weeks after final report
Paraffin blocks	10 years
Slides	10 years
Reports	10 years
Cytology	
Slides (negative-unsatisfactory)	5 years
Slides (suspicious-positive)	5 years
Fine needle aspiration slides	10 years
Reports	10 years
Non-Forensic Autopsy	
Wet tissue	3 months after final
Paraffin blocks	10 years
Slides	10 years
Reports	10 years
Forensic Autopsy	
Wet stock tissue	1 year
Paraffin blocks	Indefinitely
Reports	Indefinitely
Slides	Indefinitely
Gross photographs/negatives	Indefinitely
Accession log	Indefinitely
Body fluids and tissues for toxicology	1 year
Representative tissue suitable for DNA Analysis	Indefinitely
Clinical Pathology	
Patient test records	2 years
Serum/heparinized or EDTA plasma/CSF/Body fluids (except urine)	48 hours
Urine ²	24 hours*
Peripheral blood smears/body fluid smears	7 days
Permanently stained slides – microbiology (gram, trichrome, etc)	7 days
Cytogenetics	
Permanently stained slides	3 years
Fluorochrome stained slides	At the discretion of the laboratory director

² Exceptions may be made at the discretion of the laboratory director

Material/Record	Period of Retention
Wet specimen/tissue	Until adequate metaphase cells are obtained
Fixed cell pellet	2 weeks after final report
Final reports	20 years
Diagnostic images (digitized, prints or negatives)	20 years
Flow Cytometry	
Gated dot plots and histograms	10 years
Blood Bank	
Donor and recipient records	10 years
Patient records	10 years
Records of employee signatures, initials, and identification codes	10 years
Quality control records	5 years
Specimens from blood donors units and recipients	7 days post-transfusion

Appendix 2: Guidelines on Standard Operating Procedures (SOPs)

1. Clinical Laboratories must develop detailed SOPs that cover both analytical and operational procedures according to the scope of services described in their functional program and provided by the facility.
2. SOP is a document, which contains detailed, written instructions for both operational and analytical procedures. It describes the stepwise process and technique of performing a test or procedure in the laboratory.
3. SOPs should be simple and written in an easy language to understand.
4. SOPs may contain information on who can perform the test, how to carry out the test including pre-analytical, analytical and post-analytical stages of test/procedure, laboratory conditions required for the test/ procedure, routine care and maintenance of equipment, precautions and safety instructions, trouble shooting measures, waste disposal and linkage with reference laboratories.
5. The procedure described in the SOPs must be followed exactly by all staff members to ensure high quality results
6. Types of SOPs include:
 - 6.1 Staff appointment, training, evaluation
 - 6.2 Maintenance of laboratory conditions including work space, lighting, ventilation, temperature regulation, noise control, designated eating and smoking area
 - 6.3 Cleaning, sterilization and disinfecting procedures
 - 6.4 Equipment care, operation, calibration, validation and maintenance of equipment
 - 6.5 Data Management
 - 6.6 Precautions & Safety measures including treatment if required and appropriate vaccination of staff
 - 6.7 Handling and disposal of waste including bio-wastes
 - 6.8 Documentation of laboratory's reference ranges (In the absence of laboratory's own reference ranges, data generated officially or the reference range on the manufacturer's guidelines contained in the kit brochure may be used).
 - 6.9 Internal quality control procedures including procedure for reporting abnormal test results and corrective action procedure for quality control outliers
 - 6.10 Internal audit procedures
 - 6.11 Participation in external quality assessment programs.
7. It is important for Analytical SOP documents to be readily available in the working area and to be referred to as laboratory bench work manual.
8. SOPs are controlled documents and can be changed only with approval of the clinical laboratory quality manager and/or Director of the laboratory.
9. SOP helps to ensure uniformity, consistency and control over the processes carried out. It ensures that the procedures are done in exactly the same way each time irrespective of the operator.

10. It should be titled along with version number, dated and signed by an authorized person and updated regularly.
11. The header of SOP may display the following information on all pages:
 - 11.1 Title of SOP and Document number
 - 11.2 Version number with dates of revision
 - 11.3 Issue number and date of issue of the document
 - 11.4 Page number/Number of pages
12. The text of Analytic SOP may contain information on:
 - 12.1 Name of test
 - 12.2 Scope of test
 - 12.3 Principle of the test
 - 12.4 Equipment and materials required
 - 12.5 Detailed test procedure including type, quantity and condition of specimen required, sample processing and preparation. Alternative procedure for test in case of breakdown of equipment should also be stated.
 - 12.6 Documentation of results including calculations
 - 12.7 Limit of detection (Analytical sensitivity)
 - 12.8 Analytical Measurement Range (AMR)
 - 12.9 Reference range
 - 12.10 Clinical significance, Inference and limitation of the test
 - 12.11 Critical alert values (shall be reported immediately to the referring physician)
 - 12.12 References of test procedure
 - 12.13 Precautions & Safety
 - 12.14 Quality Control procedures
 - 12.15 Specimen preservation and storage before analysis and after analysis
 - 12.16 Data management.

Appendix 3: Guidelines on Quality Assurance:

1. All laboratories must have a Quality Assurance Program (QAP) in place to provide quality assurance (QA), and to improve their standards when necessary to ensure continuous quality improvement.
2. Quality Assurance (QA) is the total process whereby the quality of laboratory reports can be guaranteed. Incorrect Laboratory results may be due to :
 - 1.1 Pre-analytical stage: errors occurring during specimen collection
 - 1.2 Analytical stage: errors occurring during testing and/or while reporting
 - 1.3 Post-analytical stage: errors occurring during interpreting test results.
3. Quality Manager or designee or competent authorized person should review the quality control data and maintain record of evaluation. The two important tools toward maintaining laboratory quality are:
 - 3.1 Internal Quality Control (IQC) - for detection and minimization of immediate errors
 - 3.2 External Quality Assessment (EQA) - for monitoring long term precision and accuracy of results.
 - 3.3 The laboratory should treat IQC/EQA samples and patients' specimens alike and use same procedures for analysis
4. Practice of IQC includes the following:
 - 4.1 Recognition of errors which arise within the laboratory during analytical stage (testing).
 - 4.2 Taking steps to minimize errors.
 - 4.3 Equipment & method calibration, method validation.
 - 4.4 For quantitative tests, laboratories should perform IQC every day on tests run daily or every time the tests are run in case of infrequently run tests.
 - 4.5 IQC checks should be employed for qualitative tests wherever applicable.
 - 4.6 IQC for Quantitative Tests: using Levy Jennings's (LJ) chart or any similar chart may be used to plot daily QC values and Westgard rules or any similar may be used to interpret daily QC values.
5. The level of QC per day FOR **Quantitative Tests**:
 - 5.1 The following protocol may be adopted by the laboratories according to the total number of specimens analyzed per analyte:
 - 5.4.1 Less than 40 per day : apply at least one level QC once a day.
 - 5.4.1 Between 40-80 per day : apply two level QC at least once a day.
 - 5.4.1 More than 80 per day : apply two level QC at least twice a day for such analytes.
 - 5.2 For **hematology**: 2 level QC (using normal & high **OR** normal & low controls) should be analyzed at least once a day although it is preferable to run 3 level QC (using normal, high & low controls) once a day. In high volume testing laboratories at least 2 level QC per 8 hour maybe analyzed.

- 5.3 The following guidelines will be useful to the laboratories in the practice of IQC using either one level or two level QC materials:
- 5.2.1 When **one level QC is used**: Reject test run if following errors occur:
- 5.2.1.1 Value is outside 3 SD (13s)
 - 5.2.1.2 2 consecutive values are outside 2 SD on the same side, but within 3 SD (2_{2s})
 - 5.2.1.3 4 consecutive value are outside 1SD on the same side, but within 2SD (41s)
 - 5.2.1.4 10 consecutive values are above or below the mean, but within 2 SD (10x)
- 5.2.2 When **two level QC are used** : Reject test run if following errors occur:
- 5.2.2.1 Either QC value is outside 3 SD (13s)
 - 5.2.2.2 Both QC values are outside 2 SD on the same side, but within 3SD (2_{2s})
 - 5.2.2.3 Difference between the two level QC values is >4 SD i.e. one level QC is >2 SD and other level QC is < 2 SD (R4s)
 - 5.2.2.4 10 consecutive values of the same level QC are above or below the mean, but within 2 SD (10x)
 - 5.2.2.5 5 consecutive values of one level QC and 5 consecutive values of the other level QC are above or below the mean, but within 2 SD (10x)
- 5.4 Laboratories need to establish guidelines for responding to out-of control situations Tests.
- 5.5 Tests for which control material is not available or when running of control is not viable due to low volume of tests, the laboratory should apply alternate quality control techniques such as :
- 5.4.1 Retesting of any randomly chosen specimen/s
 - 5.4.2 Replicate test of specimen by different method, different machine and different person, wherever applicable
 - 5.4.3 Correlation of test results with other parameters
- 5.6 **IQC for Qualitative Tests**
- 5.5.1 Wherever applicable, appropriate controls should be used when a new kit/lot number is used. Built-in test controls should be monitored as well.
 - 5.5.2 For staining procedures, gram stains require both Gram positive and Gram negative control organisms to be used once per week.
 - 5.5.3 IQC should also be run whenever a new lot of the stain procedure kit is used and/or any of the four components of the stain procedure kit is replaced with a new lot.

Appendix 4: Health Care Workers Recommended Immunization

Vaccine	Recommendations in brief
Hepatitis B	Give 3-dose series (dose #1 now, #2 in 1 month, #3 approximately 5 months after #2). Give intramuscularly. Obtain anti-HBs serologic testing 1–2 months after dose #3.

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