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MINISTRY OF HEALTH

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Timely Accurate Diagonostics for a TB-Free Africa

Laboratory Quality Management System

Module 2: Facilities and Safety

Venue:

Presenter:

Date:

Introduction

Laboratory work space and facilities must be such that its workload can be performed without compromising the quality of work and the safety of the laboratory staff, other health care personnel, patients, and the community.

Learning Objectives

At the end of this module, participants should be able to:

- Relate how facility design impacts the efficiency and safety of laboratory workers
- Describe practices to prevent or reduce risks
- List personal protective equipment (PPE) that should be used routinely by laboratory workers
- Explain general safety requirements for the laboratory
- Describe steps to take in response to emergencies such as biological or chemical spills, or laboratory

Module Outline

- Facility and Safety Overview
- Laboratory Design
- Space Organization
- Physical aspects of premises and rooms
- Safety Management Program
- Identification of Risks
- Personal Protect Equipment
- Emergency management and First Aid

Scenario

Your laboratory specializes in Bacteriology. There is an epidemic of MDR and XDR TB in your country and the Ministry of Health names your laboratory as the reference laboratory for processing all samples.

What are the elements to consider for ensuring biosafety in your laboratory?

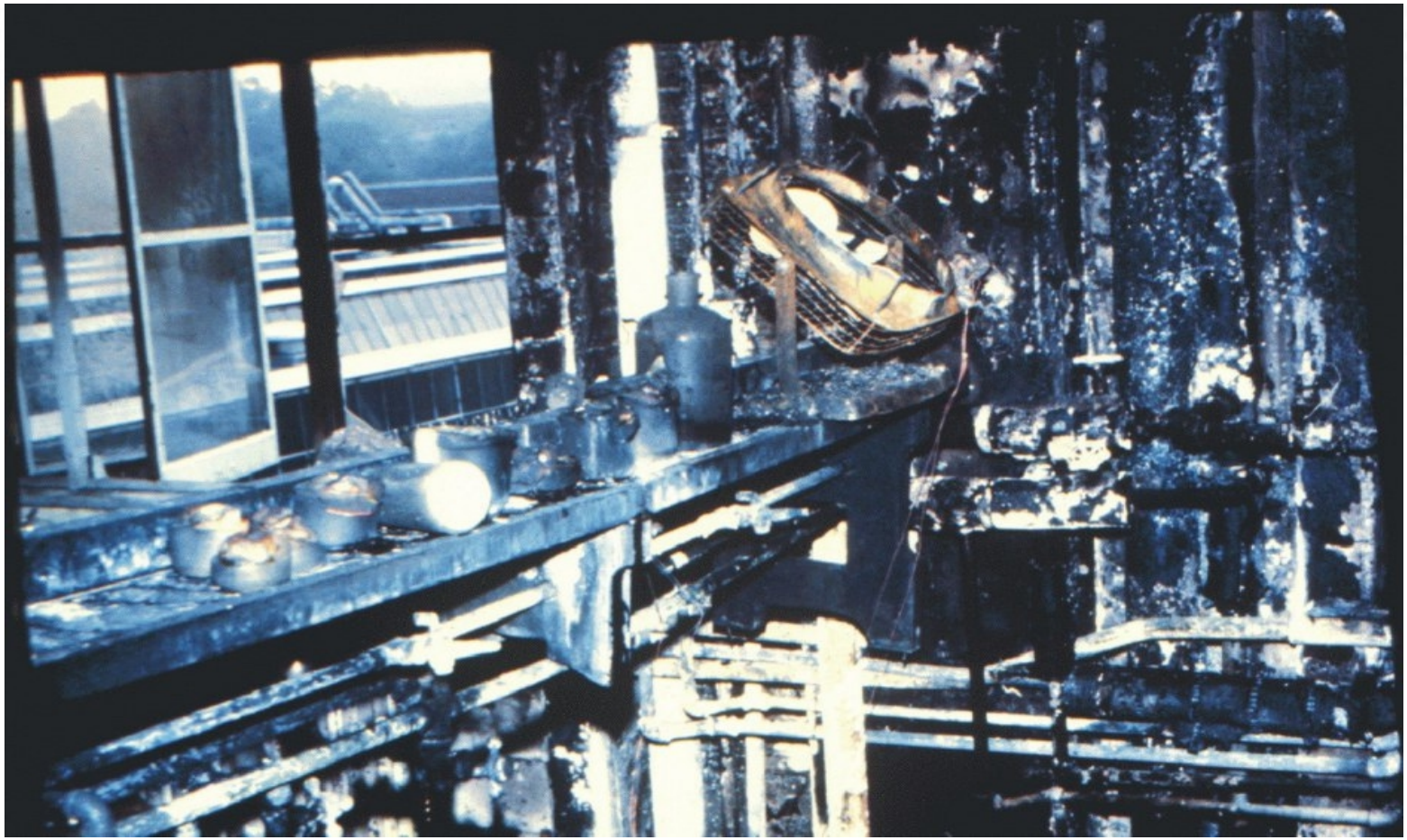
The Quality Management System

1. Facilities and Safety Overview

Importance of Safety

- Laboratory Safety program important in order to protect:
  - the lives of employees and patients
  - protect laboratory equipment and facilities,
  - protect the environment.
- Negligence of laboratory safety is very costly.

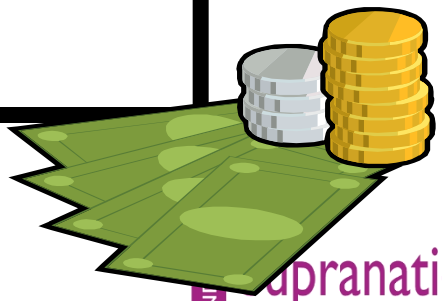
Laboratory Accident



Secondary Effects of a laboratory Accident

- loss of staff confidence
- loss of reputation
- loss of customers
- increased costs, litigation, insurance

Negligence of laboratory safety is costly!



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Lab Director -Responsibilities

•Participate in the design and planning stages of new laboratory facilities;

Assess all potential risks

consider the organization of the laboratory when developing new activities

Safety officer - Responsibilities

- develop safety rules

  ensure that personnel are trained in safety

  know the basics of safety and biosafety management issues

  perform an extensive risk assessment when developing new activities in the laboratory;

  conduct laboratory safety audits.

Laboratorian - Responsibilities

Be aware of basic safety rules and processes;

Understand the basics of safety and biosafety management issues when working with:

- toxic chemicals,
- biological samples,
- physical hazards, and when
- interacting with patients.

Safety during service

- no unauthorized persons
- no children
- no friends
- no animals

Please
CLOSE
the DOOR

EVERYONE

is responsible for quality and safety

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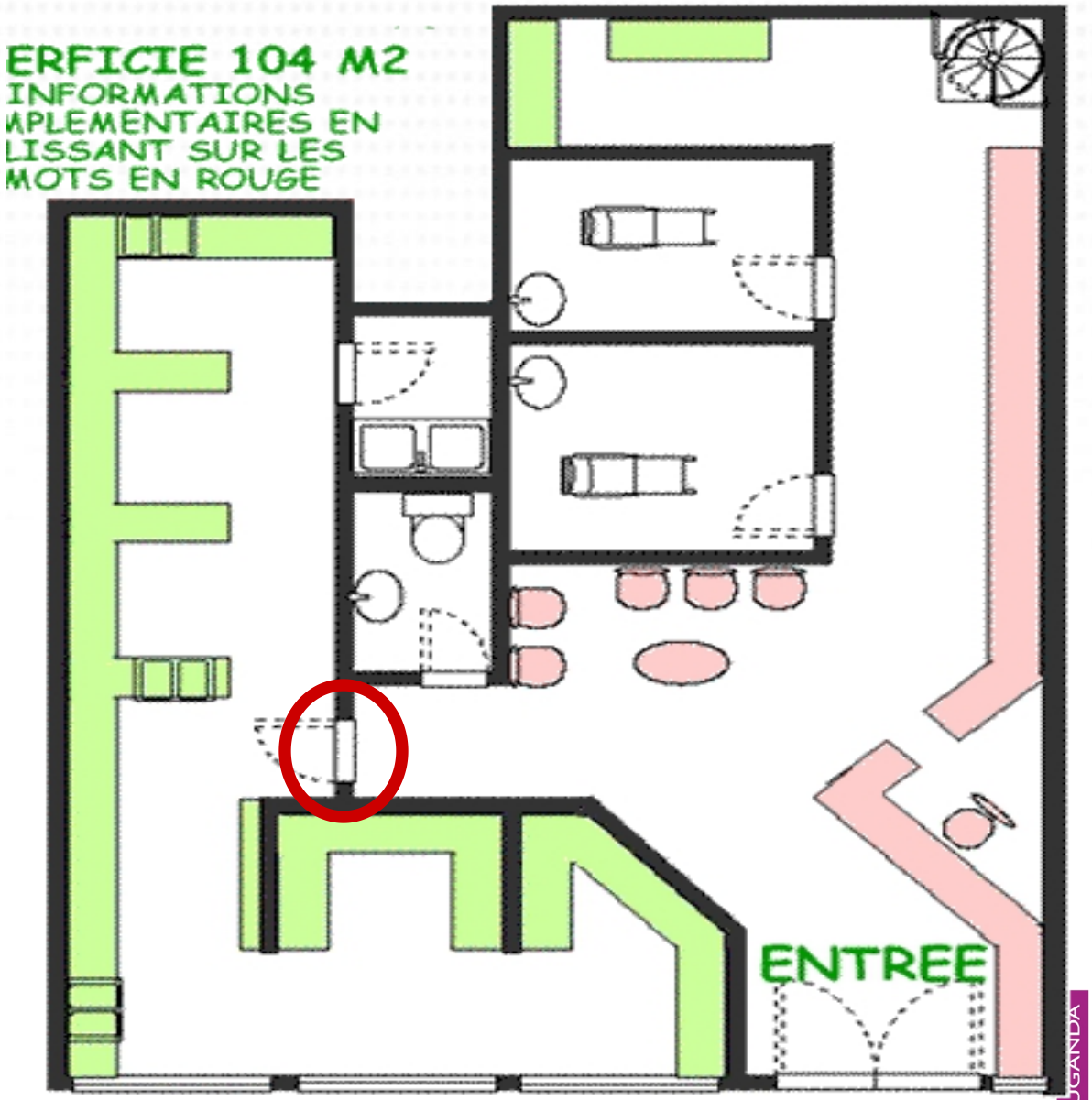
2. Laboratory Design

Designing or organizing workflow

- Ensure that:
  - patients and patient samples do not have common pathways.
  - contact between the public and biological materials can occur only in the rooms where patient samples are collected.
  - The reception desk where incoming patients register should be located as close as possible to the entry door.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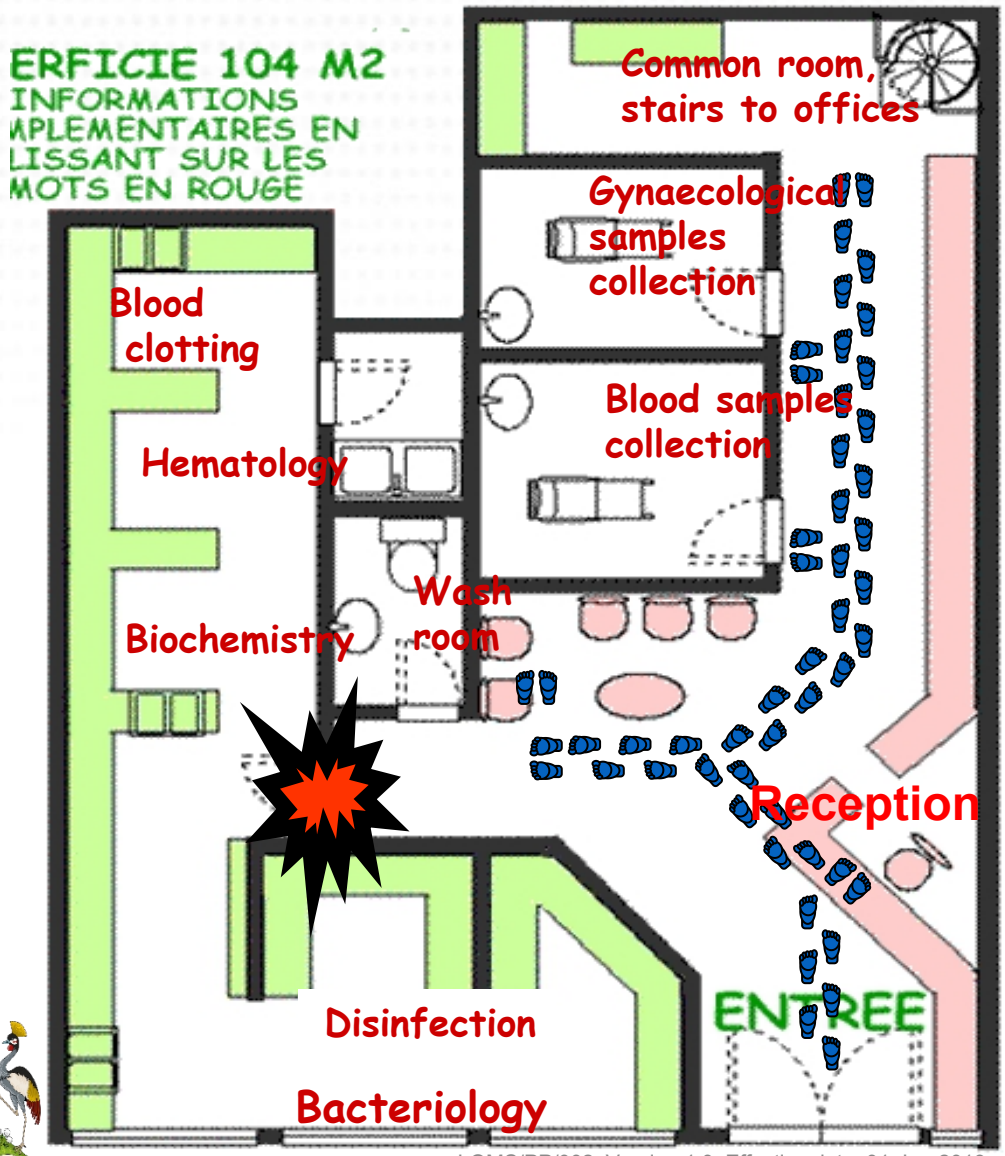

Patient Movement

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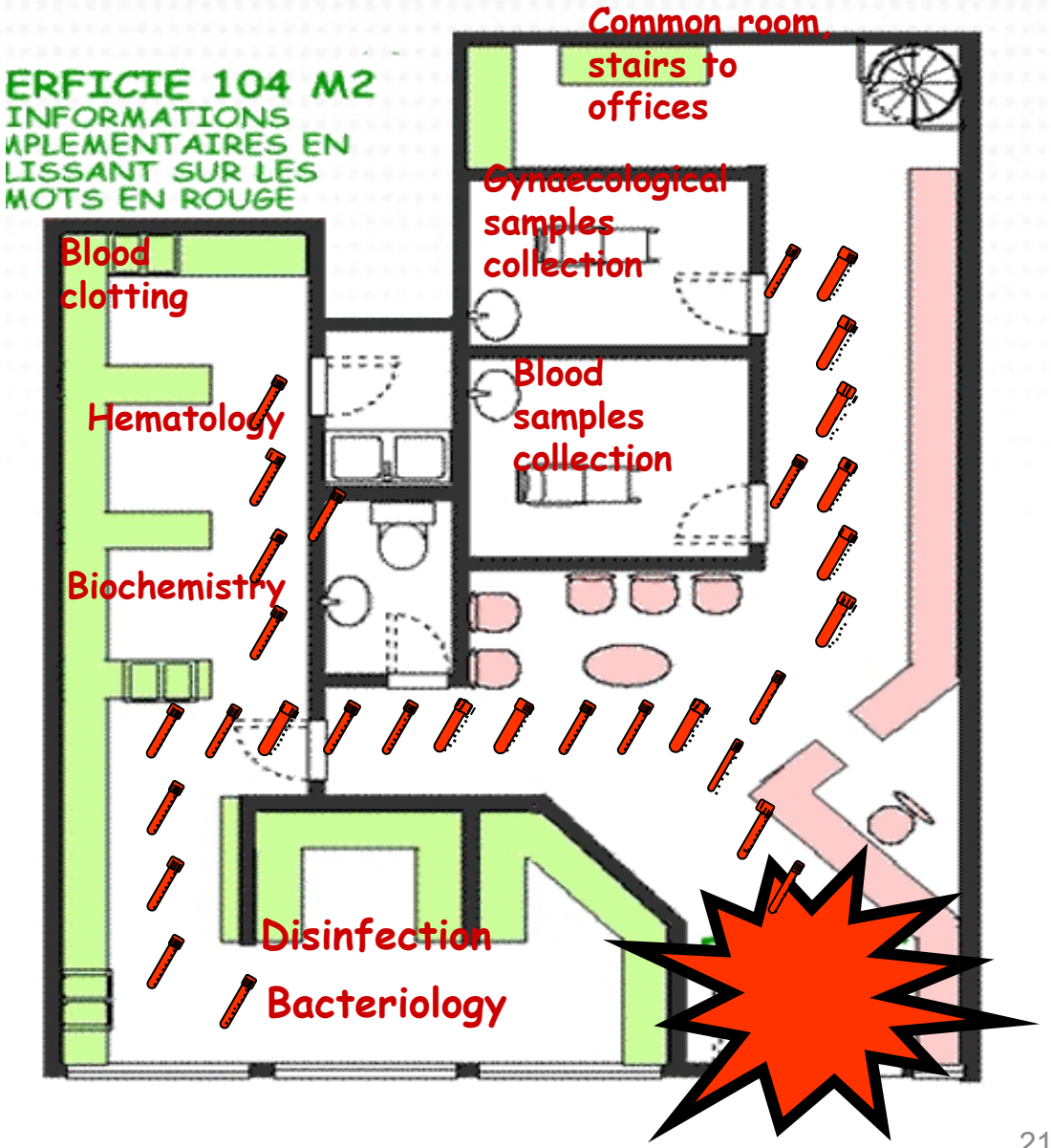
Circulation pathways

- Sample collection areas—Reception and the sample collection room located at the entrance saves time and energy.
- Sample processing areas—for sample centrifugation, should be separated from but nearby the testing areas.
- Circulation pathways of samples between different sections of the laboratory—clean and dirty laboratory materials should never cross, to avoid cross contamination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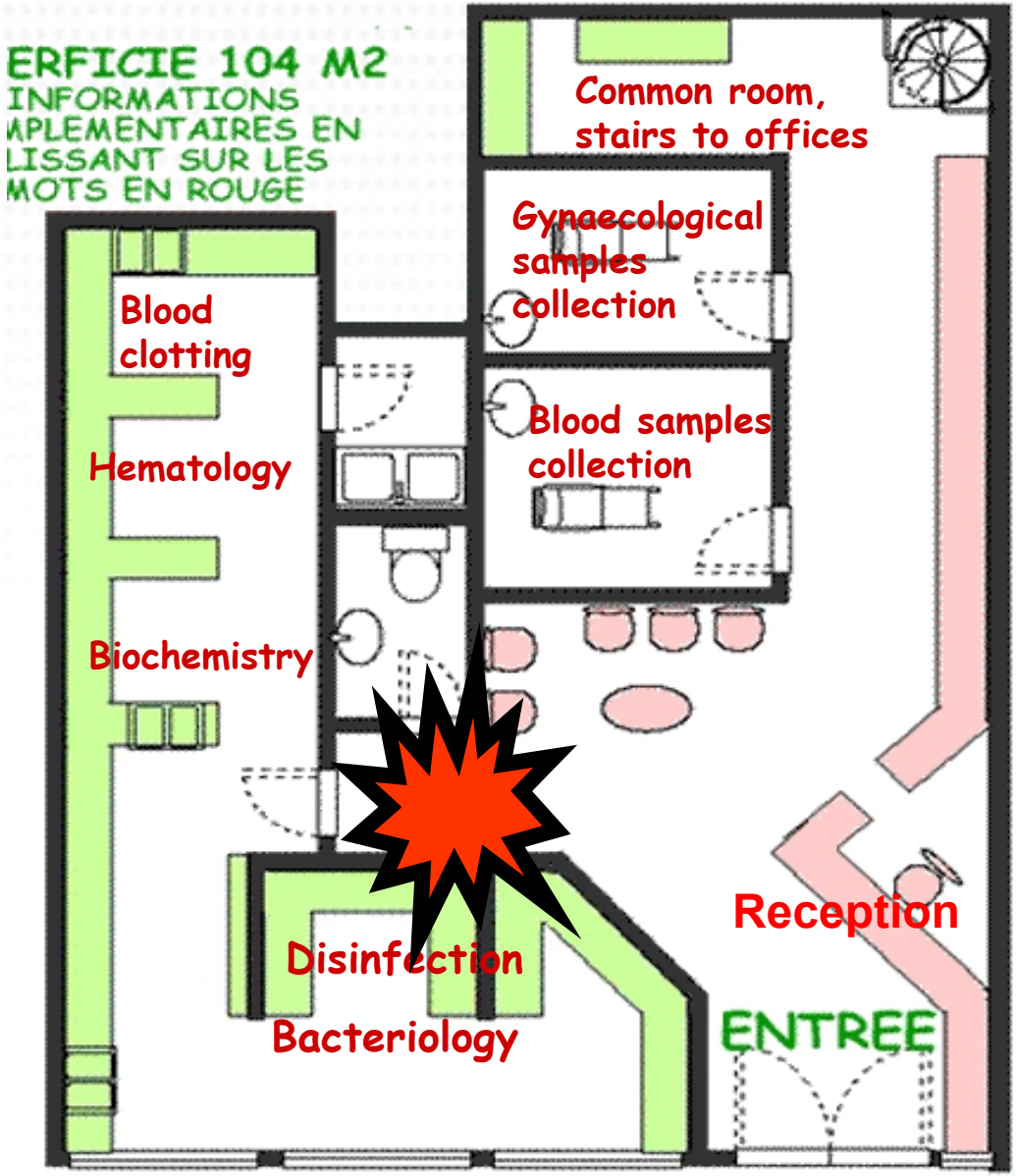
Common room, stairs to offices
Gynaecological samples collection
Blood clotting
Blood samples collection
Hematology
Biochemistry
Disinfection
Bacteriology

Sample

Laboratory Design



Waste

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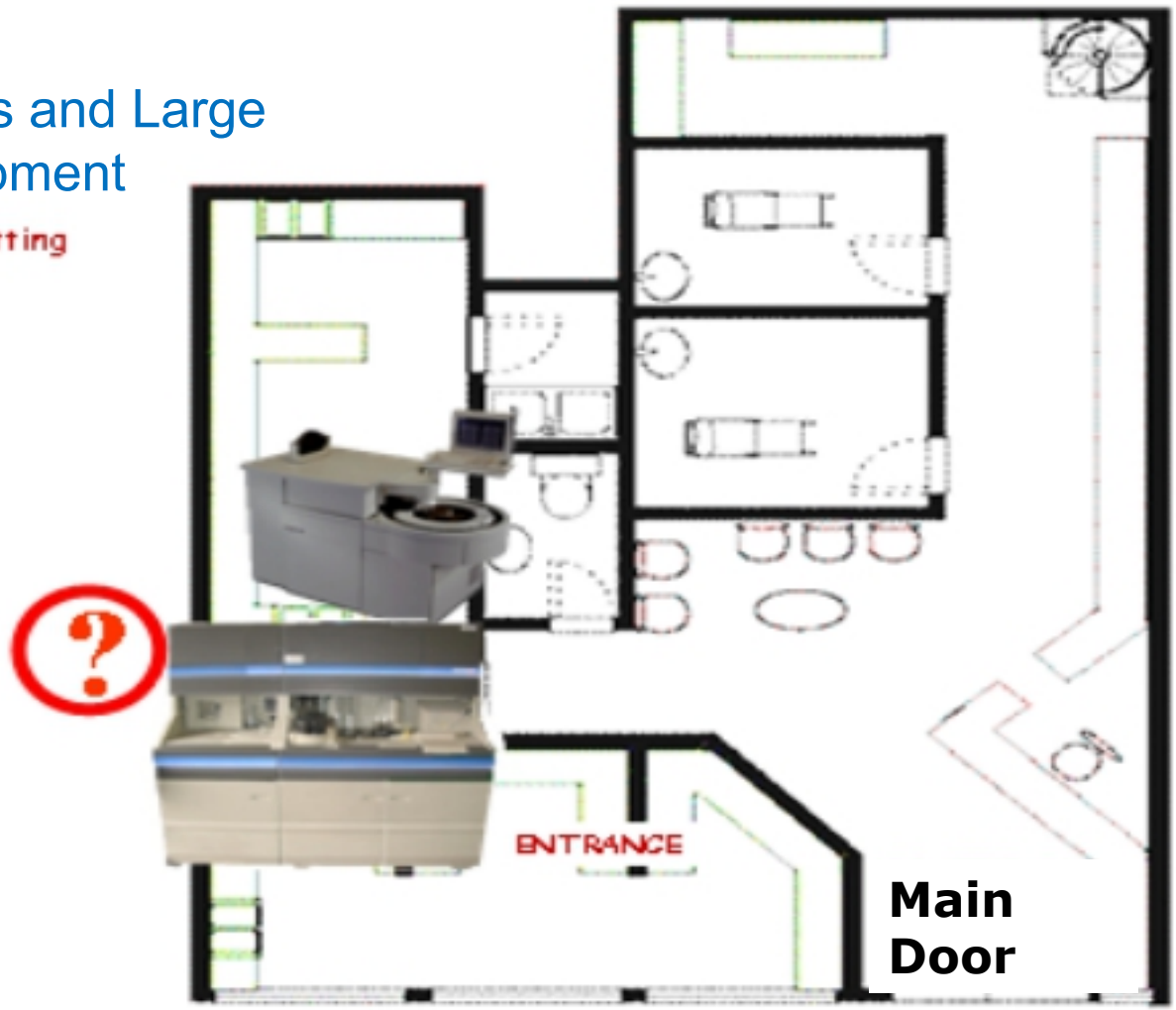
Doors and Large Equipment



Circulation pathways-----

- Post-examination pathways—for recording results.

Communication systems appropriate to the size and complexity of the laboratory

- **For the most efficient design, all related services should be located in close proximity.**

All diagnostic and health care laboratories must be designed and organized for **Biosafety Level 2** or above

3. Spatial/Space organization

Space organization

Delineation of laboratory activities—Group related activities in a single room

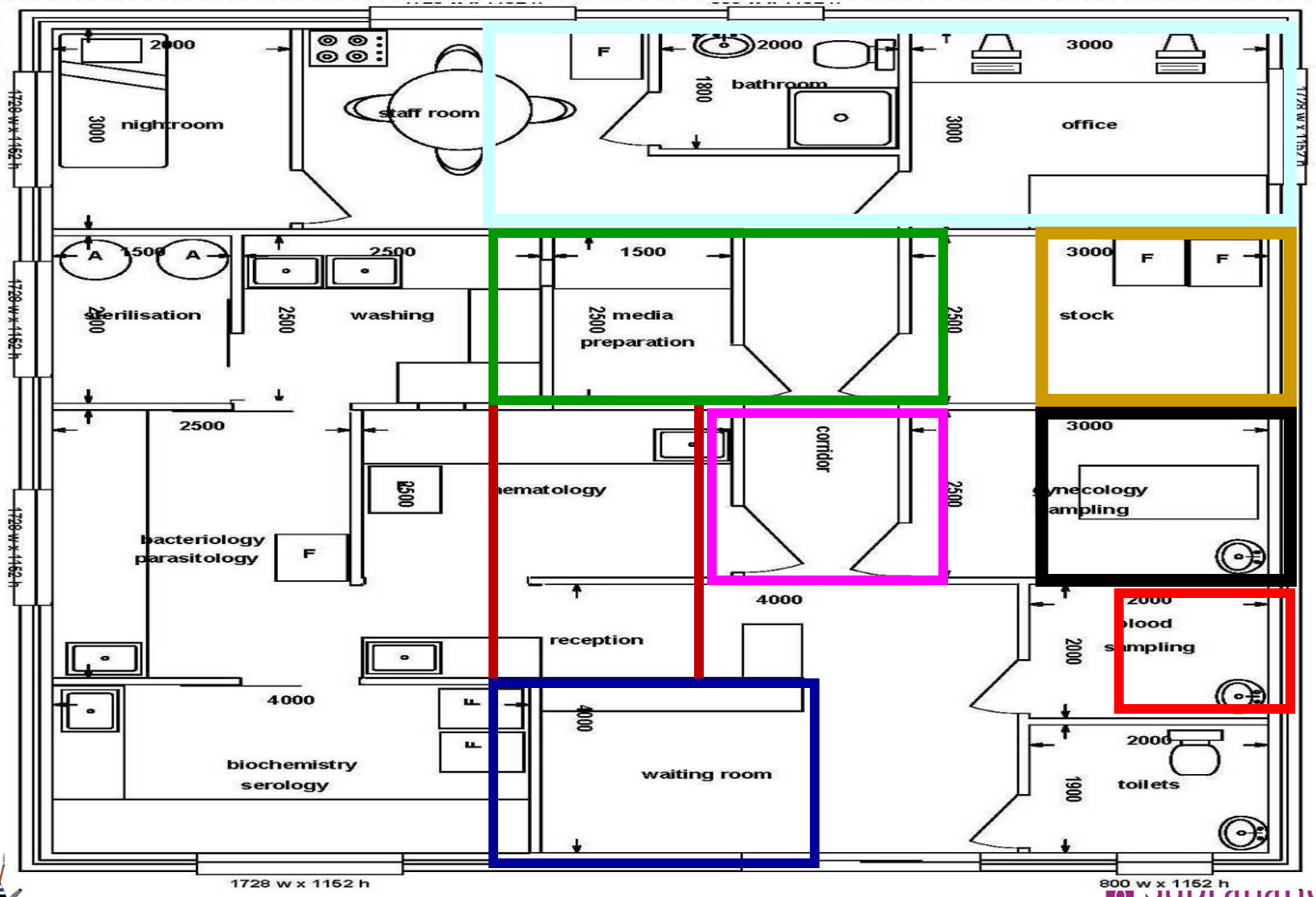
Location of service rooms—Service rooms for autoclaves, sinks, sterilization should be located in a central area

Space Organization

Location of activities with specific requirements, such as:

- molecular biology—needs to be located in a separate space, with at least two rooms, (DNA extraction and preparation of reagents, and DNA amplification)
- fluorescence microscopy—requires a dark room with proper ventilation;
- UV illumination systems for DNA gel photography—requires a dark room and appropriate eye protection equipment

Space organization - Segregated areas



Space organization - Sample Collection Room

Space organization - Stock room

4. Physical Aspects of Premises and Rooms

Physical Aspects - Facility

- Laboratory facility with proper ventilation throughout,
  - with an active ventilation system, and
  - adequate space for circulation of persons and laboratory carts and trolleys.

Physical Aspects - Room

- Room High ceiling with good ventilation

- Walls and ceiling
  - use washable, glossy paint
  - easy to clean and disinfect
- Floor
  - easy to clean and disinfect
  - No edges between the walls and floor

Physical aspects - Workbenches

- Constructed of materials that are durable and easy to disinfect.
- Wood should not be used, as it is not easy to clean or to disinfect
- Steel will rust when washed with chlorine, not good for benchtops

Physical Aspects- Workbenches

- Leave adequate space equipment and enough space to place SOP and job aids
- For microbiology procedures separate different types of samples or pathogens to minimize risks of cross-contamination.

Physical Aspects- Workbenches

Physical Aspects- Workbenches

Physical Aspects- Schedule Cleaning

- It is very important that all areas of the laboratory be cleaned and maintained on a regular basis.
  - Daily Cleaning

    Benchtops—Clean and disinfect benchtop
    - after completing examinations,
    - after any spills of samples or reagents.
  - This responsibility is generally assigned to the technical staff performing the tests.

Physical Aspects- Schedule cleaning

Daily Cleaning

floors

- These are usually cleaned by cleaning staff,
- unless restricted access allows only technical staff to disinfect the floors at the end of the day.

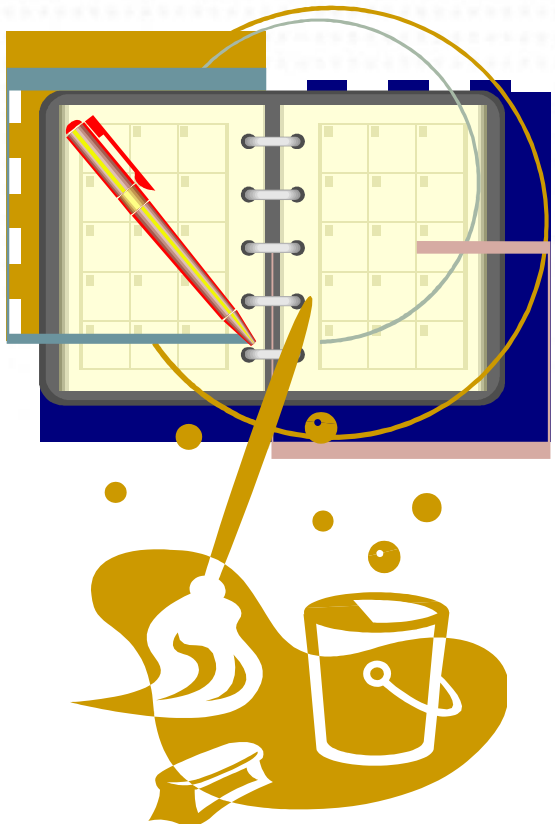
- Weekly cleaning
  - ceilings and walls

Monthly Cleaning

- refrigerators
- storage areas

- Cleaning and disinfection of laboratory areas should be recorded

- Include the date and name of the person performing the maintenance



5. Safety Management program

Safety management program

Developing a safety program and organizing appropriate safety measures for the laboratory is assigned to:

- laboratory safety officer.
- In smaller laboratories - laboratory manager or even to the quality officer.

Safety management program - Steps

Developing a manual to provide written procedures for safety and biosafety in the laboratory.

- Organizing safety / biosafety training and exercises
- Training includes
  - universal precautions,
  - infection control,
  - chemical and radiation safety,
  - personal protective equipment (PPE),
  - hazardous waste,
  - emergencies.

- Setting up a process to conduct risk assessments.
  - Initial risk assessments,
  - On-going laboratory safety audits to look for potential safety problems that can be corrected.

Safety management program - General safety equipment

The Safety Officer must ensure adequate supply of equipment for safety and biosafety

- personal protective equipment (PPE)
- fire extinguishers and fire blankets
- storage and cabinets for flammable and toxic chemicals
- eye washers and emergency shower
- waste disposal supplies/equipment
- first aid equipment.

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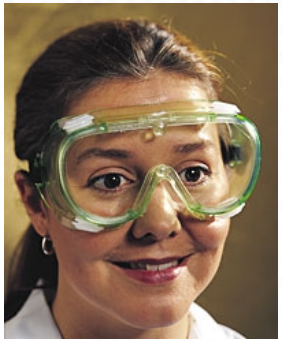
shower

eye washer

fire safety

PPE



waste disposal

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Standard safety Practices - Policies

Limiting or restricting access to the laboratory.

Washing hands after handling infectious or hazardous materials and animals, after removing gloves, and before leaving laboratory.

Prohibiting eating, drinking, smoking, handling contact lenses, and applying cosmetics in work areas.

Standard safety Practices - Policies

Using techniques that minimize aerosol or splash production when performing procedures.

Preventing inhalation exposure by using chemical fume hoods or other containment devices.

Properly storing chemicals according to

Standard safety Practices - Policies

Securing compressed gas cylinders at all times.

Decontaminating work surfaces daily.

Decontaminating all cultures, stocks, and other regulated wastes before disposal

Implementing and maintaining an insect and rodent control program.

Standard safety Practices - Policies

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.

Disposing of chemical, biological, and other wastes according to laboratory policies.

Standard safety Practices - Policies

DO NOT-

Standard safety Practices - Policies

- **Do -**

Procedures exercises – Fire Drills

Monthly and yearly exercises

- Safety officer to organize fire drills and laboratory evacuation procedures.
- Safety Officer to emphasize risks to laboratory staff and to review with them the specific procedures for evacuation, handling of incidents, and basic security precautions

Laboratory Waste Management

Laboratory waste management is a Critical issue.

- Treat harmful and dangerous materials (including liquids and radioactive materials before disposing.
- Separate waste containers for different waste, and must be clearly identified by a color code.
- For harmful contaminated waste such as sharps, needles, or broken glassware use Sharps containers

Internationally recognized labels

Figure 2. ISO 3864 safety sign formats (clockwise from top left): warning sign, prohibition sign, mandatory action sign, and safety information sign.

6. Identification of Risks

Why perform a risk assessment?

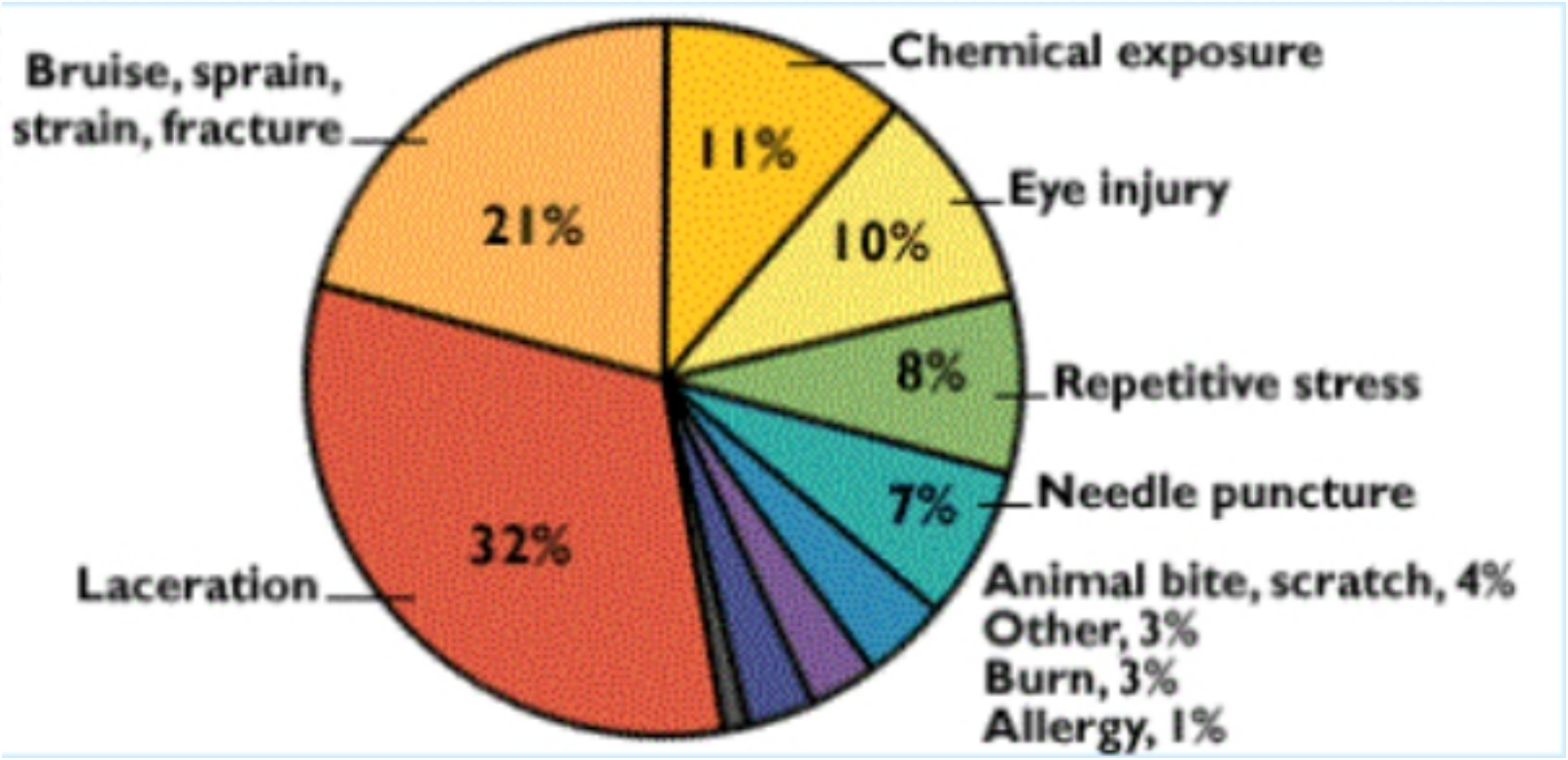
Identification of risks

- Laboratory workers encounter risks in significant numbers
- Risks vary with the types of activities and analyses that are performed.
- Risk assessment is compulsory to manage and reduce risks to laboratory employees.
- Safety officer to identify potential risks and incorporate appropriate preventive measures.

Identification of risks

- Develop safety procedures that describe what to do in case of accidents, injuries, or contamination.
- Keep a record of staff exposures to hazards, actions taken, procedures put into place to prevent recurrences.
- An outcome of a study of physical risks encountered by laboratory staff that was conducted by the Howard Hughes Medical

Research Employee Injuries (1993–1997)



Howard Hughes Medical Institute, Office of Laboratory Safety

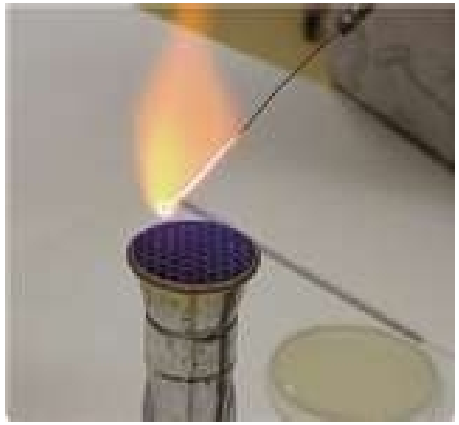
Laboratory Hazards

- Physical
- Chemical
- Biological

Physical Hazards

- Laboratory equipment – Examples autoclaves, centrifuges, compressed gas cylinders and fume hoods. – Training on specific safety procedure
- Many laboratory instruments pose a danger of electrical shock,
- Microwaves or radiation from some equipment if not properly used or maintained.
- Compressed gases stored in the laboratory requires safety precautions

Identification of Risks - Physical Hazards



Needles and Sharps

Need to be handled and disposed of appropriately to prevent risks of infection to laboratory and housekeeping (custodial) staff.

Proper disposal of sharps

- Needle recapping is not advisable or necessary.
- Put sharps in a puncture-resistant, leak-proof, sharps container.

Laboratory glass and plastic ware

- Are not considered to be sharps for disposal purposes
- Must be placed in sturdy cardboard boxes for safety during transport through the building.
- Contaminated laboratory glass must be appropriately decontaminated prior to

Never use boxes for the disposal of:

sharps;

biohazardous materials that have not been autoclaved;

liquid wastes;

chemically contaminated laboratory glassware / plastic ware;

- chemical containers that cannot be disposed of as regular solid waste.

Needles, Broken Glass, and Sharps

- Do not recap needles
- Always use puncture-resistant, leakproof, Sharps containers
- Always use specific waste disposal containers
- rok

Do you see anything wrong?

Do NOT reuse disposable injection equipment

Chemical Hazard

Exposure to toxic chemicals poses a real threat to the health and safety of laboratory staff.

Routes of entry into the body.

- Inhalation
- Absorption through skin.
- Ingestion

Chemical Hazard

To prevent or reduce incidents caused by exposure to toxic chemicals, all chemicals,

- Label with their common names, concentrations, and hazards.
- Label with date received, date opened, and date of expiration
- Store corrosive, toxic, and highly reactive chemicals in a well-ventilated area
- Store chemicals that can ignite at room temperature in a flammables cabinet.
- Specific storage areas for radioactive materials are needed.

Chemical Hazard

Biosafety Level 1 and 2 laboratories

Separate cabinets for storage:

- spill containment cabinet
- hazardous waste storage
- flammable liquids storage

Chemical Hazard

Material Safety Data Sheet (MSDS)

- The MSDS is a technical bulletin providing detailed hazard and precautionary information by the manufacturer
- Laboratories need to heed precautions listed in the MSDS in order to ensure the chemicals they use are handled and stored safely.
- Should be available to all employees prior to use of hazardous material
- Kept close to where hazardous material is located

The MSDS provides the following information:

- product information
- fire and explosion precautions
- toxicology
- health effects
- personal protective equipment (PPE) that is recommended
- storage recommendations
- leaks and spills—recommended actions
- waste disposal recommendations
- first aid.

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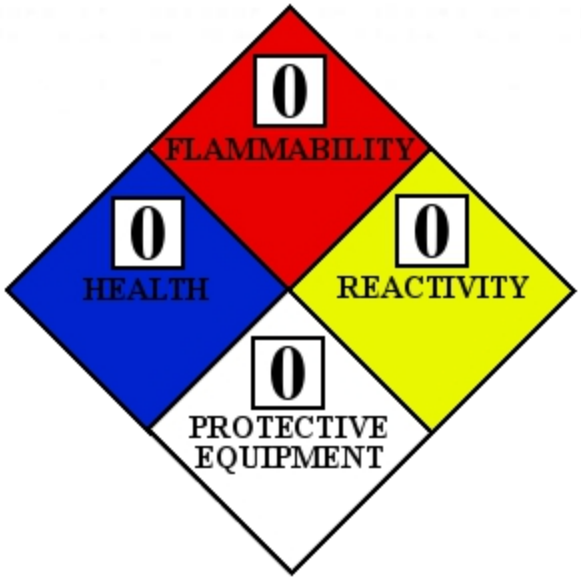
Material Safety Data Sheet (MSDS)



Biological hazard

Laboratory-acquired infections are not infrequent in medical laboratories

- Aerosols are the main sources of contamination; can occur over very long distances.
- Major target of containment systems is the blockage of aerosol diffusion in and outside the laboratory

The risks for workers

- most frequently reported infections in US, 1979-1999

Disease or Agent	No. of Cases
Mycobacterium tuberculosis	223
Q fever	176
Hantavirus	169
Hepatitis B virus	84
Brucella sp.	81
Salmonella sp.	66
Shigella sp.	56
Hepatitis non-A, non-B	28
Cryptosporidium sp.	27
Total	1074

Identification of Risks – Biological Hazard

- Containment level 2 for activities for pathogens of moderate risks
- Higher containment level laboratories must ensure a continuous inward air flow, absolute filtration of exhausted air, to avoid aerosol dissemination outside the working area and/or the whole laboratory.

Risk Identification - Biological Hazards

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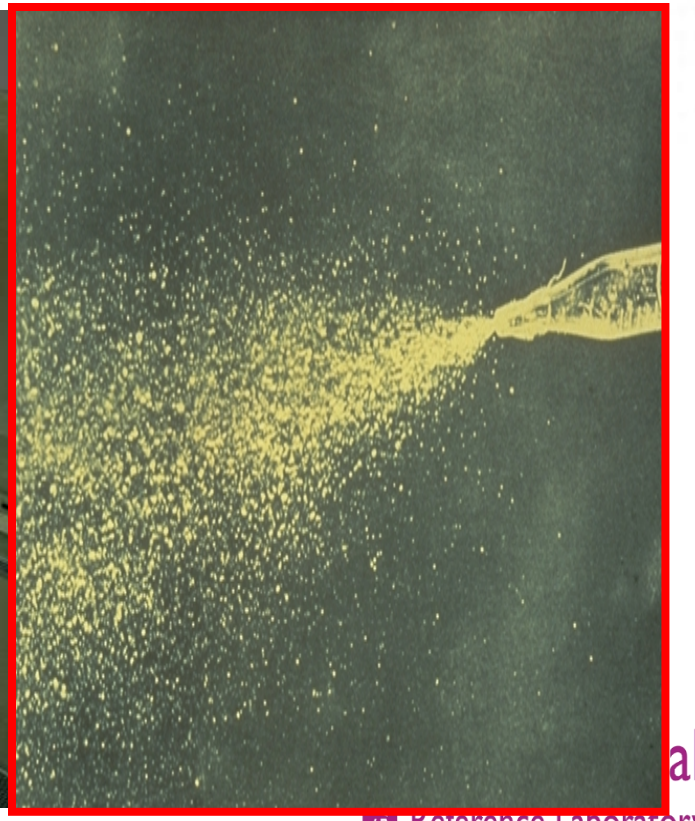
Aerosols and droplets are the main sources of contamination

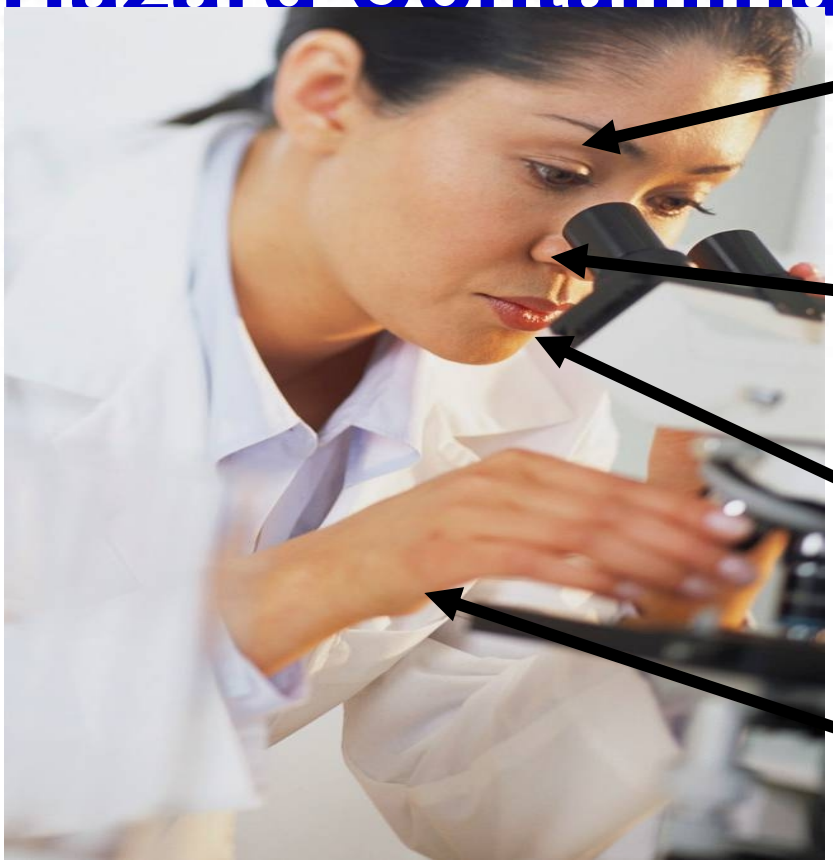


Risks identification – Biological hazard
Single-source, multiple laboratory infections

Reitman and Wedum, 1956

Disease	Probable Source	Max Distance from Source	Number Infected
Brucellosis	Centrifugation	Basement to 3rd floor	94
Coccidioidomycosis	Culture transfer solid media	2 building floors	13
Coxsackie Virus infection	Spilled tube of infected mouse tissue on floor	5 feet estimated	2
Murine Typhus	Intranasal inoculation of mice	6 feet estimated	6
Tularemia	20 Petri plates dropped	70 feet	5
Venezuelan encephalitis	9 lyophilized ampoules dropped	4th floor stairs to 3rd or 5th floor	24

Identification of Risks – Biological Hazard Contamination Routes



Ocular invasion

Inhalation

Ingestion

Skin penetration

Personal Protective Equipment (PPE)

PPE

The major routes in which laboratory staff acquire work-related infections are:

- inhalation of aerosols generated by accident or by work practices;
- percutaneous inoculation;
- contact between mucous membranes and contaminated material;
- accidental ingestion.

PPE

To reduce the risk of these occurrences

- Staff should have access to personal protective equipment (PPE),
- Be trained in how to properly use it, use it habitually
- Goggles, face shields, splatter guards, masks, or other eye and face protection should be worn when handling infectious/hazardous materials

PPE

Hand protection

Gloves should be worn in all instances, and be available to laboratory staff on a routine basis.

1. Remove gloves after work to prevent contamination of telephone, door handles, and pens.
2. Never re-use gloves.
3. Do not wash or decontaminate gloves — they develop microcracks, become more porous, and loose their protective properties.
4. After use, gloves **must** be disposed of in the contaminated waste

PPE

Face Protection -Goggles

- Droplets occur when opening patient sample containers.
- Use of goggles will protect eyes from these droplets.
- Manipulate the specimen tubes behind a screen, glass or plexiglass, or face shield.
- Contact lenses do not offer protection from splashes.
- **Masks**—Masks serve as a barrier when splashes or sprays occur.

PPE

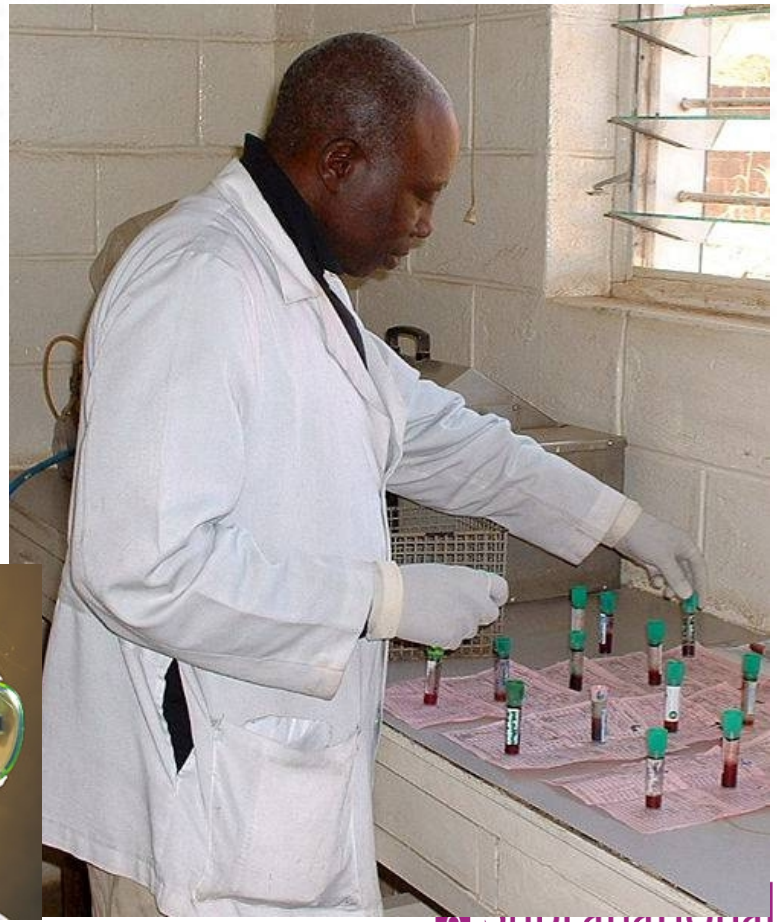
Body Protection – Lab coats

- **Lab coats** are compulsory in the level 2 laboratory.
- A disposable laboratory coat is compulsory in level 3 laboratories or in specific instances such as sample collection when highly dangerous pathogens can be involved, such as
  - H5N1 avian influenza or
  - severe acute respiratory syndrome (SARS).

Personal Protective Equipment

BSL 1 and 2

- laboratory coat
- gloves
- goggles or face shield
- masks
- hearing protection



8. Emergency management and First Aid

Emergencies

Should have written procedures (SOPs) in place on how to deal with accidents and emergencies.

Laboratory Emergencies include

- Chemical spills
- Biological spills
- Laboratory fires

Emergencies- Chemical Spill

The recommended steps for dealing with a minor spill include:

alert coworkers, then clean up spill;

follow procedures for disposal of materials used to clean up spill;

absorb free liquids with an appropriate absorbent, as follows:

- caustic liquids—use polypropylene pads or diatomaceous earth;
- oxidizing acids—use diatomaceous earth;
- mineral acids—use baking soda or polypropylene pads;
- flammable liquids—use polypropylene pads.

Emergencies- Chemical Spill

- neutralize residues and decontaminate the area.
- Anything beyond a minor spill and requiring help from outside of the laboratory group constitutes a **major** spill. Steps to deal with major spills include alerting
- co-workers, moving to a safe location, and calling authorities to report the situation

Emergencies- Chemical Spills

- anything beyond a **minor** spill and requiring help from outside of the laboratory group constitutes a **major** spill

Emergencies - Biological spills

When **surfaces are contaminated** by biological spills, the appropriate actions to take are:

1. define/isolate the contaminated area;
2. alert co-workers;
3. put on appropriate PPE;
4. remove glass/lumps with forceps or scoop;
5. apply absorbent towel(s) to the spill; remove bulk and reapply if needed;

Emergencies - Biological spills

6. apply disinfectant* to towel surface;

7. allow adequate contact time (20 minutes);

8. remove towel, mop up, and clean the surface with alcohol or soap and water;

9. properly dispose of materials;

10. notify the supervisor, safety officer, and other appropriate authorities.

Emergencies – Biological Spill

Disinfectant:

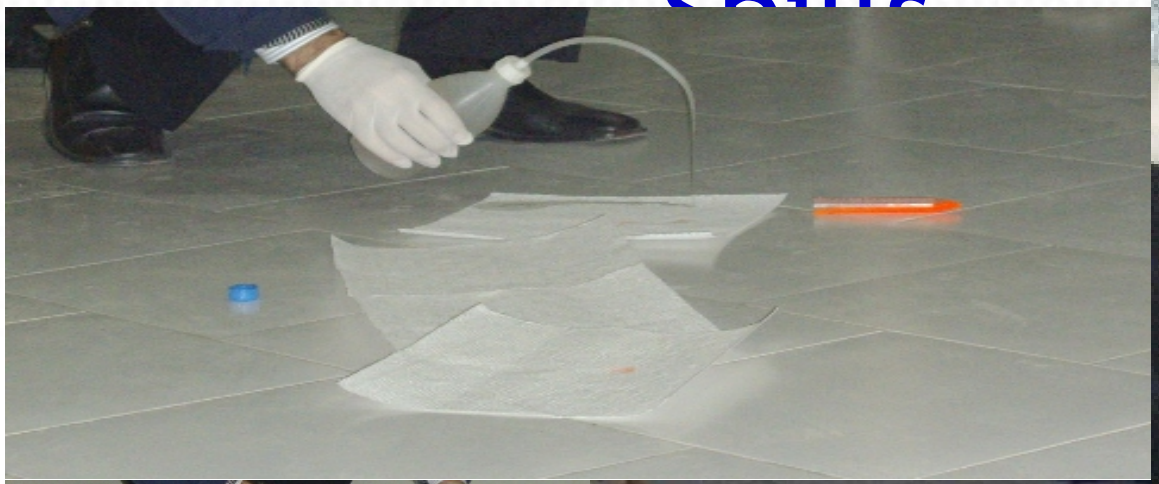
- For most spills, use a 1:100 solution of household bleach (hypochlorite).
- For spills containing large amounts of organic material, use a 1:10 solution of household bleach, or an approved mycobactericidal.
- Alcohols are not recommended as surface decontaminates because they evaporate quickly, thus decreasing “contact time”.

Emergencies – Biological Spill

If **laboratory personnel become contaminated** with biological hazards due to splashes or spills, immediate steps to take include:

1. clean exposed skin or body surface with soap/water, eyewash (for eye exposures), or saline (for mouth exposures);
2. apply first aid and treat as an emergency;
3. notify supervisor, safety officer, or security desk (after hours);
4. follow appropriate reporting procedures;
5. report to physician for treatment/counseling.

Emergencies -Biological Spills



Emergencies - Laboratory fires

- Alert for conditions that might pose a risk for fires.
- Liquids with low flash points may ignite if near heat sources such as hot plates, steam lines, or equipment that produce a spark or heat.
- A small laboratory fire is extinguishable within 1-2 minutes. The appropriate action to take is to cover the fire with an inverted beaker or wet paper towels. If this fails, use a fire extinguisher.
- For large fires, call the appropriate local authorities, usually the fire department and the

Emergencies -Laboratory Fire Safety

Learn how to operate a portable fire extinguisher

Assessment

1. Why is infrastructure arrangement key in assuring laboratory safety
2. Who is responsible for safety in the laboratory
3. What measures should be in place to ascertain safety

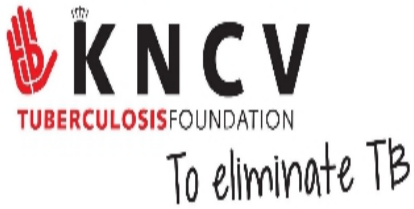
Summary

- When designing a laboratory or organizing workflow, ensure that patients and patient samples do not have common pathways
- Neglecting laboratory safety is costly.
- It jeopardizes the lives and health of employees, patients, laboratory reputation, equipment, and facilities.

References

- ISO 15190:2003 Medical Laboratories — Requirements for safety
- ISO 15189:2012 Medical Laboratories - Requirements for Quality and Competence
  « Clause 5.2. »
- CLSI
- ASLM

Acknowledgement



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