SAND2012-2754P

Engineering Controls & Laboratory Equipment

Instructor Guide – draft – November 2011

Sandia National Laboratories

International Biological Threat Reduction

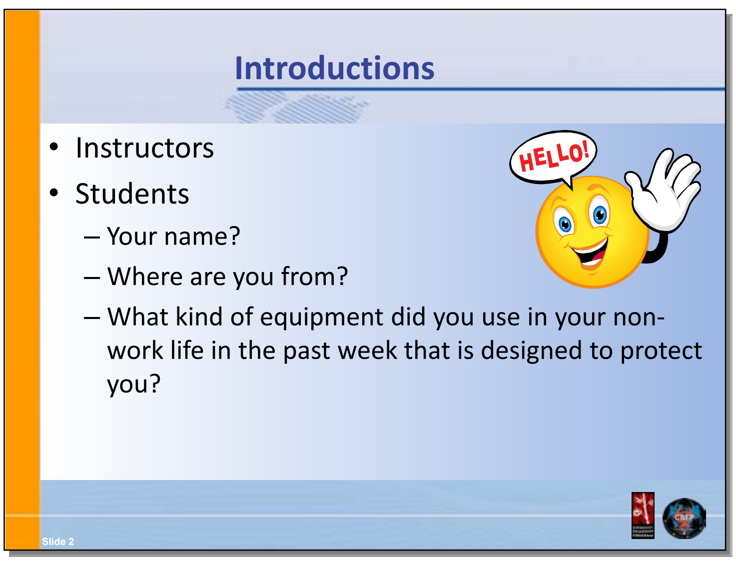
Biosecurity Engagement Program

CBEP Cooperative Biological Engagement Program

Welcome & Introductions

Slide 1

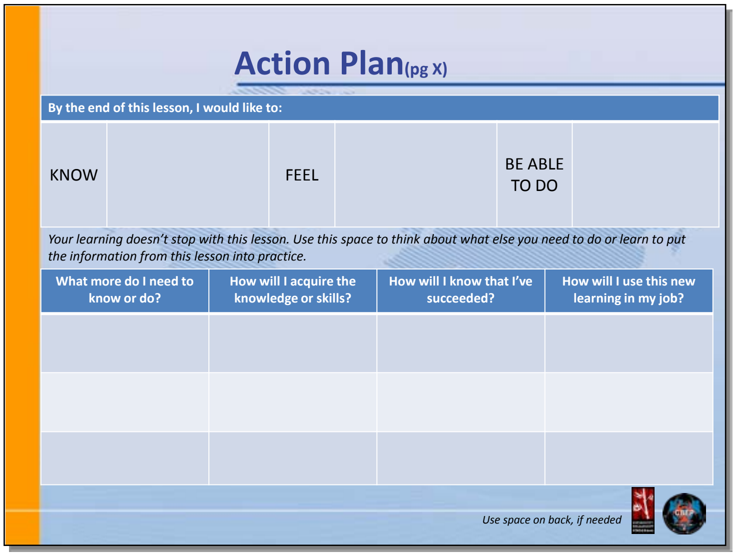
Slide 2



Instructor(s): Introduce yourselves briefly, including name, organization, and brief background.
Ask each student to introduce themselves, by giving their name and where they are from. Ask each student to think of something engineered that they used to protect themselves over the past week (designed to start thinking about what engineering controls are)

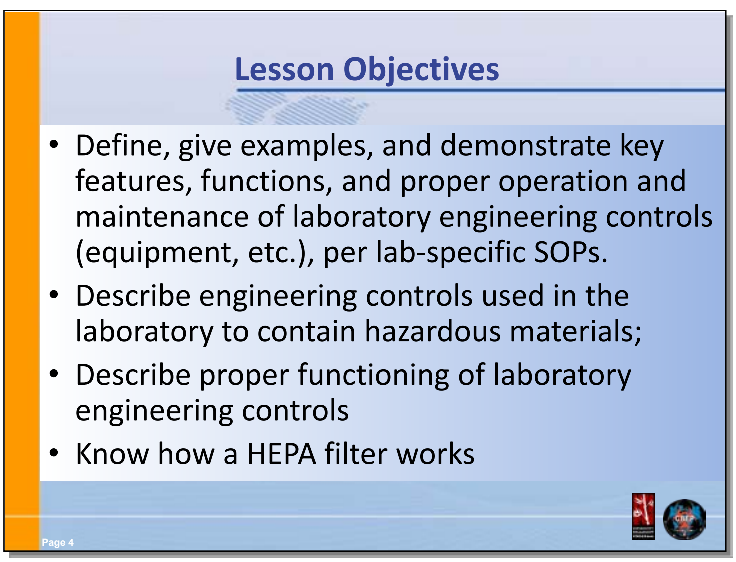
Welcome & Introductions

Slide 3



Insert standard Action Plan language

Slide 4

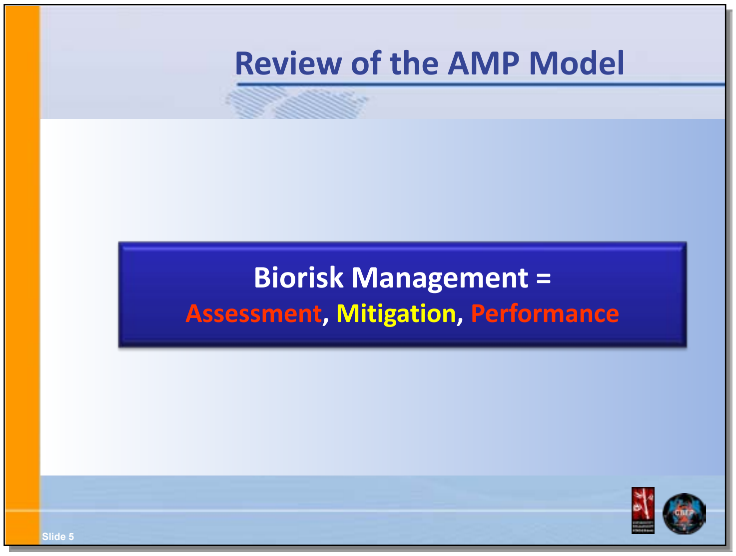


Welcome & Introductions

The objectives of this course are to introduce the concepts of engineering controls and laboratory equipment as they apply to biorisk mitigation. It is important to remind the students that they each will have very specific engineering controls and laboratory equipment in their labs – each of these requires more specific training and should also have written SOPs associated with them. This training course is designed to help them explore the reasons why engineering controls are chosen and how to make the right choice and the factors to use in designing effective SOPs when it comes to engineering controls and laboratory equipment.

Review of Biorisk Management and Mitigation

Slide 5

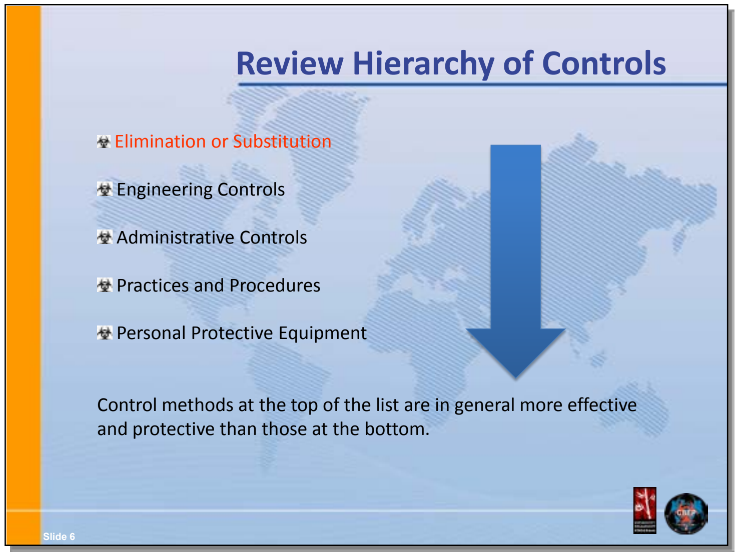


The first part of this course is a review of materials from previous lectures. Participants should have completed the Risk Mitigation Strategies course prior to taking this.

This should be a review for participants. Review by asking individuals to describe “Assessment”, “Mitigation” and “Performance” to remind and verify that everyone remembers the AMP model

Review of Biorisk Management and Mitigation

Slide 6



This should be a review for participants. Review by asking individuals why Engineering controls are considered more effective in general than PPE and the other controls.

Expected Answers: Engineering controls (if used properly) will remove the hazard from the environment and protect everyone in the lab (not just the wearer as in PPE)

Biological Containment

Slide 7

Small group activity (10 minutes).

Activity Instructions (to students)

1. Think about containment as is relates to biorisk management and
2. Work in groups to develop a definition for “containment” and write your definition in your workbook and
3. Ask a representative to write your group’s definition on your flipchart.

You have 5 minutes to complete this activity

Directions for Instructor:

- Have each group present their definitions and develop a working definition from input of the entire audience

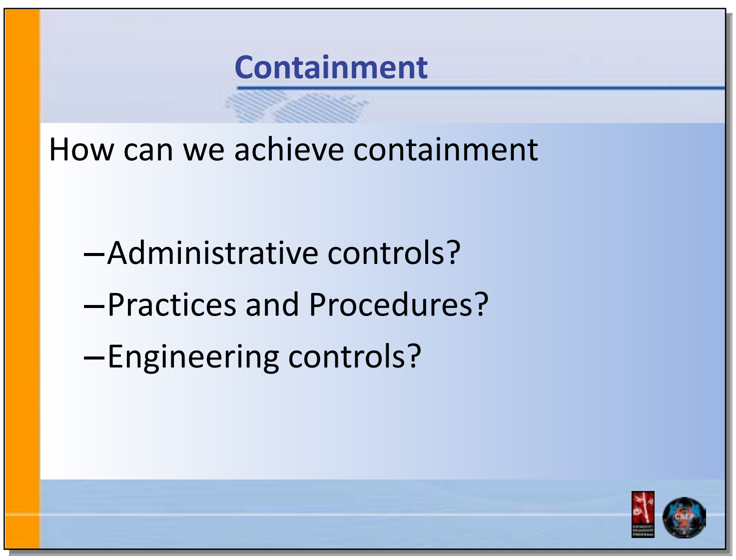
Biological Containment

Expected Responses

A structure or system designed to prevent the accidental release of biohazardous materials from the laboratory

New Responses from Students:

Slide 8



Biological Containment

Plenary Discussion (5 minutes). *(if this discussion is based on a projected slide, this block should follow the image of the slide)*

Question(s) to consider: How is containment achieved using:

- Administrative Controls?
- Practices & Procedures?

Directions for Instructor:

- Ask participants, in plenary, to discuss these mitigation strategies.
- Note: One of the reasons why we don't include PPE on this list is that PPE generally is not designed to achieve containment but acts as a barrier and protection to the user when containment is lost. That is one of the reasons why PPE is on the bottom of the hierarchy of controls.

Expected Responses

New Responses from Students:

Biological Containment

Small group activity (10 minutes).

Activity Instructions (to students)

1. Work in small groups for at least 5 minutes to list all of the different kinds of engineering controls found in the laboratory that help to achieve containment.
2. Capture each engineering control on a sticky note.
3. The instructor will collect the notes and make a master list as you generate the sticky notes.

You have 5 minutes to complete this activity

Directions for Instructor:

- A master list can be collected and discussed at the front.
- Point out that engineering controls are generally the most significant means for achieving containment.
- Many of the practices and procedures revolve around the proper use of engineering controls

Biological Containment

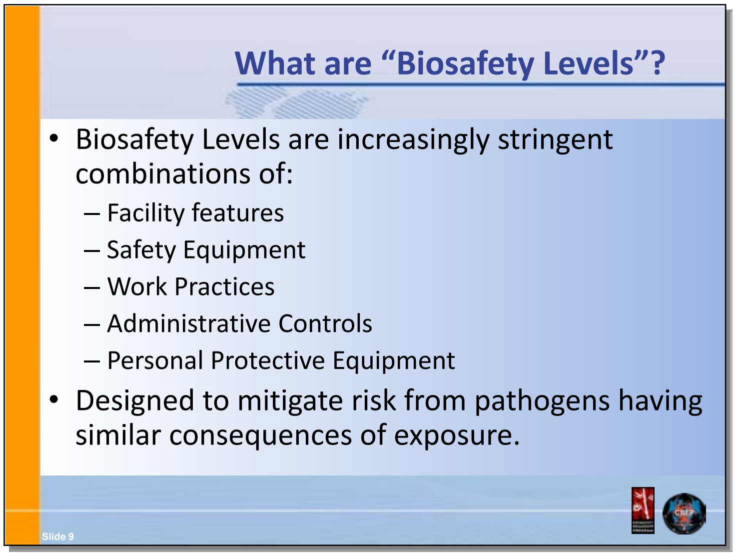
Expected Responses

- Administrative controls –
- Practices & Procedures –
- Engineering Controls –
- Building ventilation system
- Laboratory separated from areas that are open to unrestricted access
- Engineered traffic flow patterns
- Sealable lab with ducting systems that allow for gaseous decon
- Hands free controls
- Backflow prevention devices
- Autoclave
- Sealed, unbreakable, leakproof containers
- Controlled access systems (locks, alarms, card readers, etc.)
- HEPA filters
- Plastic test tubes (vs. glass)
- BSCs
- Fume hood
- Doors
- Sealed (unopenable) windows with safety glass
- Directional airflow
- Locks
- Interlocks
- Airlocks
- Effluent decontamination systems
- Safety caps on centrifuge buckets
- Engineered self locking syringe. (all the engineered safety needles)
- Puncture proof sharps container
- Anterooms
- Coved flooring
- Gasketed seals

New Responses from Students:

Biological Containment

Slide 9



The concept of biosafety levels originated to group mitigation strategies in 4 consequence-based groupings. Notice that there is no such thing as a Biosafety Level X agent. BSLs encompass the mitigation strategies that should be effective for mitigating agents with similar consequences of exposure.

Plenary Discussion (5 minutes). *(if this discussion is based on a projected slide, this block should follow the image of the slide)*

Question(s) to consider: What is the disadvantage to relying on the description of Biosafety Levels for mitigation strategies?

Directions for Instructor:

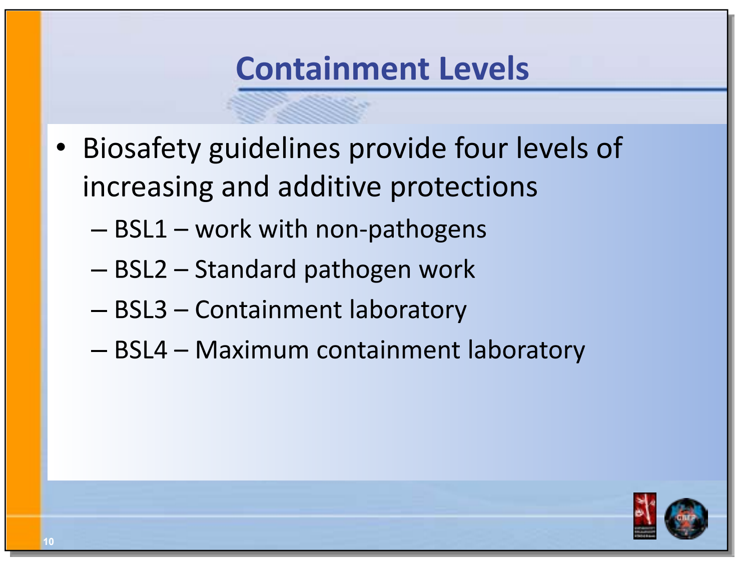
- Ask participants what might happen if BSLs are relied upon strictly for mitigation strategy assignments.

Expected Responses

The descriptions of BSLs are designed to cover a range of pathogens with similar consequences. Different experimental scenarios might change the risk making the mitigation strategies inappropriate. Also the BSL criteria are designed to be a collection of possible mitigation strategies. Not every criteria is required to appropriately mitigate risk.

New Responses from Students:

Slide 10



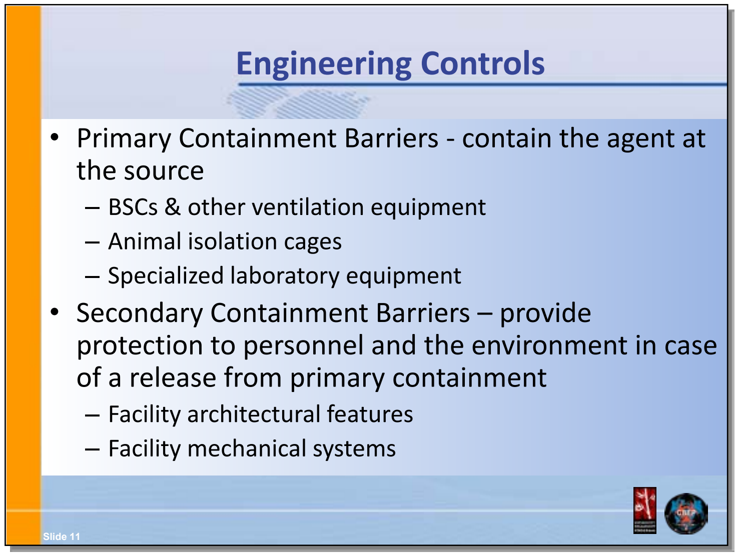
Biological Containment

Talk briefly about Biosafety Levels. At each level there is increasing and additive protections from a combination of Administrative controls, practices and procedures, engineering controls and PPE.

This should be a quick pass through slide. Participants should already be familiar with Biosafety levels. Discuss further if warranted. Some standards such as the BMBL are more prescriptive in what combinations of controls are required for each level whereas other biosafety standards describe what needs to be achieved and allow the users to develop the controls necessary to achieve the standard.

Engineering Controls

Slide 11



Engineering Controls

Instructor presents this definition for "primary" and "secondary" containment barriers. If time permits, have participants separate their listed controls under the headings "Primary", "Secondary", or "both". Instructor should also verify that participants are familiar with and understand the concepts of directional airflow, negative and positive pressure.

5 minutes

Expected Answers

Primary: BSCs, Puncture proof sharps container, Engineered self locking syringe. (all the engineered safety needles), Fume hood, Plastic test tubes (vs. glass), Sealed, unbreakable, leakproof containers

Secondary: Coved flooring, Anterooms, Building ventilation system, Laboratory separated from areas that are open to unrestricted access, Directional airflow, Doors, Locks, Effluent decontamination systems, Engineered traffic flow patterns, Sealed (unopenable) windows with safety glass, Sealable lab with ducting systems that allow for gaseous decon, Controlled access systems (locks, alarms, card readers, etc.), Backflow prevention devices, Autoclave

Both: Gasketed seals, Safety caps on centrifuge buckets, Airlocks, Interlocks, HEPA filters, Hands free controls

Engineering Controls

Small group activity (10 minutes).

Activity Instructions (to students)

1. Using the sticky notes that represent engineering controls, place each sticky note into a "primary" or "secondary" barrier or "both" category

You have 5 minutes to complete this activity

Directions for Instructor:

- This exercise might work to use the floor or large space on a wall. Have each participant gather a handful of sticky notes and place them appropriately.

Expected Responses

Primary: BSCs, Puncture proof sharps container, Engineered self locking syringe. (all the engineered safety needles), Fume hood, Plastic test tubes (vs. glass), Sealed, unbreakable, leakproof containers

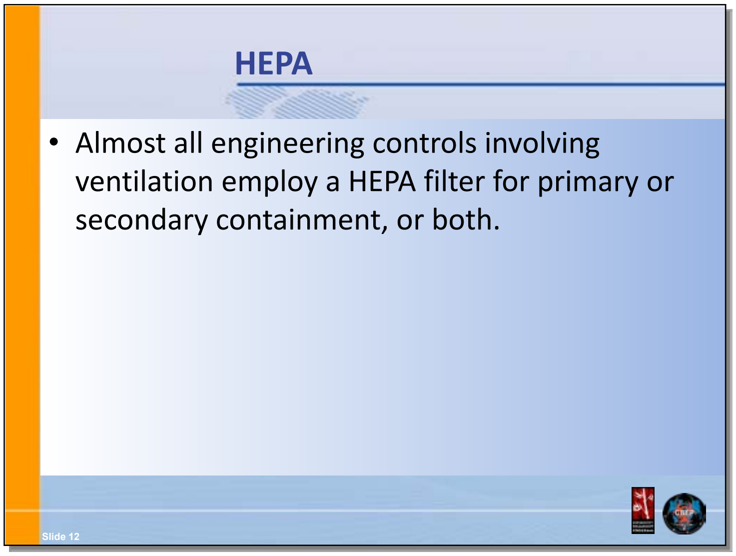
Secondary: Coved flooring, Anterooms, Building ventilation system, Laboratory separated from areas that are open to unrestricted access, Directional airflow, Doors, Locks, Effluent decontamination systems, Engineered traffic flow patterns, Sealed (unopenable) windows with safety glass, Sealable lab with ducting systems that allow for gaseous decon, Controlled access systems (locks, alarms, card readers, etc.), Backflow prevention devices, Autoclave

Both: Gasketed seals, Safety caps on centrifuge buckets, Airlocks, Interlocks, HEPA filters, Hands free controls

New Responses from Students:

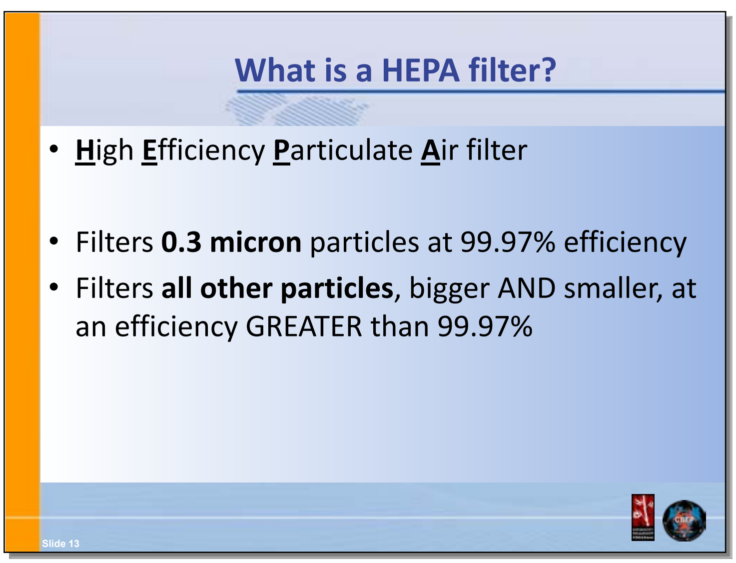
HEPA Filtration

Slide 12



One of the most important mitigation measure to understand and one of the most commonly misunderstood is the HEPA filter.

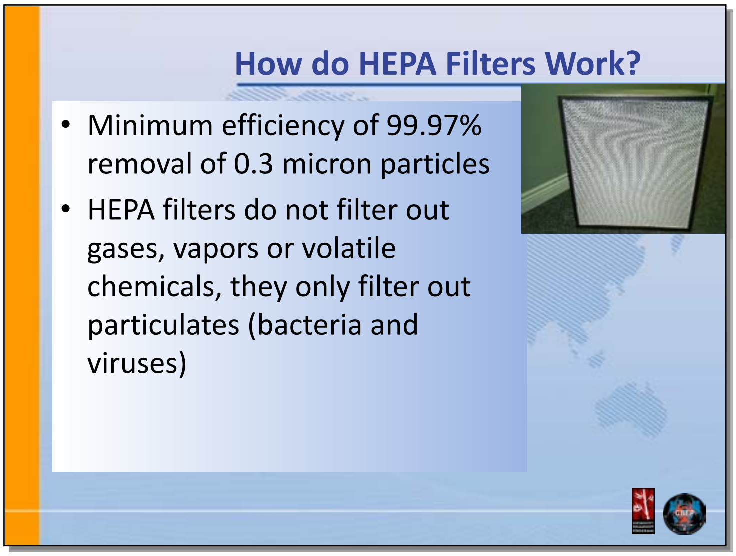
Slide 13



HEPA Filtration

It is imperative to understand that HEPA filters are the LEAST efficient when filtering particles that are 0.3 microns. With bigger and smaller particles, they are much more efficient.

Slide 14

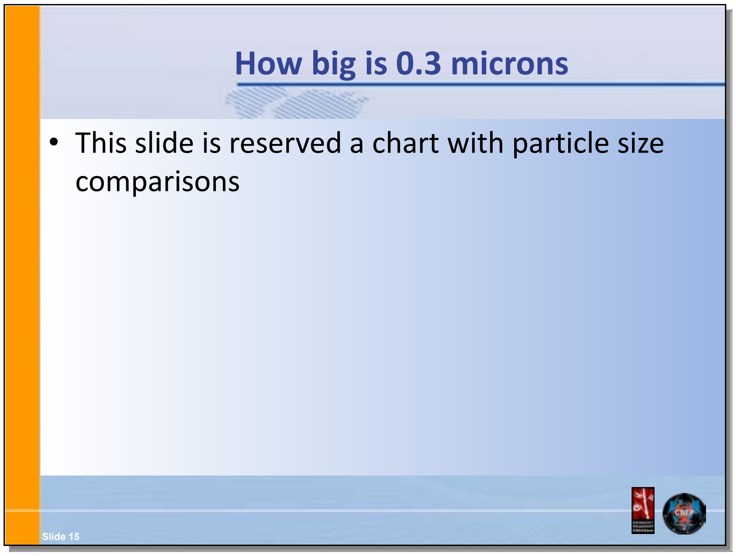


Replace slide

It is also critical to understand that HEPA filters filter ONLY particulates. They have NO effect on gases, vapors, or volatile chemicals. While a HEPA filter will keep a bacteria or virus from re-entering the work space once filtered, it will not keep chemicals from entering the work space or building up within the biological safety cabinet.

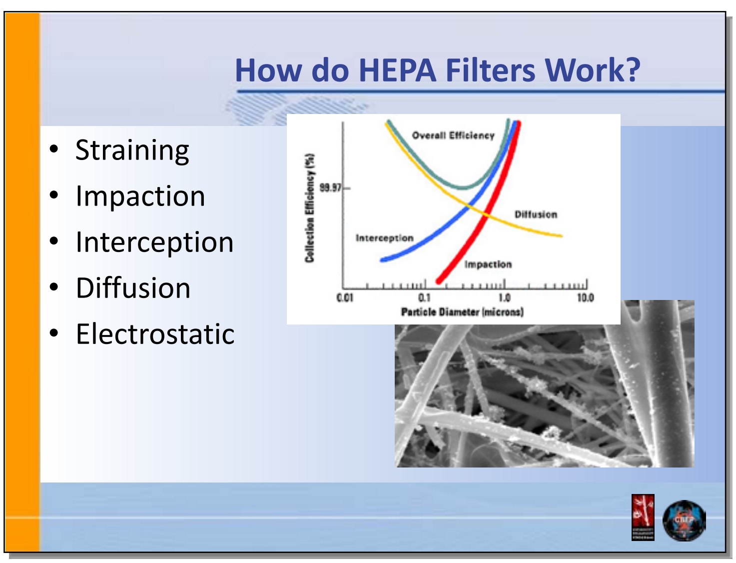
HEPA Filtration

Slide 15



The important thing here is that viruses are smaller than 0.3 microns and therefore readily captured. Bacteria are larger than 0.3 microns and therefore also readily captured in a HEPA filter.

Slide 16

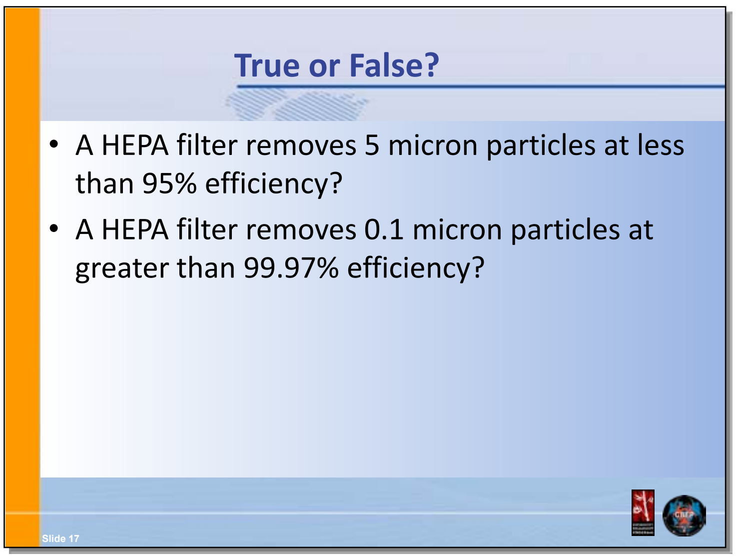


HEPA Filtration

HEPA filters are one of the most important engineering controls in a biocontainment. Airflow into the workspace of the BSC is HEPA filtered as is exhaust air from the BSC. HEPA filters capture and remove particles from the air through the following five ways: Straining, Impaction, Interception, Diffusion and Electrostatic capture.

Instructor - this is a good point to do a “role play” where some students assume the role of fibers in the HEPA filter while other students play the various particles that might be filtered by various methods. The point is that all the particles are subject, due to their unique electrical or physical properties, to filtration.

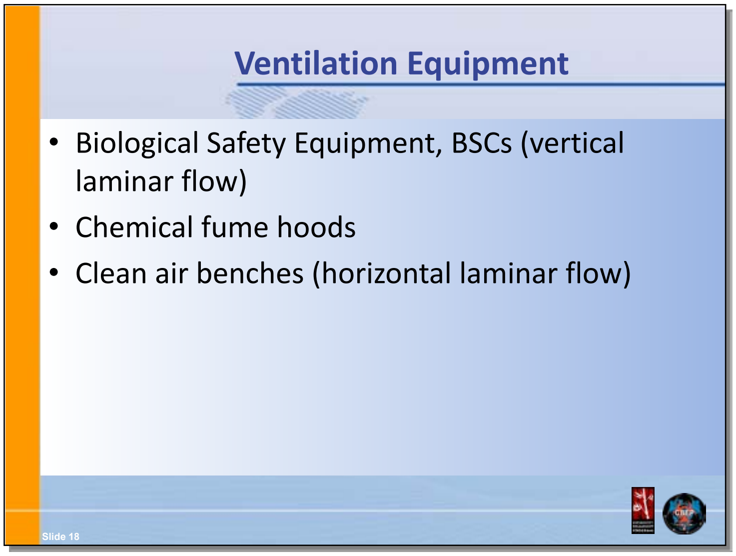
Slide 17



Hopefully the answers are a resounding FALSE and TRUE. Ask the students to articulate why the first question is FALSE and the second is TRUE. They should be able to repeat back to you the concepts of the previous slides. Re-emphasize that they need to be ready to explain this to their co-workers. HEPA filters are not “typical” filters with a nominal filtration size.

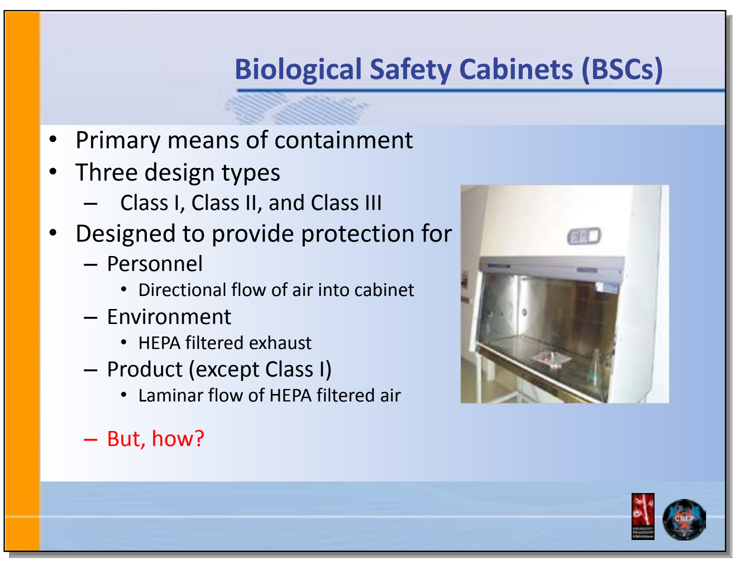
Biological Safety Cabinets

Slide 18



There are three primary types of ventilation equipment, separate from facilities which is covered in a different course, to be addressed.

Slide 19



Biological Safety Cabinets

Instructor presents this class and asks participants to think about how a BSC provides the protections listed above. This question is just to get them thinking and answer is not sought. The function of BSCs will be described in further slides.

Slide 20

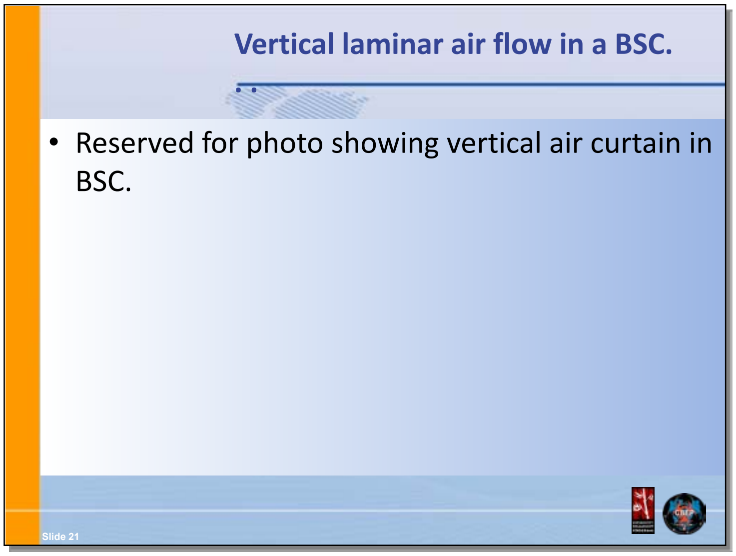
(need to include the video in our folder)

BSCs provide protection through two key features: direction airflow and HEPA filtration. This video demonstrates the directional, laminar airflow in a BSC.

Key things during the video for the instructor to point out. . .

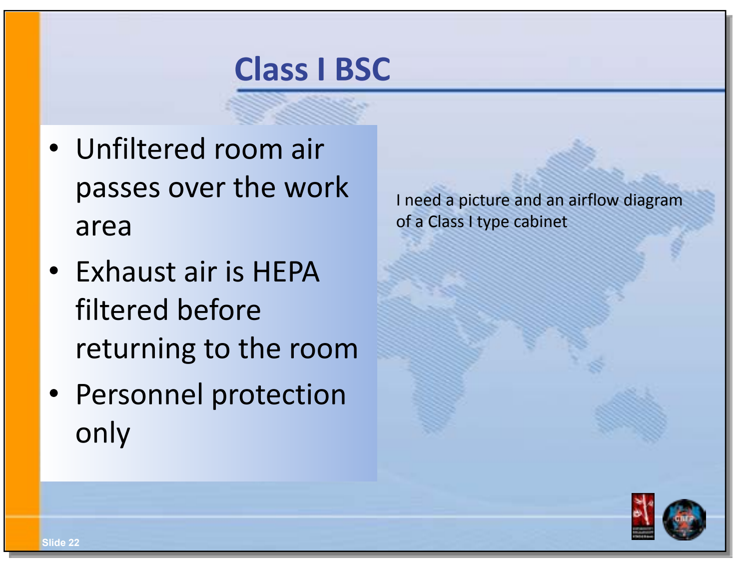
Biological Safety Cabinets

Slide 21



Use a photo or video to assure that the vertical laminar flow is shown if it is not shown effectively in the previous video.

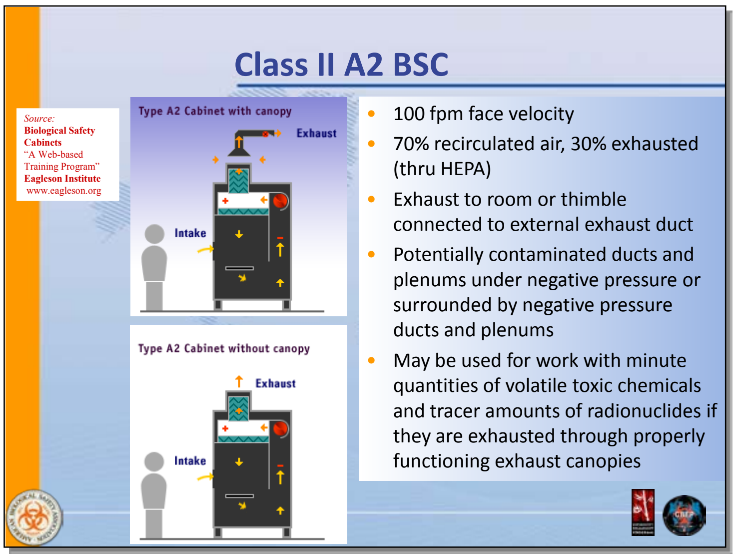
Slide 22



Biological Safety Cabinets

Instructor should spend about five minutes discussing the purpose, function and use of a Class I Cabinet. The key is that the Class I cabinet provides personnel protection and environment protection, BUT NOT product protection. Ask the class to say why a Class I protects 1) personnel and 2) environment, but not 3) product.

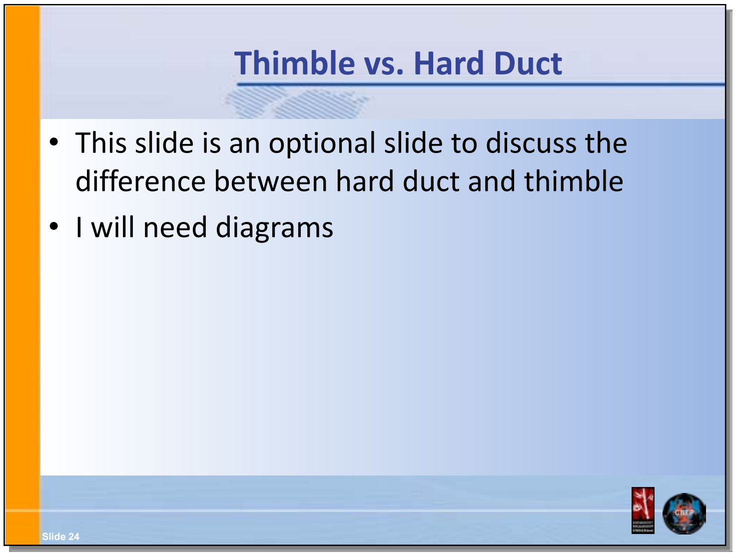
Slide 23



This is the type of BSC that most people think of when a BSC is referred to. Instructor should review the features of a Class II, Type A2 BSC and ask the class why this class protects all three components: personnel, environment and product.

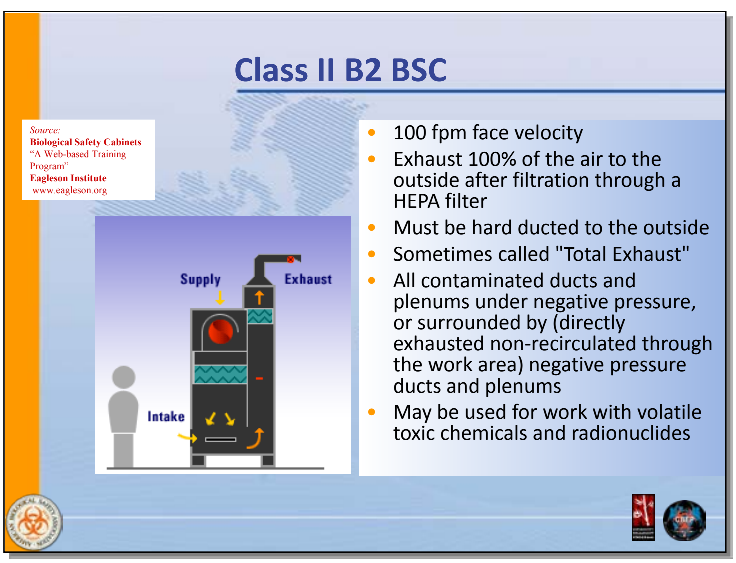
Biological Safety Cabinets

Slide 24



Reminder that cabinets that are hard ducted should not be turned off since their functioning is likely critical to the air balance that has been designed into the laboratory.

Slide 25



Biological Safety Cabinets

The instructor should also mention the other Class II BSCS: Types B1 and B2 and the benefits and disadvantages of each (can use small amounts of chemicals, but must be hard-ducted and thus are much more expensive and harder to maintain.

Slide 26

Biological Safety Cabinets

- The Class III biological safety cabinet (is sometimes referred to as a glove box) was designed for work at agents requiring biosafety level 4 (BSL-4) containment, and provides maximum protection to the environment and the worker. It is a gas-tight enclosure with a non-opening, completely sealed, viewing window. Access to the interior of the cabinet is through a double-door pass-through "interchange" box (such as an autoclave) that can be decontaminated between uses and/or a dunk tank that is accessible through the cabinet floor. Reversing that process allows for safe removal of materials from the Class III biosafety cabinet.

- Both supply and exhaust air are HEPA filtered. Exhaust air must pass through two HEPA filters, or a HEPA filter and an air incinerator, before discharge to the outdoors. Air Flow is maintained by a dedicated independent exhaust system exterior to the cabinet, which keeps the cabinet and all associated ducting under negative pressure.

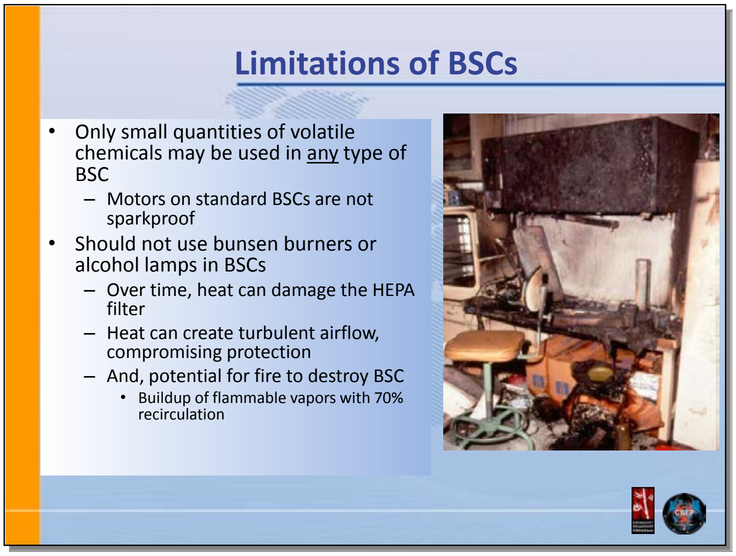
- Long, heavy-duty rubber gloves are attached in a gas-tight manner to ports in the cabinet and should permit replacement without compromising containment. Although these gloves restrict movement for the manipulation of the materials isolated inside the cabinet, they prevent the user's direct contact with the hazardous materials. The trade-off is clearly on the side of maximizing personal safety.

- Depending on the design of the cabinet, the supply HEPA filter provides particulate-free, somewhat turbulent, Air Flow within the work environment. To minimize interior turbulence, however, the inflow air should be ducted to a distribution manifold located on the rear wall just above the work surface. The distribution manifold also provides the means to house an anti-static bar, bathing plastic materials with both positive and negative ions.

- Several Class III cabinets can be joined together in a "line" to provide a larger work area. Such cabinet lines are custom-built; the equipment installed within the cabinet line (e.g., refrigerators, small elevators, shelves to hold small animal cage racks, microscopes, centrifuges, incubators, etc.) is generally custom-built as well. Furthermore, Class III cabinets are usually only installed in maximum containment laboratories that have controlled access and require special ventilation or other support systems (such as steam for autoclaves). The reader should consult more definitive literature on these systems.

Biological Safety Cabinets

Slide 27



Ask students to use what they've learned about BSCs to determine what might have happened to cause this explosion and fire? Give them 5 minutes to discuss in small groups and then discuss the answer in plenary.

Expected answer: flammable chemicals or natural gas building up in the plenum of the cabinet, followed by ignition of a flame (and, unintentionally, the gas in the plenum) in the BSC. Or possibly ignition of the HEPA filter.

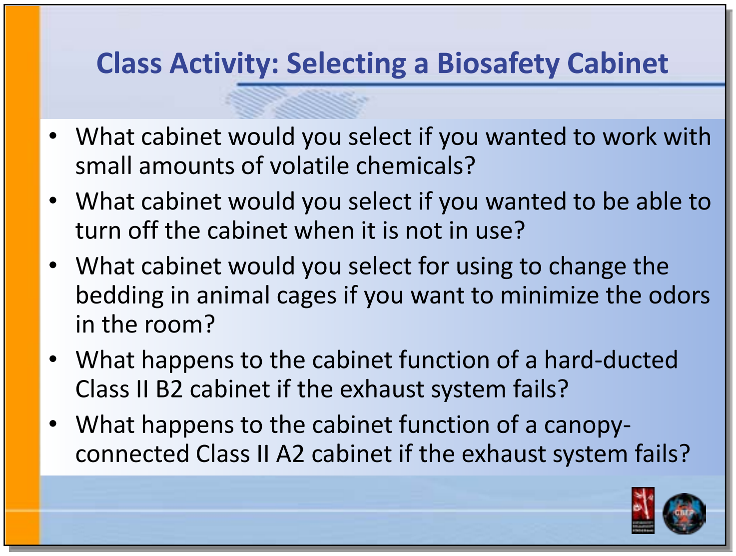
Biological Safety Cabinets

Slide 28

Ask students why this isn't considered a BSC?

This picture was taken in a laboratory where staff indicated that this was their Biological Safety Cabinet. You may get some splash and splatter protection but the wood surfaces will make decontamination difficult and there is not HEPA filtration, laminar air flow and therefore little product or personnel protection.

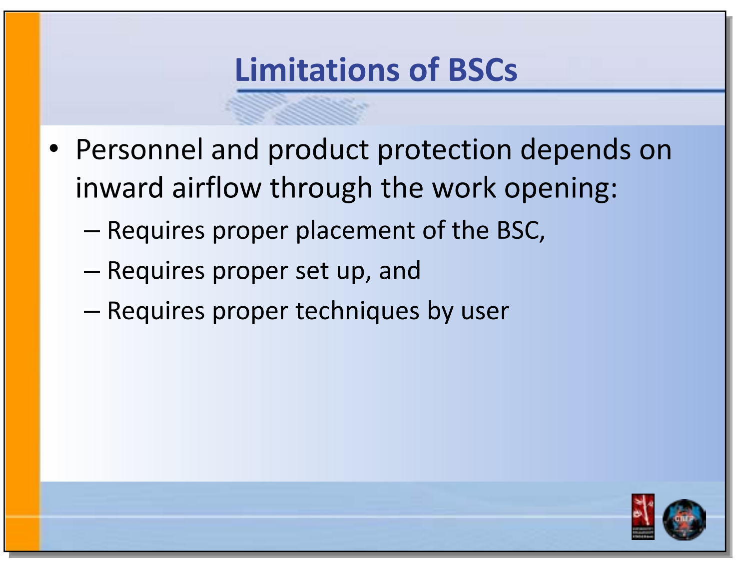
Slide 29



Ask each group to address one or two of these questions.

(Need to have expected answers)

Slide 30



Biological Safety Cabinets

Ask in plenary: “What are some things that could disrupt the airflow at the front of the cabinet?”

Expected answers:

- Repeated and quick motions of hands in and out of the cabinet (especially side to side sweeping movements)
- Cabinets placed near door or window openings
- Walking past the cabinet (don’t locate cabinets near high traffic flow areas in the lab)
- HVAC supply vents

Slide 31

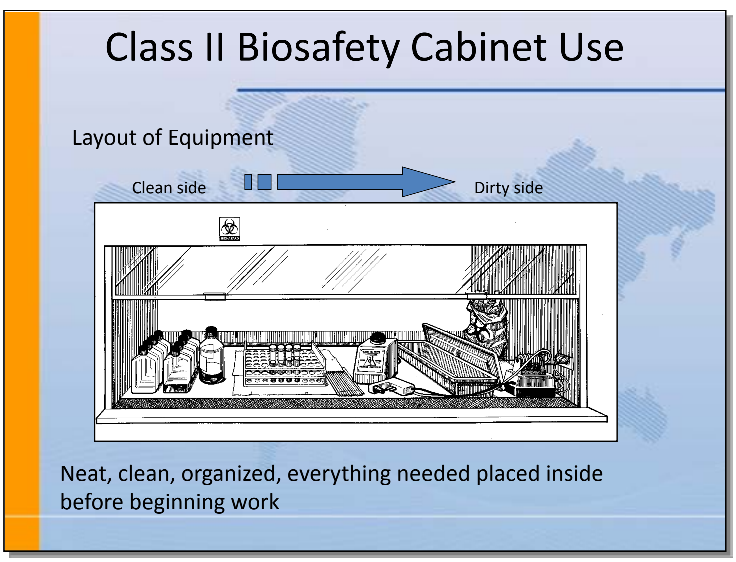
The image on the right shows a poor placement for the BSC: next to the door and underneath a supply air exhaust. Breezes and gust near the cabinet could disrupt the airflow and leave product and personnel less protected. The picture on the lower left shows baffles (shielding) in place on the supply/exhaust vents to prevent disruption of airflow near the cabinet. This cabinet has also been properly located away from high traffic areas.

Biological Safety Cabinets

Slide 32

In addition to the above, make sure the sash height is set in the appropriate position. Too high or too low will result in improper airflow and can result in loss of product or personnel protection.

Slide 33



Biological Safety Cabinets

Due to the down flow of air in the cabinet, passing dirty items back over the top of clean items in the cabinet can result in contamination. Always work from clean to dirty.

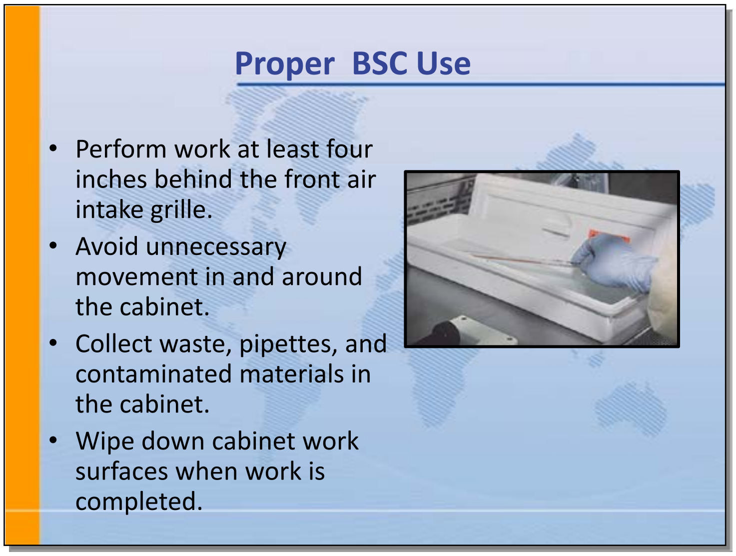
Slide 34

Ask students to address why the grilles must be kept clear? What is the outcome if they are not?

Expected answers: obstructs air flow which might create an opportunity for particulates to escape into the breathing zone. Or contaminated air can be introduced into the work space which can affect the experiment or sample.

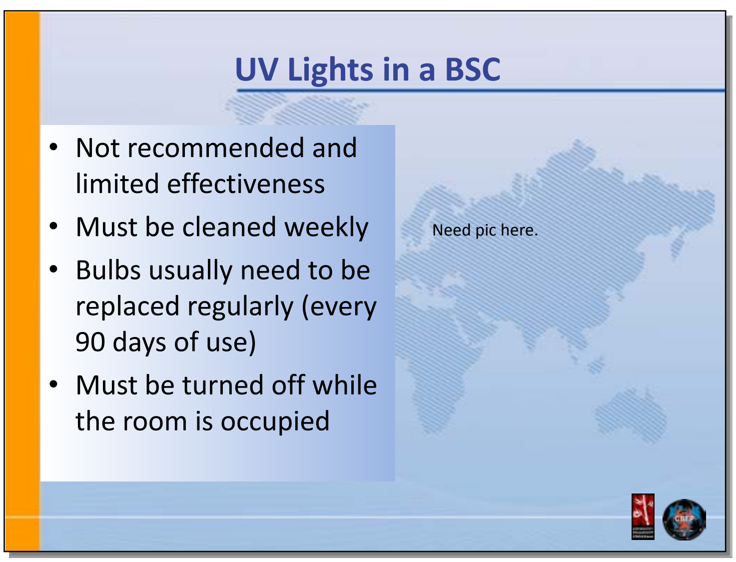
Biological Safety Cabinets

Slide 35



- Frequent in and out movements can compromise both personnel and product protection
- Never place your face below the sash opening while working (never put you head inside the cabinet) Example of SARS LAI?

Slide 36



Biological Safety Cabinets

UV lights are not recommended. If they are used, they must be cleaned weekly to remove any dust and dirt that may block the germicidal effectiveness of the light. UV intensity should be checked when the cabinet is recertified to ensure light emission is appropriate. UV must be turned off while the room is occupied to protect eyes and skin from inadvertent exposure

Slide 37

How do you make sure that your BSC, which is a very complex piece of equipment, is functioning correctly?

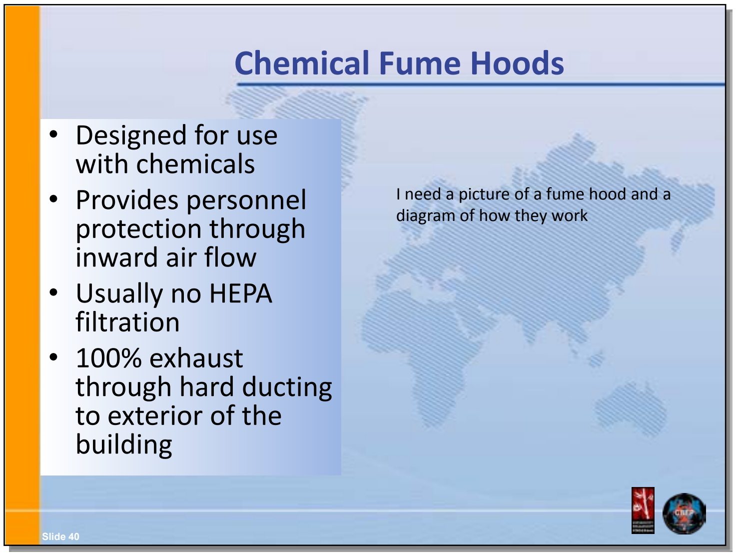
Biological Safety Cabinets

Slide 38

- The functional operation and integrity of each BSC should be certified to national or international performance standards at the time of installation and regularly thereafter by qualified technicians, according to the manufacturer's instructions.
- Evaluation of the effectiveness of cabinet containment should include tests for cabinet integrity, HEPA filter leaks, downflow velocity profile, face velocity, negative pressure/ventilation rate, air-flow smoke pattern, and alarms and interlocks. Optional tests for electrical leaks, lighting intensity, ultraviolet light intensity, noise level and vibration may also be conducted.
- Special training, skills and equipment are required to perform these tests and it is highly recommended that they are undertaken by a qualified professional.
- Instructor should also mention decontamination: BSCs must be decontaminated before filter changes, before servicing, and before being moved. The most common method is by fumigation with formaldehyde gas. However, there are also other options including vapor phase hydrogen peroxide, and chlorine gas. Any of these methods should only be performed by qualified professionals.

Other Ventilation Equipment

Slide 39

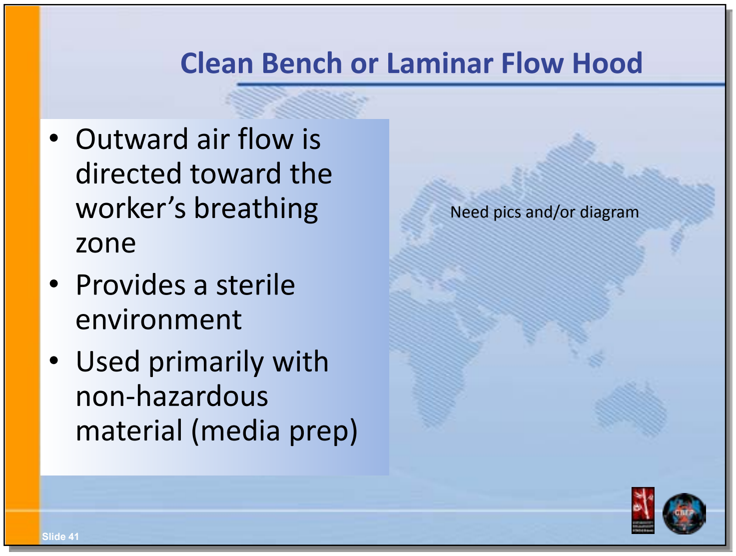


Instructor presents how a fume hood works and emphasizes the following points:

- Designed for use with large amounts of chemicals
- Provides personnel protection through inward airflow through the sash opening
- Does not provide any product protection since contaminated air from the laboratory is drawn directly over the work surface
- Does not provide any environment protection (typically no HEPA filtration of exhaust air)
- 100% of air is exhausted through a hard ducting usually to a tall stack on the roof of the building.

Other Ventilation Equipment

Slide 40

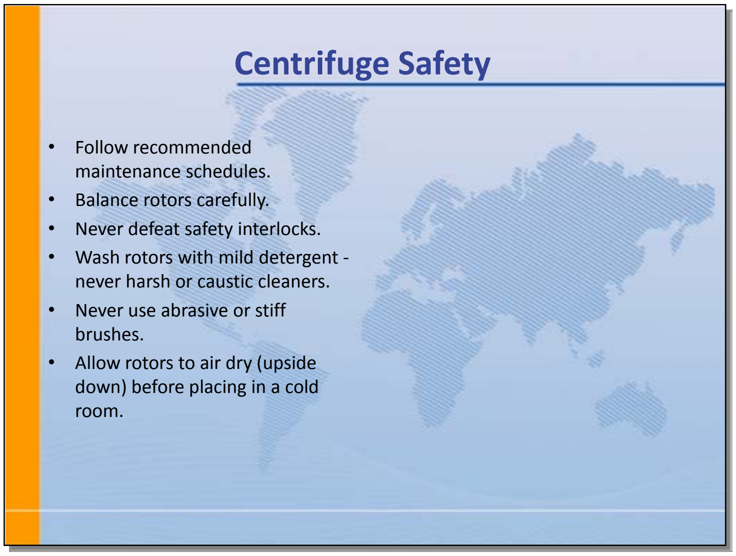


Clean benches are engineering controls designed strictly to protect PRODUCT. There is no personnel or environmental protection.

Do not confuse "horizontal laminar flow" for "vertical laminar flow"

Other Lab Equipment

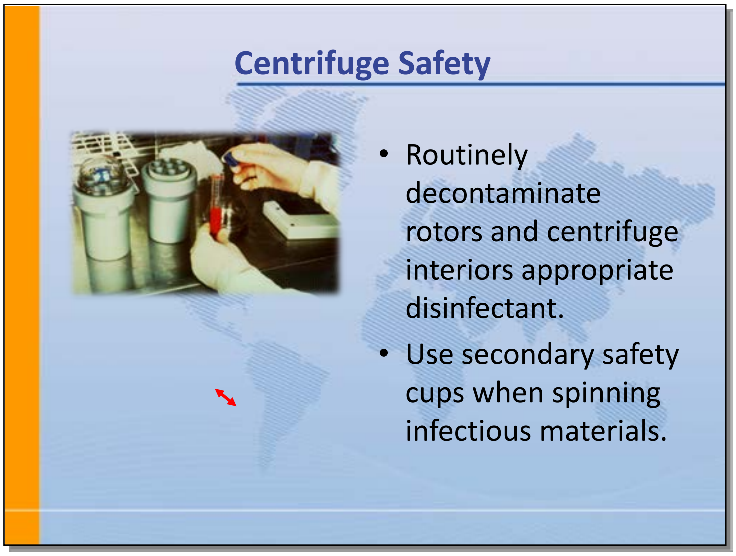
Slide 41



Ask students whether a centrifuge could be considered to be an engineering control. (Without certain safety devices, the answer is no). Why should centrifuge procedures use safety devices and what are they designed to protect against? (Due to high speed centrifugation, the possibility of aerosolization and pressurization of contents is high. If a tube or a rotor is damaged or if there is a significant malfunction of a centrifuge, unexpected and undetected aerosols may be released (see Sabia incident)

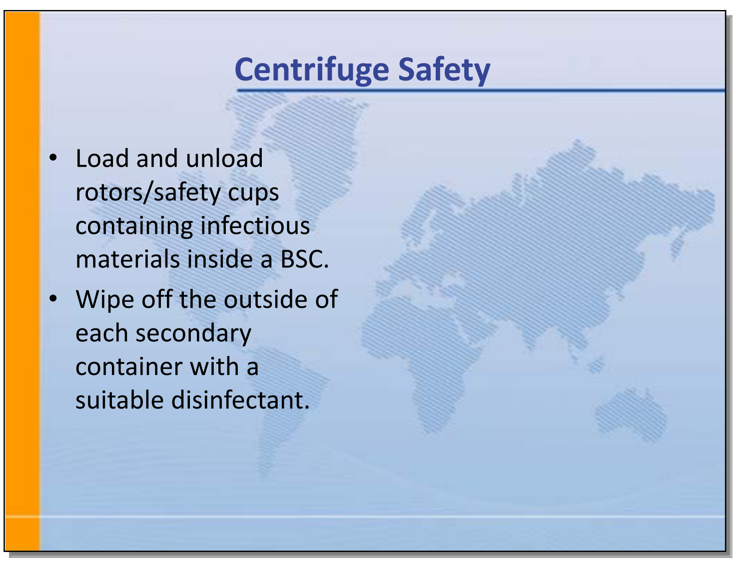
Other Lab Equipment

Slide 42



Ask students to address why these are good practices to protect against undetected exposure to infectious agents.

Slide 43



Other Lab Equipment

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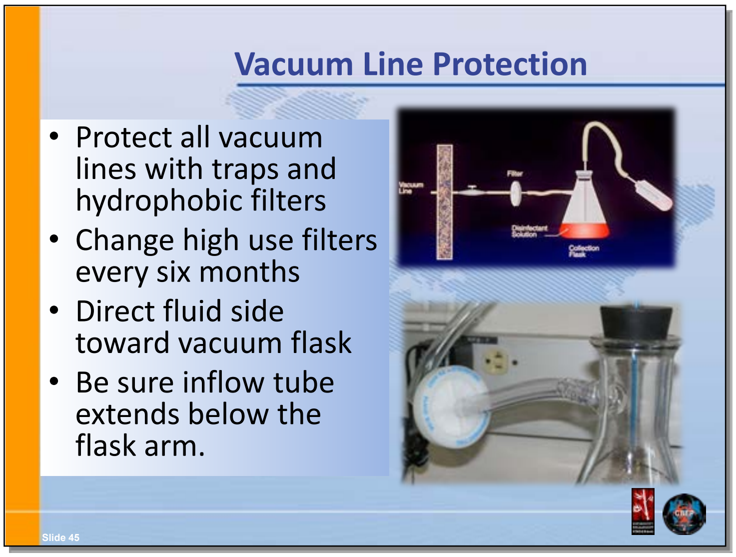
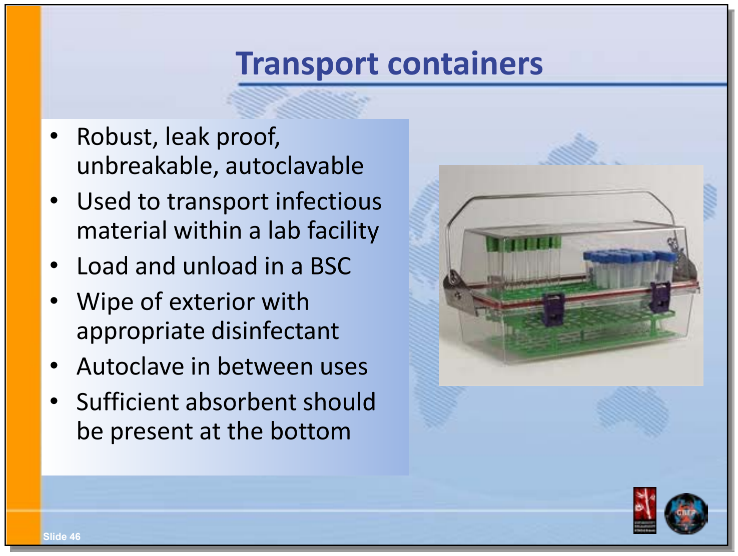
Slide 44



- Ask students what the risks are with unprotected vacuum lines (contamination of vacuum lines can result in an unknown and undetected aerosolization of infectious agents; also can contaminate a “house” vacuum system, if it exists)
- Disinfectant solutions need to be changed regularly depending on the disinfectant and should be defined by lab SOP. Note the concentration of disinfectant needs to be appropriate for a full container. (If using bleach, it should be changed at least weekly)

Other Lab Equipment

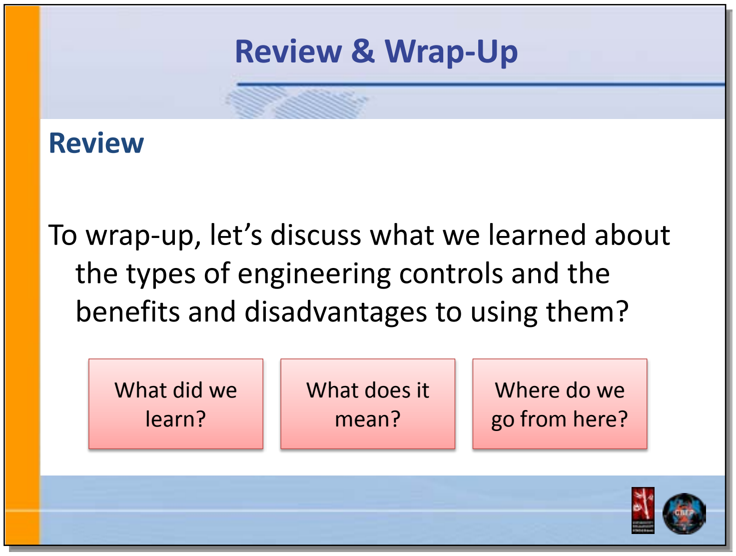
Slide 45



Ask students why a transport container is considered an engineering control. Ask what risks a transport container is designed to mitigate. Also ask what advantage a clear container has over one that you can't see in?

Review & Wrap Up

Slide 46

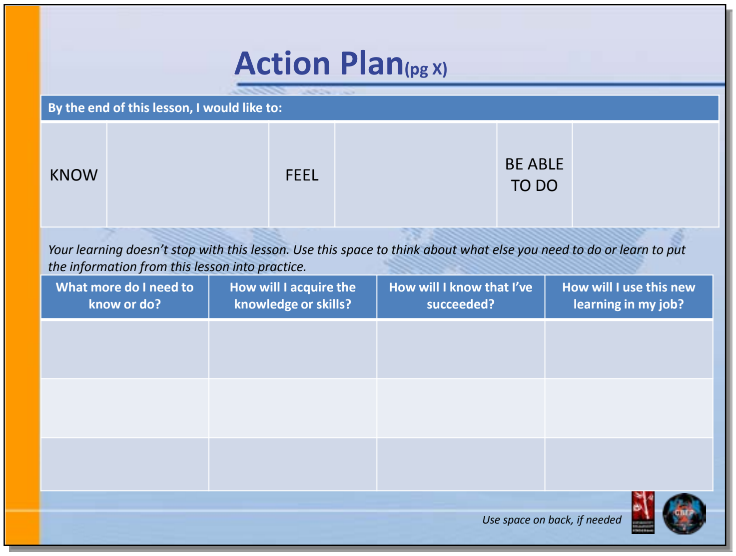


Ask students to look at their list of engineering controls and to pick one primary and one secondary barrier. For each control, list the benefit (the risk that the control is designed to engineer out) and the disadvantages(s) to using that control.

As students report out, ask them to list one fact or practice about engineering controls or lab equipment that they will take back to their co-workers.

Review and Wrap-Up

Slide 47



Remind students to look over their action plan and see if they need to add any new things to learn or next steps to take. Suggest that they put a date on each action item to give themselves a target to hit.

Slide 48