shock); or general accidents must be documented and submitted to the Safety Officer or designee.

Incident reports must be reviewed by the Safety Officer periodically. This review must not exceed one month from time of submission. Timeliness of incident reports will allow for rapid correction of a problem to prevent recurrence. Safety reports must be incorporated into the Quality Management (QM) program. This would allow the lab to note trends and correct problems to prevent recurrence.

Laboratory Design:

When organizing the path of workflow, ensure that patients and samples do not have common pathways. Movement should be planned and designed in such a way that contact between the patients /caregivers and biological materials can occur only in the rooms where patient samples are collected. The reception area where incoming patients register should be located as close as possible to the entrance door. Dirty areas should be segregated from clean areas. To identify where improvements in laboratory design may be needed to prevent or reduce risks of cross-contamination, follow the path of the sample as it moves through the laboratory during the pre-examination, examination and post-examination phases of testing.

Access to rooms where handling or analysis of samples takes place, or where hazardous chemicals or other materials are stored, must be restricted to authorized personnel, usually laboratory technical staff and maintenance staff. Restricted access must be accomplished by having locks on doors when appropriate, using signs/labels on doors and by providing identity badges to staff.

Cleanliness and Housekeeping

Good housekeeping is essential to ensure a clean, safe and pleasant work environment. It provides work areas devoid of physical hazards, prevents the accumulation of materials (from current and past examinations/activities) that constitute a hazard to laboratory personnel and prevents the creation of aerosols of hazardous materials as a result of the procedures used.

Appropriate hazard warning signs should be posted where necessary. There should be adequate ventilation and lighting in the work area. Laboratory floors and bench areas should be free of clutter. Corridors and aisles should be free of tripping hazards, and fire exits should not be blocked. Designated bins for biohazard waste and sharps should be conveniently located. Wastes should be disposed of safely and promptly. Personal belongings and clothes should be kept in lockers outside the lab and not left where they can be contaminated or cause obstruction It is very important that all laboratory work areas and equipment are thoroughly cleaned and decontaminated after use on a regular basis. Working concentrations of the appropriate decontamination agents e.g. 0.1% NaOCl-changed daily: (Annexure 7.1) or 70% Ethanol should

be available at all times. Workbenches must be cleaned and disinfected daily after completing examinations, and after any spills of samples or reagents. This responsibility is generally assigned to the technical staff performing the tests. Laboratory floors should be clean and dry, and in good condition. All spills should be dealt with immediately to prevent slipping and tripping hazards, and risk of contamination. Cleaning staff usually clean floors unless restricted access allows only technical staff to disinfect the floors at the end of the day. Other areas of the laboratory should be scheduled for cleaning on a weekly or monthly basis, depending on laboratory conditions. For example, ceilings and walls may require cleaning weekly, whereas items such as refrigerators and storage areas might be scheduled for a monthly cleaning. Cleaning and disinfection of laboratory areas should be recorded, including the date and name of the person performing the duty. Protective clothing (lab coats, gloves, shoe covers etc.) should be left behind when leaving the laboratory.

Physical Safety:

Laboratory equipment like autoclaves, centrifuges, and fume hoods are a significant source of potential injury to laboratory staff. Therefore having trainings in specific safety procedures and precautions is important. Many laboratory instruments pose a danger of electrical shock and must therefore be periodically checked. All electrical outlets should carry a grounding connection requiring a three-pronged plug and all electrical equipment should be wired with a grounding plug. Check all electrical outlets for current, grounding and polarity at least annually. Ensure there are a sufficient amount of electrical outlets to avoid multi plug adaptor use. Staff should know how to cut off the electrical supply to the laboratory in the event of an emergency. Minimize the use of extension cords and avoid placing them across areas of pedestrian traffic. Do not overload electrical circuits, do not create electrical hazards in wet and damp areas, frayed cords must be promptly replaced, loose cords properly coiled up. Use only carbon dioxide or dry chemical fire extinguishers for electrical fires.

Personal Safety:

Laboratory staff typically acquire work-related infections through direct contact, percutaneous inoculation, accidental ingestion or inhalation. Personal Protective Equipment includes items for personal protection that provide a barrier between the route of exposure and the hazard. Selection and adequacy of the PPE (e.g. Gloves, lab coat, eye protection, bonnet, shoe covers and mask) will depend on risk assessment and hazard identification. *PPE should NOT be left in the work area and should be disposed of appropriately!* Training of staff in the proper use of PPE is necessary while working in the laboratory.

Gloves: Gloves (both latex and non-latex) reduce the incidence of contamination of hands but cannot prevent penetrating injuries by needles and other sharp instruments. Gloves should be worn in all instances, and should be available to laboratory staff on a routine basis.
Gloves should be:

- Worn to protect from infectious agents/chemicals being transmitted or absorbed via hands, while working with body fluids, mucous membranes non-intact skin and contaminated equipment and surfaces, while collecting/handling blood specimens, and blood soiled items or whenever there is a possibility of exposure to blood or body fluids containing blood
- Worn while disposing laboratory waste
- Well fitting, disposable and must be changed if visibly contaminated with blood/breached (soiled, punctured or torn)
- Removed when leaving the working area to prevent contamination of other areas such as the telephone, door handles and pens. Hands must be washed upon removal of gloves
- Never be reused. Do not attempt to wash or decontaminate gloves-they will develop micro cracks, become more porous and lose their protective properties
- Disposed of in the contaminated waste immediately after use

Laboratory Coats: Laboratory coats protect clothing from contamination with potentially infectious material. They should cover the body fully, fit close to the body and cover the arm to the wrist. Front closed lab gowns should be worn when in the laboratory and should be removed before leaving the laboratory. Plastic aprons should be used while cleaning infected reusable articles and during the disposal of waste. Laboratory coats are compulsory in all instances in a HIV laboratory.

Shoe and Head Covers: Shoe covers are worn to provide a barrier against possible exposure to airborne organisms or to prevent contact with a contaminated environment and head covers to protect the hair and scalp from possible contamination when sprays or airborne exposure is anticipated.

Masks: Masks serve as a barrier when splashes or sprays occur. Surgical masks help protect your nose and mouth from splattered body fluids (e.g. blood, respiratory secretions, vomit, urine or feces).

Eye Goggles: May be worn if splashing or spraying of blood/body fluids is expected.

Occlusive Bandage: All skin defects e.g. cuts, scratches or other breaks must be covered with water-proof dressing before patient care.

Hand Washing:

- The washing of hands is mandatory immediately after contamination with blood / body fluids, after removing laboratory gowns and gloves, while touching contaminated equipment, before leaving the laboratory; before eating; before and after using the restroom, at the beginning and at the end of a work shift
- Hands should be washed thoroughly in running water with soap. Figure 7.1 shows the

appropriate method to use during hand washing.

- Ideally, liquid soap dispensers should be installed in the laboratories and they should be regularly cleaned and maintained. If not feasible, soap bars should be made available. The soap bars after washing should be left in a dry tray to prevent contamination with some micro-organisms which grow in moist conditions
- Gloves should not be regarded as a substitute for hand washing

Figure 7.1: The appropriate hand washing method.

Source: *WHO Guidelines on Hand Hygiene in Health Care*

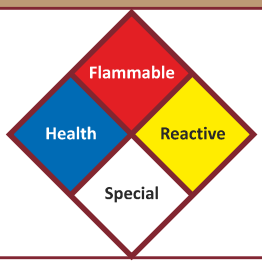
Hands may be washed with an alcohol-based hand sanitizer, if they are not visibly soiled, dirty or contaminated with blood or body fluids. After having covered all surfaces of your hands and fingers, including areas around and under fingernails continue rubbing hands together until alcohol dries. This should take at least 10-15 seconds before hands feel dry.

Chemical Safety

A chemical is hazardous if it is toxic, corrosive, irritant, flammable, explosive or poisonous. Different chemicals in a HIV lab that are hazardous include sodium hypochlorite, ethanol, sodium azide, buffers and wash solutions.

All chemicals must be properly and adequately labelled (Table 7.1) and stored in their respective designated cabinets. Hazardous and combustible materials should be kept to the minimum. All containers must be capped and sealed, except when being used. This is to reduce the possibility of a spill and reduce any release of fumes into the laboratory.

Table 7.1 - Universally recognized labels used for hazardous chemicals:

Label	Hazard Type	White symbols	Hazard Level
	blue health red fire yellow reactivity white other information	OX oxidizer ACID acid ALK Alkali COR corrosive W– water reactive	4 extreme 3 serious 2 moderate 1 slight 0 no or minima


Flammable


Oxidizing material


Poisonous


Corrosive


Compressed gas

A chemical "Spill kit," should always be readily available and include leak proof containers, forceps, absorbents such as paper towels, sponges, disinfectant, masks, and rubber gloves. The following basic principles are useful in developing specific procedures for dealing with accidental spills of potentially hazardous materials in the open laboratory:

- Get everyone out of the affected area, do not re-enter until the extent of the hazard is determined
- Determine the necessity for treating persons exposed to the potentially hazardous materials
- Establish what material has been spilt to know what personal protective measures should be followed and to understand the specific information related to spill containment and clean-up. This information can be obtained from a Material Safety Data Sheet (MSDS)
- Absorb free liquids with an appropriate absorbent, neutralize residues and decontaminate the area
- At the completion of the spill clean-up, all absorbent or contaminated material should be placed in sealed containers, labelled and disposed of as contaminated waste

Material Safety Data Sheet (MSDS):

Laboratories need to follow precautions listed in the MSDS in order to ensure the chemicals they use are handled and stored safely. These are technical bulletins that contain detailed information on physical and chemical hazards, handling procedures and emergency response procedures for hazardous chemicals and storage and handling precautions. The information includes nomenclature (chemical family and formula), hazardous ingredients, physical data, recommended PPE; storage recommendations; fire and explosion hazard, toxicology; health hazard, spill and leak with recommended actions ; waste disposal information; first aid and special protection information. MSDS for chemicals are available from the manufacturer, supplier, or on an official Internet site.

There must be a MSDS for every chemical used and stored in a laboratory including chemicals that are used for testing and those that are for general use (NaOCl, denatured spirit, disinfectants, etc.). They must be available to all employees prior to use of hazardous materials and kept close to where the hazardous material is used and located. Laboratory personnel must be trained on reading the MSDS. It is recommended that an index of MSDS be maintained and that all MSDS should be updated periodically (within a two-year period) so that personnel are equipped with the most current hazard and first aid information.

Biosafety:

Biosafety is the application of knowledge, techniques and equipment to prevent personal, laboratory, and environmental exposure to potentially infectious agents or biohazards. A biohazard is an infectious agent, or part thereof that presents a real or potential risk to the well-being wellbeing of man, animals, plants and/or the environment.

The Principles of Biosafety are:

Containment: "Containment" describes safe methods for managing infectious materials in the laboratory to reduce or eliminate exposure of laboratory workers, other persons, and the environment. Primary containment protects personnel and the immediate laboratory environment and is provided by good microbiological technique and use of appropriate safety equipment. Secondary containment protects the environment external to the laboratory and is provided by facility design and construction.

Biosafety Levels: BSLs provide appropriate levels of containment needed for the operations performed, the documented or suspected routes of transmission of the infectious agent, and the laboratory function or activities. The four BSLs, designated 1-4, are based on combinations of laboratory practice and techniques, safety equipment (primary barriers), and laboratory facilities (secondary barriers). Each BSL builds on the previous level to provide additional containment.

The Biosafety Manual:

The laboratory director/Safety Officer is responsible for ensuring that a laboratory-specific safety manual is developed, adopted, annually reviewed, and accessible to all laboratory personnel. All laboratory employees must read this manual, and the safety officer must maintain records of personnel who have read it. The manual should be reviewed and updated annually and whenever procedures or policies change. Annual training in biosafety practices is recommended for all personnel who access the laboratory. Recommended topics include the following.

- Institutional and laboratory safety policies
- Management, supervisor, and personnel responsibilities
- Regulations and recommended guidelines

- Routes of exposure in the laboratory
- Risk assessment and reporting of exposures
- Biosafety principles and practices
- Standard precautions for safe handling of infectious materials
- Standard operating procedures
- Hazard communication and biohazard signs
- Engineering controls
- Administrative and work practice controls
- PPE
- When and how to work in a BSC
- Transport of bio-hazardous materials
- Emergency procedures
- Decontamination and disposal of bio-hazardous waste
- Training program and documentation
- Medical surveillance and exposure evaluation procedures

The laboratory director is ultimately responsible for identifying potential hazards, assessing risks associated with those hazards, and establishing precautions and standard procedures to minimize employee exposure to those risks. In a HIV laboratory, the general recommendation is that the bio¬safety level (BSL)-2 standard and special practices be followed for all work, and the Standard Precautions (gloves, gowns, and protective eyewear) and BSL-2 practices be employed during handling of all blood and body fluids.

Example of a General Procedure for Dealing with Spillages :(Refer Table 7.2)

1. **Evacuate** the contaminated area.
2. **Decontaminate** the eyes and skin of exposed personnel immediately.
3. **Inform** the designated person, who coordinates the necessary actions.
4. Determine the **nature** of the spill.
5. **Evacuate** all the people not involved in cleaning up if the spillage involves a particularly hazardous substance.
6. Provide **first aid** and medical care to injured individuals.
7. **Secure** the area to prevent exposure of additional individuals.
8. Provide adequate **protective clothing** to personnel involved in cleaning up.
9. **Limit** the spread of the spill.
10. **Neutralize or disinfect** the spilled or contaminated material, if indicated.
11. **Collect** all spilled and contaminated material. **(Sharps should never be picked up by hand;** brushes and pans or other suitable tools should be used.) Spilled material and disposable contaminated items used for cleaning should be placed in the appropriate waste bags or containers.
12. **Decontaminate or disinfect** the area, wiping up with absorbent cloth. The cloth (or other

absorbent material) should never be turned during this process, because this will spread the contamination. The decontamination should be carried out by working from the least to the most contaminated part, with a change of cloth at each stage. Dry cloths should be used in the case of liquid spillage; for spillages of solids, cloth impregnated with water (acidic, basic or neutral, as appropriate) should be used.

13. **Rinse** the area, and wipe dry with absorbent cloth.
14. **Decontaminate or disinfect** any tools that were used.
15. **Remove** protective clothing and decontaminate or disinfect it, if necessary.
16. **Seek medical attention** if exposure to hazardous material has occurred during the operation.
17. **Report** the incident and document the response.

Table 7.2: Example of a list of items for spillage cleaning :

Action	Tools or items
Approaching the spillage	PPE (gloves, coveralls, leg protectors
Containing the spillage	Absorbent material (e.g. absorbent paper, towels, gauze pads)
Neutralizing or disinfecting the spillage,(if necessary)	For infectious material: disinfectant* For acids: sodium carbonate, calcium carbonate or other base ** For bases: citric acid powder or other acid** For cytotoxic material: special chemical degradation substances**
Collecting the spillage	For liquids: absorbent paper, gauze pads, wood shavings, calcium bentonite, diatomaceous earth For solids: forceps, broom, dustpan or shovel For mercury: mercury sponge or vacuum pump
Organizing containment for disposal	Plastic bag (red or yellow, as appropriate), sharps container
Decontaminating or disinfecting the area	For infectious material: disinfectants* For hazardous chemicals: suitable solvent or water**
Documenting the spillage	Report of incident to the superior

*Disinfectant: For most biological spills, use 1.0 % sodium hypochlorite solution containing 1 g/l chlorine (Annexure-7.1). Alcohols are not recommended as surface decontaminating agents because they evaporate quickly, thus decreasing contact time.

** Refer to MSDS

Emergency Safety Equipment:

Laboratories need to have procedures in place for how staff should deal with accidents and emergencies. General written procedures for first aid should be developed and made available to all staff so they know the first things to do, and who to call or notify in case of minor cuts and bruises, major wounds or skin contamination. Laboratories should develop an emergency response plan *BEFORE* an emergency and review with employees and make sure they understand the plan completely. Emergency Response Plan should include: recognizing emergencies; lines of authority; methods of communication; safe sites and evacuation routes; site security and control, decontamination procedures; provisions for medical treatment; emergency alerting and response procedures; PPE and emergency equipment for clean-up and follow up.

The following safety equipment / items must be in the laboratory to ensure the continued safety of laboratory staff and any authorized individual who may enter the laboratory:

- First Aid Box. All staff must familiarize themselves with the contents of the first aid kit and learn how to use them.
- Site map shows locations of fire exits and extinguishers, evacuation routes, emergency showers, eye wash. Emergency Exit Signages.
- Spill management kits
- Sharps containers
- Bio-safety hood
- Eye wash
- Emergency shower
- Fire extinguishers. All laboratory personnel must learn how to operate a portable fire extinguisher. Remember the acronym "PASS" when using the extinguisher:
  - **P:** Pull and twist the locking pin to break the seal.
  - **A:** Aim low, and point the nozzle at the base of the fire.
  - **S:** Squeeze the handle to release the extinguishing agent.
  - **S:** Sweep from side to side until the fire is out.

The First-Aid Box: The first-aid box should be constructed from materials that will keep the contents dust- and damp-free. It should be kept in a prominent position and be easily recognized. By international convention, the first-aid box is identified by a white cross on a green background.

The first-aid box should contain:

- Instruction sheet giving general guidance
- Individually-wrapped sterile adhesive dressings in a variety of sizes
- Sterile eye-pads with attachment bandages
- Triangular bandages
- Sterile wound coverings
- Safety pins

- A selection of sterile but un-medicated wound dressings
- An authoritative first-aid manual, e.g. one issued by the International Red Cross.

The laboratory must inspect equipment on the following schedule:

- Eye wash must be flushed weekly and must be inspected monthly for signs of contamination and replaced prior to expiration or as required by manufacturer.
- Emergency shower must be flushed at least once per month.
- Fire extinguishers must be inspected monthly to ensure proper charge and recharged as required by local standards or the manufacturer's requirements, if applicable. Staff must participate in a fire drill at least once a year
- Sharps containers must be inspected daily and replaced when three-fourths full.
- The platform /stage of the bio-safety hood must be cleaned every time after the completion of the test with 70% alcohol.
- In spill management system kit, replace the 1% hypochlorite solution on the date expiration with the freshly prepared one

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Documentation: The laboratory must document the testing and/or inspection of safety equipment Documents recording the testing and/or inspection of safety equipment must be signed and dated by the personnel performing the task.

Standard Laboratory Safety Practices:

- Limiting or restricting access to the laboratory
- Washing hands after handling infectious or hazardous materials and animals, after removing gloves, and before leaving the laboratory
- Prohibiting eating, drinking, smoking, handling lenses and applying cosmetics in work areas
- Not storing food or drink in a refrigerator which is used to store laboratory materials
- Prohibiting mouth pipetting
- Using techniques that minimize aerosol or splash production when performing
- Procedures-biosafety cabinets should be used whenever there is a potential for aerosol or splash creation, or when high concentrations or large volumes of infectious agents are used
- Preventing inhalation exposure by using chemical fume hoods or other containment devices for vapours, gases, aerosols, fumes, dusts or powders
- Properly storing chemicals according to recognized compatibilities-chemicals should not be stored on the floor or in chemical fume hoods
- Decontaminating work surfaces daily
- Decontaminating all cultures, stocks and other regulated wastes before disposal via autoclave, chemical disinfection, incinerator or other approved method
- Implementing and maintaining an insect and rodent control programme
- Using PPE such as gloves, masks, goggles, face shields and laboratory coats when working in the laboratory

- Prohibiting sandals and open-toed shoes to be worn while working in the laboratory; Wear shoes with closed toes and closed heels
- Never undertaking any work unless the potential hazards of the operation are known as precisely as possible, and the appropriate safety precautions are adopted
- Disposal of specialized wastes (e.g. broken glassware, biological and chemical substances) according to laboratory policies and in containers reserved for the particular type of waste
- Labelling all safety equipment and maintaining them in good operating condition. Checking and inspecting safety equipment for correct operation in accordance with the manufacturer's instructions and report, in writing, any requirement for maintenance
- Ensuring that all safety equipment remains accessible to the laboratory personnel at all times
- Posting appropriate signages (Table 7.3)

Table 7.3: Some signage that should be used in the laboratory:

S No.	Description	Signage
1	A "BIOHAZARD SYMBOL" should be pasted on the outer surface of the package containing samples.	
2	"MOBILE PHONE NOT ALLOWED" should be pasted inside the laboratory.	
3	"EMERGENCY EXIT" should be pasted on the surface of the emergency door.	
4	"NO EATING OR DRINKING" should be pasted inside the laboratory.	
5	"NO SMOKING" should be pasted inside the laboratory.	
6	"NO ENTRY FOR UNAUTHORISED PERSONNEL" should be pasted on the surface of the laboratory door.	

Waste Management

An HIV laboratory must establish a waste management plan. As part of an on-site waste management plan, the responsibilities of the laboratory management or the designated safety officer are to

- Establish a waste-reduction or minimization program;
- Identify and define all categories of waste generated by the laboratory;
- For each category of waste generated, determine applicability of national, state, and local regulations, including how that category of waste will be segregated, packaged, labeled/color-coded, stored, transported, and tracked within the laboratory, outside the laboratory, and outside the facility to comply with the applicable regulations;
- Segregate all regulated waste to prevent access by the public or customers;
- Establish a system for reporting and responding to all issues or problems regarding medical waste management; and
- Establish treatment and disposal processes. Disposal of regulated waste must be by a company meeting state and local licensure requirements.

Classification of Laboratory Waste with Examples:

A. Hazardous Waste:

- **Sharps Waste:** (Used or unused) Needles, broken glass, Petri dishes, slides and cover slips, broken pipettes.
- **Infectious and Pathological Waste:** Waste suspected to contain pathogens and that poses a risk of disease transmission. Blood and body fluids, microbiological cultures and stocks, tissue, infected animal carcasses, tubes and containers contaminated with blood or body fluids.
- **Chemical, Pharmaceutical and Cytotoxic Waste:** Fixatives; formalin; xylene, toluene, methanol, methylene chloride and other solvents; broken lab thermometers

B. Non-Hazardous or General Healthcare Waste: Waste that does not pose any particular biological, chemical, radioactive or physical hazard. Packaging, paper, plastic containers.

The simplest waste-segregation system is that of general, non-hazardous waste, potentially infectious waste and used sharps into separate containers and is referred to as the “three-bin system”. Table 7.4 is segregation and disposal as per the national BMW management Rules.

Note 1: The recommended thickness of bags for infectious waste is 70 µm (ISO 7765 2004). Plastics used for either containers or bags should be chlorine-free. Not all plastic bags can withstand temperatures of 121 °C, and some can melt during an autoclave process.

Note 2: For the disposal of laboratory waste, always follow the color code of the bag as per the local guideline of state pollution control board / Local Municipality.

Table 7. 4: Container and color coding for disposal of bio-medical wastes

S No.	Type of Waste	Type of container	Color coding	Treatment /Disposal option
1	Anatomical waste, soiled waste contaminated with blood & body	Leak-proof plastic bag or container. With biohazard symbol.	Yellow	Incineration / Deep Burial (No chemical pre-treatment before incineration)
2	Microbiology & bio-technology waste; Non sharps solid waste	Strong, leak-proof plastic bag, or container capable of being autoclaved marked "HIGHLY INFECTIOUS", with biohazard symbol	Red	Autoclaving/ Microwaving/ and shredding for recycling
3	Waste sharps	Re-usable/ single-use puncture proof containers of plastic or metal. Marked "SHARPS", with biohazard symbol	Blue/ White	Deep Burial / sharps pit
4	General waste	Plastic bag	Green/ Black	Disposal into MSW landfill

Disposal of liquid waste:

Non-infectious:- Chemical waste should first be neutralized with appropriate reagents and then flushed into conventional sewer system.

Infectious: Liquid waste is treated with 1% sodium hypochlorite solution or autoclaved for decontamination.

Highly infectious waste, such as diagnostic laboratory samples and waste from infectious patients in isolation should be collected separately and autoclaved at the point of generation. Once disinfected, the waste would leave a medical area in the infectious health-care waste container.

Autoclave safety

- Gravity displacement steam sterilizers (autoclaves) are frequently used for onsite decontamination in the HIV laboratory.
- Personnel who operate the autoclave must be trained to package, load, and label materials to be autoclaved

- Never autoclave materials that contain toxic agents, corrosives (e.g., chlorine, acids, bases, phenol), solvents or volatiles (e.g., ethanol, methanol, acetone, chloroform), or radioactive materials.
- Place all biomedical waste to be autoclaved in an approved, biohazard-labeled autoclave bag before autoclaving.
- Place all sharps (e.g., needles, scalpels, pipettes, or broken glass) into an approved, leak-resistant, labeled, and rigid sharps container before sterilizing.
- When decontaminating a bag of dry goods, such as bench paper or paper gowns, place 100 mL of water into the autoclave bag to facilitate steam production within the bag.
- Do not overfill bags or the autoclave unit; this might result in inadequate steam circulation, which could interfere with the sterilization process.
- Close autoclave bags loosely with twist ties or other means that allow steam inside.
- Place bags onto stainless steel or polypropylene trays for autoclaving. Do not place bags directly into the autoclave.
- Always allow an autoclave unit to cool before opening. Allow the contents to cool before handling. Always use thick, elbow-length, heat-resistant, liquid-impervious gloves to remove hot items from the autoclave.
- After autoclaving, check the autoclave indicator tape to be sure the bars are black. If the indicator tape is not activated, re-sterilize the load.
- At least weekly, use a biological indicator such as Geobacillus stearothermophilus Spore strips (or equivalent) to ensure the autoclave is performing properly.
- Establish and follow a regular maintenance schedule for this equipment that evaluates seals, drains, and other critical aspects.

The infectious waste storage place must be identified as an infectious waste area by using the biohazard sign. Floors and walls should be sealed or tiled to allow easy disinfection. Storage times for infectious waste (e.g. the time gap between generation and treatment) should not exceed 48 hours during the cool season and 24 hours during the hot season.

Documentation:
The laboratory must record the classification of waste and their regular disposal.

Archiving and Storage Spaces
Space must be allocated for the archiving of data in a secured insect proof, water proof and fire-proof environment that is accessible only to authorized personnel. These documents may be archived either on- or offsite, based on the laboratory's discretion.

Laboratory storage areas must be allocated to adequately preserve the identity, purity, and stability of laboratory reagents, control materials, calibrators, and other laboratory materials.

Biosecurity

Biosecurity is the protection of pathogens, toxins, and sensitive information from loss theft and subsequent misuse. The objectives of biosecurity are to protect against loss, theft, diversion of dangerous pathogens and minimize intentional misuse. Biosecurity protects unauthorized access to pathogens from dangerous people. Limit access to laboratories that contain certain biological agents.

Biosafety and Biosecurity are complementary. Biosecurity relies on a sound biosafety program. Both biosafety and biosecurity procedures include the inventory and tracking of biological materials. Also integral to both biosafety and biosecurity is the safe packaging, accurate documentation, and transport of infectious materials. Program management should embrace laboratory safety and security as a code of practice for responsible research and operation. Management should ensure the adoption, implement and accountability of biosafety and biosecurity programs. In addition, these programs should be reinforced by training on general practices, specific SOPs and awareness of potential risk and hazards. All of these are essential to ensuring the daily implementation of safety and security policies.

The components of a successful biosecurity program are:

1. Program Management
2. Physical Security and Access Control. Prevent unauthorized material removal. Examples of access control are Guards, Cameras, Alarms, ID Badges, Manual Lock & Keys, Electronic Keys, Biometrics
3. Personnel Management
4. Inventory & Accountability. Tracks agent Use, Storage, Transfer, Destruction. Remember the Three “w” Who’s = Responsible person; What = Identifies agent; Form of agent & Amount; Where = Location/s and ensure documentation
5. Information Security. Protect sensitive information or data and limit/restrict data access
6. Transport of Biological Material. Movement of materials may be Internal (between laboratories or storage) or External (transfers or shipments). Establish, maintain and monitor procedures for Control, Accountability & Containment and Documented records (chain-of-custody)
7. Accidents, Injuries & Emergency Response. Coordinate in Advance with Medical, Fire, Police, Maintenance Staff and have written response plans
8. Reporting & Communication. Establish “Chain-of-Notification” and roles & responsibilities
9. Training, Practice, Drills are essential are required for all hazards. They strengthen emergency response, Enforces roles & responsibilities, Identify program deficiencies and facilitate advance resolution
10. Updates and Re-evaluation. Annual review and update and after any biosecurity incident. Document the evaluation process. It should be a comprehensive process including risk assessment process, risk statement, biosecurity plan and biosecurity systems

Chapter 7

Bioethics

Bioethics is the study of the ethical and moral implications of biological discoveries, biomedical advances and their application in the field of genetic engineering and drug research.

Key points

- "First, do no harm" remains a principal belief of any health system.
- Laboratory safety involves good staff training, the availability of SOPs, staff competence in risk management, appropriate containment equipment, proper facility design, correct operation and maintenance, and administrative considerations to minimize the risk of worker injury or illness
- Staff is expected to follow safe working practices (biosafety), to keep their work and materials secure (biosecurity)
- Laboratory biosafety describes the containment principles, technologies and practices that are implemented to prevent unintentional exposure to, or accidental release of, pathogens and toxins.
- The key considerations of biosecurity are to understand what needs to be protected; apply highest security to the most critical assets; employ a graded security approach; reduce risk to acceptable level; obtain strong management support

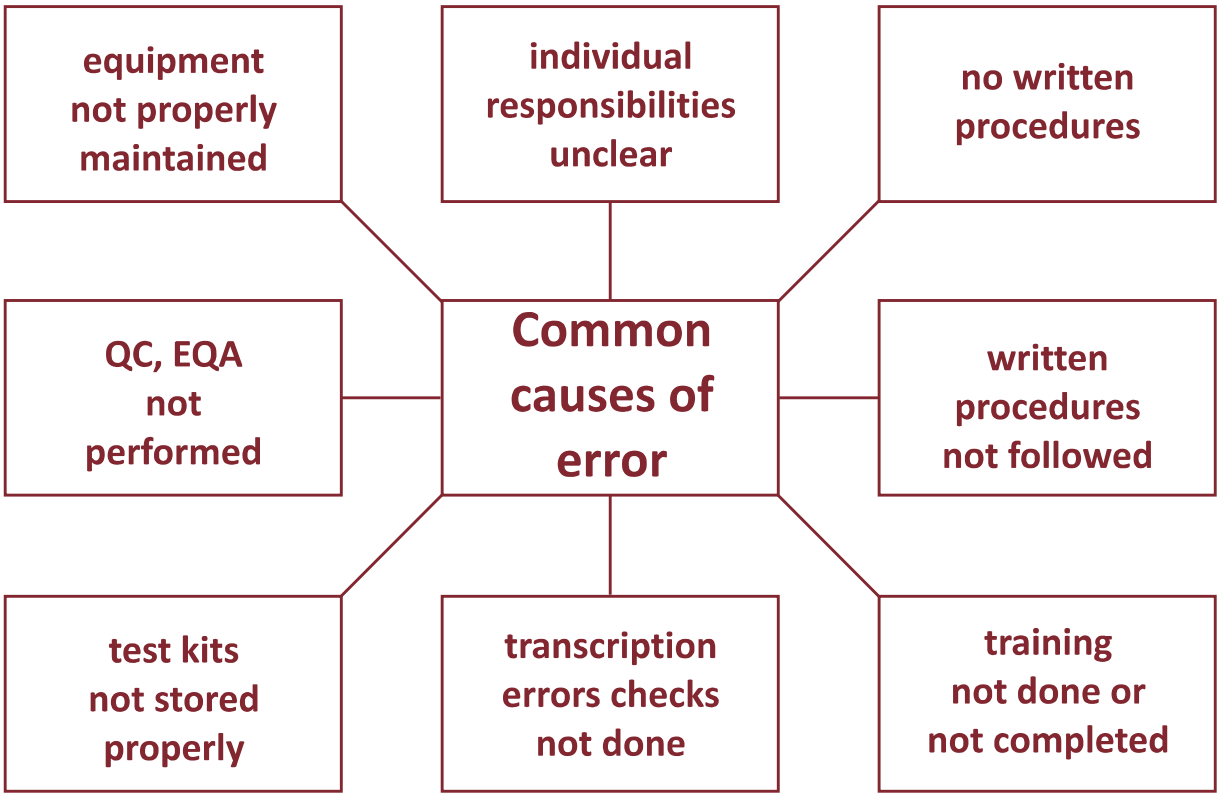
Continual Quality Improvement

Continual Quality Improvement (CQI) is a philosophy and attitude for repeatedly analyzing and improving capabilities, policies, processes and procedures to achieve the objective of quality test results and customer satisfaction. It is the core of the QMS in a clinical laboratory and it requires commitment, leadership, planning, preparation, structure, implementation, appraisal and evaluation. It is possible to achieve continual improvement through small, incremental changes using scientific methods.

CQI is a dynamic set of activities wherein a laboratory has an approach and methodology for detecting errors and incidents, reviewing and categorizing them, resolving them through the planning and implementation of corrective action, following up on them to ensure effectiveness and finally, documentation and reporting of the same. It emphasizes the need for continuous improvement rather than only inspection to correct errors.

Continual improvement will always be a goal. Process improvement is something that is never finished, but rather continues on "forever". In the laboratory, this process is applied to all procedures and processes that are a part of the path of workflow. When the process identifies opportunities for improvement, the laboratory management should address them regardless of where they occur.

Figure 8.1: Common causes of error in a laboratory.



Chapter 8

Errors and problems occur even in the most well managed and monitored testing laboratories. Designing and implementing strategies to prevent or reduce errors or to detect and correct them before the reporting of the test result, constitutes quality improvement.

At any point in time, certain aspects of the laboratory path of workflow should be clearly targeted for improvement. Figure 8.1 shows where the most common errors occur in a laboratory and an insight into where improvement can be realized in the HIV serology laboratory. These errors for improvement might be:

Pre-analytic Process:

1. Specimen mislabeling or logging in, mismatched requisition forms (no cross verification of requests)
2. Inappropriate collection tube
3. Specimen transported or stored inappropriately
4. Test kits/ reagents stored or handled improperly (cold storage temperatures not checked daily)
5. Insufficient or inadequate training / competence of staff.

Analytic Process:

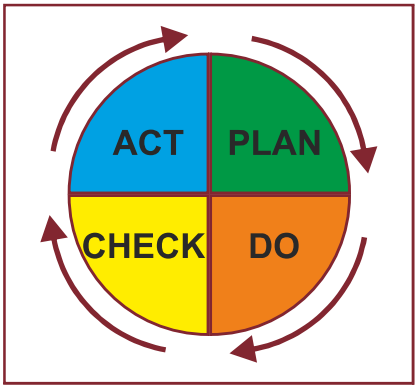
1. Appropriate QC not performed or not used effectively
2. Equipment not calibrated or malfunction not detected (calibration status of pipettes, centrifuge, timer, thermometer not checked)
3. SOPs not available or not followed
4. Algorithm not followed
5. Incorrect timing of tests, incubation temperatures
6. Misinterpretation of results
7. Pipetting or dilution errors
8. Failure to document all QCs or comments

Post-analytic Process:

1. Transcriptional errors from worksheet to report forms or computers
2. Lack of adequate supervisory review
3. Proper archiving / identification of specimen location
4. Turnaround times for results are not being maintained
5. Failure of proper documentation
6. Failure of or incorrect biohazard safety precautions and/or waste disposal.
7. Improper packaging and/or transport re-check specimens for EQAS to referral laboratory, or inappropriate storage until next shipment to referral laboratory, if needed.

Quality management concepts in use today are primarily an outgrowth of manufacturing and shop processes. W. Edwards Deming, one of the originators of the concept of continual improvement worked with manufacturing and industrial processes, and introduced many of the tools used in quality improvement efforts; his ideas and concepts are used today to produce reliable, quality laboratory results. The Deming PDCA Cycle, standing for Plan-Do-Check-Act, shows how to achieve continual improvement in any process (Figure 8.2).

Figure 8.2: PDCA cycle



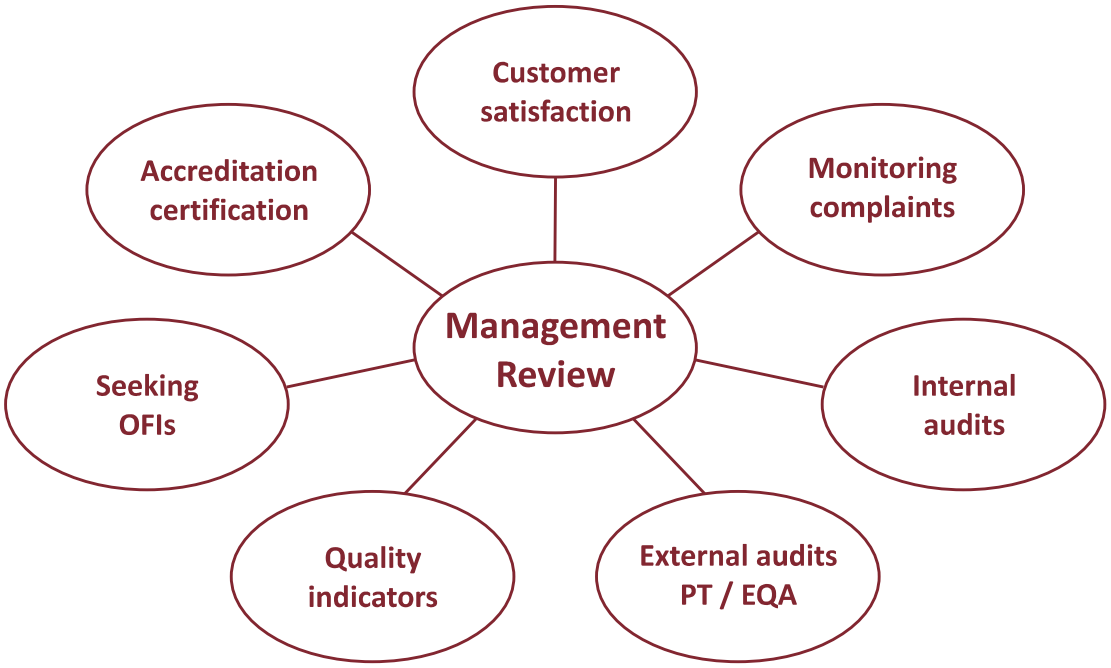
Plan- identify potential sources of any system Weakness or error by implementing a regular Systematic review of all operational procedures By laboratory management, from which Action plans for improvement can be developed;
Do- implement the plan; put the plan into action.
Check-this refers to the monitoring process. Review The effectiveness of the action through the process of Focused review and audit;
Act-adjust the action plan and implement changes to the quality system in accordance with the review and audit results. Take any corrective action that is required, and then re-check to be sure that the solution has worked. Provide educational and training opportunities, not only for laboratory personnel, but also for relevant users of laboratory services.

Tools for Continual Quality improvement are: (Figure 8.3)

- Development of **quality indicators** for systematically monitoring and evaluating the laboratory's contribution to patient care
- **Identification and control of Non-Conformities (NC)**, Implementing immediate action , **Root Cause Analysis (RCA), Corrective Action and Preventive Action (CAPA)** and improvement processes also known as Non-Conforming Event (NCE) Management
- Assessment of **customer/user satisfaction and complaints**
- Carrying out assessments/**audits both internal and external**
- Performing **management reviews**

CQI involves a team approach involving all laboratory personnel including bench level staff. Definite timelines should be established, responsibilities assigned and appropriate tools be used to implement CAPA. The quality improvement activities, findings, and progress of corrective action should be reported to management and also to laboratory staff.

Figure 8.3: Tools for Continual Quality Improvement



Quality Indicators

To manage quality one must measure it. Quality indicators are those observations, statistics, or data that typify the performance of a given work process. The analysis of daily QC charts is the indicator most familiar to laboratory personnel, but there are measures of all aspects of the service. The concept of the path of workflow: pre-analytical, analytical and post-analytical, inpatients and outpatients and referral laboratories must be considered when developing quality indicators. For example, a sample that is damaged or changed as a result of improper collection or transport cannot provide a reliable result. A test report that is delayed or poorly written, can undo all the effort of performing the test well. Measurement of quality objectives results in early detection of unfavourable trends/ patterns and their rapid, timely correction.

Quality indicators are specific information or data that are systematically monitored, measured, quantified or otherwise analysed to evaluate the laboratory's contribution to patient care and identify opportunities for improvement. They are specific targets that are regularly examined using objective methods, in order to determine if the goals of compliance to the established QMS are being met. It is information that is measured to analyze the performance of a process; determine quality of services; highlight potential quality concerns; identify areas that need further study and investigation; track changes over time; define and measure the progress made towards the goals set by the laboratory.

While developing quality indicators the laboratory must realize that fewer are better; at any given time too many quality indicators cannot be effectively implemented as tracking becomes

difficult. Generally laboratories can address not more than four or five indicators at a single time. Start with changes that can be easily accomplished and have the biggest impact such as sample rejection, IQC & EQAS results, TAT but ultimately all quality system essentials (QSE) must be addressed.

The objectives of quality indicators, their methodology and duration of measurement must be established prior to implementation. The same indicators must not be adhered to over long periods of time since making these measurements takes time and resources. There should be a plan as to when to stop using a particular indicator and replace it with another. A quality indicator should be used only as long as it provides useful information. Once it is indicating a stable and error-free operation, a new quality indicator ought to be selected.

Examples of pre-analytical indicators are: incomplete requisitions; patient identification accuracy (percent of specimen identification errors); phlebotomy efficiency (repeat draws, complications of phlebotomy); specimen acceptability rates (percent acceptable/unacceptable specimens); adequacy of collected samples; accuracy of sample accessioning; inappropriate Specimen transport or storage.

Examples of analytical indicators are : QC and EQA results/failures; equipment/Computer down times; frequency of unscheduled service and repairs; supplier performance-(backorders, delays, incorrect shipments, damaged shipments); inventory-(shortages, emergency orders, expiries/outdating); on-time performance-calibrations and maintenance; incomplete test runs (i.e., technical problems); invalid test results (i.e., controls out of range); missed follow-ups; misinterpretations; missed diagnoses.

Examples of post-analytic indicators are: Turn-Around Times (TAT); reporting errors (percent amended reports); timeliness of critical value reporting; unavailability of archived samples.

Other Quality Indicators include: number and type of laboratory accidents (needle sticks); Personnel attrition rate; completeness of training; competence evaluation outcomes. Document problems discovered-outdated, incomplete, incorrect; number and type of security breaches, inability to retrieve archived information, problems with data integrity; customer complaints-physicians, other health care staff, patients; numbers and types of non-conformances; employee satisfaction; external customer satisfaction with phlebotomy, quality of telephone responsiveness, physician satisfaction with services; physician satisfaction with report format and content; number and type of continuous improvement projects ongoing.

Key points for Quality Indicators are:

- Rationale for selecting a QI
- Set goals

- Develop formats for data collection
- Data review
- CAPA
- Monitor

Occurrence (Non-Conforming Event / Incident / Error) Management

There are many procedures and processes that are performed in the laboratory and each of these must be carried out correctly in order to assure accuracy and reliability of testing. An error in any part of the path of workflow can produce a poor laboratory result. A method of detecting errors and resolving the problems at each phase of testing is needed if quality is to be assured.

An "occurrence" is an error or an event that should not have happened. A system is needed to detect these problems, to handle them properly, to take action so that they do not happen again and to thus learn from mistakes. This system known as **Occurrence Management (OM)** ensures that problems are identified and investigated, root cause identified, CAPA planned and implemented, actions tracked and their effectiveness verified.

Occurrence management is thus defined as the system for defining, identifying & investigating NCs in the laboratory's quality & technical policies, processes and procedures. Non-conformity is a *non-fulfillment of a requirement.* It is a failure or a refusal to meet a requirement of the QMS or the relevant standard (ISO 15189: 2012 & NABL 112). The system requires that each episode of NC be documented and recorded, appropriate and effective CAPA be taken against NCs, and the records be reviewed at regular specified intervals by laboratory management to detect trends and effectiveness of CAPA.

Implementing an effective and fully compliant OM system is a multi-step process. Each step must be thoroughly documented to provide historical data for a quality improvement plan.

The steps are:

1. **Identification (Occurrence is detected):** The first step is to define the problem. It should include, the source of the information, detailed explanation of the problem and documentation of the available evidence that a problem exists. The problems can be identified through a variety of sources such as process monitoring, proficiency testing, data trend, staff observations, internal audits and customer complaints. In identifying the problem, list all information that demonstrates the problem exists. This could include source documents, data and audit reports.

2. **Immediate/Remedial Action:** Action taken at the time of the nonconformity to alleviate its immediate effects is considered 'immediate/remedial' action. Appropriate laboratory staff should be identified to oversee the various steps of remedial action including consideration of the medical significance of the NC and communication appropriately with all those affected by

the error or problem. If necessary further testing should be stopped and reports withheld until the problem is rectified. Any nonconforming results already released must be identified and recalled. Any pending results must be reviewed before release and the authority for the resumption of testing must be identified.

3. **Root Cause Analysis (RCA):** This analysis can be done by one person or a group. A list of causes is created and data is collected to determine the primary cause of the problem. Some of the causes to consider when investigating a problem are lack of SOPs, lack of training for personnel, lack of understanding of GCLP, defective SOP/WI and failure to supervise/enforce rules

4. **Develop a Solution:** Once the problem and cause are identified, it must be resolved by all concerned staff involved in the improvement process, as they can provide good suggestions for solving problems. The solution should resolve the immediate problem; consider whether similar problems exist in other areas and prevent the problem from reoccurring i.e. CAPA.

5. **Implement the Solution:** The solution should have a corrective action which resolves the immediate problem and consider whether similar problems exist in other areas and implement a preventive action so that the problem does not recur. A corrective action (reaction) is a planned action taken to eliminate the root cause of a detected non-conformity or other undesirable situations. Preventive action is a pro-active process for identifying opportunities for improvement rather than a reaction to the identification of problems or complaints (i.e., nonconformities).

In addition to the review of the operational procedures, preventive action might involve analysis of data, including trend- and risk-analyses and external quality assurance and the monitoring of quality indicators. Resources such as personnel, financial, equipment, individual responsibilities and a schedule for completion of CAPA must be specified.

6. **Document the Solution:** The progress should be regularly documented and reviewed in order to stay on target with the established timeline.

7. **Communicate the Solution:** the findings must be communicated to all key personnel involved. Follow-up training for any changes in procedures that may result must be provided. SOPs must be developed / updated to guide the staff accordingly. Staff should be actively involved in the improvement process and encouraged for their participation.

8. **Conduct an Evaluation:** This will allow verification of the successful completion of the identified tasks and assess appropriateness and effectiveness of actions taken and determine whether actions taken have any adverse effects.