



Biosafety Standards and Common Protocols in Lab Animal Science

Guglielmo Vismara



TOPICS

- **Principles of biosafety: risk classification and assesment**
- **Primary and Secondary barriers: examples**
- **Biological risk inside the Animal lab: evaluations and examples**
- **Biosafety cabinets: principles and good practices**
- **Design of Biocontainment Labs**



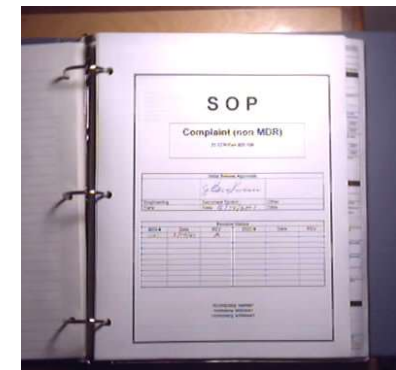
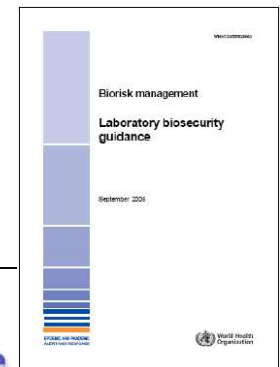
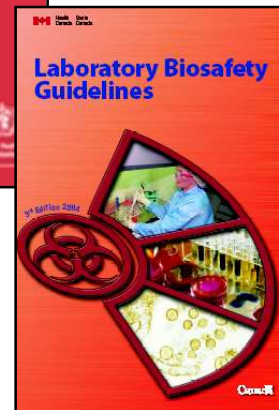
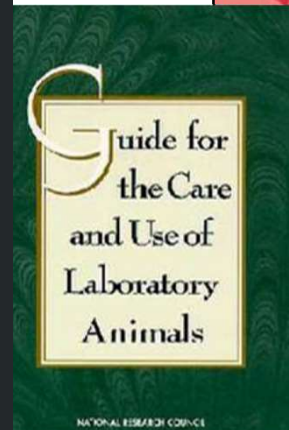
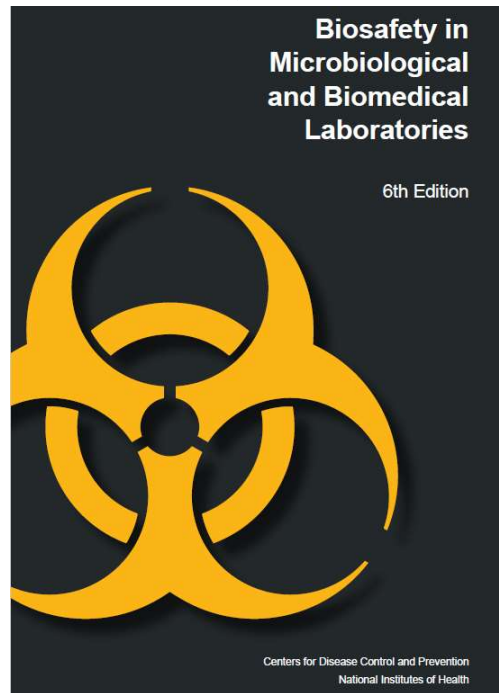
1. Principles of Biocontainment

- **Biological risk:** risk associated to biological agents
Microorganisms, Animals manipulation, Allergens...
- **Invisible risk**, it could be underestimated
- It must be assessed by experienced and responsible people (**biosafety officer**), for evaluation of the optimal working conditions
- **Risk = probability of accident x consequence of accident**
- The risk is **always present**. It can be minimized but never eliminated at all
- The **prevention is multi-factorial**: building construction, equipment, procedures, training of personnel are all important and all to be evaluated



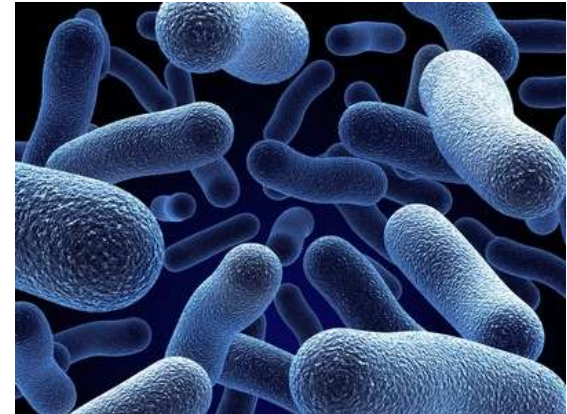
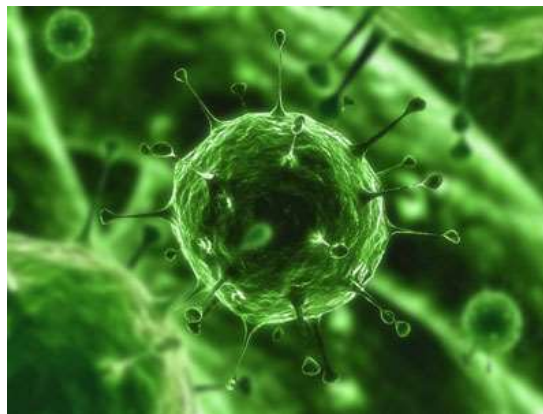
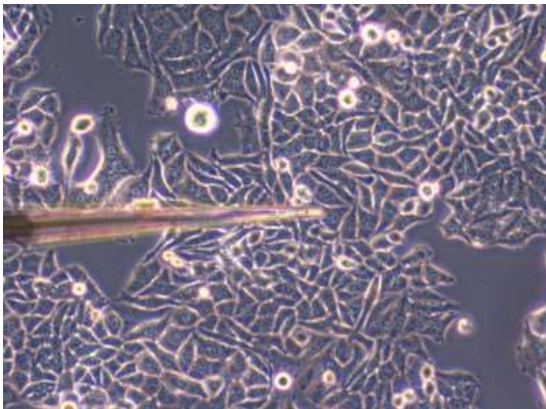
Guidelines - References

BMBL 6th Edition (CDC/NIH) – 2020 Update

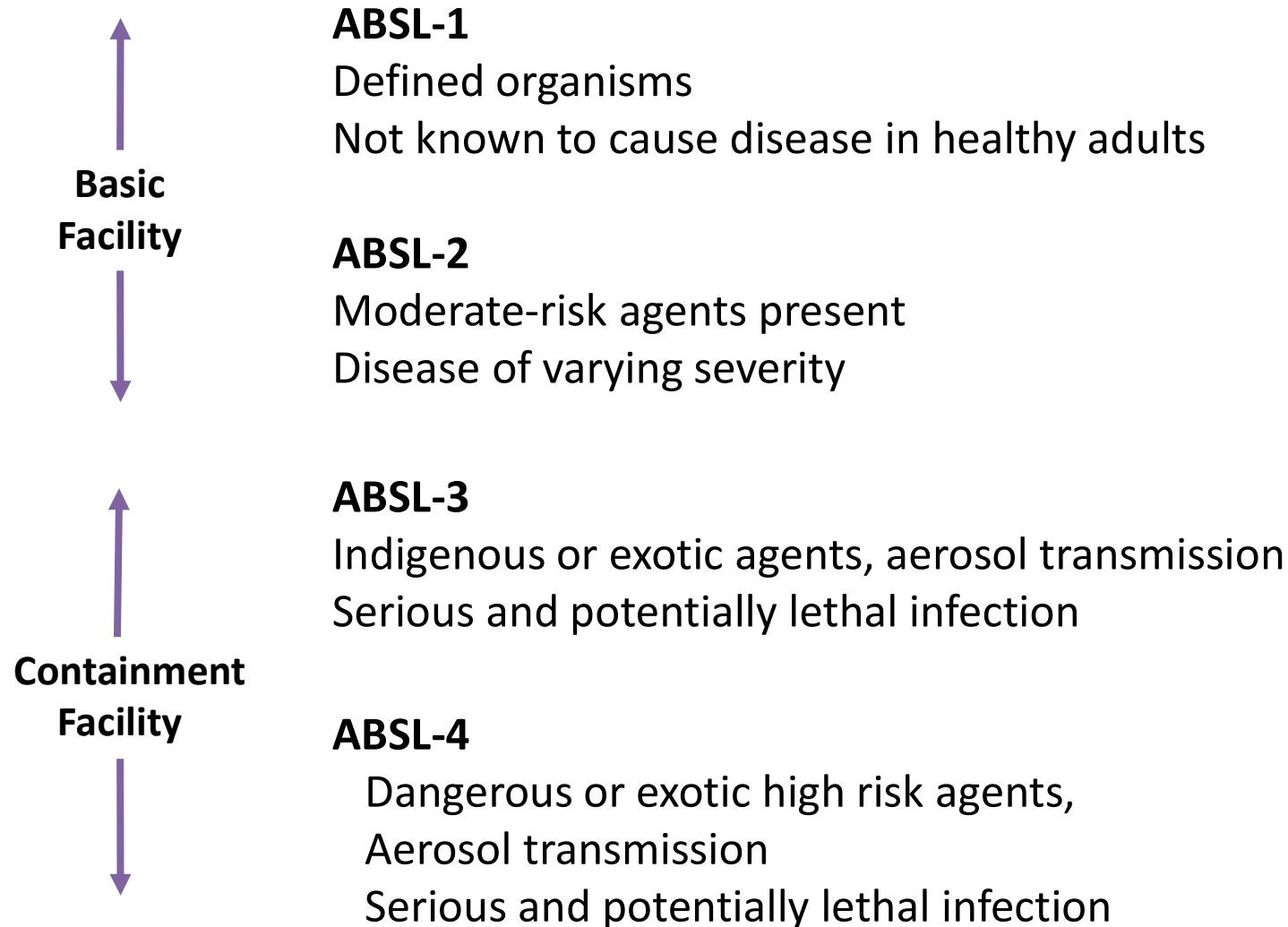


The biological agents risk classifications

- **Micobacterium Tuberculosis:** level 3 (CDC-NIH)
- **Avian Influenzae H5N1:** level 2/3 (CDC), level 3 (NIH)
- **Human adherent cancer cells:** generally level 2
- **Herpes, Papilloma, Citomegalovirus:** level 2



The Risk is Classified – The Lab is Classified



Risk Assessment

Evaluation of the risk



Multiple Factors



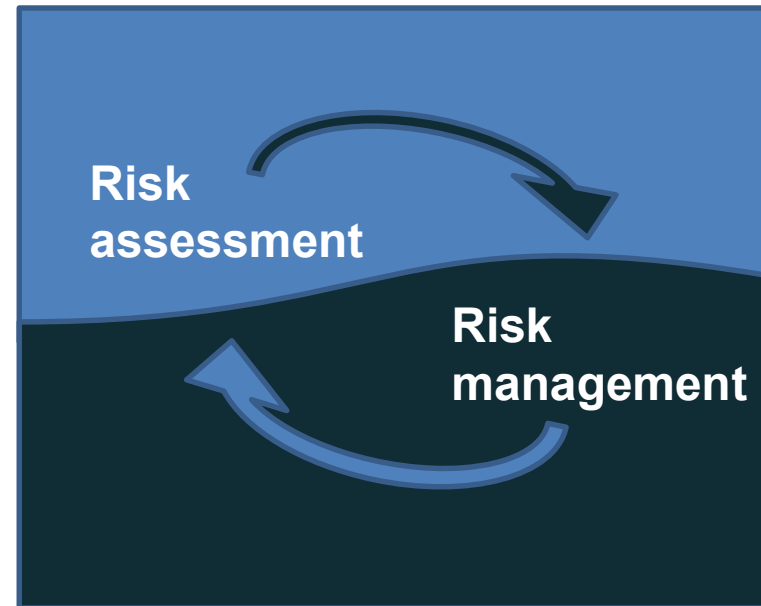
Management of the risk



Validation and surveillance



Corrective actions



Risk Management- examples

- 1) **Prevention:** decreases the probability of accidents.
Training to personnel, choice of the right equipment, room ventilation,...
- 2) **Protection:** reduces the damage magnitude.
PPE, equipment, SOPs...
- 3) **Managing the emergencies**
First aid protocol, SOPs, training to people

Example: personnel heart attack

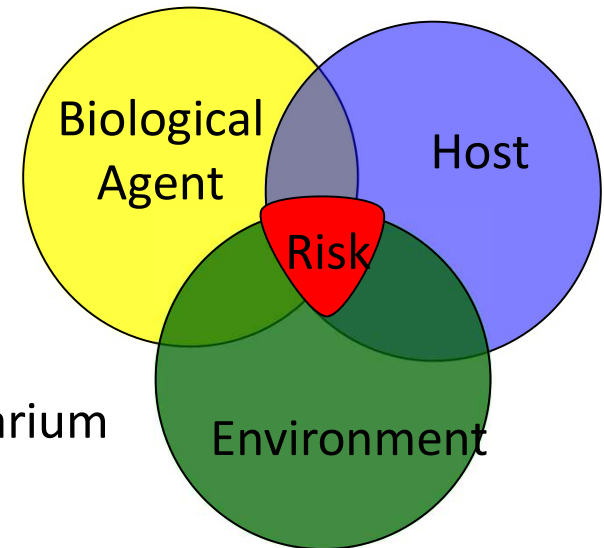
- Who can assist
- Who can enter the containment lab
- What procedure to take the person to the hospital/first aid
- How to decontaminate the patient, his clothes
- How to react fast



Risk Management

To involve all the aspects in the lab activities

- Equipment choice, and best use
- Organization of the room layouts
- Organization of logistic in the room
- Evaluate the people and material flow in the vivarium
- Write and “publish” the SOPs
- Train of people



All this process is DYNAMIC and subjected to revisions



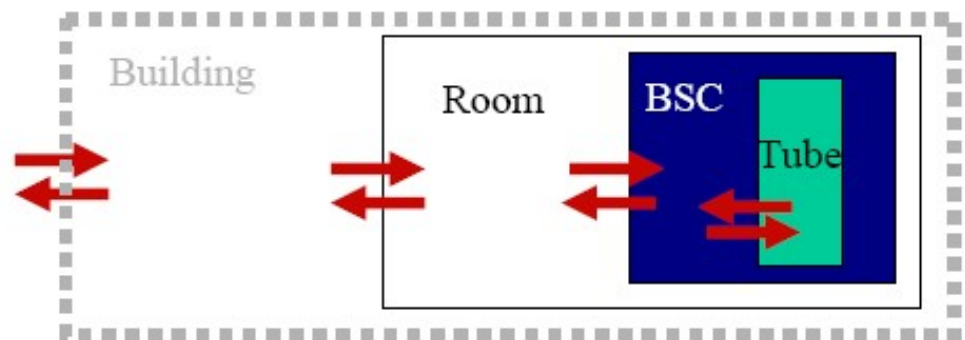
2. Primary and Secondary Barriers

Primary barrier:

- first protective barrier from biohazard to the operators
- to protect people and environment close to the source of contamination
- physical shield

Biosafety cabinet, animal ventilated/sealed cage, tube, centrifuge...

Every equipment must be associated with SOPs to be an effective barrier



Primary barriers

Can be considered at different levels



Primary barriers

In many animal studies Personal Protection Equipment (PPE) forms the primary barrier between personnel and the infectious agent.

PPE's:

Gloves

Coats/Gowns

Respirators

Goggles

Face shields

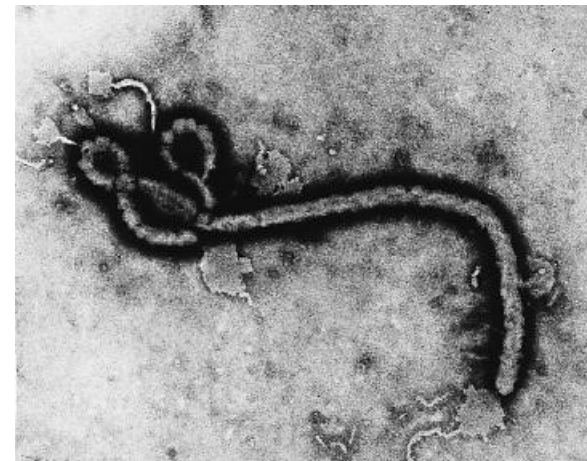
Shoe covers



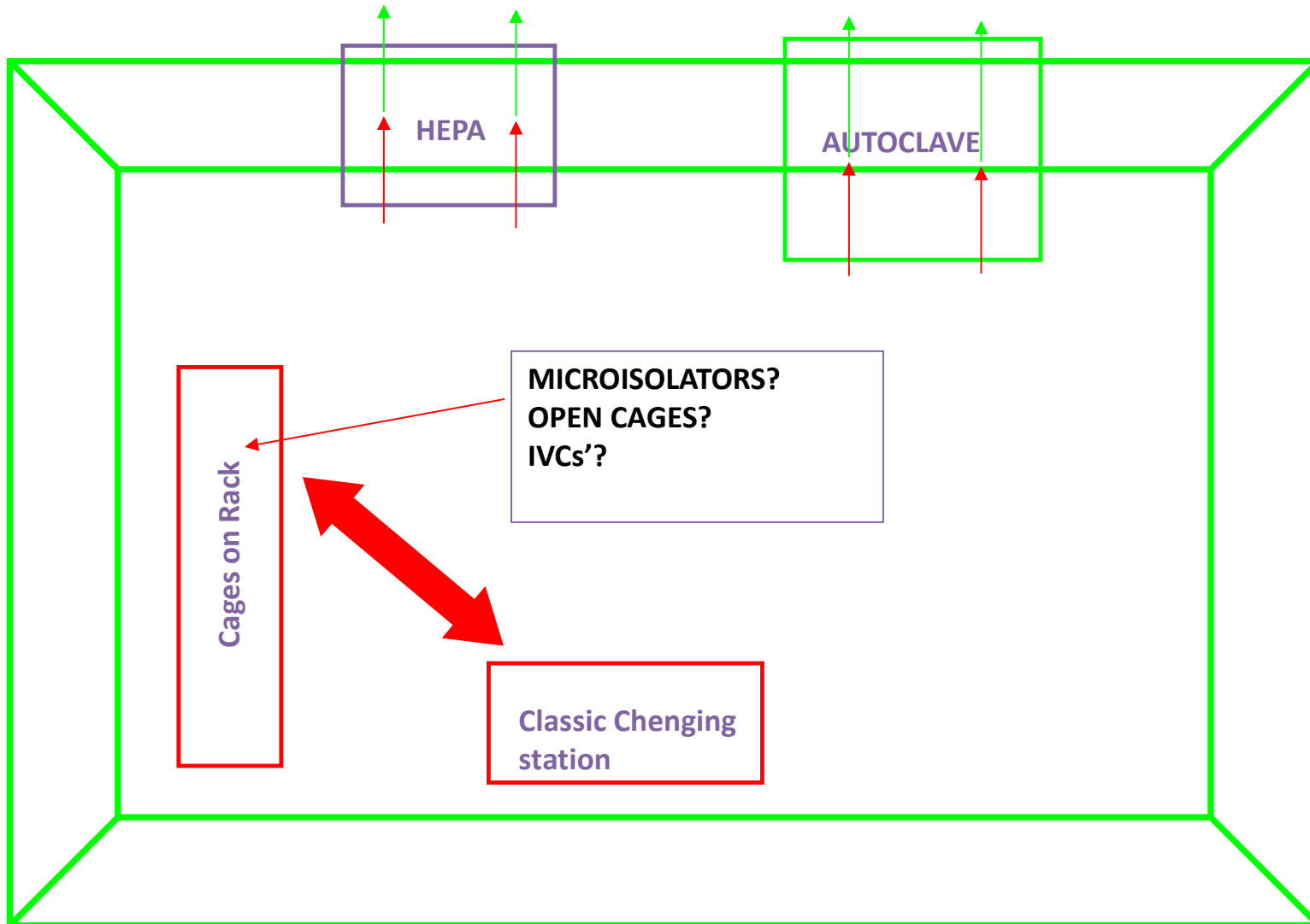
Secondary barriers

Depend on the transmission risk of agents used.

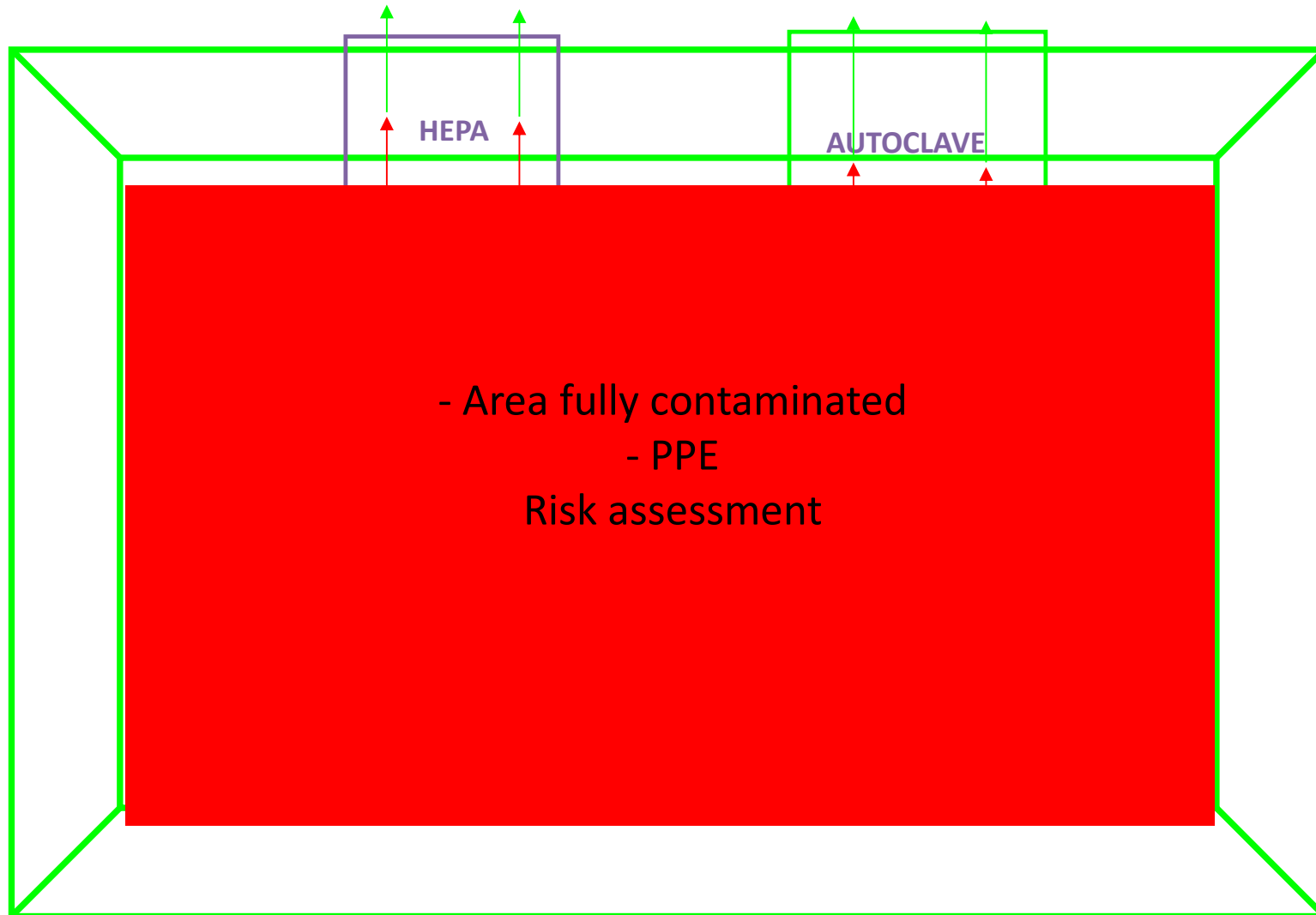
The design, engineering and construction of the facility provides protection for the laboratory workers' & provides a barrier to protect persons outside the laboratory.



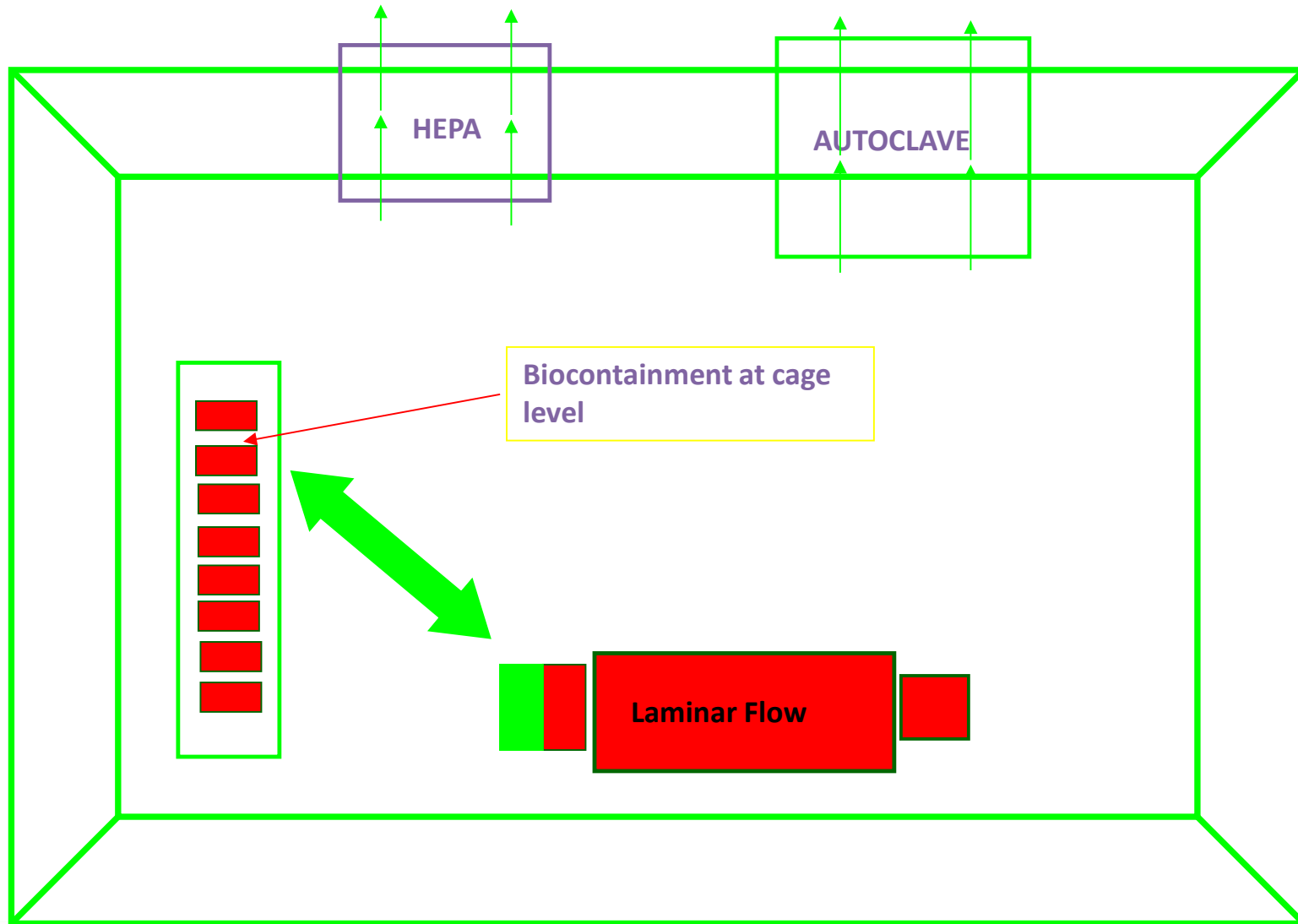
3. ABSL3 vivarium: what's "HOT"???



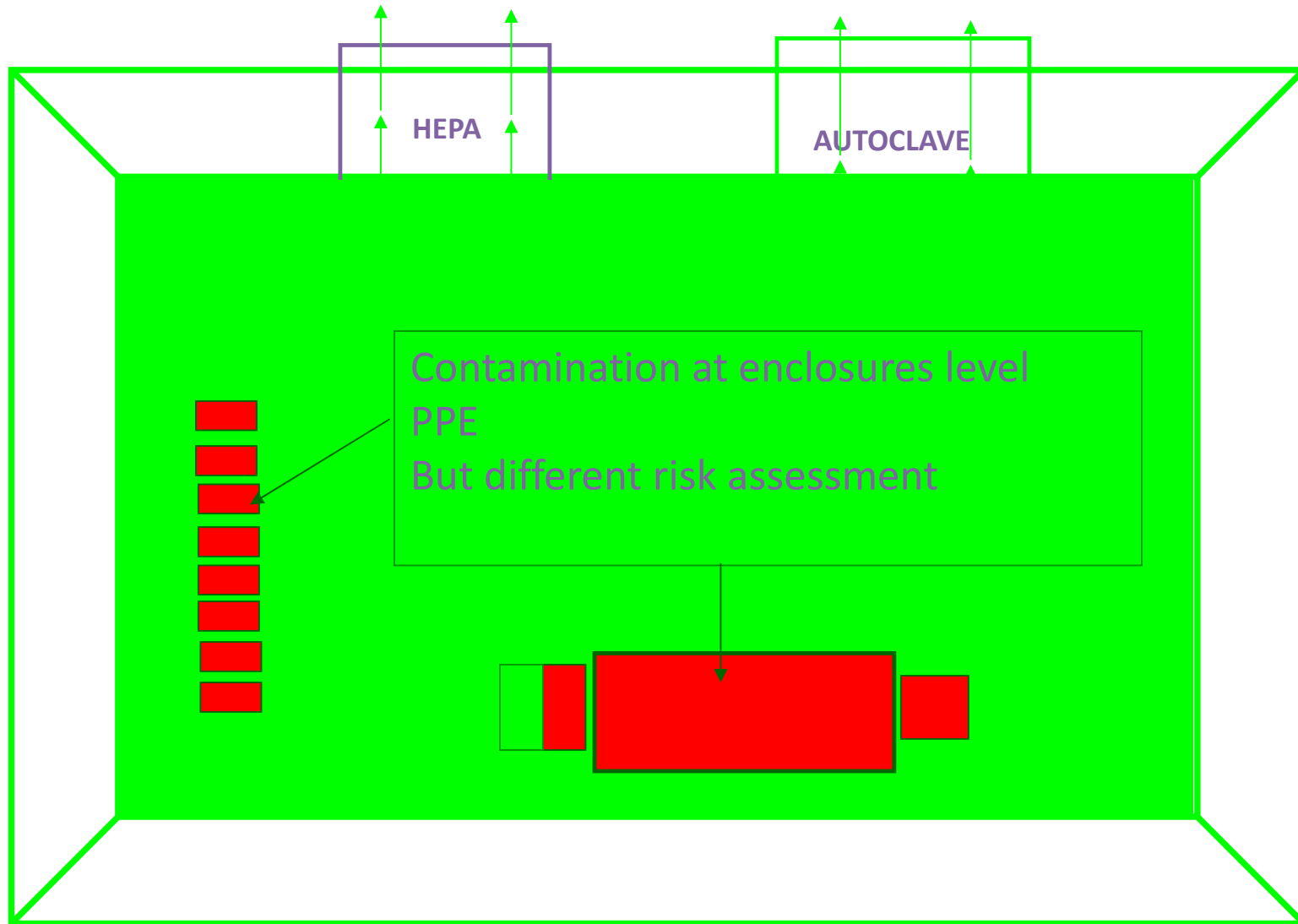
BSL3 vivarium: what's "HOT"???



BSL3 vivarium: what's "HOT"???

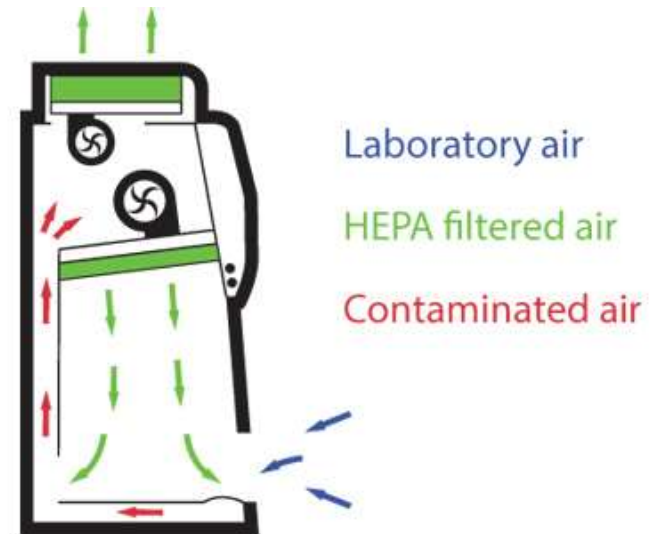


BSL3 vivarium: what's "HOT"???

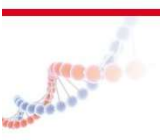
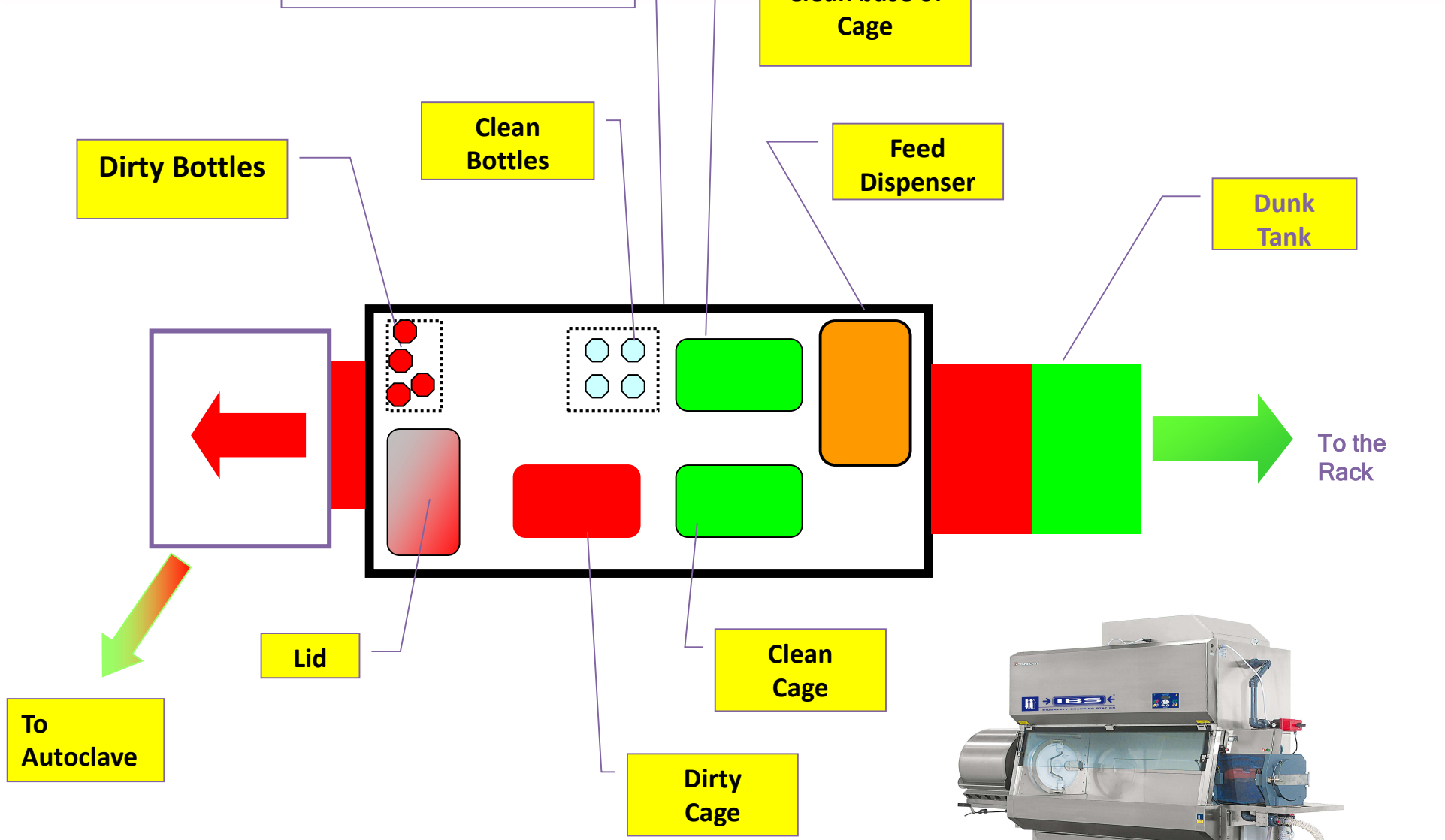


4. Biosafety Cabinets

- Very important equipment for procedures/animal cage change/biological agents manipulation
- Mandatory for BSL and ABSL > 1
- Certified equipment, requires training and ability to use
- Laminar Flow, protects product, people and environment under specific certifications



Laminar Flow Cabinet



Biosafety Cabinets

Certification BSC class II

- European normative: EN12469
- American NSF49

Classes of Biosafety Cabinets

- Class I = total air exhaust (100%)
- Class II = air is partially recirculated
- Class III = glove box, closed cabinet



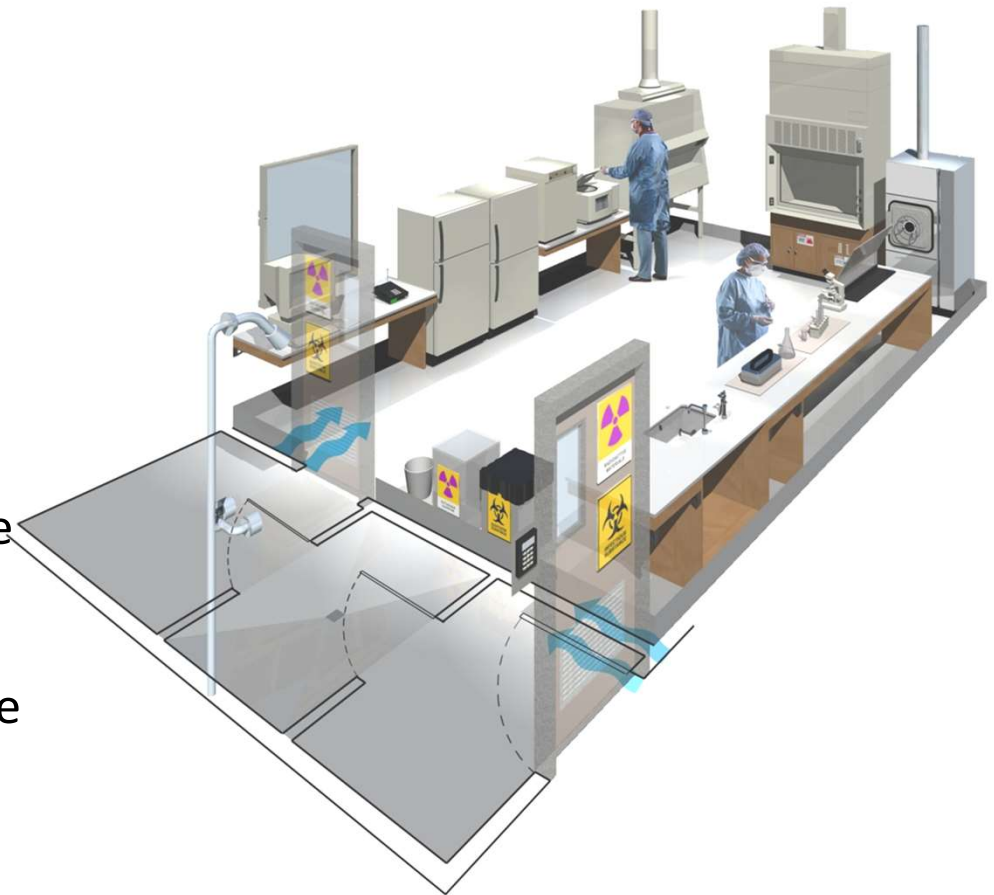
Some BSL3 Layouts

■ Primary barriers:

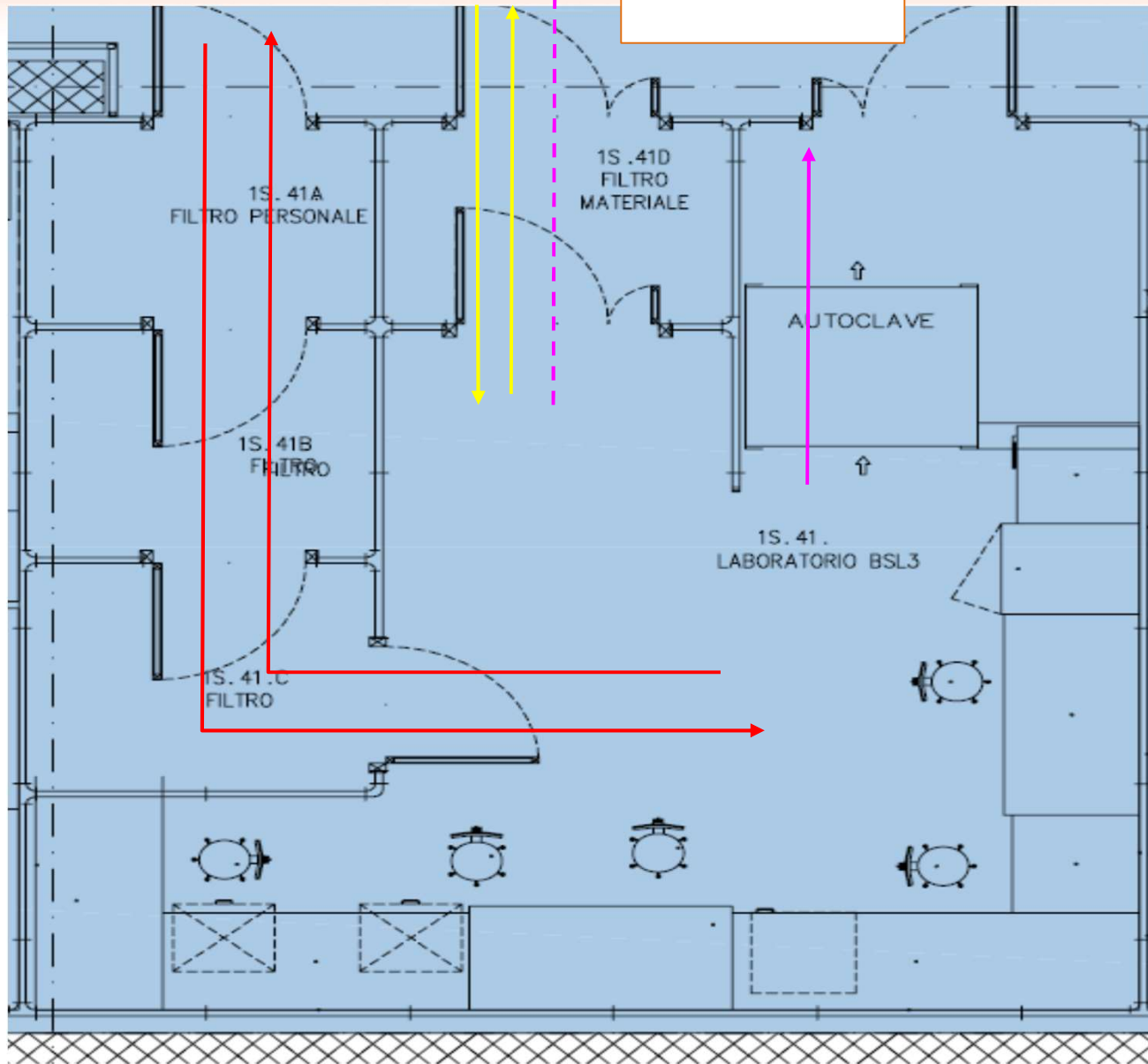
- Similar to BSL-2 personal protective equipment
- Respiratory equipment if risk of infection through inhalation

■ Secondary barriers:

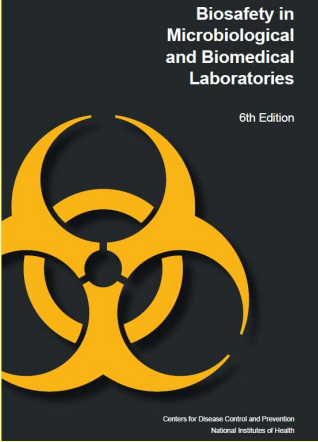
- Autoclave inside
- Corridors separated from direct access to lab
- Access through self-closing double doors, locked
- Air handling systems to ensure negative air flow (air flows *into* the lab)
- BSC II or BSC III



BSL 3



Guidelines

	Double Door Entry	Access Control Devices	Personnel Shower-Out	Hand Washing Sink	Hands Free Hand Washing Sink	Autoclave Available	Pass-through Autoclave	Dunk Tank and/or Fumig Chamber	Single-Pass Air, Directional Airflow	HEPA Filtered Exhaust	HEPA Filtered Supply	Supply/Exhaust Interlock	Gas-Tight Dampers (Room Level)	Visual Airflow/Pressure Monitor	HEPA Plumbing Vents	Effluent Decontamination	Vacuum Line Protection	Monolithic Walls & Ceiling	Seamless Flooring	Airtight Construction	Breathing Air System	Chemical Shower
BSL-2 Laboratory		○		●		●			○								●		○			
ABSL-2 Animal Facility		●		●		●	○		●								●	○	○			
BSL-3 Laboratory	●	●	○	●	●	●	○	○	●	○	○	●	○	●	○	○	●	●	●			
ABSL-3 Animal Facility	●	●	○	●	●	●	○	○	●	○	○	●	○	●	○	○	●	●	●			
BSL-3 Ag Animal	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●		
BSL-4 Lab/Animal (Suit)	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
● = Required by BMBL (5th ed.) ○ = Not required by BMBL (5th ed.), however, generally considered as an enhancement																						



Thanks for your attention!

