Animal Biosafety: Biosafety Officer's Experiences and Perspectives

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Overview

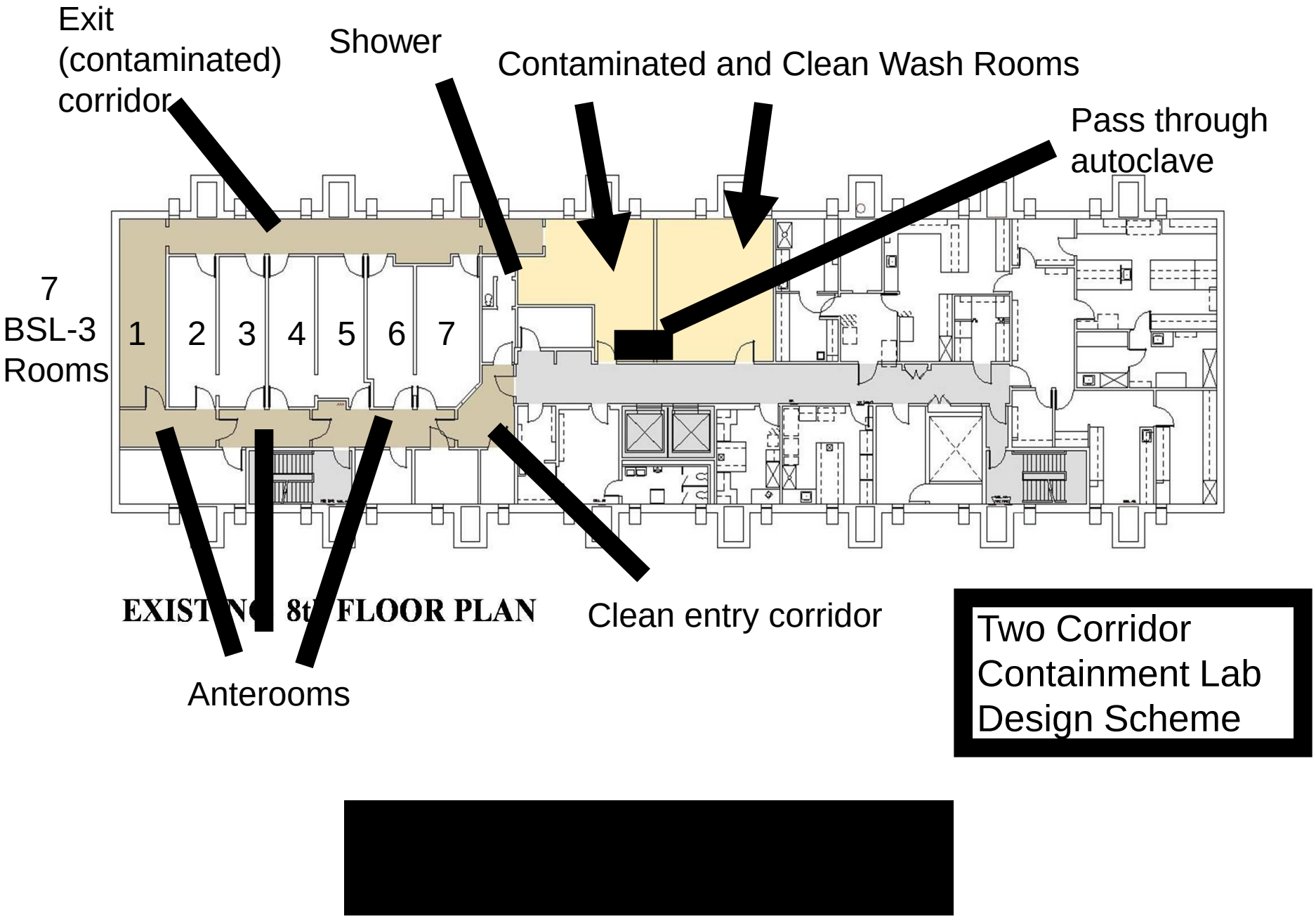
- Risk Assessment Challenges
- Training Strategies
- Augmenting SOP’s

Framework for RA/RM

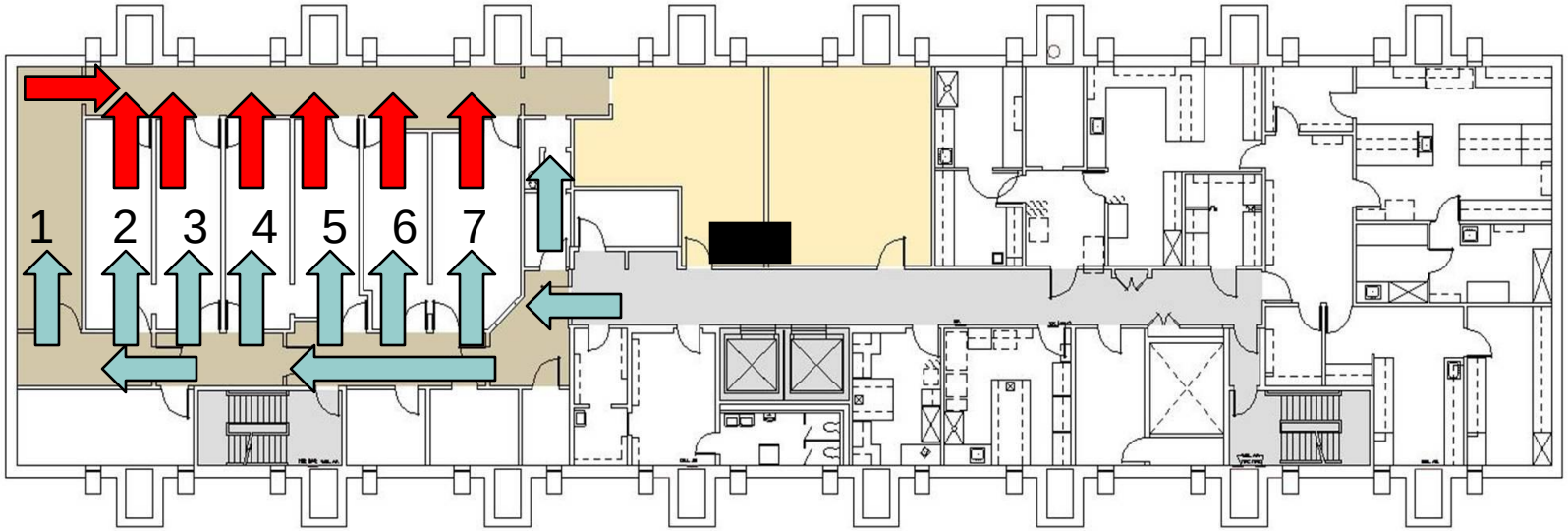
Risk Assessment	Risk Management (SOP's & Training)
Pathogen	Practices (good work practices)
Procedures (SOP's) (Training)	Protective equipment (clothing and equipment)
Personnel (Training)	Place (facility design)

Risk Assessment Challenges

- Diverse research in shared facilities
- Limited BSL3 facilities for animal studies
  - Aged, older designs
- Different agents = different SOP's
  - West Nile virus, Creutzfeld Jacob agent, Rickettsia conorii, LCMV, HIV, VSV lab strain
- Animal technicians prefer standardized protocol


Exit (contaminated) corridor
Shower
Contaminated and Clean Wash Rooms
Pass through autoclave
7 BSL-3 Rooms
1
2
3
4
5
6
7
EXISTING 8th FLOOR PLAN
Clean entry corridor
Anterooms
Two Corridor Containment Lab Design Scheme

Lab Airflow



EXISTING 8th FLOOR PLAN

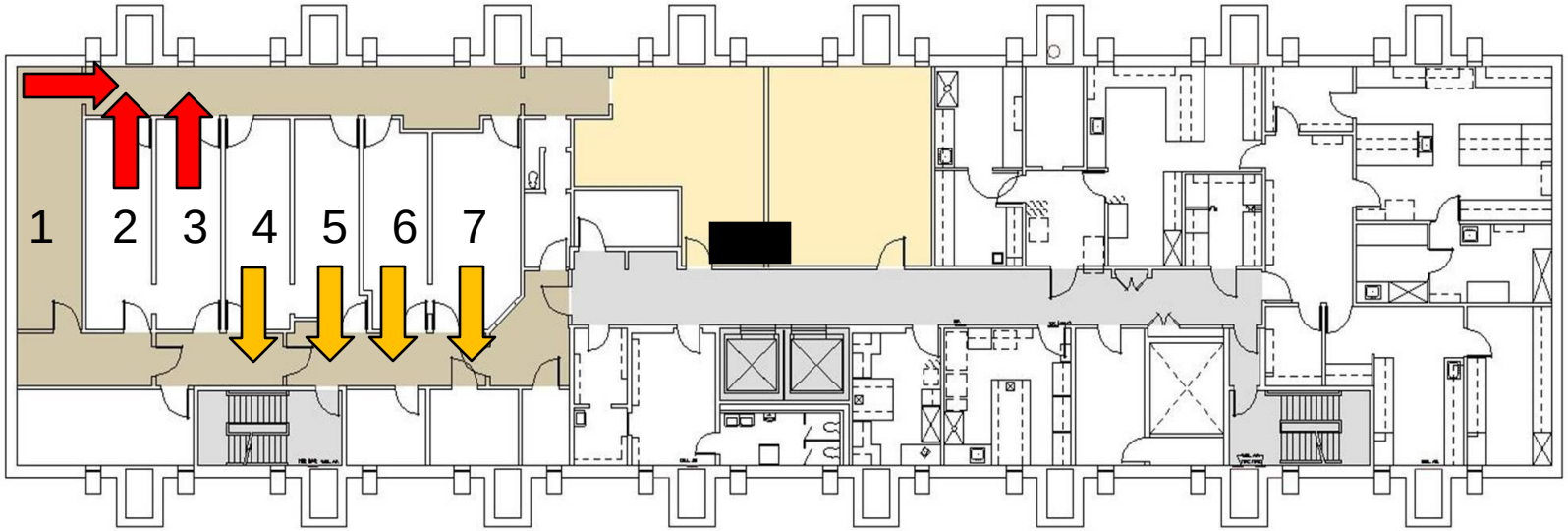
Two Corridor Containment Lab Design Scheme

[redacted]

Risk Assessment Challenges

- All animal BSL3 experiments in one facility
- Two “exit” SOP’s agreed upon
  - Exit via contaminated corridor
    - Respiratory protection required
  - Exit back to clean corridor
- “Accepted” by all

Laboratory Exit



EXISTING 8th FLOOR PLAN

Two Corridor Containment Lab Design Scheme

[redacted]

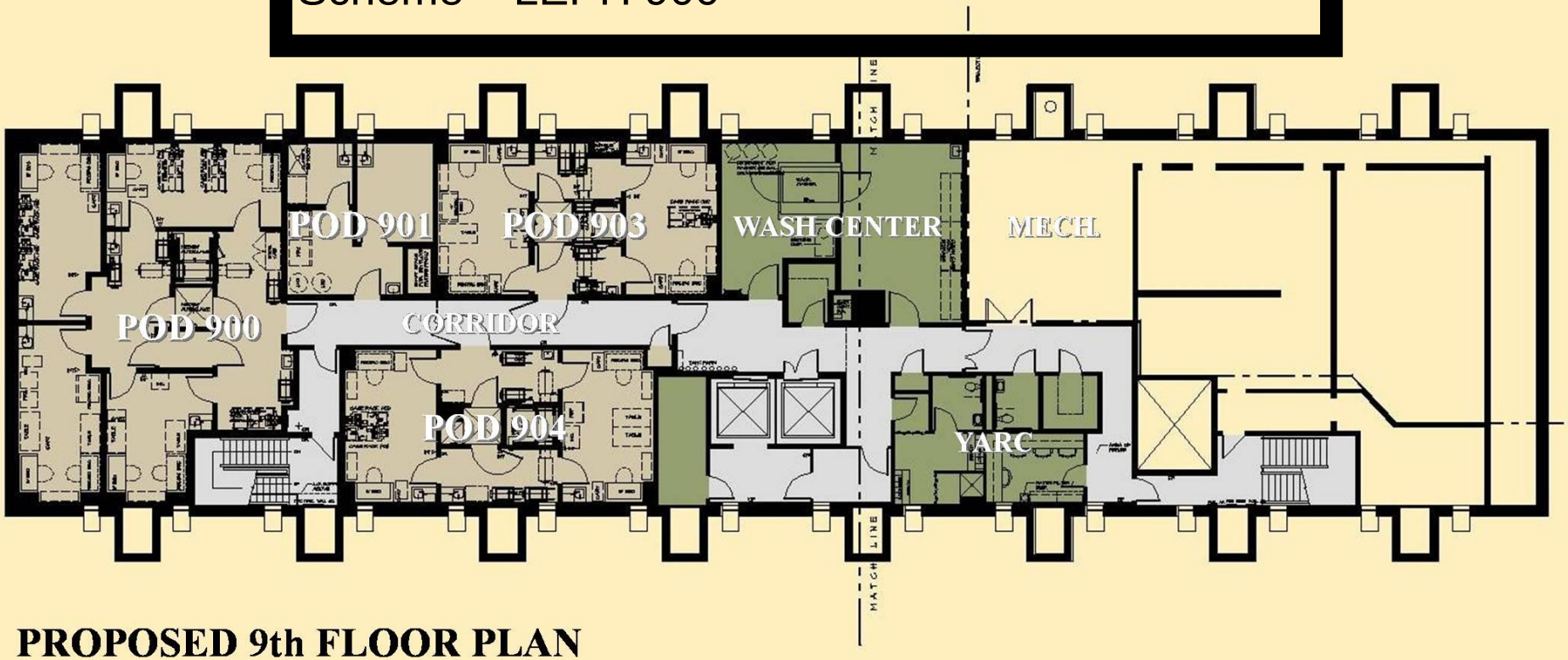
Risk Assessment Challenges

- New biohazard protocols
  - Mycobacterium tuberculosis
  - Highly Pathogenic Avian Influenza virus (H5N1)
- Projected additional requirements
  - Shower out may impact ALL in facility
- Not “accepted”
- Pod concept hatched

Road to the Pod

- Renovate old animal facility
- Create segregated BSL3/ABSL3 laboratories
  - Each self contained
- Separate high risk and regulated agents
- Group similar risk agents in super pod

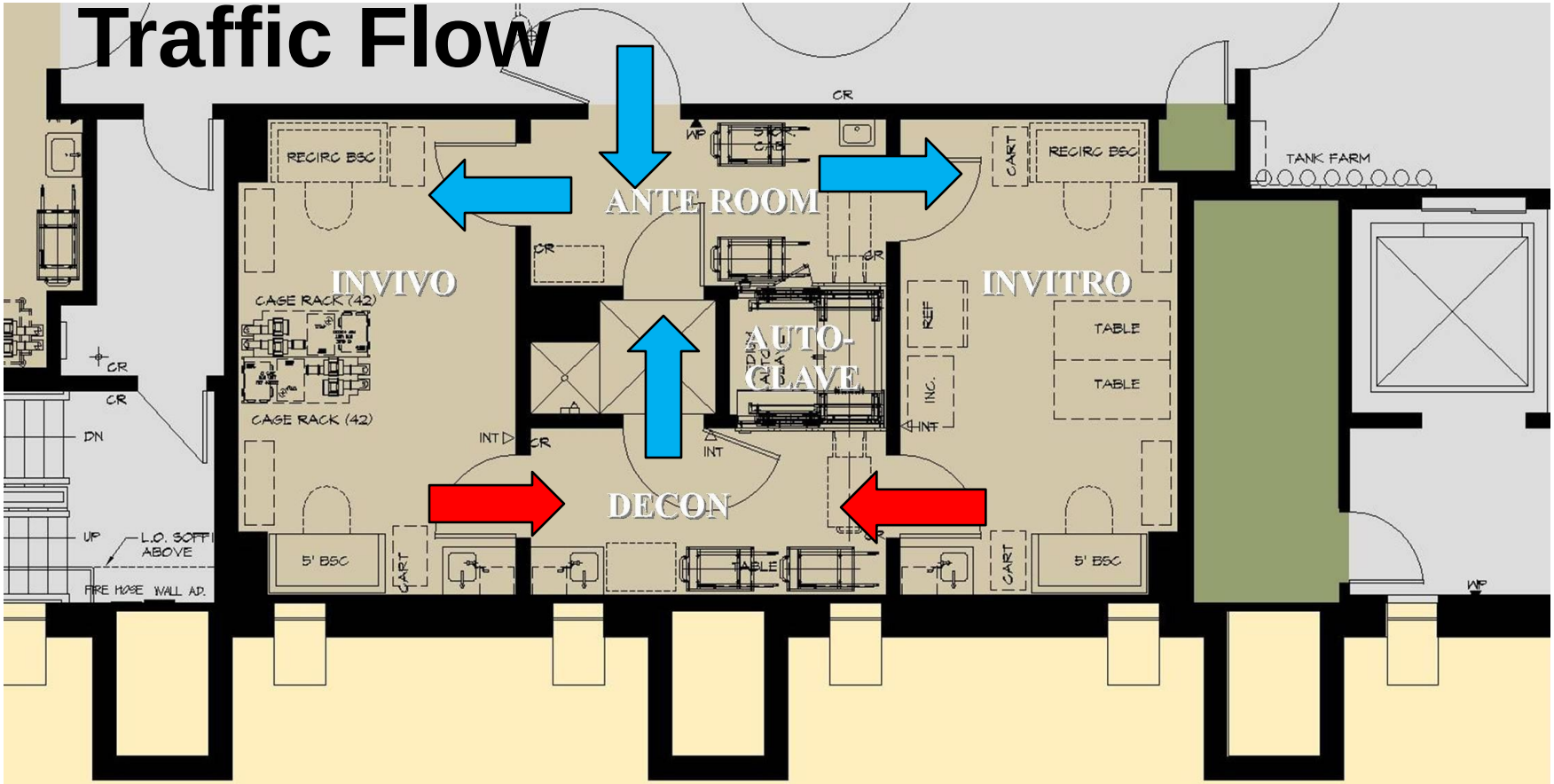
Single Corridor “Segregated” Facility Design Scheme – LEPH 900



PROPOSED 9th FLOOR PLAN

[redacted]

Traffic Flow



Clean (Anteroom) and Dirty (DECON)

Passageways

PROPOSED 9th FLOOR PLAN - Pod 904

[redacted]

One Segregated BSL3 Suite w/in BSL3 Facility: Lab and Animal Experiments Combined

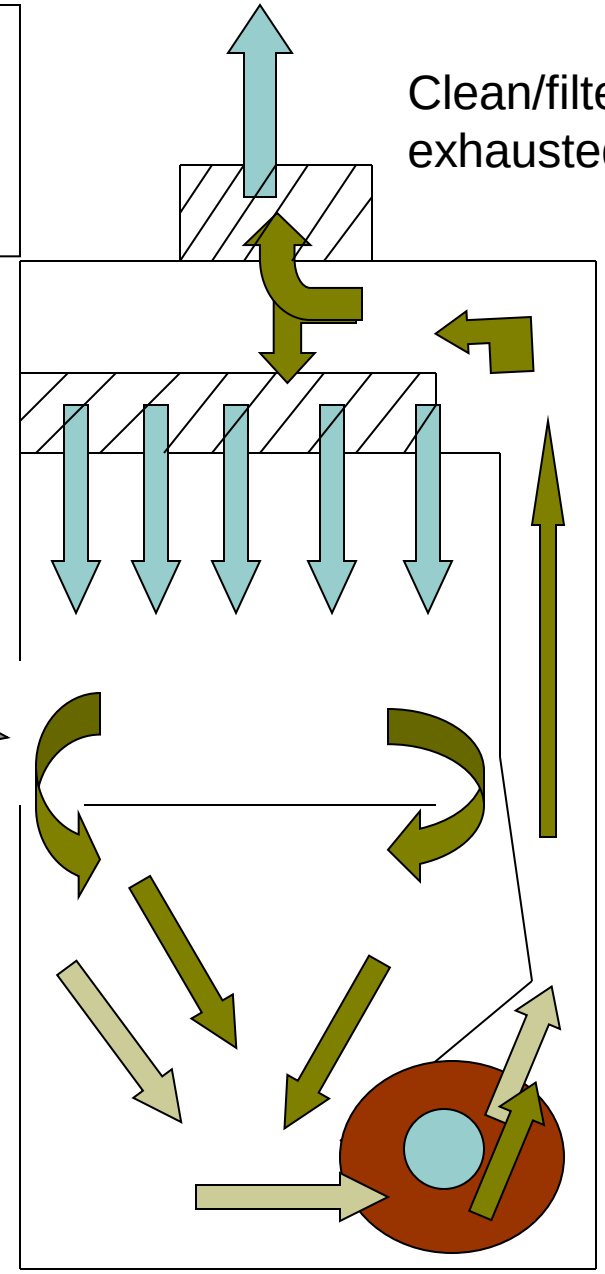
Evolution of Training

- Adult learning techniques incorporated
- More frequent delivery & shorter segments
- Modern techniques required
- Multiple trainers with shared responsibilities

Evolution of BSL3 Training

- Life cycle of BSL3 trainee
  - Discussion of risk →Initial training
  - Facility orientation→ SOP walkthrough
  - Shadow authorized BSL3 researchers
  - Observe BSL3 work
  - Perform BSL3 procedures with mock materials

Airflows Within a Class II Biological Safety Cabinet



Clean/filtered air exhausted back to room

Supply & Exhaust HEPA filters

Clean/filtered air supplied to work area

Dirty room air enters at 100 fpm

Contaminated air in work area is directed down below work surface through front and rear grills

Blower directing room and “dirty” air up through HEPA filters

Getting used to “all work inside the biosafety cabinet”

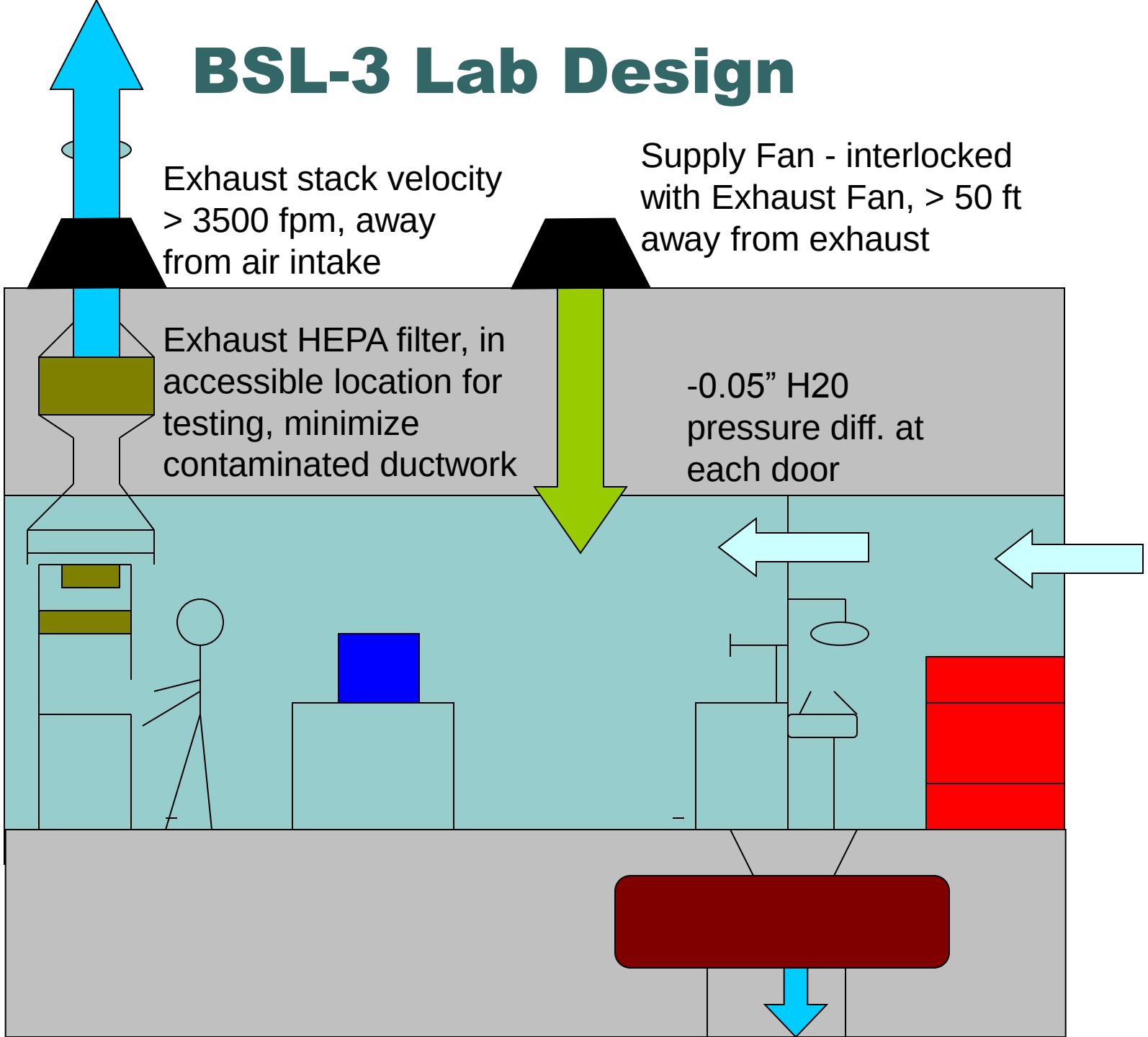
Pre-Occupancy Training

- Risk Awareness
- Understanding containment
  - Facility
  - Equipment
  - Work practices
- Knowledge regulations and site-specific policies
- Incident response
- Tours, classroom and hands-on

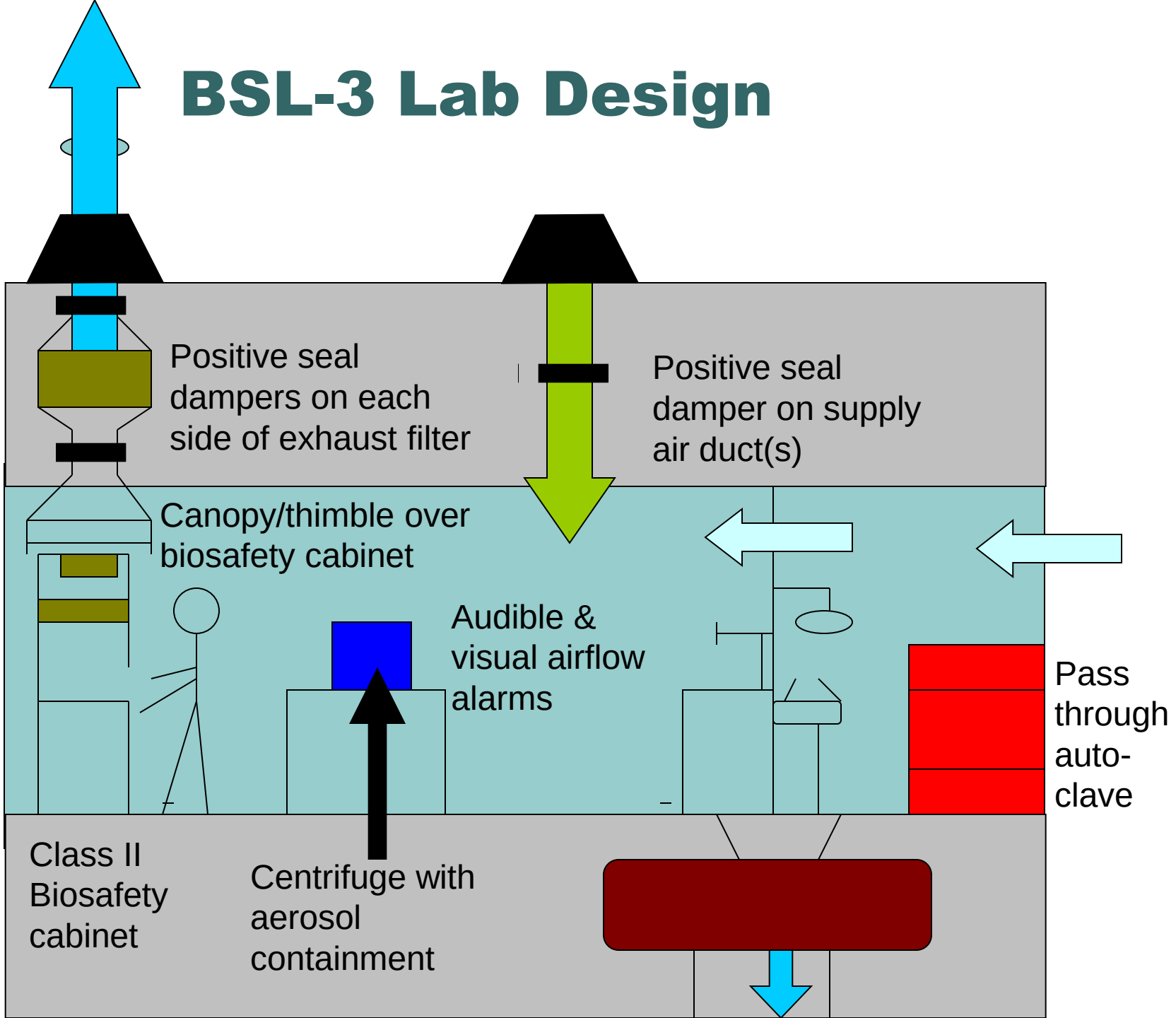
Personnel Training

- Classroom
  - Biosafety, Bloodborne Pathogens, Lab Chemical Safety, BSL-3 Training, Shipping/Transport, Biosecurity, Emergency Response (Drills)
- Tours
  - Orientation covering entry, facility equipment and use, and exit
  - Review of monitors, alarms and contingency plans

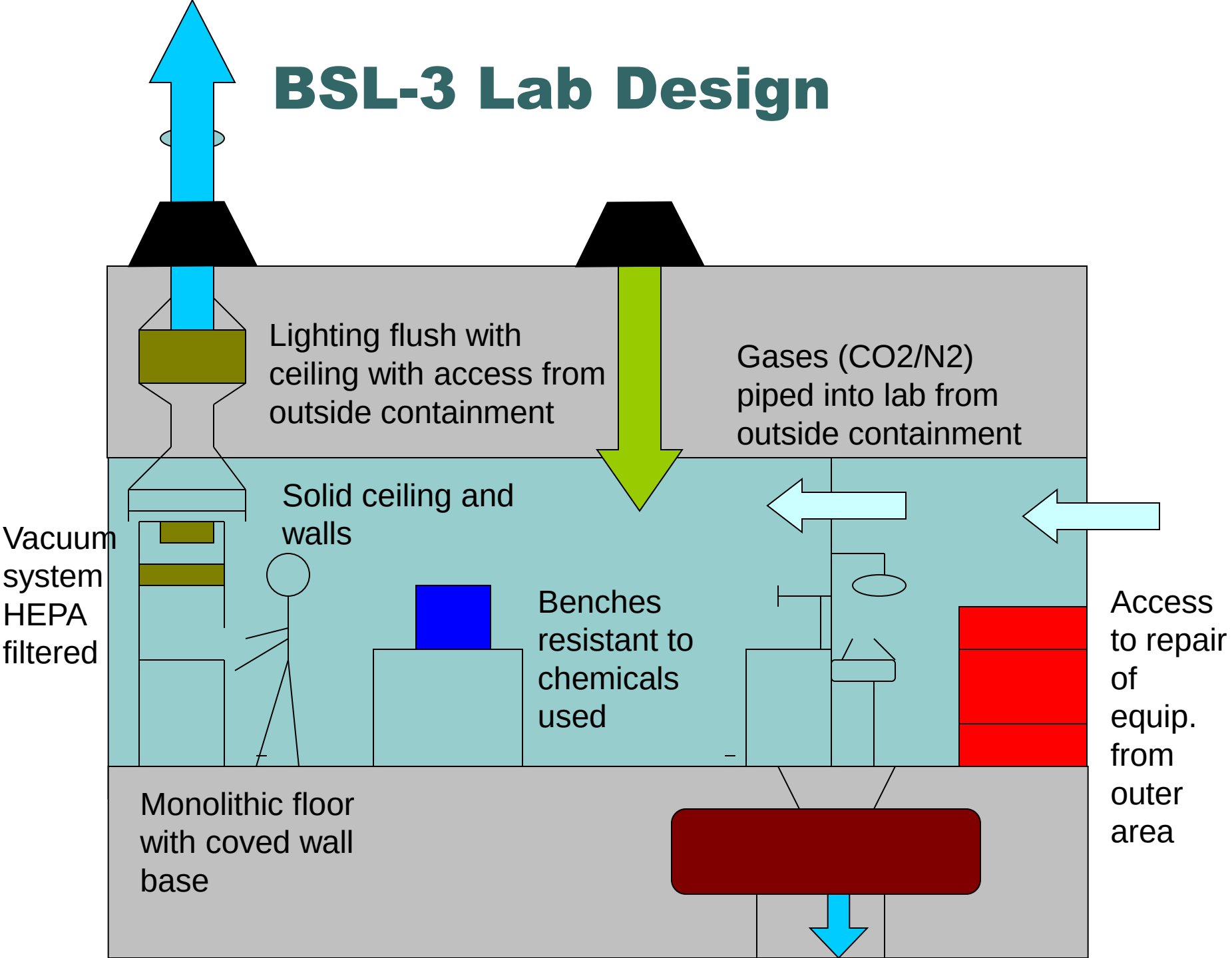
BSL-3 Lab Design



BSL-3 Lab Design



BSL-3 Lab Design



Personnel Training

- Prior work experience
  - 2 months with BSL-2 pathogens
  - 15 hours (15 supervised visits) at BSL-3
  - Separate BSL-3 requirements for lab and animal authorization
  - Relevant education
- Accept training from other institutions, but…
  - Require onsite training/orientation &
  - Successful completion of observation

Training and use of personal protective equipment

Repetition with entry/exit protocols

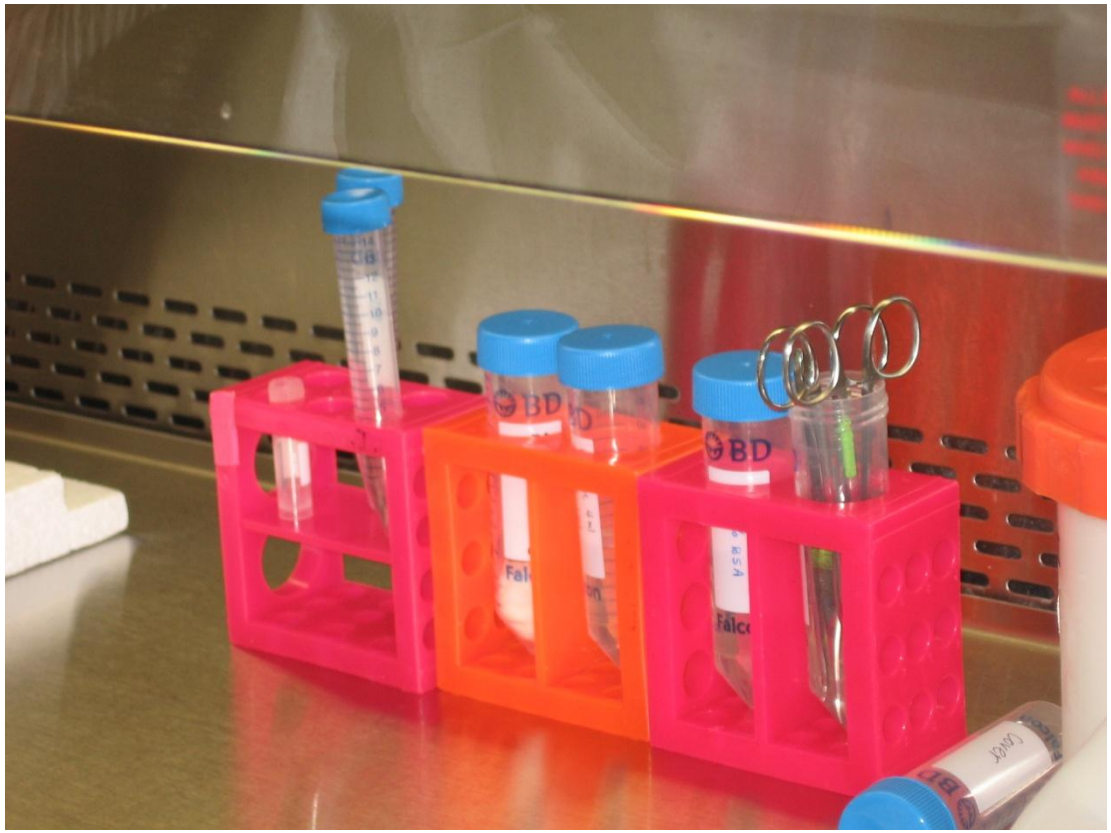
Mentoring

BSL3 Training Life Cycle

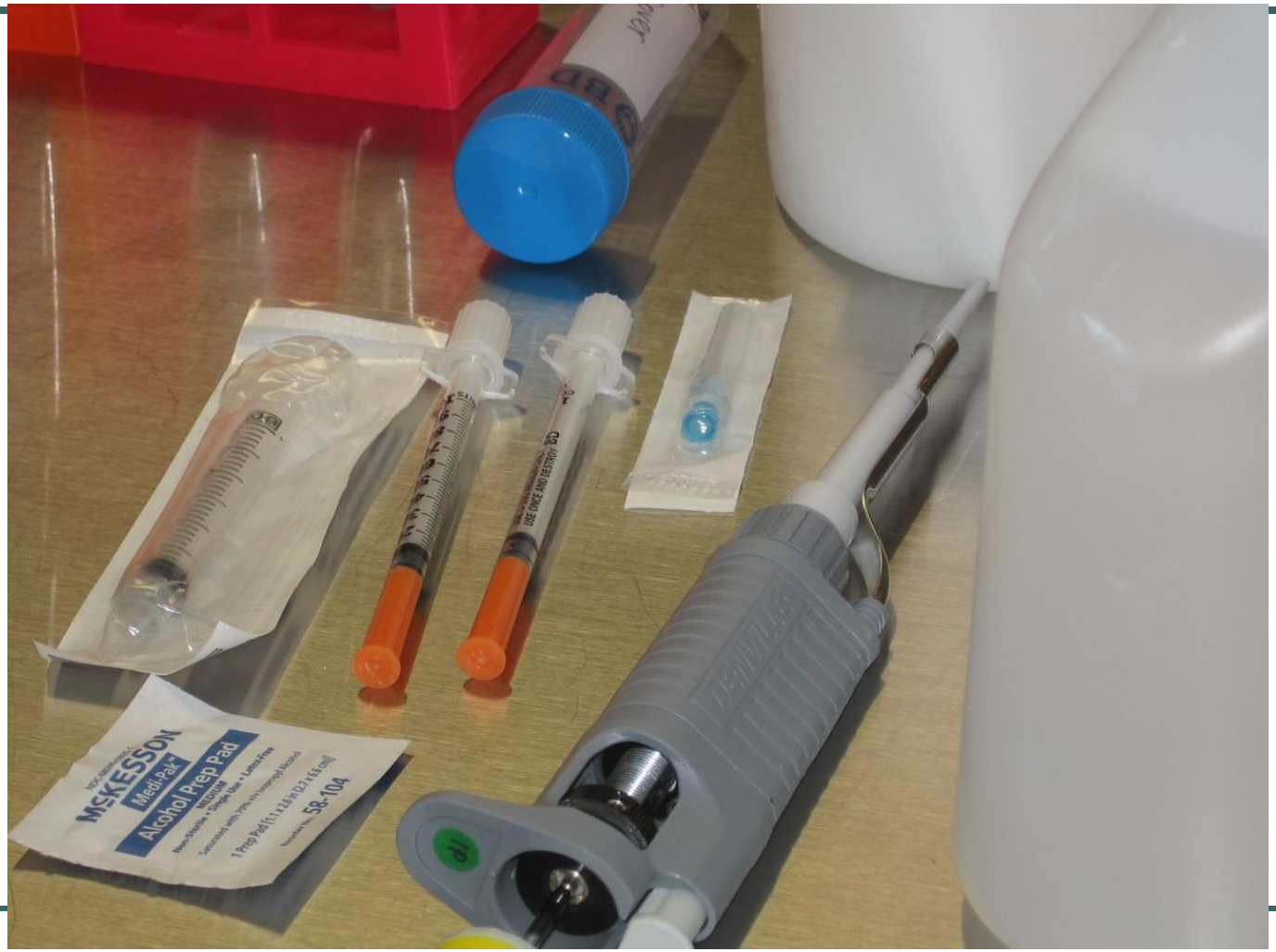
- Life cycle (cont.)
  - Perform BSL3 procedures under supervision
  - Gain independent authorization through direct proficiency observation evaluation
  - Transition to becoming a trainer
- Retraining
  - Don’t tell trainees what they already know
  - Focus on critical steps that must be addressed

Emergency Intercom to Yale 24/7 Security Dispatch (in each lab)

Position supplies in the work area



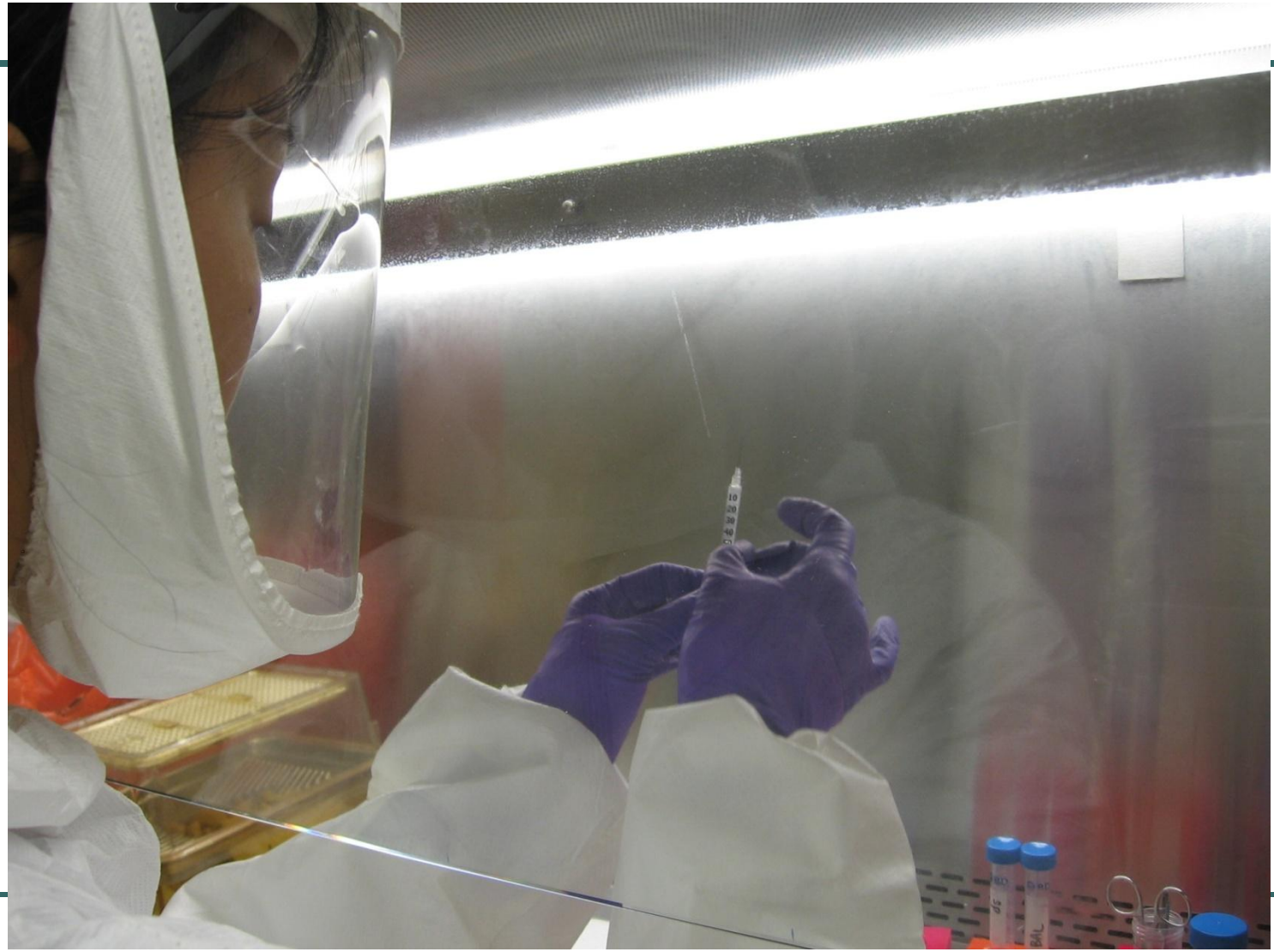
Keep items in the biosafety cabinet to a minimum



Use of video clips

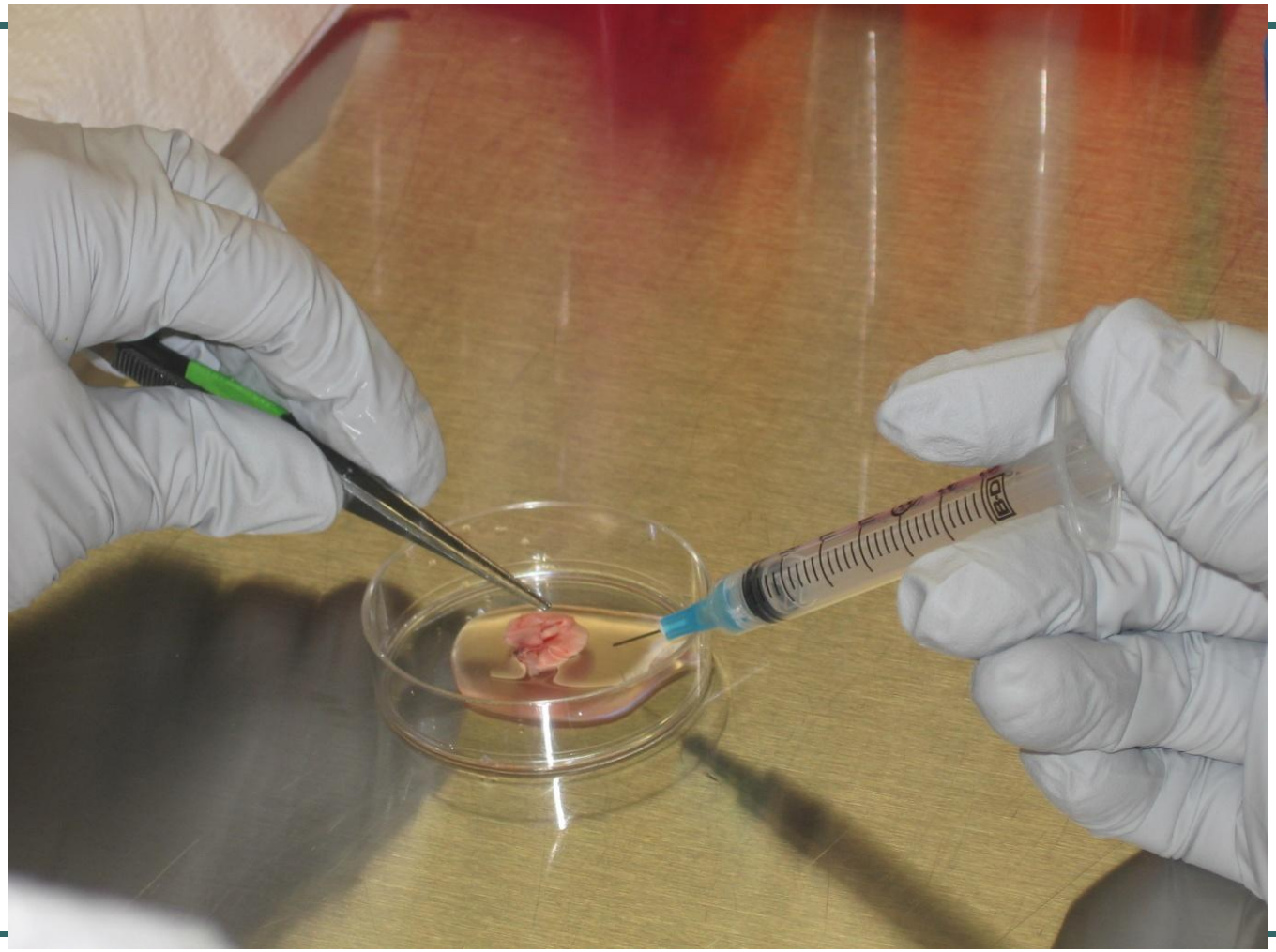
Sharps Safety

Recognition of aerosol generating procedures

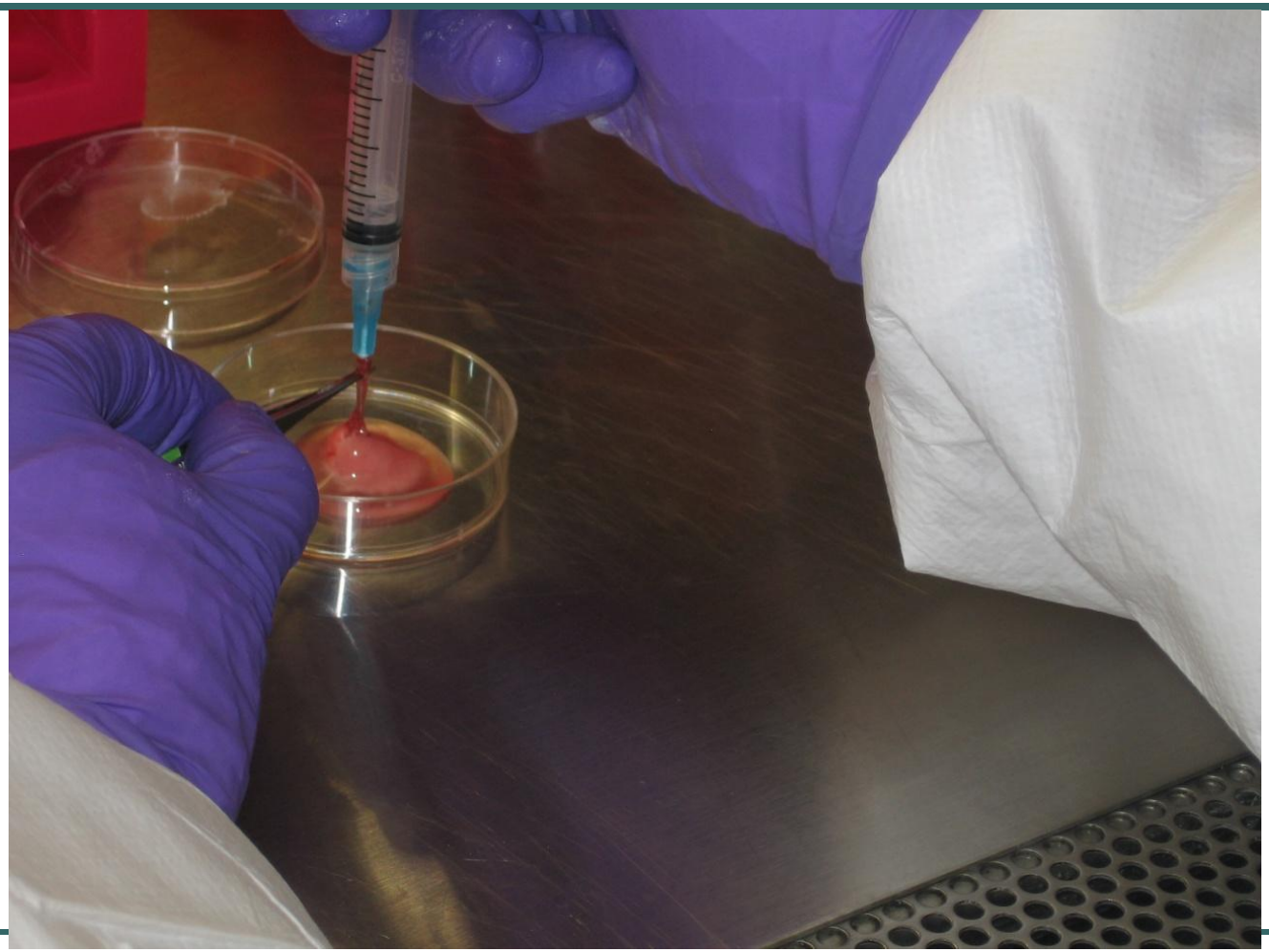


Use of video clips

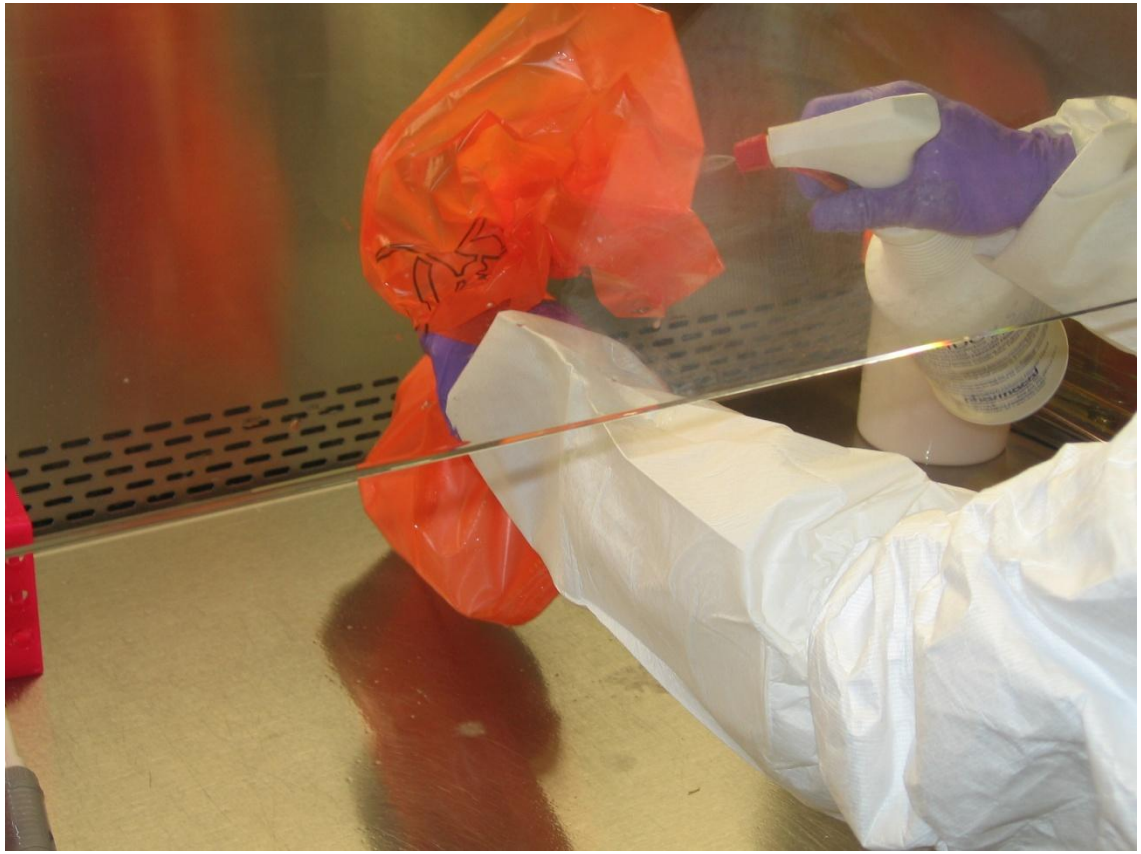
Observe All Procedures Post Necropsy



Keeping hands/fingers away from sharps



Termination of Work



Termination of Work

BSL-3 Work Practice Observation

- 2 Reviewers from BSL-3 Subcommittee
- Monitor:
  - Entry/exit
  - Compliance with PI's approved SOP
  - Aerosol containment
  - Safe handling of sharps (animal BSL-3)
  - Awareness of emergency procedures
  - Comfortable? Safe? Proficient?

Animal protocol SOP start-up meeting

- Researchers, animal technicians, veterinary care, biosafety, IACUC representative
  - **Non-EHS safety representatives on staff in animal care and IACUC**
- Begin with baseline template
- Discuss, review and develop final protocol

Researcher SOP Development

- Best written by those performing work
  - (Beati, Jacoby/Smith, Iwasaki)
- Clear/concise w/ sufficient detail to describe the process
- Reviewed, approved and updated
- Augment SOP’s w/ posters (prompts, reminders)

Biosafety Cabinet Checklist

Yale

Before Use

- Cabinet on?
- Drain valve closed?
- All waste containers and supplies loaded inside?
- Disinfectant prepared and in cabinet?

During Use

- Perform all work inside the cabinet
- Keep grilles clear
- Discard waste inside the cabinet
- Disinfect all items prior to removal
- Remove gloves or disinfect them before removal from the cabinet

Work Completion

- Seal all waste containers before removal from the cabinet
- Disinfect all items before removal
- Disinfect all work surfaces upon completion
- Back, sides, inside front view screen
- Rear grill, work surface, front grill

Environmental Health & Safety 135 College Street, Suite 100, New Haven, CT
T 203-785=3550 / F 203-785-7588 www.yale.edu/ehs

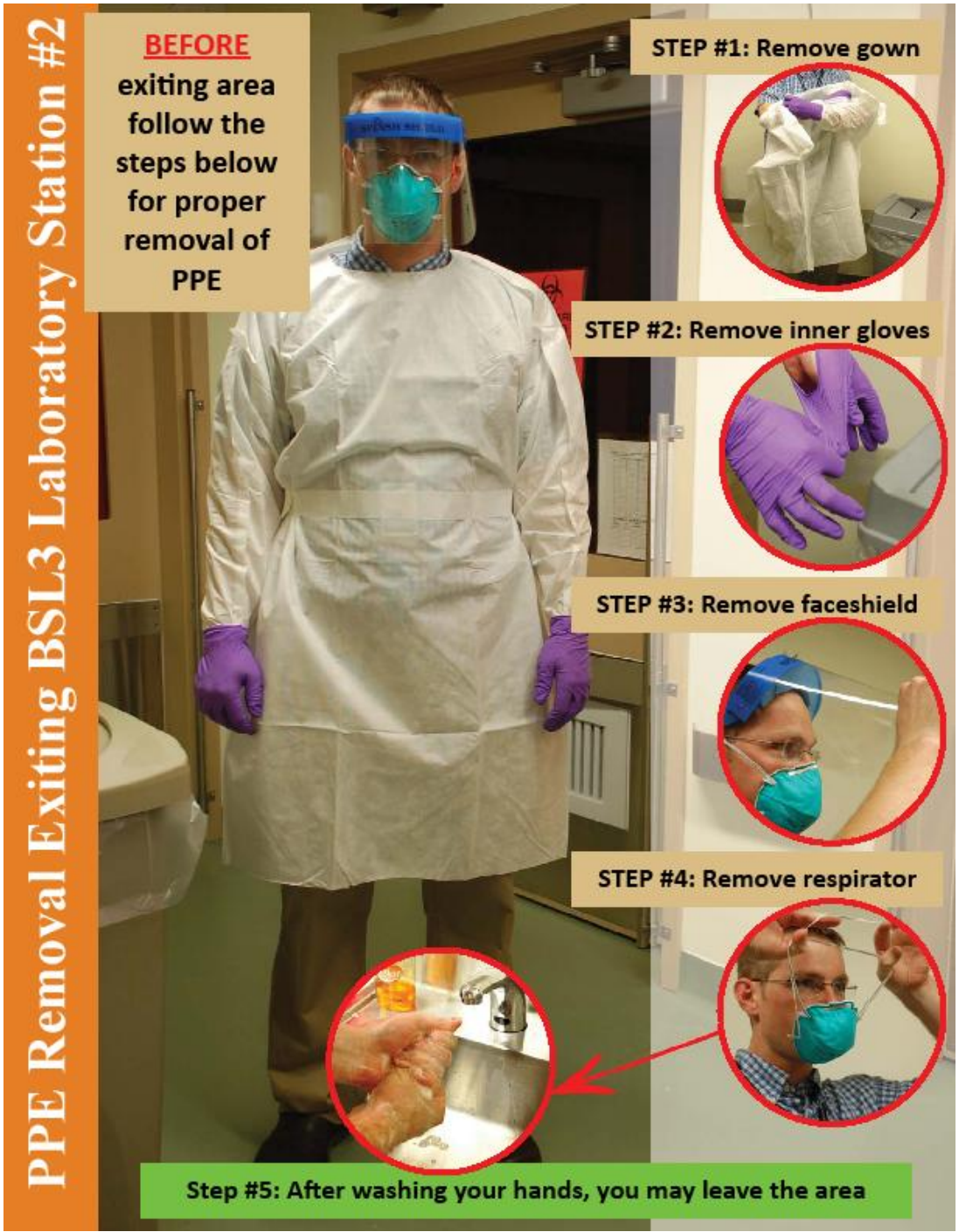
Focus on simple essential practices

Donning PPE Poster Located in Entry Anteroom

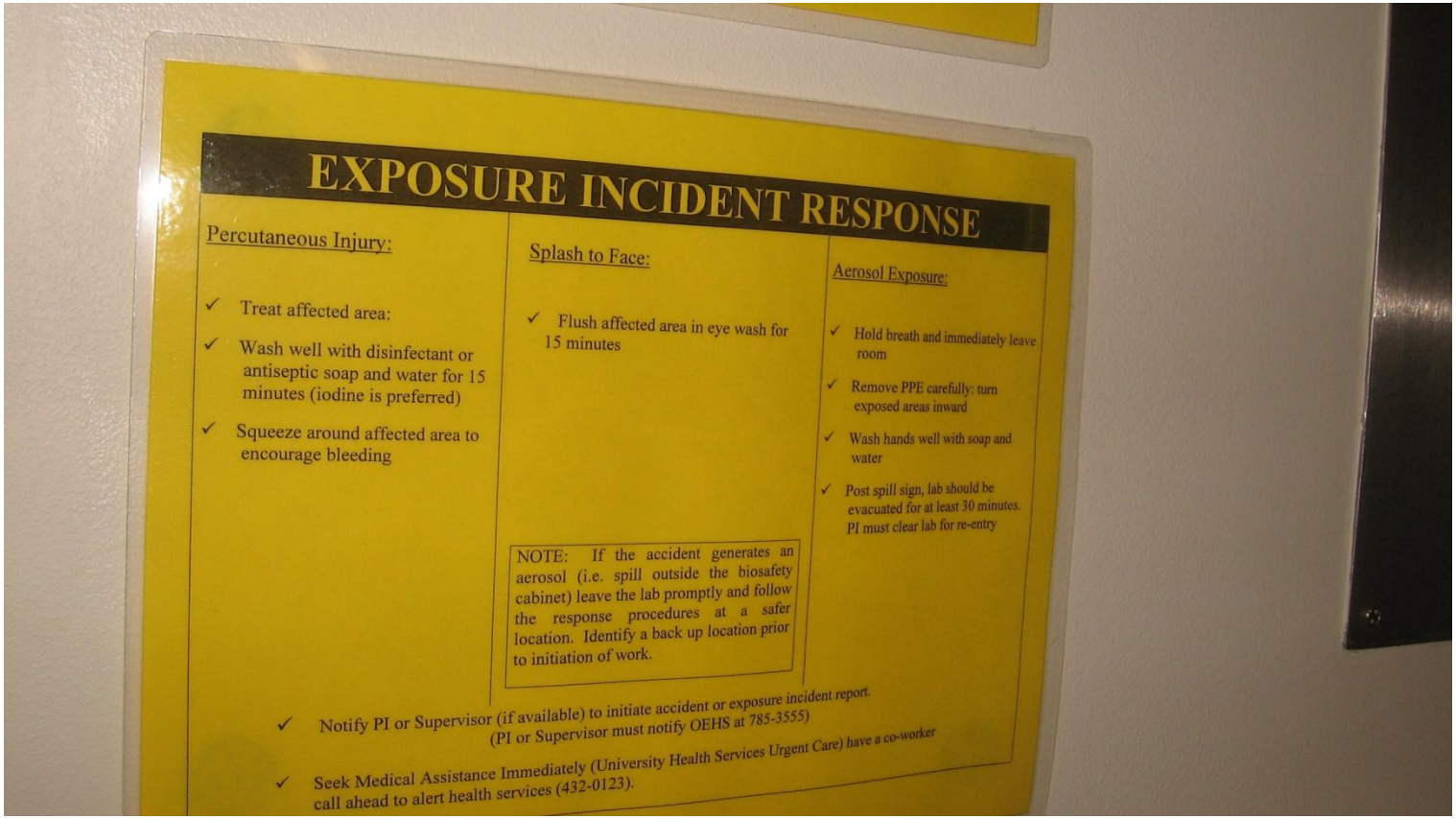
PPE Removal Exiting BSL3 Laboratory Station #1

Instructions for PPE Removal Before Lab Exit to Rear Anteroom

Removal of Remaining PPE, Hand Washing and Lab Exit



Exposure Response Poster



EXPOSURE INCIDENT RESPONSE

Percutaneous Injury:

- ✓ Treat affected area:
- ✓ Wash well with disinfectant or antiseptic soap and water for 15 minutes (iodine is preferred)
- ✓ Squeeze around affected area to encourage bleeding

Splash to Face:

- ✓ Flush affected area in eye wash for 15 minutes

Aerosol Exposure:

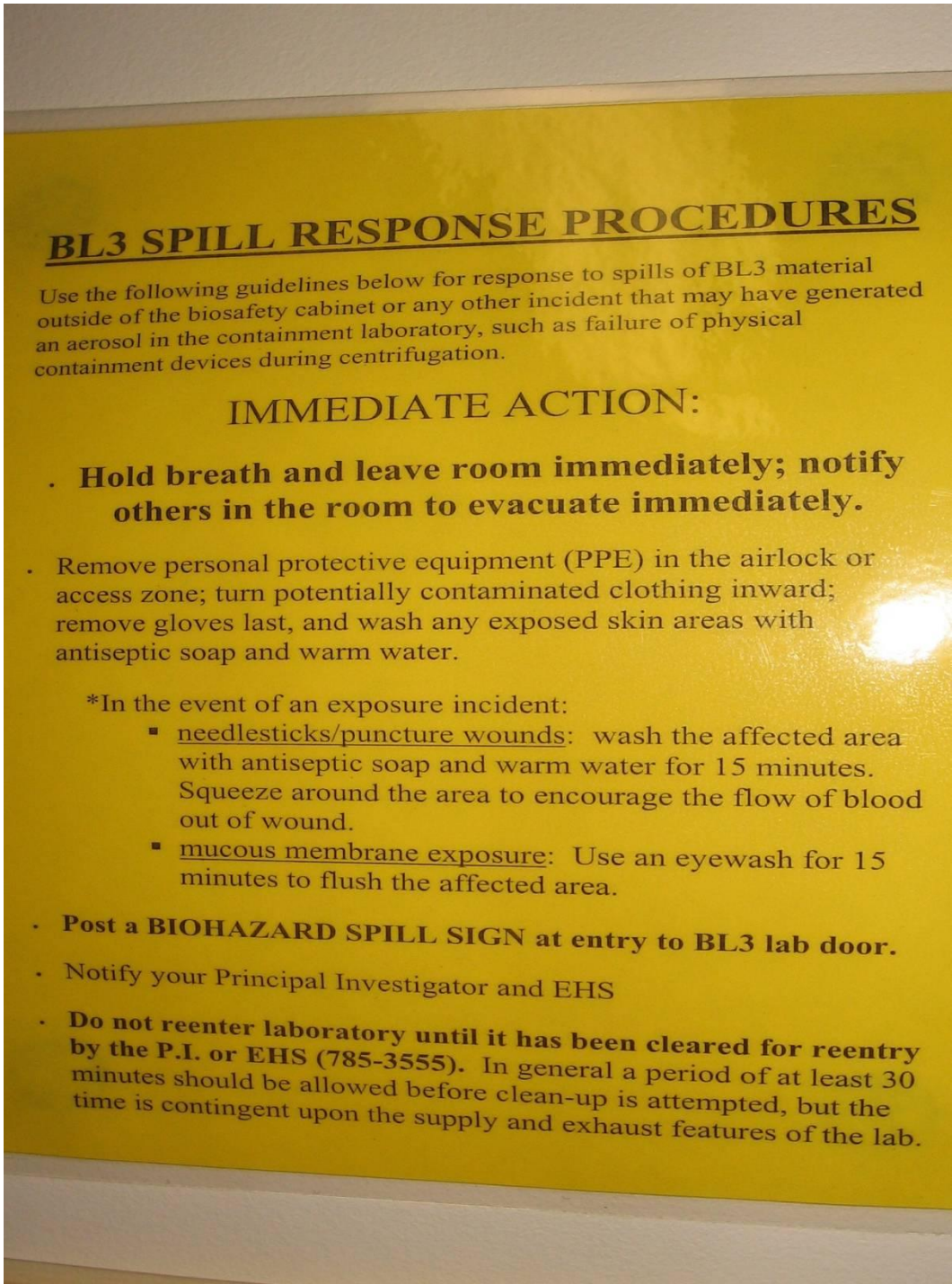
- ✓ Hold breath and immediately leave room
- ✓ Remove PPE carefully: turn exposed areas inward
- ✓ Wash hands well with soap and water
- ✓ Post spill sign, lab should be evacuated for at least 30 minutes. PI must clear lab for re-entry

NOTE: If the accident generates an aerosol (i.e. spill outside the biosafety cabinet) leave the lab promptly and follow the response procedures at a safer location. Identify a back up location prior to initiation of work.

- ✓ Notify PI or Supervisor (if available) to initiate accident or exposure incident report. (PI or Supervisor must notify OEHS at 785-3555)
- ✓ Seek Medical Assistance Immediately (University Health Services Urgent Care) have a co-worker call ahead to alert health services (432-0123).

Centrifuge Spill Response SOP

Spill Response Protocol



BL3 SPILL RESPONSE PROCEDURES

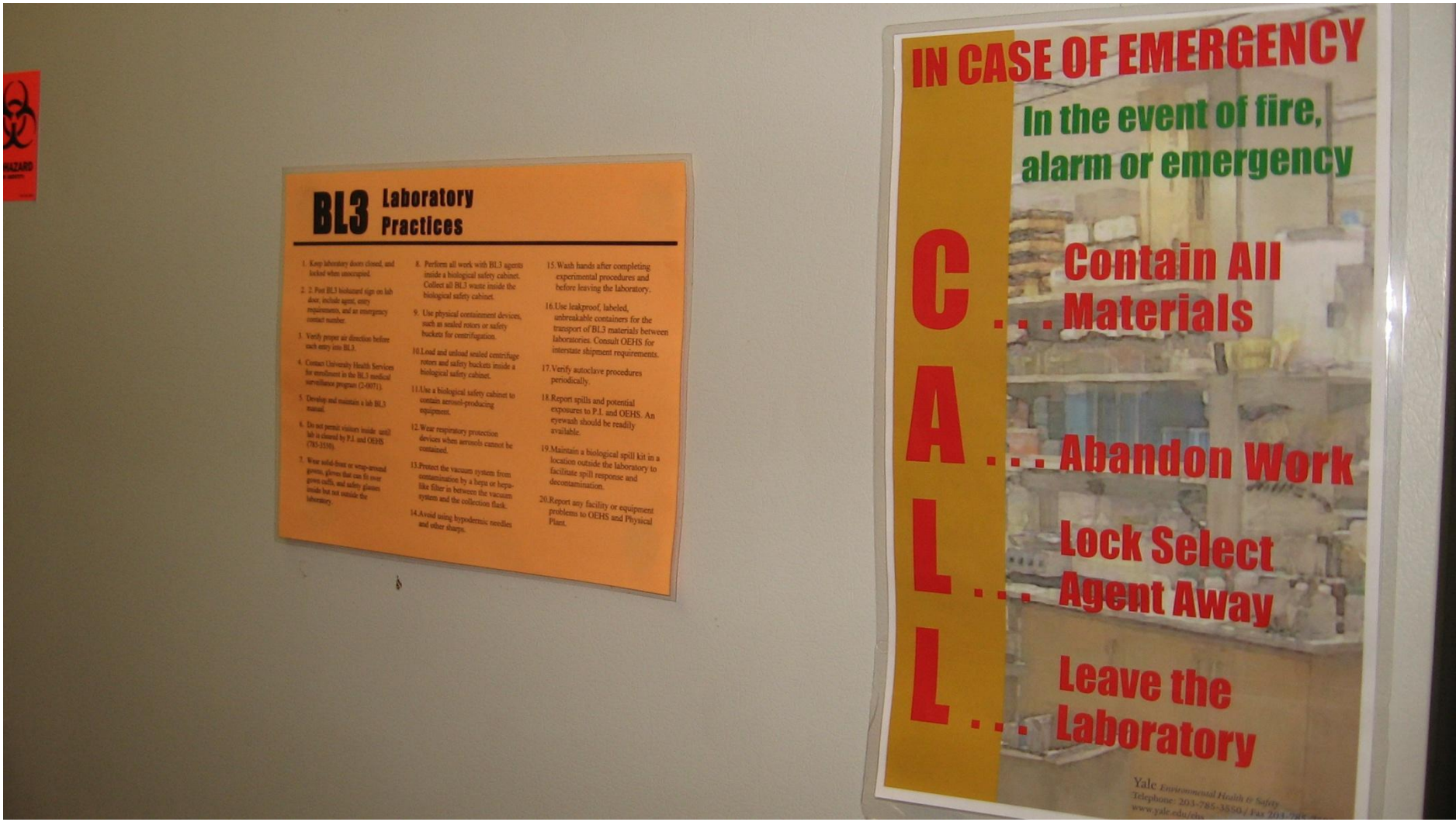
Use the following guidelines below for response to spills of BL3 material outside of the biosafety cabinet or any other incident that may have generated an aerosol in the containment laboratory, such as failure of physical containment devices during centrifugation.

IMMEDIATE ACTION:

- **Hold breath and leave room immediately; notify others in the room to evacuate immediately.**
- Remove personal protective equipment (PPE) in the airlock or access zone; turn potentially contaminated clothing inward; remove gloves last, and wash any exposed skin areas with antiseptic soap and warm water.

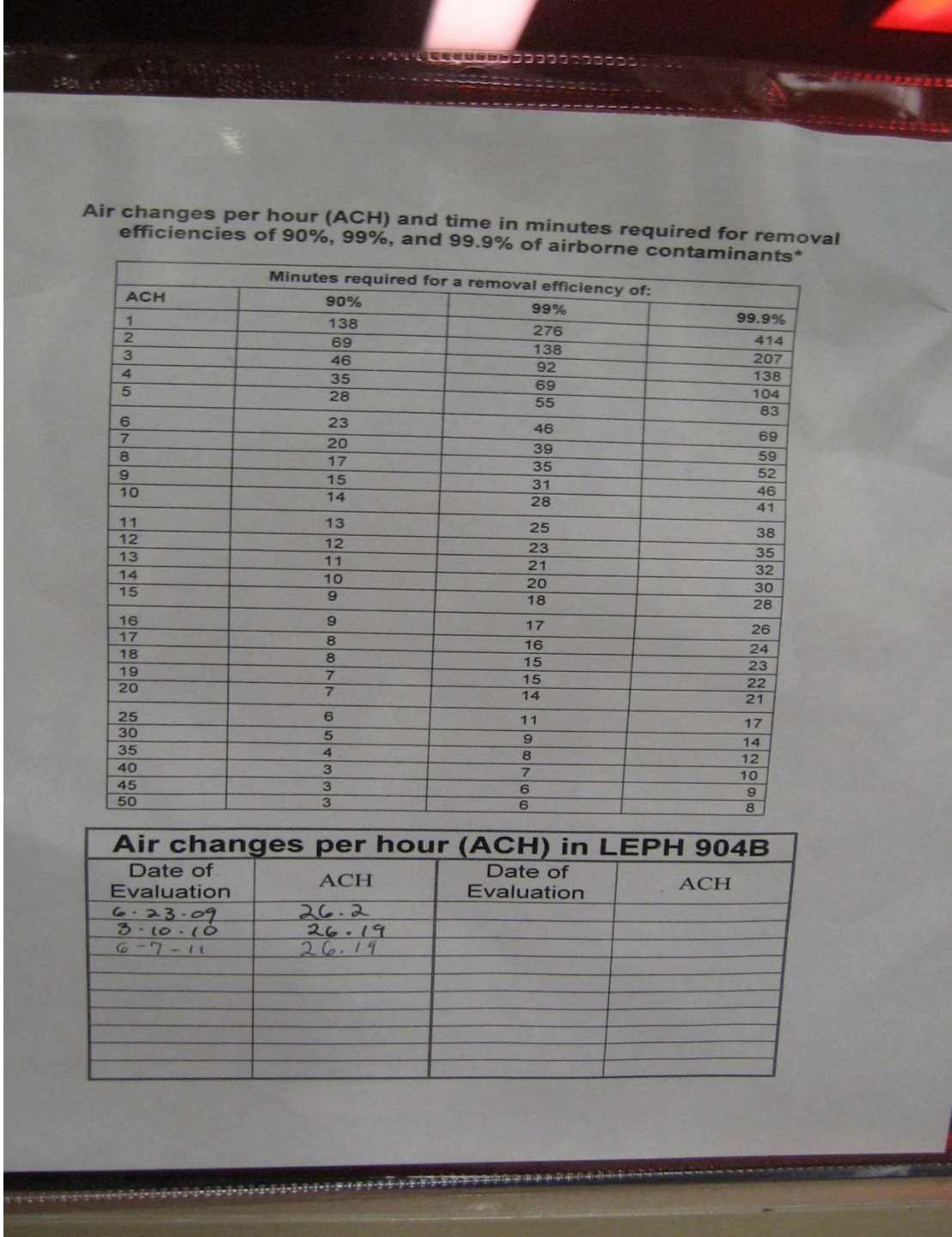
  *In the event of an exposure incident:
  - needlesticks/puncture wounds: wash the affected area with antiseptic soap and warm water for 15 minutes. Squeeze around the area to encourage the flow of blood out of wound.
  - mucous membrane exposure: Use an eyewash for 15 minutes to flush the affected area.
- **Post a BIOHAZARD SPILL SIGN at entry to BL3 lab door.**
- Notify your Principal Investigator and EHS
- **Do not reenter laboratory until it has been cleared for reentry by the P.I. or EHS (785-3555).** In general a period of at least 30 minutes should be allowed before clean-up is attempted, but the time is contingent upon the supply and exhaust features of the lab.

BSL3 Work Practices Poster



Effluent Decontamination SOP

Air Changes Per Hour Poster



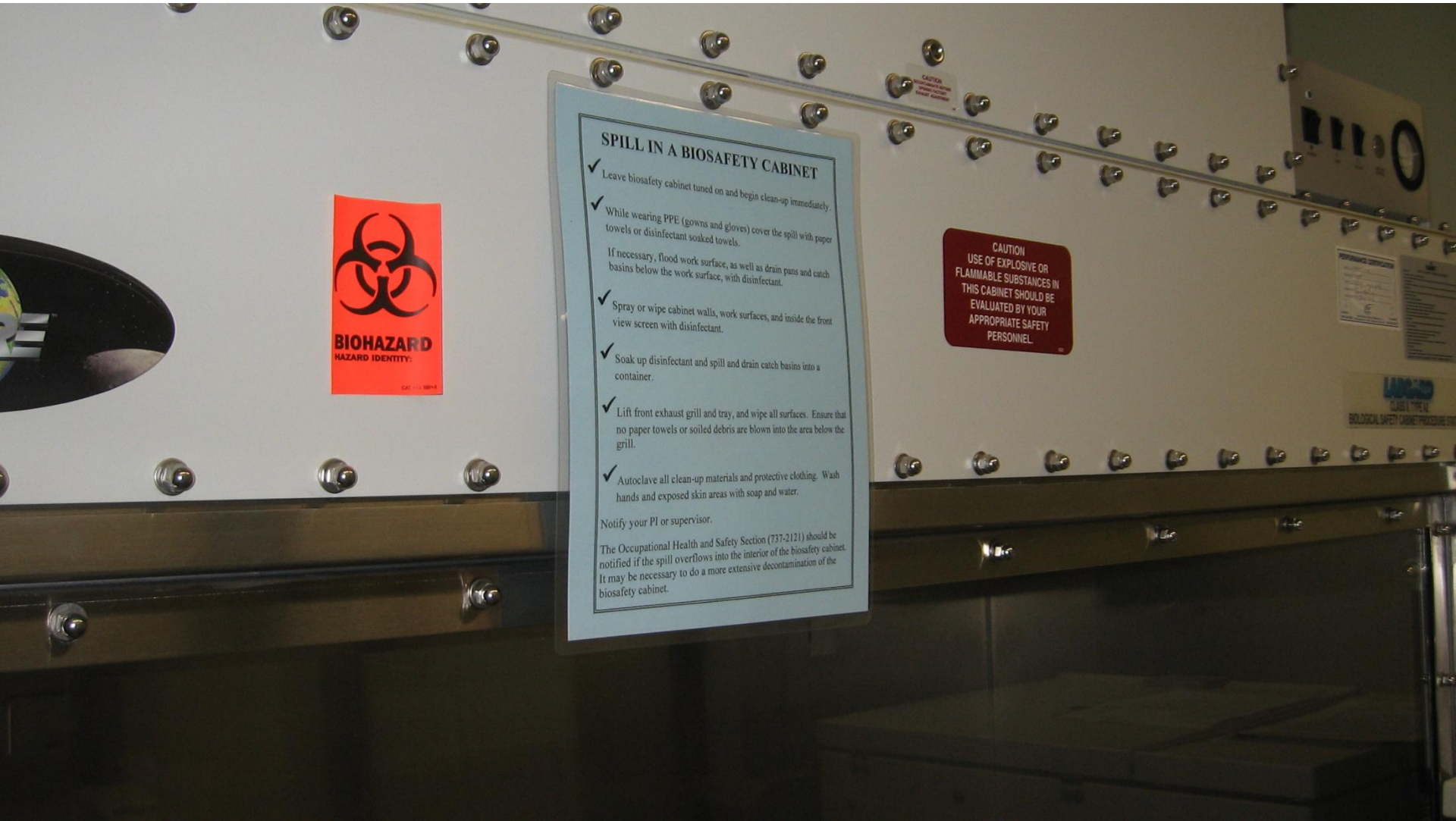
Air changes per hour (ACH) and time in minutes required for removal efficiencies of 90%, 99%, and 99.9% of airborne contaminants*

ACH	Minutes required for a removal efficiency of: 90%	99%	99.9%
1	138	276	414
2	69	138	207
3	46	92	138
4	35	69	104
5	28	55	83
6	23	46	69
7	20	39	59
8	17	35	52
9	15	31	46
10	14	28	41
11	13	25	38
12	12	23	35
13	11	21	32
14	10	20	30
15	9	18	28
16	9	17	26
17	8	16	24
18	8	15	23
19	7	15	22
20	7	14	21
25	6	11	17
30	5	9	14
35	4	8	12
40	3	7	10
45	3	6	9
50	3	6	8

Air changes per hour (ACH) in LEPH 904B

Date of Evaluation	ACH	Date of Evaluation	ACH
6·23·09	26.2		
3·10·10	26.19		
6-7-11	26.19		

Spill Inside a Biosafety Cabinet



Conclusion

- It takes a village
- Best practices are developed together
  - “None of us is as smart as all of us.” Satchel Paige
- Share your knowledge, but listen and learn
- Evolve with your programs