UNITED ARAB EMIRATES
MINISTRY OF HEALTH & PREVENTION

الإمارات العربية المتحدة
وزارة الصحة و وقاية المجتمع

Clinical Laboratory Regulations

Empowerment And Health Compliance Department

Ministry Of Health And Prevention

(2018)

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Acknowledgment

Ministry of Health & Prevention (MOHAP) is pleased to present the MOHAP Clinical Laboratory Regulation which represents a milestone towards fulfilling the MOHAP strategic objective in providing "A world class integrated health system that ensures excellence in health and healthcare for the United Arab Emirates.

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 ministry of health and prevention (MOHAP) to assess the Clinical Laboratories performance in the United Arab Emirates 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 MOHAP regulatory requirements and the United Arab Emirates (UAE) federal laws.

I. Scope

This regulation specifies requirements for licensure, competence and safety particular to clinical laboratories subject to licensure under the ministry of health and prevention (MOHAP) establishment law, including semi-governmental, private clinical laboratories.

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

II. Purpose

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

CHAPTER ONE:

CLINICAL LABORATORY DESIGN

REQUIREMENTS

1. 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:

1.1 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

2.1 Signage shall be provided to direct people unfamiliar with the Clinical Laboratory to the entrances and other areas in the laboratory.

3.1 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.

4.1 Special consideration should be given to the choice of fireproof construction for the buildings according to the building and design codes of emirates Municipalities and Civil Defense Department requirements.

5.1 Public corridors shall have a minimum width of 1.5 meters.

6.1 The minimum door opening width for patient use shall be 0.86 meters (2 feet 9.97 inches). If the facility serves patients confined to wheelchairs, the minimum width of the door shall be 1.1 meters.

7.1 The minimum ceiling height shall be 2.4 meters (7 feet 10 inches)

8.1 Color contrast between walls, floors and doors shall be considered as it may reduce falling risk of blurred vision patients.

2.0 Reception and Waiting Area

2.1 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.

2.2 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.

2.3 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.

2.4 Access to laboratory areas should be strictly limited to laboratory personnel, so the general public should get no further than the reception areas or waiting rooms.

3.0 Phlebotomy room/Specimen Collection Area:

3.1 Phlebotomy room shall have minimum space of 6.0 square meters, a seating space, and a hand-washing station shall be in the room.

3.2 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.

3.3 Room shall be furnished with reclining chair or gurney for patients who become unsteady.

4.0 Laboratory Furniture Design and Exit Paths

4.1 Work benches shall be 0.75m wide.

4.2 Aisle clearance between benches shall have a minimum of 0.6 meters.

4.3 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 0.9 meter must be maintained at the face of the access/ exit door.

4.4 The space between adjacent workstations and laboratory benches should be 1.52 meter or greater to provide ease of access.

4.5 All furniture in the clinical laboratory must be strong and cleanable.

5.0 Laboratory Work/Testing area

5.1 Laboratory working area for basic clinical pathology tests shall have a minimum clear floor area of 15 square meters (161.4 square feet).

5.2 Laboratory work area shall have appropriate facilities for storage and refrigeration of blood, urine, and other specimens.

5.3 Work counters and equipment space shall be provided to accommodate all on-site tests identified in the functional program of the facility.

5.4 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.

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5.6 Food items or cosmetics must not be stored in testing areas.

5.7 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.

5.8 Each laboratory must contain a sink for hand washing. Taps for hand washing should be elbow operated/foot operated/sensor operated.

5.9 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.

6.0 Staff room

6.1 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.

6.2 Laboratory professionals must have access to the following:

6.2.1 Hand-washing stations and counter sink(s).

6.2.2 Communication service such as telephone

6.2.3 Electrical service

6.2.4 Eye washing station shall be accessible from the work area.

6.2.5 Laboratory work area shall have appropriate facilities for storage and refrigeration of blood, urine, and other specimens.

7.0 Chemical/Waste Storage

7.1 Sufficient space or facilities (e.g., storage cabinets with partitions) shall be provided so that chemicals and reagents can be physically separated and stored.

7.2 Chemical storage shelves shall not be placed above laboratory sinks.

8.0 Flooring

8.1 Selected flooring surfaces shall be easy to maintain, readily cleanable, and appropriately wear-resistant.

8.2 The floor shall be non-pervious and with covings to the walls and cabinets to ensure that spills cannot penetrate underneath.

8.3 Tiles and wooden planks are not appropriate.

8.4 Joints for floor openings for pipes and ducts shall be tightly closed.

8.5 Highly polished flooring, walling or finishes that create glare shall be avoided.

8.6 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.

8.7 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.

9.0 Walls

9.1 Wall finishes shall be washable, moisture-resistant and smooth.

9.2 Wall finish treatments shall not create ledges or crevices that can collect dust and dirt.

9.3 Color contrast between walls, floors and doors shall be considered as it may reduce falling risk of blurred vision patients.

9.4 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

10.0 Lighting

10.1 Laboratory areas shall be provided adequate natural or artificial illumination to ensure sufficient visibility for operational safety.

10.2 Windows must be well sealed and provided with blinds.

11.0 Clean ability

11.1 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.

11.2 If the bench abuts a wall, it must be coved or have a backsplash against the wall. Walls should be painted with washable, anti-bacterial and anti-fungal paints.

11.3 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.

11.4 Spaces between benches, cabinets, and equipment must be accessible for cleaning and allow for servicing of equipment.

11.5 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.

12. 0 Autoclave and Sterilization Area

12.1 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.

12.2 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.

13.0 Filing Cabinets and Storage

13.1 Filing cabinets and storage shall be provided for the safe and secure storage of patient's laboratory profiles with provisions for easy retrieval.

13.2 Filing cabinets and storage must be in safe and restricted location.

14. 0 Administrative Activities

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.

15.0 Equipment and Supply Storage

15.1 Dedicated waste collection and storage area

15.2 General storage facilities for supplies and equipment shall be provided based on the functional program facility.

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

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

16.0 Fume hoods

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:

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

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

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

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

17.0 Fire Safety Design

17.1 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.

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

17.3 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.

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

18.0 Special Standards for Use with Strong Oxidants

18.1 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.

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

18.3 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.

18.4 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.

19.0 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:

19.1 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.

19.2 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.

19.3 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.

19.4 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).

20.0 Bio-safety in Microbiological and Biomedical Laboratories:

20.1 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.

20.1.1 **Bio-safety Level 1 (BSL-1)** represents a basic level of containment that relies on standard microbiological practices with no special physical barriers.

20.1.2 **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:

20.2.1.1 Biological safety cabinets, safety centrifuge cups, etc., (used to minimize aerosol or high splash potential).

20.2.1.2 Hand washing sinks.

20.2.1.3 Autoclaves or other waste decontamination equipment.

20.1.3 BSL- 2 design requirements include:

20.1.3.1 Doors for access control (lockable door if housing restricted agents)

20.1.3.2 Hand washing sink

20.1.3.3 Bench tops impervious to water and resistant to moderate heat and organic solvents, acids, alkalis, and chemicals used for surface decontamination

20.1.3.4 Sturdy laboratory furniture

20.1.3.5 Screens on windows if they are operable

20.1.3.6 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

20.1.3.7 Eyewash station readily available

20.1.3.8 Autoclave available in the facility

20.1.3.9 No fabrics or carpeting; and new facilities with inward airflow (negative pressurization) without recirculation of air outside the laboratory (100% outside exhaust).

20.1.4 **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:

20.1.4.1 Physical separation from access corridors

20.1.4.2 Self-closing, double door access

20.1.4.3 Exhausted air not re-circulated

20.1.4.4 Entry through air lock or anteroom

20.1.4.5 Hand washing sink near the laboratory exit

20.1.5 **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:

20.1.5.1 Separate building or isolated zone

20.1.5.2 Dedicated supply and exhaust, vacuum, and decontamination systems.