ALMUSTAQBAL UNIVERSITY

College of Health and Medical Techniques Medical Laboratories Techniques Department

Stage: Fourth year students

Subject: Laboratory Managment - Lecture 1

Lecturers:

Professor Dr Mahdi A. Abed

Assistant professor Dr. SADIQ . J. BAQIR



Laboratory premises

Laboratory General design objectives

- 1. The primary goal in laboratory design is to provide a safe and accessible environment for laboratory personnel to do their work.
- 2. The secondary goal is to allow for maximum flexibility for safe research and teaching use.

Therefore, health and safety risks must be anticipated and assessed carefully so that protection measures can be taken and incorporated into the design wherever possible.

Laboratory is a place specially prepared for studies and experiments (for all scientific branches) To perform research, scientific preparations, discoveries, analyzes, or all activities.

Laboratories are usually located in scientific facilities such as schools, institutes, colleges and universities, as well as in hospitals, health centers, research centers, and research institutions in addition to government agencies that are concerned with monitoring and investigation procedures and providing recommendations such as police stations(forensic affairs), quality control, food control and customs ports.

Laboratory types and classification

Types of laboratories

Laboratories require a deep understanding of the specific needs, purposes and risks associated with each of them. Some of these requirements are specific to an industry (e.g. pharmaceutical, chemical), or to an activity (e.g. small volume manufacture of high potent products, work with biological agents).

1. Analytical and Quality control Laboratories

In analytical and quality control laboratories the products and materials are tested against conformity to certain specifications and the absence of impurities. These laboratories form an essential component within the production and the supply chain.



2. Biosafety Laboratories

The purpose of biosafety laboratories and suites is the containment of potentially harmful biological agents. The containment is achieved through a thoughtful combination of methods, facilities and equipment. The levels of containment go from BSL1 to the highest level of BSL4.

3. Cleanrooms

In cleanrooms, the number of dust particles permitted per air volume defines the clean room's classification. All aspects of the people and materials flow, the mechanical systems and the room finishes are to be consistent with each other. The design and engineering need to follow certain standards like "ISO 14644-1" – "FED STD 209E" – "BS 5295" or "GMP EU" classification.



4. Clinical and Medical Laboratories

These laboratories are equipped for diagnostic tests on tissue, blood and other patient samples. They can be subdivided into various processes such as pathology, serology, histology, virology, bacteriology and molecular biology with PCR technologies.

5. Incubator Laboratories

Laboratories conducting microbiological, and cell or tissue culture work require incubators to protect these cultures from the environment. Parameters such as temperature, humidity, and O₂ and CO₂ levels need to be controlled.



6. Production Laboratories

Pilot production or small volume laboratories as a scale-up between R&D and commercial production, or for the production for clinical trials, form a category on their own. Such laboratories can be found in the pharmaceutical, biotech, and the science and technology sectors. Quite often special attention needs to be given towards containment and air quality.

7. Research & Development (R&D) Laboratories

This category covers a broad spectrum of laboratories with various risk qualifications and containment requirements such as: Bio Safety Laboratories, laboratories with radio-active risks etc. Also, specialized laboratories for life sciences research are part of this category.

Biosafety levels

Biosafety levels (BSLs) are a combination of technical and activity laboratory machinery, safety equipment, and laboratory equipment suitable for conducting experiments (classification is based on hazards and possibilities arising from handling dangerous substances and infectious pathogens.

How Are Biosafety Levels Defined?

The <u>biosafety levels</u> indicate what specific controls a laboratory must have in place for the containment of microbes and biological agents. Each biosafety level — BSL-1 through BSL- 4 is defined based on the following:

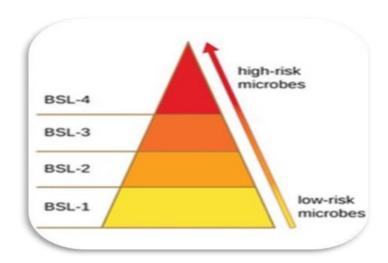
- Risks related to containment
- Severity of infection
- Transmissibility
- Nature of the work conducted within the lab
- Origin of the microbe
- Agent in question
- Route of exposure

Biosafety levels dictate the types of work practices allowed to take place in a lab setting; they also heavily influence the overall design of a facility and the type of specialized safety equipment in it.

1. Safety Level I (BSL1)

The lowest of the four biosafety levels, biosafety level 1 (BSL-1) applies to laboratory settings when dealing with non-pathogenic agents of healthy individuals, which represent the lowest risks to laboratory personnel and the environment, such as isolating and diagnosing microorganisms that do not cause any disease to humans or are of low risk and cause environmental damage only (E. coli).

- 2. Safety Level II (BSL2) is designed to deal with microbial pathogens of medium risk to humans and the environment, as it includes dealing with bacterial and viral agents that cause mild or moderate diseases to humans or pathogens that are not transmitted through inhalation or contact with them such as hepatitis A and B.
- 3. Safety Level III (BSL3) This level is usually intended for medical applications such as laboratory diagnosis and scientific research, or to work with agents that may be dangerous or fatal, that is, cause harmful diseases to humans after inhaling them, such as *Mycobacterium tuberculosis*, *Leishmania donovani and yellow fever virus*. This type of laboratory needs people with experience and culture in dealing with deadly pathogens, where the work is under the supervision of specialized researchers, and the work area here is called the **warm zone**.
- 4. Safety Level IV (BSL4) is working at this level with microorganisms that cause serious or fatal diseases that are transmitted through breathing or obstruction, and that cannot be treated or vaccinated against, such as the Ebola virus.



Conditions and specifications of laboratories:

- 1. The quality of the laboratory and the tests must be determined, and the work area must be wide.
- **2.** The air-conditioner must be designed to permanently pass air from outside the laboratory into it.
- 3. Laboratory rooms must be equipped with fans to draw air with special filters.

- **4.** A special room must be provided for sterilizers to sterilize farms, blood samples and biological wastes.
- **5.** A private pharmacy must be provided in the laboratory for the purpose of first aid and laundries.
- 6. A non-combustible construction is preferred