دانشگاه علوم پزشکی و خدمات بهداشتی درمانی کردستان

کارگاه آموزشی سیستم مدیریت کیفیت در آزمایشگاه های تشخیص پزشکی بر مبنای ISO 15189:2022

سنندج

۳۱ مرداد و ۱ شهریور ۱۴۰۳

Laboratory Quality Management System

ISO 15189-2022

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Aug. 2024

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Facilities and Safety

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Laboratory accidents: Primary effects

Some of the main reasons why attention to proper facility and safety management is so important are to prevent:

- **Laboratory acquired infections**
- **Accidental release or spread of infectious pathogens**
- **Injury**
- **Damage**

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Laboratory accidents: Secondary effects

Some of the main reasons why attention to proper facility and safety management is so important are to prevent:

- **Neglecting laboratory safety can be costly, both in terms of reputation and financially. Secondary effects:**

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Who is responsible for safety and quality?

Everyone!

- A team of lab professionals educated on ways to promote a safe work environment and motivated to follow through on this goal is critical.
- When it comes to ensuring safety in any lab, everyone is responsible.

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Laboratory hazards

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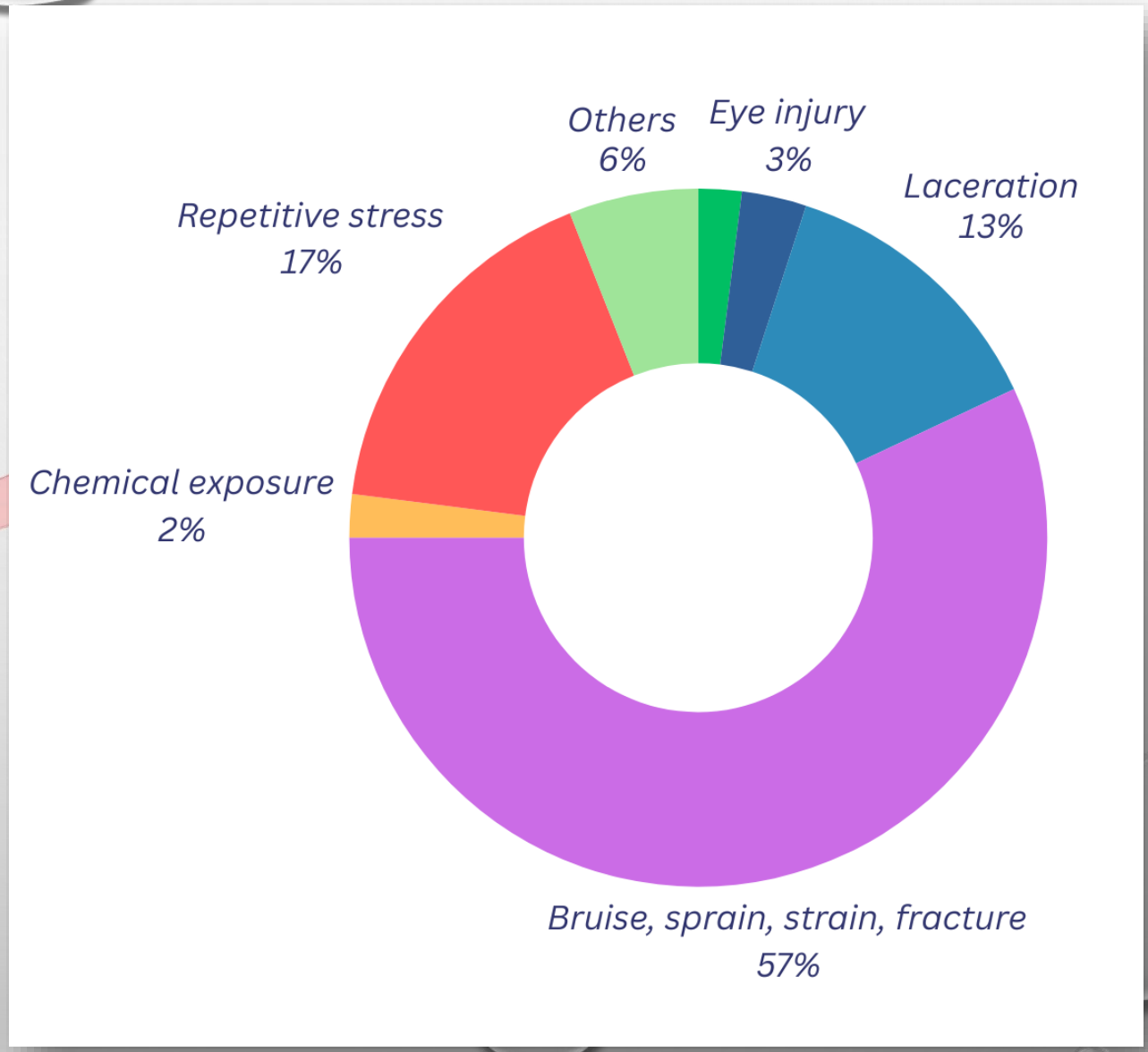
Physical hazards

laboratory injuries



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Physical hazards

- Physical hazards are responsible for the majority of injuries occurring in lab (57%).
- Often, the perceived biggest hazards in the lab, biological hazards and chemical exposure, are responsible for a relatively small part of the injuries actually occurring in the lab environment (2%, 2%, 3%).
- Repetitive stress (17%) is the second biggest risk for lab workers due to the nature of lab work, which involves a lot of repetitive movements (e.g. pipetting).
- Laceration (13%) ranks as the third biggest risk because the work in the lab involves a lot of sharps handling.

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Chemical hazards

Chemical storage

- **These hazards can be prevented with the use of appropriate cabinetry to store different types of chemicals.**

Should be built with high edges to keep leaking chemicals inside.

Well ventilated cabinets are required to remove hazardous fumes.

To safely store flammable liquids, you must install cabinets especially designed to delay fire from reaching chemicals.

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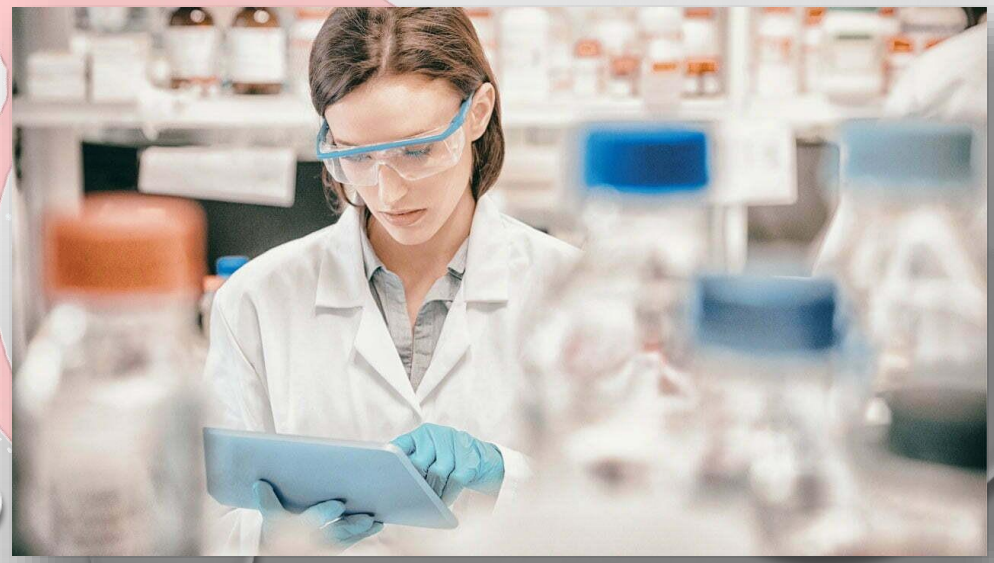
Material Safety Data Sheets (MSDS) (SDS)

- In every storage area, the lab is advised to have a folder with MSDS for all the chemicals stored in that area.
- MSDS (SDS) provides all the necessary (safety) information for a chemical.
- MSDS (SDS) should be prepared on the local language.



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Biological Hazards

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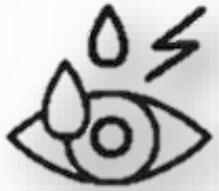
Contamination Routes

- Ocular invasion
- Inhalation
- Ingestion
- Skin penetration



- Aerosols and droplets are the main sources of contamination and are a biological hazard in the lab.

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Laboratory Design

- All diagnostic and health care laboratories must be designed and organized to take biosafety into account.
- As soon as the lab handles living microorganisms, it should be designed with biosafety in mind.
- An important factor that should be taken into account in designing the lab building and rooms is the **Path followed by a sample**:

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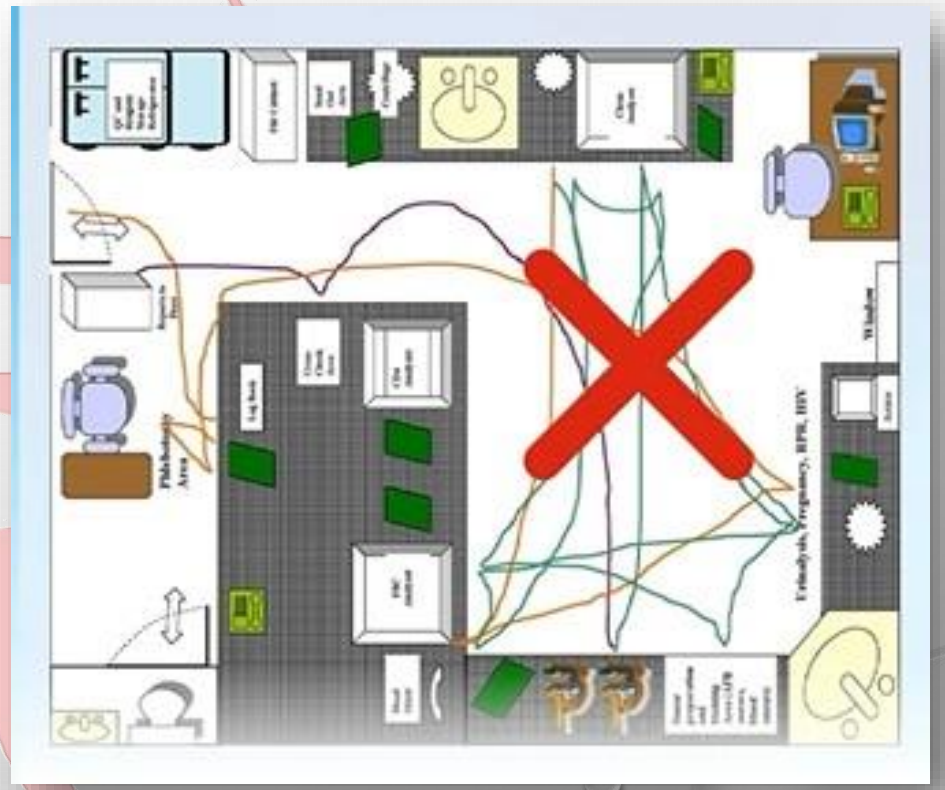
Laboratory Design

Spaghetti Diagram

- The path followed by a sample should cross itself as little as possible.
- It is good exercise to make a spaghetti diagram in which you visualize the path followed by a sample on a map of your lab building.



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Laboratory premises

- The basic materials for lab premises:
- Ceilings: should be high and have good ventilation.
- Walls and ceilings: should be covered with washable, glossy paint which should be easy to clean and disinfect.
- Floors: should be made of material that is easy to clean and disinfect.

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What is the best material for the benchtop surface?

The best lab workbenches are made of phenolic resin or epoxy resin.

Phenolic resin or epoxy	Benchtops should be made of non-porous material. Easy to clean and resistant to chemicals and disinfectants. These materials have excellent chemical, heat, impact, and bacteria resistance.
Ceramic tile	Workbenches made of tiles are frequently used, but not recommended! Because the joints between the tiles are porous and cannot be cleaned properly. Moreover, tiles are poorly impact resistant.
Wood	Wood should not be used as a benchtop, as this material is porous.
steel	Should not be used as a benchtop surface because it is not resistant against certain chemicals such as chloride.

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General safety practices

DO		DON'T	
Apply appropriate hand washing techniques	Use effective personal protective equipment (PPE)	Smoke in the laboratory	Apply make-up in the laboratory
Wash hands as often as needed, at least when leaving the laboratory room	Segregate biohazardous waste	Use your cell phone in the laboratory	Eat and drink in the laboratory
Put safety chains around gas cylinders to prevent them from falling over			

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Safety equipment

As part of general safety practices, safety equipment is indispensable in the laboratory and includes the following:

- Personal Protective Equipment (PPE)
- Showers
- Eye washer
- Fire safety equipment
- Waste disposal containers

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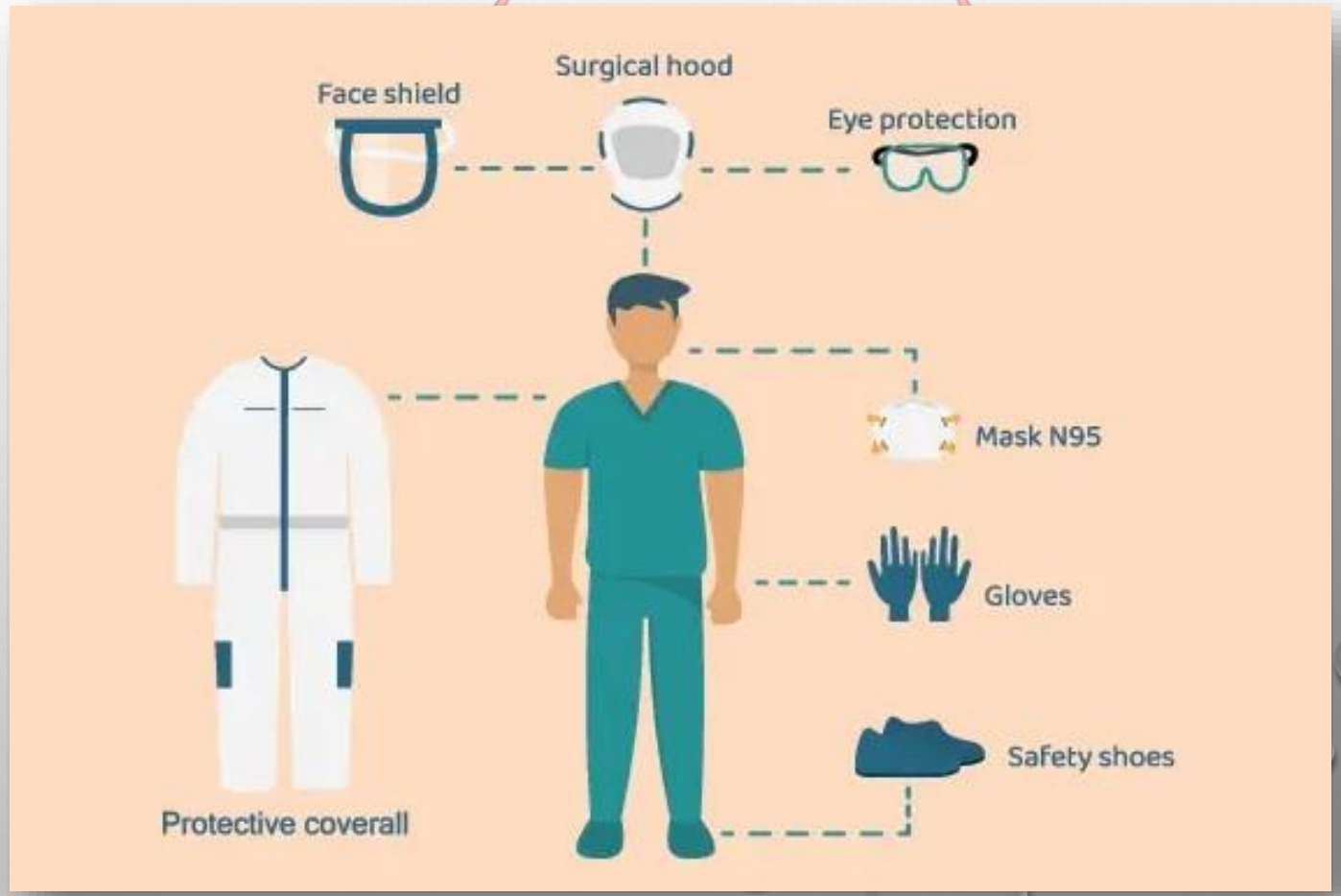
Personal Protective Equipment (PPE)



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Personal Protective Equipment (PPE)

In clinical and diagnostic laboratories, the following PPE should be used:

- **Safety Goggles or Glasses**
- **Lab coat or long sleeves**
- **Gloves**
- **Long pants**
- **Closed-toe Shoes**

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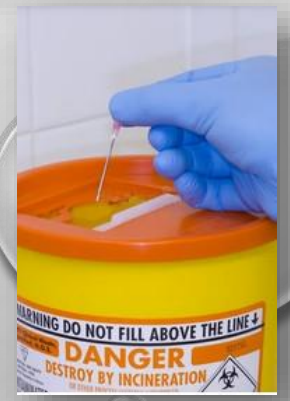
Other laboratory safety concerns

There are many potential dangers in the laboratory.

- Workers must be informed of the proper procedures for dealing with fire and handling glass, needles, and sharps.

Fire	• Knowing how to operate a portable fire extinguisher. • The lab should train all staff. • The lab should regularly service its extinguishers to ensure that they stay proper in working condition.
Glass	• Never directly handle broken glass • Use cardboard to pick up glass from the floor • Always use appropriate waste disposal containers
Needles and sharps	• Do not recap needles • Always use puncture – resistant sharps containers • Always use specific waste disposal containers



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Safety signs

- **Every entrance in the laboratory should have signs to inform people entering a specific room about the hazards present in that room. (ISO 3864)**

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Safety management

Managing a safe laboratory with adequate facilities is hard work. A great deal needs to be arranged to keep everything running smoothy.

Appoint a (bio)safety officer	• Somebody who may be held responsible for coordinating all management activities. • The lab should make a lab-specific biosafety manual containing SOP related to safety practices and equipment.
Have a through training program in place	• For all lab staff • About risks present in the lab and how to adhere to safety procedures.
Establish proper waste segregation procedures	For management of chemical, biological, and general waste.

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5.6 Risk management

a) Laboratory management shall establish, implement, and maintain processes for identifying risks of harm to patients and opportunities for improved patient care associated with its examinations and activities, and develop actions to address both risks and opportunities for improvement .

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5.6 Risk management

b) The laboratory director shall ensure that these processes are evaluated for effectiveness and modified, when identified as being ineffective.

Note 1: ISO 22367 provides details for managing risk in medical laboratories.

Note 2: ISO 35001 provides details for laboratory biorisk management.

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The Risk assessment frame work

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(Bio) Risk assessment

Besides implementing general safety equipment, practices and procedures, the laboratory should also conduct a thorough biorisk assessment to identify all the laboratory-specific risks.

- **To identify all the laboratory- specific risks.**
- **This will provide information on how to eliminate these risks, or implement proper mitigation measures to decrease these risks, and make the lab even safer and more secure.**

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(Bio) Risk assessment

Risk assessment can be performed to evaluate the:

- **Biological agents that exist at the facility**
- **Facility processes and procedures**
- **Bio-risk mitigation measures already in place**
- **Potential adversaries of the facility**

(specifically related to biosecurity).

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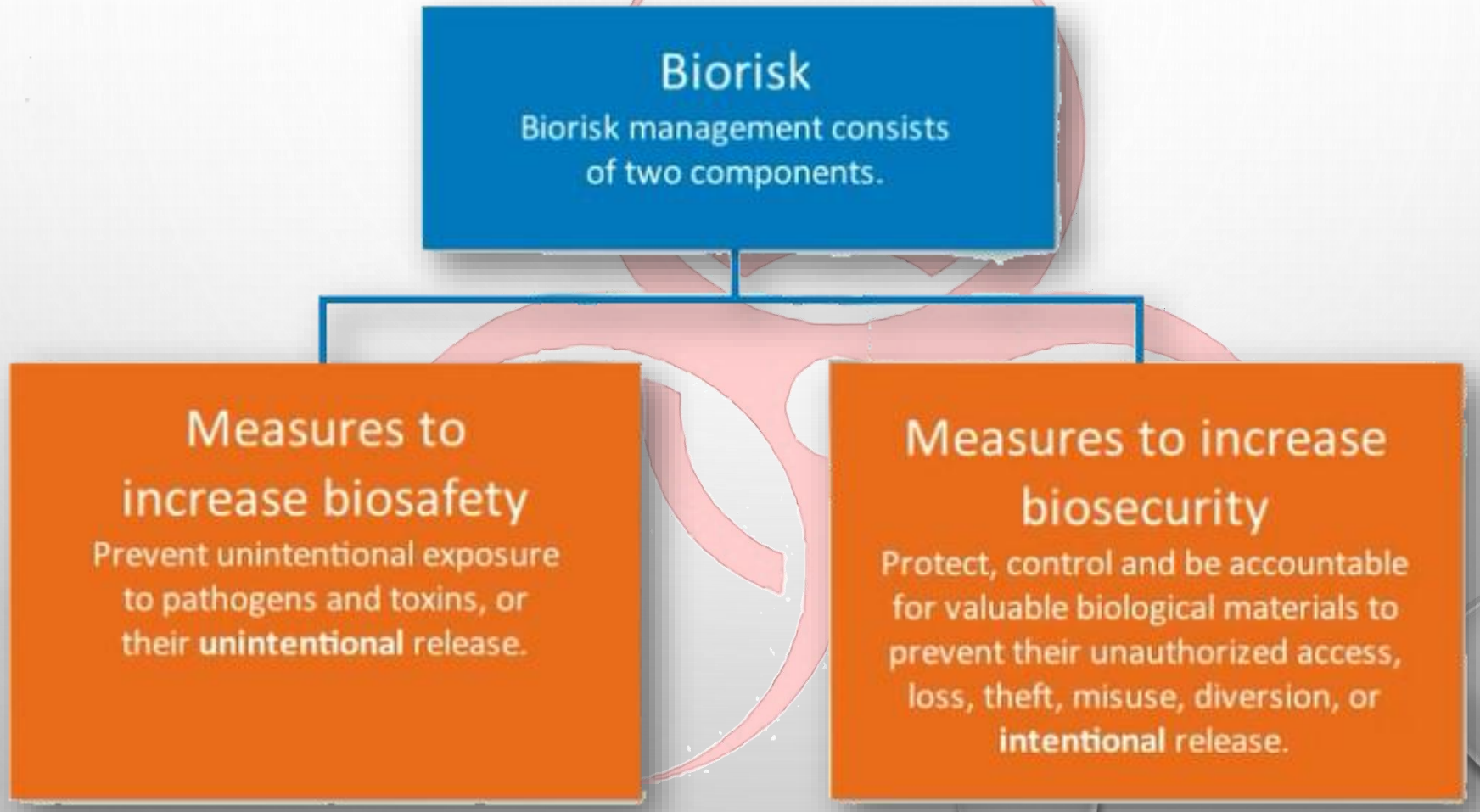
Bio-Risk Management



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Think about it…

Consider this scenario:

A two-year-old child is left alone in a kitchen while there is boiling water on the stove.

- **What could go wrong?**
- **What do you think is the single most important risk for this scenario?**
- **What is the hazard for that risk?**

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Biorisk assessment-definitions

Hazard

A source of object that can cause harm.

Risk

The likelihood of an event with a hazard that has consequences, in other words:

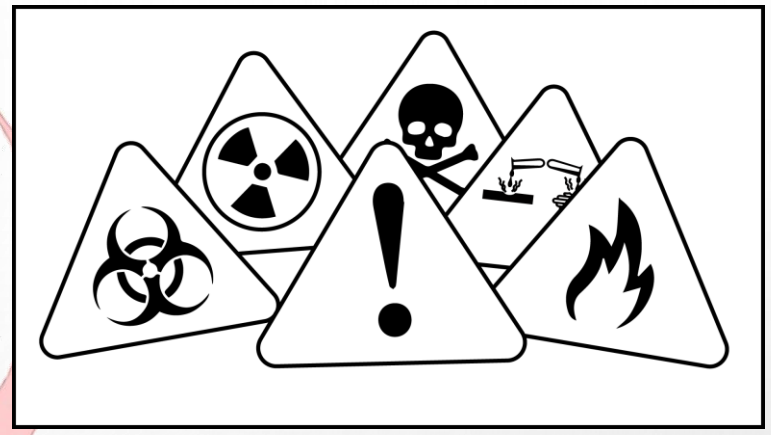
Risk= Likelihood X Consequence

Likelihood

The probability of an event occurring

Consequence

The severity of an event



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What do you think?

Back to the scenario

What is the risk and hazard for this child left alone with boiling water in the kitchen?

Risk: Child being burned by the boiling water

Hazard: pot of boiling water on the stove

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Bio-risk assessment - Approach

For each pathogen handled in the laboratory:

- **Risk identification:**

Identify all risks related to the pathogen, process, and procedures.

- **Hazard identification:**

Identify all the hazards in a procedure.

- **Likelihood evaluation:**

Estimate the likelihood that a risk indeed leads to an accident.

- **Consequences evaluation:**

Estimate the severity of consequences if the risk indeed leads to an accident.

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Bio-risk assessment – Method and Outcome

- It is best to do risk assessment using a specific framework or software.
- Risk assessment software especially developed for clinical and public health labs is available for purchase on the internet.
- Once the risks are assessed, you need to decide your response:

Eliminate	First, if the risks outweigh the benefits of doing an activity, it is wise to stop the activity.
Replace	If it is not possible to stop the activity, the lab is advised to investigate if it is possible to replace the high risk pathogen/material with an alternative pathogen/material that has lower risk.
Mitigate	If the replacement is not possible, the lab should implement all the necessary mitigation measures.

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Mitigation measures

INCLUDE:

- **Engineering controls**

Introduction of equipment and improving facilities to mitigate safety and security risks.

- **Administrative controls**

Improving the way things are organized responsibilities and authorities.

- **Practices and procedures**

Implementing additional practices and procedures to mitigate safety and security risks.

- **Personal Protective Equipment**

Implementing the use of specific PPE to mitigate safety risks.

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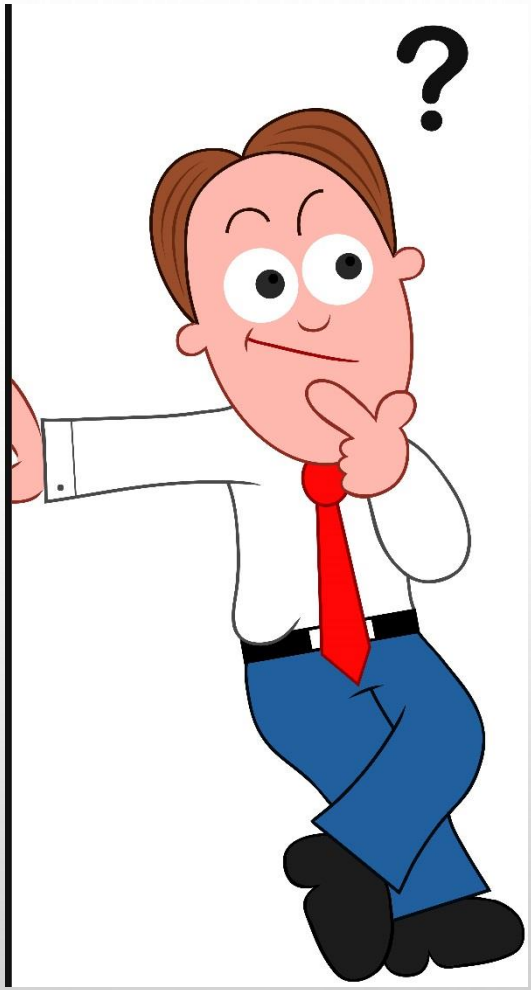

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Thank you for Your Attention…