



LABORATORY DEPARTMENT

GDIPC

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Element : D-4

- **Sub- Element (12)**
- **Activities for auditing:**
 - ✓ **(D)** documentation
 - ✓ **(SI)** staff interview
 - ✓ **(O)** observation
- **Score (0-1-2-NA)**

Sub- Element (D-4.1)

There is a written policy and procedures for IC in the laboratory. (D)

Review the policy, which should be:

- 1) **Comprehensive**: it covers all aspects of infection control in the laboratory, including (but not limited to):
 - Laboratory biosafety
 - Laboratory aerosol generating procedures / Biological Safety Cabinets (BSC) & other containment devices
 - Infection control practices: Hand hygiene / PPE / Transporting and handling of biohazardous materials / Infectious waste management (especially high-risk laboratory waste as cultures plates) / Environmental cleaning & disinfection / Dealing with different types of spills ...etc.
 - Reporting, follow up and management of occupational exposures: sharp injuries, blood or body fluid exposures and chemical exposures
 - Biosafety in mycobacteriology laboratory that manipulates suspected or confirmed cultures of *Mycobacterium tuberculosis* (if applicable)

Sub- Element (D-4.2)

Access is restricted with a sign incorporating the universal biohazard symbol posted at the entrance. (0)

- Laboratories are special unique work environments that present identifiable infectious disease threats to the laboratory personnel working in it.
- The Laboratories deal with infectious materials like clinical samples, bacteria, viruses, and fungi so lab personnel must follow specific Infection Control Guidelines to reduce the risk of transmission during manipulation of patient specimens, cultures, contaminated sharps, and diagnostic equipment.
- Laboratory personnel are also at risk of exposure to blood-borne pathogens related to injuries from contaminated sharps, splashes to the eyes or mouth, and unprotected exposure of blood/body fluids onto non-intact skin.
- Therefore, access inside the laboratory must be restricted & controlled in order to prevent risk of accidental exposures and to ensure safety.

Observe the laboratory entrance:

- There is a sign that indicates “restricted area – for authorized personnel only”.
- There is a universal bio-hazard sign posted at the entrance.

Sub- Element (D-4.3)

Eating, drinking, handling contact lenses, and storing food are not permitted. (O, SI)

Observe different laboratory area(s) and supplies' refrigerator(s):

- To exclude the presence of any foods or drinks.
- Open the different refrigerators at random and assess if any eatables or drinks are stocked.
- Observe if there is any area / pantry inside the laboratory working area which is used for eating & drinking etc. (If yes it means all such leisure activities are done inside the lab. This is strictly prohibited)

Ask the laboratory staff:

- Where they are spending their break time & where they are keeping their food items and personal belongings,
- Ask about the health risks associated with eating, drinking, storage of food & use of contact lenses is done inside the lab.
- No food or drinks are allowed in the clinical laboratory.
- No food or drink will be stored in refrigerators in the laboratory work area.
- Smoking is not allowed in laboratory buildings.
- Application of cosmetics and contact lenses is prohibited in the laboratory working area
- Hair should be worn or secured so that it cannot become either a safety hazard or a source of contamination.

Sub- Element (D-4.4)

All manipulations of infectious materials that may generate aerosols are properly contained or conducted in a biological safety cabinet (BSC - class II-B). (O,SI)

Observe the laboratory area(s):

- If biological safety cabinet (BSC) is available, determine its class: it should be class II-B (i.e: exhaust air from BSC discharged to outside through HEPA filters)
- If biological safety cabinet (BSC) is not available or not used, aerosol generating procedures are properly contained.

Ask the laboratory staff:

- What are the aerosol generating procedures inside the laboratory?
- How can they handle aerosol generating procedures in presence or absence of biological safety cabinet (BSC) (proper containment)
- What are the safety measures that are required during operation of biological safety cabinet (BSC)?

Aerosol generating procedures include blowing out pipettes, shaking or overtaxing tubes, stirring, opening snap top tubes, breakage of culture containers, flaming loops or slides, pulling needles out of septa, filling a syringe, pouring liquids, centrifugation steps such as filling centrifuge tubes, removing plugs or caps from tubes after centrifugation, removing supernatant, breakage of tubes during centrifugation, and centrifugation itself

Biosafety Cabinet:

Biosafety cabinet is primary containment device designed to draw air inward by mechanical means in order to contain infectious splashes or aerosols generated during certain laboratory procedures. There are three types of biosafety cabinets, class I, II and class III. Most laboratories use class I and class II cabinets.

Class 1: Ventilated negative pressure cabinet, which is usually operated with an open front and inward airflow at a minimum velocity of 75 linear feet/minute (75 lf pm) to protect personnel (not product protection).

Class 2: Ventilated negative pressure cabinet, which is designed with inward airflow at a velocity to protect personnel (75 – 100 linear feet/minute (75 - 100 lf pm)); HEPA-filtered downward vertical laminar airflow for product protection and HEPA-filtered exhaust air for environmental protection. These are further subdivided into two types (A and B) based on construction, airflow velocities and patterns, and exhaust systems.

Class 2, Type A: Type A cabinets are suitable for microbiological research in the absence of volatile or toxic chemicals and radio-nucleotides, since air is recirculated within the cabinets. The HEPA filtered air is conducted into the room.

Class 2, Type B: Type B cabinets are hard-ducted to the building exhaust system and contain negative pressure plena. Type B permit work to be done with toxic chemicals or radio-nucleotides. The HEPA filtered air is conducted outside the room.

Class 3 or Glove box: Class 3 are totally enclosed, ventilated cabinet of gas-tight construction and offers the highest degree of personnel and environmental protection from infectious aerosols, as well as protection of research materials from microbiological contaminants. Operations are conducted through attached rubber gloves. Both supply and exhaust air are HEPA filter.

Notes:

- ❖ HEPA filters (High efficiency particle air filter). It removes the bacteria, viruses, fungi and spores by 99.97% efficiency.
- ❖ Biosafety cabinets should be tested and certified at the time of installation within the laboratory, at any time the BSC is moved, and at least annually

Cabinet	Operations and uses
CLASS 1	Class I cabinets are negative pressure, ventilated cabinets usually operated with an open front and a minimum face velocity of air of at least 75 linear feet/minute (lfpm) to protect personnel (not product protection).
CLASS 2	Cabinet is designed with inward air flow at a velocity to protect personnel (75-100 lfpm); HEPA-filtered downward vertical laminar airflow for product protection and HEPA-filtered exhaust air for environmental protection. These are further subdivided into two types (A and B) based on construction, airflow velocities and patterns, and exhaust systems.

Cabinet	Operations and uses
Class 2 Type A	Type A cabinets are suitable for microbiological research in the absence of volatile or toxic chemicals and radio-nucleotides since air is recirculated within the cabinets. The HEPA filtered air is directed into the room.
CLASS 2 TYPE B	Type B cabinets are hard-ducted to the building exhaust system and contain a negative pressure system. Type B permit work to be done with toxic chemicals or radio-nucleotides. The HEPA filtered air is conducted outside the room.
CLASS 3 OR GLOVE BOX	Class 3 are a totally enclosed, ventilated cabinet of gas-tight construction and offers the highest degree of personnel and environmental protection from infectious aerosols, as well as protection of research materials from microbiological contaminants. Operations are conducted through attached rubber gloves. Both supply and exhaust air are HEPA filtered.

Sub- Element (D-4.5)

Biological Safety Cabinets (BSC - class II-B) dedicated for aerosols generating procedures are well maintained, tested and certified at least annually. (D)

Review the following documents for the biological safety cabinet (BSC):

- Copy of maintenance records: PPM and Quality control records for the last 2 years
- Valid annual certificate from authorized company. (Check cabinet's certification sticker expiration date is within 1 year.)
- Check the dates to confirm when last maintenance was done & all-important parameters are checked for functionality like HEPA filters, UV light etc.



Checklist for Safe Use of Biological Safety Cabinets

Use this checklist as a daily reminder of the activities/tasks needed for safely working in a Biological Safety Cabinet (BSC), as a training tool, or for annual audit of operational protocols. This job aid is a component of the free, on-demand CDC training course “Fundamentals of Working Safely in a Biological Safety Cabinet.” Find the course at <https://www.cdc.gov/labtraining>.

Biological Safety Cabinet (BSC) Checklist

Preparing for Work in a BSC:

- Put on PPE according to your laboratory SOP.
- Turn UV light OFF (if used).
- Turn fluorescent light ON.
- Turn the cabinet ON, allow it to run for 4 minutes (or manufacturer’s recommended time) to purge the BSC of particulates. Some cabinets may alarm until purge is complete.
- Verify proper sash height and that sash alarm is ON.
- Verify drain valve underneath the cabinet is closed (valve handle is perpendicular to valve body).
- Check cabinet’s certification sticker expiration date is within 1 year.
- Record the pressure differential gauge reading (if present), compare it against the calibration set point.
- Verify inward airflow according to your laboratory SOP (e.g., tissue test, smoke test).
- Schedule uninterrupted work time, if possible.
- Decontaminate all surfaces of the cabinet, according to your laboratory SOP.
- Collect all materials needed for the work.

Safe Use of a BSC:

- Place absorbent plastic-backed material to protect the work surface, if required by your lab SOP.
- Wipe the external surfaces of any equipment or supplies that you will need to place in the BSC.

Sub- Element (D-4.6)

Whenever possible, plastic tubes are used instead of glass ones to avoid sharp injuries. (O,SI)

Review the following documents for the biological safety cabinet (BSC):

Observe the laboratory area(s):

- Observe different workstations inside the clinical laboratory & exclude the presence of any glass tubes.

Ask the laboratory staff:

- About the risk associated with use of glass tubes.
- Is there a need to use glass tubes during some procedures inside the laboratory?
- What are the indications for using glass tubes inside the laboratory (if any)?

Microbore glass capillary tubes, used for hematocrit determination, pose a serious and avoidable risk of blood-borne pathogen transmission to health care workers. The fragile blood-filled tubes sometimes break, especially when the health care worker pushes one end of the tube into sealing clay. The glass typically fractures near the worker's fingers where force is applied and can cause lacerations and introduce blood directly into the wound.

Sub- Element (D-4.7)

Each work area contains a dedicated well-equipped sink for washing hands together with easily accessible eyewash facility to be used in emergency in case of exposure to blood and body fluids. (D,O,SI)

During the audit visit of lab request documents for periodic maintenance and regular testing of eyewash station.

- Review the functionality checklist & verify if there is regular check with appropriate documentation to ensure functionality of the eyewash facility to be used in case of accidental exposures.
- Observe the laboratory area(s) for the presence of easily accessible dedicated sink for handwashing at each working area which well equipped with paper-towel and soap dispensers.
- Observe the laboratory area(s) for easily accessible eyewash station to be used in emergency in case of accidental exposure to blood and body fluids.

Ask the laboratory staff:

- What are the first aid measures in case of exposure to blood or body fluid splashes inside the laboratory (if any)?
- Ask any lab personnel staff to demonstrate how to use eye wash facility to check if its functioning.

Sub- Element (D-4.8)

Specimen collection and receiving area are equipped with hand washing facilities, waterless hand hygiene facilities (optional) and proper PPEs. (O)

Observe the specimen collection area and receiving area for:

- The availability of easily accessible hand washing facilities and supplies (sinks with hot & cold water / plain soap / towels) and other waterless hand hygiene facilities (alcohol - based hand rub dispensers).
- The availability of PPEs e.g. Gloves, gowns, masks, goggles/ face shields etc. with proper quality in order to avoid risk of acquiring infection.
- Observe the staff compliance to hand hygiene and appropriate use of PPE

Sub- Element (D-4.9)

Mycobacteriology Laboratory that manipulates cultures suspected or confirmed to contain Mycobacterium tuberculosis complex is at least Biosafety Level III Laboratory (BSL-3 laboratory). (D,O ,SI)

Request the following documents:

- Separate policy with definite procedures for manipulating suspected or confirmed cultures of Mycobacterium tuberculosis in the mycobacteriology laboratory
- Copies of the original charts or project scheme for ventilation system inside mycobacteriology laboratory: one-pass (non-recirculating) separated ventilation system / directional airflow pattern is from clean to least clean area / exhaust air is filtered through High-Efficiency Particulate Air (HEPA) filters.
- Local laboratory records for regular monitoring (daily recording by laboratory staff) of negative pressure differences \pm air changes per hour ACH (optional) with corrective interventions if readings are not matching the acceptable values
- Copies of maintenance records for regular monitoring (recording by maintenance team every 3 months) * of negative pressure differences + air changes per hour (mandatory 6 – 12 ACH) with corrective interventions if values are out of acceptable range
- Preventative Maintenance (PPM) schedule for Biological Safety Cabinet - BSC with copies from PPM records for regular maintenance in the last 2 years (regular check- up with replacement of filters as per the manufacturer recommendations - corrective interventions when indicated).
- Valid annual certificate for BSC - class II-B from authorized company

Observe the suite specified for growth and manipulation of TB cultures.

- Separate suite specifically designed for mycobacterial culture (i.e., isolated from other parts of building with a controlled entrance through an anteroom)
- The availability of biological safety cabinet and its class (Biological Safety Cabinet Class II, or III with exhaust air discharged to outside through HEPA filters).
- Ventilation monitoring device in culture area (to record negative pressure differences
- \pm air exchanges per hour ACH): it is valid and recorded values in local laboratory logs are identical to the actual readings

Ask the laboratory staff:

- What is meant by Biosafety Level III?
- What is meant by BICSL & N95 fit testing?
- Show me your card of BICSL license (it should be a valid license)
- How do you safely operate Biological Safety Cabinet – BSC or other containment devices?
- How do you correctly manipulate cultures suspected or confirmed to contain Mycobacterium tuberculosis complex?
- How can you report a lab? Technician who had exposed who had exposed to a case of open pulmonary TB?

Sub- Element (D-4.10)

Microbiological cultures should be autoclaved within the laboratory in an autoclave that is placed in appropriate location and fulfils quality control parameters (except cultures for organisms not mentioned in the approved list of highly infectious microorganisms, that could be double packed and send to the contractor for final disposal as infectious medical waste. (D, O,SI)

Review the following documents:

- Log book for the autoclave that must have the loads number and date.
- Quality performance tests for the autoclave operation (results of physical indicators (bowie dick), chemical indicators and biological indicators).
- Infection control list of highly infectious microorganisms that their cultures must be autoclaved in the laboratory department before being disposed as infectious medical waste. (the list mentioned below)

Observe the following:

- Presence of working autoclave in a dedicated well-ventilated place that is physically separated from other areas in the department.
- Presence of the autoclave bags that are used to sterilize the culture plates to avoid adherence of the load in the autoclave chamber.
- Availability of physical indicator (bowie dick), chemical indicator strips and biological indicator.

Review the staff knowledge about:

- Cultures that must be destroyed before being disposed in yellow biohazard bags.
- Awareness about the list of that cultures and samples.
- The method of disposal of the cultures that not included in the list

AGENTS TO BE DESTROYED ONSITE BEFORE DISPOSAL



NO	Pathogen type	Select agents
1	Viruses	<p>Crimean-Congo hemorrhagic fever virus; Ebola viruses; Cercopithecine herpesvirus 1 (herpes B virus); Lassa fever virus; Marburg virus; monkeypox virus; South American hemorrhagic fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito); tick-borne encephalitis complex (flavi) viruses (Central European tick-borne encephalitis, Far Eastern tick-borne encephalitis [Russianspring and summer encephalitis, Kyasnaur Forest disease, Omsk hemorrhagic fever]); variola major virus (smallpox virus); and variola minor virus (alastrim)</p> <p>Exclusions: Vaccine strain of Junin virus (Candid. 1#)</p>
2	Bacteria	Rickettsia prowazekii, R. rickettsii, Yersinia pestis, TB, Brucella
3	Fungi	Coccidioides posadasii

4	Toxins	<p>Abrin; conotoxins; diacetoxyscirpenol; ricin; saxitoxin; Shiga-like ribosome inactivating proteins; tetrodotoxin</p> <p>Exclusions: The following toxins (in purified form or in combinations of pure and impure forms) if the aggregate amount under the control of a principal investigator does not, at any time, exceed the amount specified: 100 mg of abrin; 100 mg of conotoxins; 1,000 mg of diacetoxyscirpenol; 100 mg of ricin; 100 mg of saxitoxin; 100 mg of Shiga-like ribosome inactivating proteins; or 100 mg of tetrodotoxin</p>
5	Genetic elements, recombinant nucleic acids, and recombinant organisms	<ul style="list-style-type: none"> • Select agent viral nucleic acids (synthetic or naturally-derived, contiguous or fragmented, in host chromosomes or in expression vectors) that can encode infectious and/or replication competent forms of any of the select agent viruses; • Nucleic acids (synthetic or naturally-derived) that encode for the functional form(s) of any of the toxins listed in this table if the nucleic acids: <ul style="list-style-type: none"> a. are in a vector or host chromosome; b. can be expressed in vivo or in vitro; or c. are in a vector or host chromosome and can be expressed in vivo or in vitro; • Viruses, bacteria, fungi, and toxins listed in this table that have been genetically modified.

Sub- Element (D-4.11)

Working surfaces and equipment are regularly cleaned and disinfected. (D, O, SI)

Review the following documents:

- Equipment cleaning checklist for the laboratory equipment.
- Housekeeping schedules for the laboratory environmental surfaces and equipment & checklists.
 - Who is responsible for housekeeping (authorized and trained staff)
 - What are procedures or methods of cleaning/disinfection activities and list of environmental surfaces intended to be cleaned
 - Which housekeeping ingredients and equipment are used (detergent/disinfectant MSDS, preparation, usage, contact time, precautions and required PPE).
 - How frequent housekeeping activities are indicated with practical detailed checklist

Review the following Observe the laboratory environment for the following::

- To exclude the presence of any dust or dirt.
- To exclude the presence of any blood or body fluid spills.
- The availability of housekeeping ingredients, supplies and equipment (as regard their quantities and qualities)
- The availability of biological and chemical spill kits.

Ask the laboratory staff (lab. technicians) and allocated housekeeping staff about:

- Ask the laboratory technician's role & responsibility in cleaning/disinfection activities (e.g., recommended procedure for cleaning and disinfection of certain equipment) / methods of cleaning / tools, agents & materials to be used / handling blood or body fluids spills / handling spills of chemicals.
- Ask the allocated housekeeping staff for their role & responsibility in cleaning/disinfection activities (e.g., recommended procedure for cleaning and disinfection of different working services / environmental surfaces) / methods of cleaning / tools, agents & materials to be used / handling blood or body fluids spills / handling spills of chemicals.

Sub- Element (D-4.12)

Laboratory personnel perform hand hygiene and wear appropriate PPE when indicated. (O,SI)

Observe (2 - 3) of the laboratory staff:

- To evaluate how they are properly performing hand hygiene (Indications / Technique / Duration)
- To evaluate how they are correctly using PPE according to the standard and transmission-based precautions (Indications for use / Technique of donning & doffing / Safety measures during use)
- You may observe Laboratory staff working with gloved hands & gown on computer & moving within the lab with PPE etc. (Take note of such wrong practices)

Ask (2 - 3) of the laboratory staff:

- To perform hand hygiene in front of you to evaluate how they are properly performing hand hygiene (Technique / Duration)
- How to select appropriate PPE / When to wear / When to remove (Indications for use / Safety measures during use)?
- To use some PPE in front of you to evaluate how they are correctly using PPE (Technique of donning & doffing / Safety measures during use)