CLINICAL LABORATORY DESIGN FOR BIOSAFETY LEVELS

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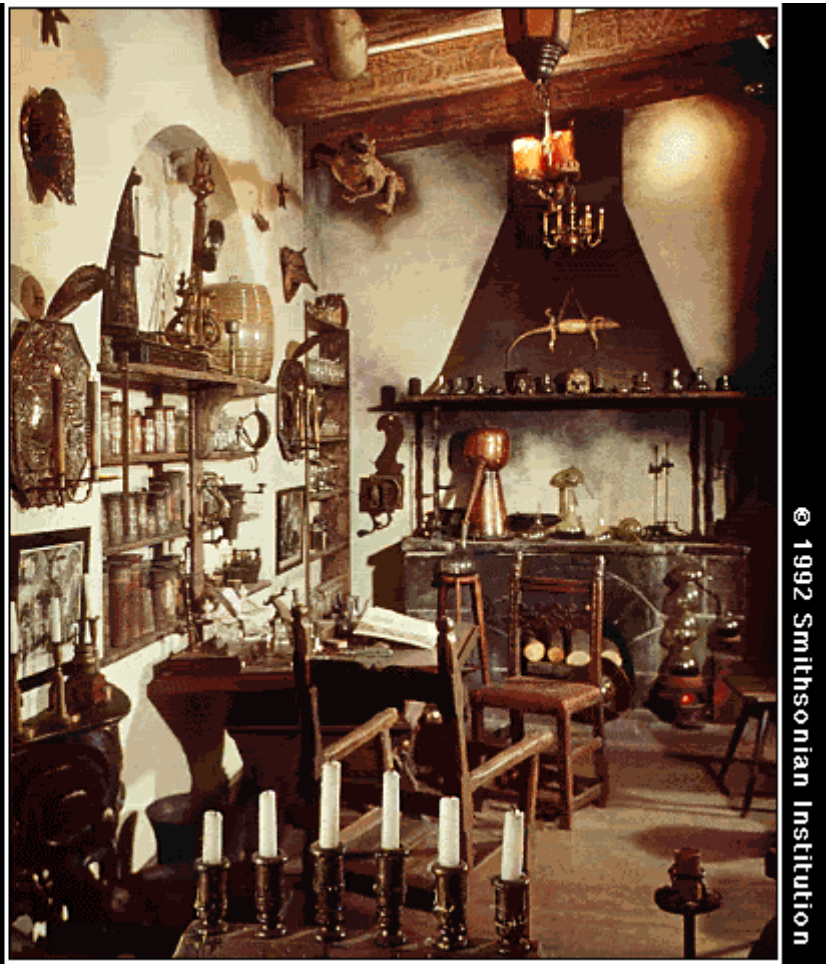
Workshop outline

- Where did Biosafety levels/ decisions come from?
- What Biosafety levels for what clinical laboratory areas?
- How do they relate to other codes, guidelines and recommendations?
- How to we design to meet the criteria?
- What are other safety issues for Clinical Labs?
- Some examples

Laboratory Associated Infections (LAIs)

- 4079 reported LAIs between 1930 an[redacted] 1978
  - 168 deaths
- 1978 to 1998 126 [redacted] overt infections
  - 22 deaths
    - some of which we[redacted] fetuses caused b[redacted] workers spontane[redacted] abortion as the re[redacted]



Laboratory Associated Infections (LAIs)

- Top causes, that were identifiable
  - Brucella sp
  - Coxiella burnetti
  - Hepatitis B & C
  - Salmonella sp, Shigella sp.
  - Francisella tularensis
  - Mycobacterium tuberculosis
  - Blastomyces dermatitidis
  - Venezuelan equine encephalitis virus
  - Chlamydia psittaci
  - Cocidioides immitis

New agents to be aware of

- Antibiotic resistant strains of bacteria
- Genetically modified agents
  - Found in recombinant DNA
- Bioterrorism with agents not normally found in our region

How risks are based

- **Potential to release microorganisms into air as aerosols and droplets
- Nature of work
- Severity of disease
- Infectivity
- Transmissibility
- Origin of agent
  - indigenous
  - exotic

Routes of transmission in a laboratory

- Inhalation of infectious aerosols
  - Most work with liquid suspensions of microorganisms cause aerosols and droplets
    - When inhaled are kept in human lungs if small
    - Fall on work surfaces if large
- Hand to mouth exposure
- Ingestion of liquid with the infectious agent
- Sticks from a contaminated needle (sharps)
- Bites from infected agent or vector
- Direct skin, eye, or mucus membrane

How aerosols are created

- Pipetting
- blenders
- non-self contained centrifuges
- sonicators
- vortexes, mixers
- Splattering from incinerators – sizzling of liquids on hot wire loop
- Spills

Why Isolate?

- To protect the laboratorians
- Create a barrier to protect people outside of the lab
  - Non laboratory personnel
  - Public
  - Environment

Clinical laboratories

- Infectious nature of specimens is often unknown
- Initial processing and serological testing can safety be done at BSL2
  - Consistent with OSHA bloodborne pathogen
  - Requires specific precautions with all clinical specimens
  - CLSI also has some recommendations
- Segregation of laboratory functions is the decision of the lab director.
  - Need to determine proper biosafety levels for the

What is required?

- Codes are requirements from the government
  - Federal, state, city, county….. Must follow strictest no matter who writes it.
- Guidelines are strong recommendations
  - Be careful when ignoring guidelines, such as ADA, as you can still get sued.
  - Accreditations may be determined by following guidelines.

CDC Manual

- Is not a code
  - Meant to be a voluntary code of practice – a guideline
  - Advisor in most circumstances
  - Meant to safeguard laboratory workers and to protect the public and environment.

Other organizations with biosafety guidelines

- Looked at risk groups by other health organizations
  - WHO
  - NIH
- Criteria for determining Risk Groups 1 through 4 is the same as noted previously.

Codes

- OSHA - Occupational Safety & Health Administration
  - Enforced by States; Public Law 91-596
  - Failure to comply with rules may mean fines and other penalties
- NFPA – National Fire Protection Association
  - Local Fire officials
- State government
  - Want to know what they consider mandatory, sometimes use the HHS/ AIA Guidelines and will not give building permit/license without compliance
- Federal government
- “Code like”
  - Facility Rules and Regulations

Guidelines

- CAP – College of American Pathologists
  - Accreditation agency – need to comply if you want to be certified by them.
  - If undergo inspection and fail twice they can send results to the State who can revoke your license.
- CLSI – Clinical and Laboratory Standards Institute
  - Guidelines created from other sources including codes and accreditation
- JCAHO – Joint Commission on Accreditation of Healthcare Organizations

Biosafety Level 1 (BSL1)

- Agents do not cause disease in normal healthy people
- Most risk from direct contact with agents in samples or on direct work surfaces
- Basic containment with no special primary or secondary barriers

Biosafety Level 2 (BSL2)

- Moderate-risk agents
- Cause disease of varying severity
- Most risk from direct contact with agents in samples or on direct work surfaces
  - By ingestion
  - By percutaneous or mucous membrane exposure

Biosafety Level 3 (BSL3)

- Known to cause serious and possibly lethal disease
- Potential for aerosol transmission

Biosafety Level 4 (BSL4)

- High risk of lethal disease
- Infectious aerosols
- No treatment available

BSL4

- Work with dangerous and exotic agents that can have the risk of life-threatening disease
- transmitted via aerosols
- No treatment available
- Any manipulation of specimens is dangerous
- Use Class II BSC, full body suit
- Separate building or completely isolated zone
- Special ventilation and waste management

BSL1 – Clinical departments?

- Used with teaching labs or those labs done with only defined organisms not know to cause disease in adult humans.
  - Generally not used in normal Pathology (Clinical or Anatomic) teaching laboratories
    - Teaching samples same as testing samples
    - Most samples have possibility of harboring organisms that will cause disease
    - Always have the “unknown” factor

BSL2 – Clinical Departments?

- Applicable to clinical, diagnostic, teaching and labs where the work is on a broader menu of organisms that could cause disease.
  - Appropriate when work is done on blood, body fluids, tissues or primary cell lines where agents are unknown.
  - Would include almost any pathology department whether clinical path or anatomic path.
    - Exceptions would be those that require a level 3 area.

BSL3 – Clinical Departments?

- Applicable to clinical, diagnostic, teaching, research, or production where there is a potential for respiratory transmission by the agent.
- Typical Clinical areas affected
  - Virology
  - Mycology
  - TB
  - Molecular Diagnostics

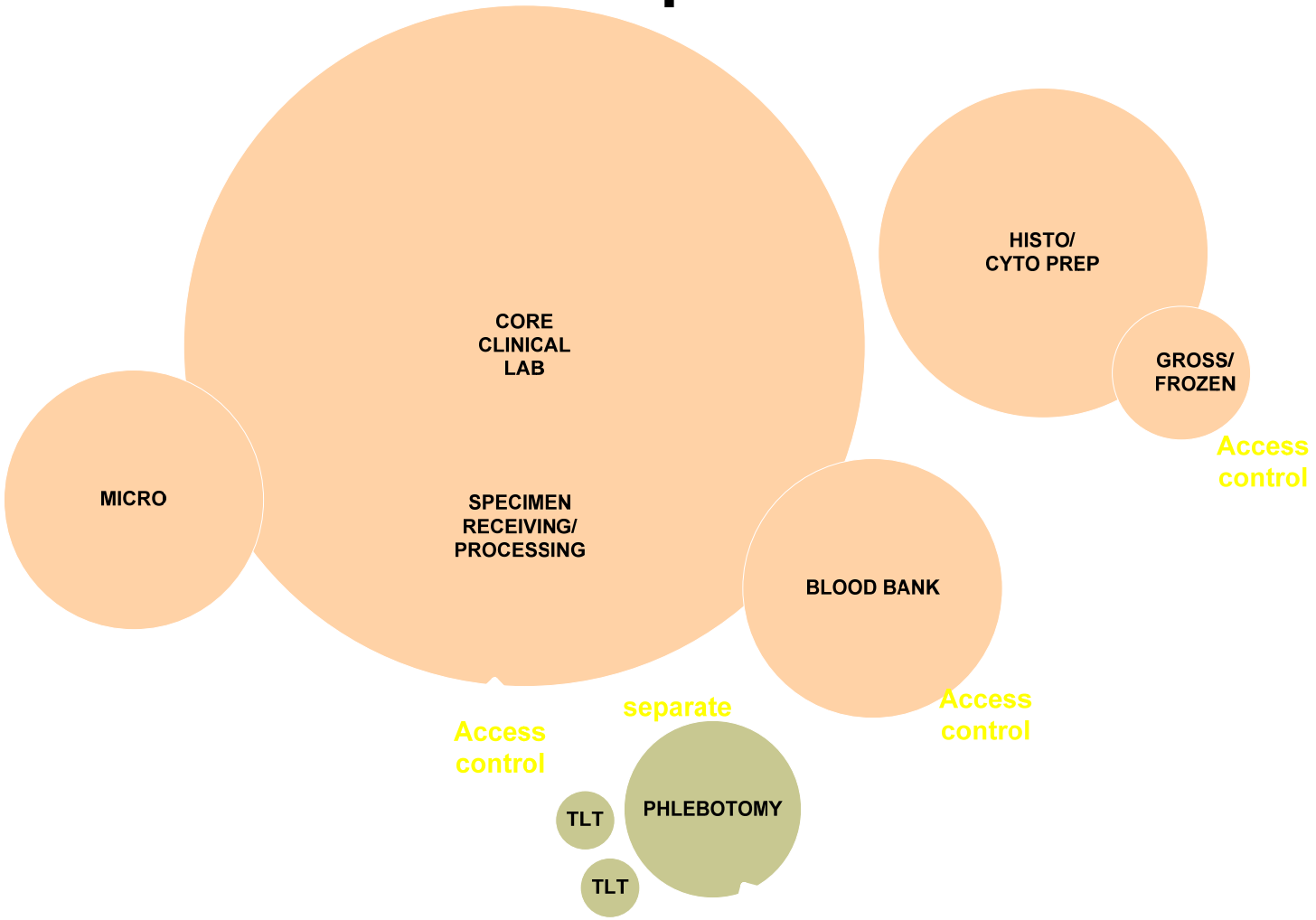
BSL1 – Separation

- Don’t necessarily have to be separated from the general traffic in the building
  - Not considered to have dangerous aerosols so can be open to areas where non-laboratory work is being conducted.
  - Cannot be open to eating areas.
- Should have doors for access control
  - This conflicts with the comments on being allowed to be part of the general traffic of the facility, unless you can close off the whole facility as part of the access control

BSL2 – Separation

- Doors should be self-closing and have locks
- Have to control access into the laboratory
  - Cannot have doors that someone can enter without being seen. Ideally all doors should be locked, or at least monitored by someone who can screen visitors.
  - Different shifts will require differences in locked areas, access, visibility.
- Options in design
  - Alcoves for courier access

BSL2 - Separation



Courier Alcove

BSL3 – Separation

- More emphasis on primary and secondary barriers; protect people in contiguous areas, the community and environment
- Policies to control access to the lab
- Physical separation from areas that are open to unrestricted traffic flow in the building
- Self-closing, doors with locks
  - Restricted to entry by a series of two self-closing doors

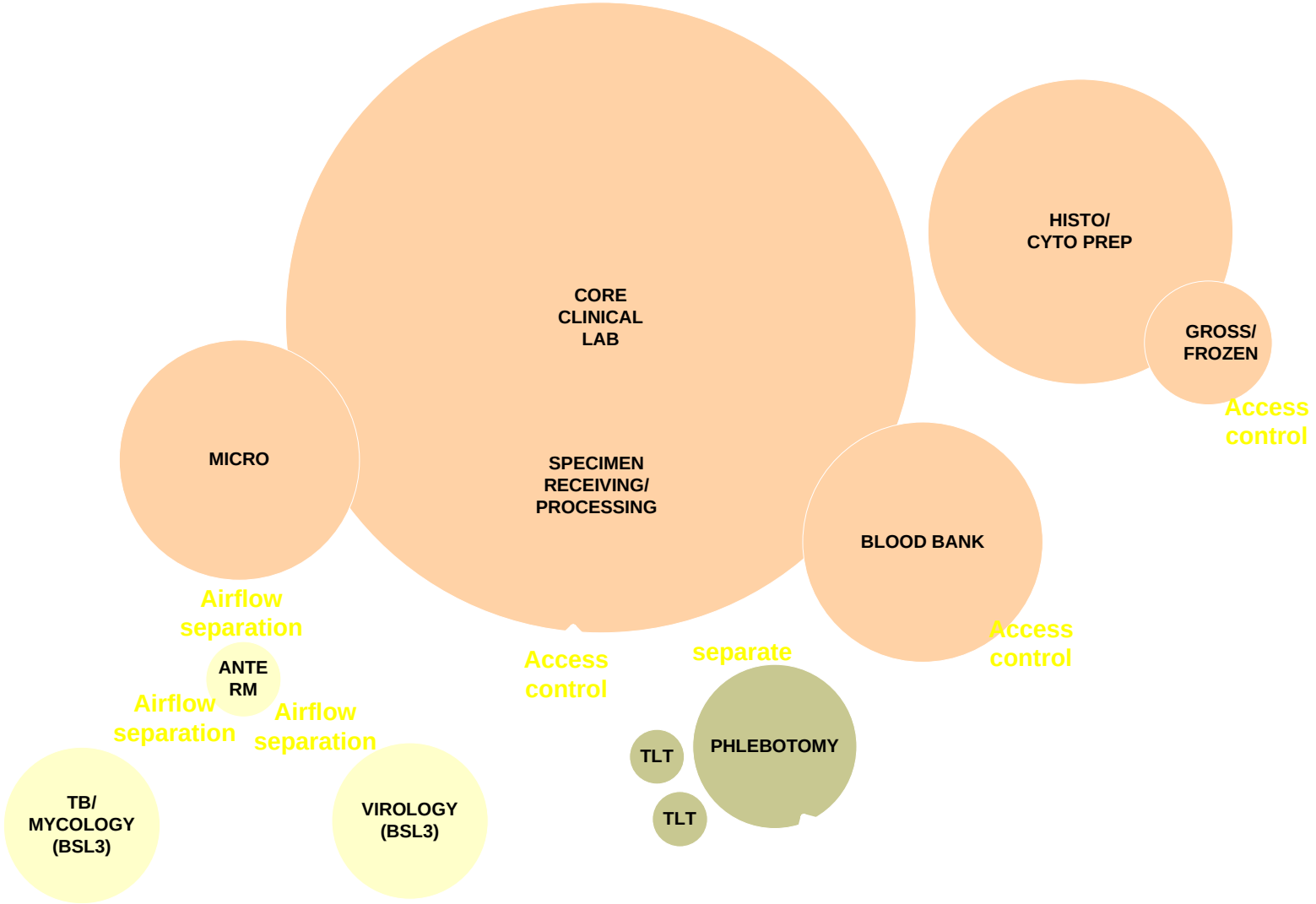
Separation – other criteria

- CAP
  - Is the laboratory properly separated from inpatient areas?

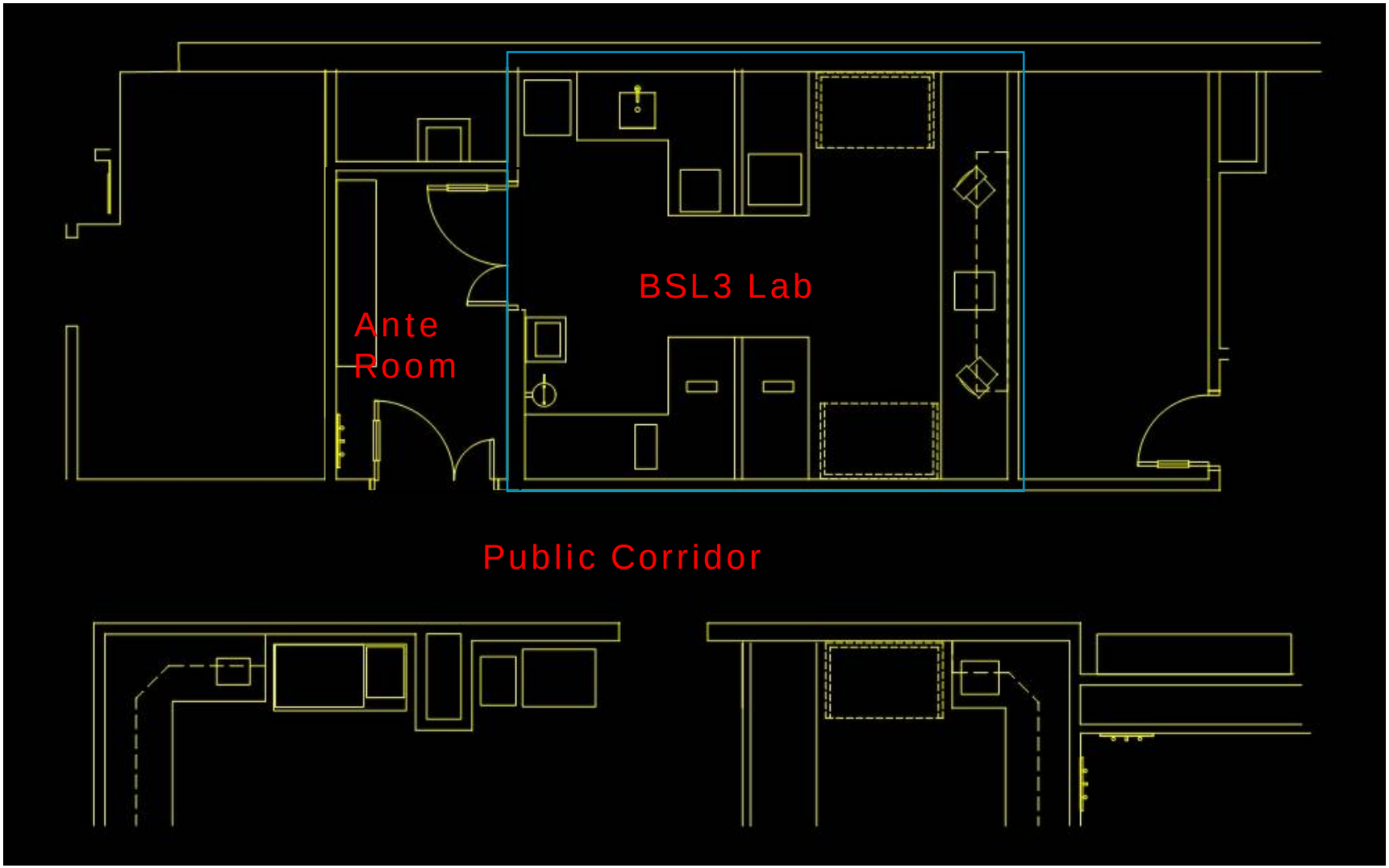
Separation - Design

- Series of two self-closing doors/ separated from areas open to unrestricted traffic
  - Can be interpreted to utilize other laboratory spaces as the “ante” room.
    - Microbiology lab with self closing doors with TB room opening off the lab instead of the corridor
  - Large labs with many doors can prove difficult so best to have ante room.
- Utilize ante rooms for other purposes to support lab work efficiently
  - Refrigerators, some storage, autoclaves,

BSL3 - Separation



Ante Room



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BSL1 – Minimize contamination

- Must have handwashing sink.
- No eating, drinking, smoking, storing of food, applying cosmetics, handling contact lenses
- Prepare for handling of sharps and broken glass

BSL1 – Minimize Contamination

- Protective lab coats, gowns or uniforms are recommended
- Protective eyewear for splashing procedures
- Gloves must be worn

BSL2 – Minimize contamination

- Must have handwashing sink.
  - Must wash hands after working and before leaving facility
    - a handwash sink must be available inside the testing area.
    - Ideally near exit doors and high contamination areas.
    - May be manual, hands-free or automatic.
  - Handwash sinks should not be used for any procedures other than disposal of DI water.
    - Best to be isolated from testing areas so will not be “accidentally” contaminated. May be manual,

BSL2 – Minimize contamination

- A method for decontaminating wastes should be available in the facility
  - Autoclave, chemical disinfection, incineration or other valid method
    - Room to store biohazardous waste while waiting for transport
    - Do not have to have autoclaves in the actual lab room.
    - Needs to be secure –problems

BSL2 – Minimize contamination

- No eating, drinking, smoking, storing of food, applying cosmetics, handling contact lenses

Food and Drink

- Bloodborne pathogens – OSHA 1910.1030
  - To protect lab workers from diseases transmitted via contact with human blood, products, tissues, fluids, etc.
    - No food, drink, smoking or applying of cosmetics
- CAP
  - prohibits smoking, eating, drinking, application of cosmetics and lip balm, manipulation of contact lenses and mouth pipetting in all technical work areas

Food and Drink

- Design
  - Do not have any refrigerators or cabinets with food/drink inside lab
  - No drinking fountains
  - No mirrors for primping – or at least notations saying they cannot apply makeup
  - Do not provide tables used for meals
  - Do not have eating areas that open only into the testing areas as staff will carry food and drinks through the BSL2 areas
  - Aerosols do not obey tape on the floor separating clean and dirty areas

Food and Drink

- Design ideas
  - Be sure to provide appropriate eating areas so staff does not create their own spaces in the labs for convenience.
    - Second and third shift technologists often cannot leave the labs for more than a few minutes at a time due to small staff and timed work.
  - To provide easy access and visibility for lab staff to lounges provide door/ window into main testing area but provide clean door from corridor to bring food into lounge
    - Make sure lounge is positive pressure to keep

Food and Drink

BSL2 – Minimize contamination

- Prepare for handling of sharps and broken glass
  - Ensure there is room for sharps containers
    - Can be on countertops, on floors, in storage areas
    - Will have in use containers, filled to be taken away, and clean to be used.
  - Have locked cupboards for storage of needles
    - Relates to other security issues in the labs and bring into question “open” concept of BSL1 lab areas.
    - Should be in area where someone cannot sneak in unseen

BSL3 – Minimize contamination

- A method for decontaminating wastes should be available in the facility
  - Preferably within the laboratory
  - Autoclave, chemical disinfection, incineration or other valid method
- Vacuum lines should have HEPA filters

Sterilizers/ Autoclaves

- HHS/AIA
  - Facilities and equipment shall be provided for terminal sterilization of contaminated specimens before transport. Not required for specimens that are incinerated on site.
- CAP
  - Are specimens and used media disinfected, sterilized, or contained in a manner to minimize the hazard of an accident during transportation to a remote autoclave or incinerator?

BSL3 – Minimize Contamination

BSL2 – Minimize Contamination

- Protective lab coats, gowns or uniforms are recommended
  - Need room for in-use coat hooks, linen carts for those waiting to be washed/ or trash for disposal, room for clean coats, etc.
- Protective eyewear for splashing procedures
  - Room to store eyewear near work area
- Gloves must be worn
  - Room to store gloves near work areas

BSL2- Minimize Contamination

- Eyewash station must be available
  - Good to locate where it can easily be found if eyes are contaminated.
    - Create a “safety” station near the exit doors.
  - Must meet ANSI criteria as adopted by OSHA

Handwashing

- Bloodborne pathogens – OSHA 1910.1030
  - To protect lab workers from diseases transmitted via contact with human blood, products, tissues, fluids, etc.
  - Handwashing facilities must be available
    - Employees to wash hands before eating, drink or using restrooms
  - Require a facility that has running water, soap and a way to dry hands that is readily accessible to personnel.
- HHS/AIA
  - Handwashing stations shall be located within 25 feet of each workstation and within each room with a

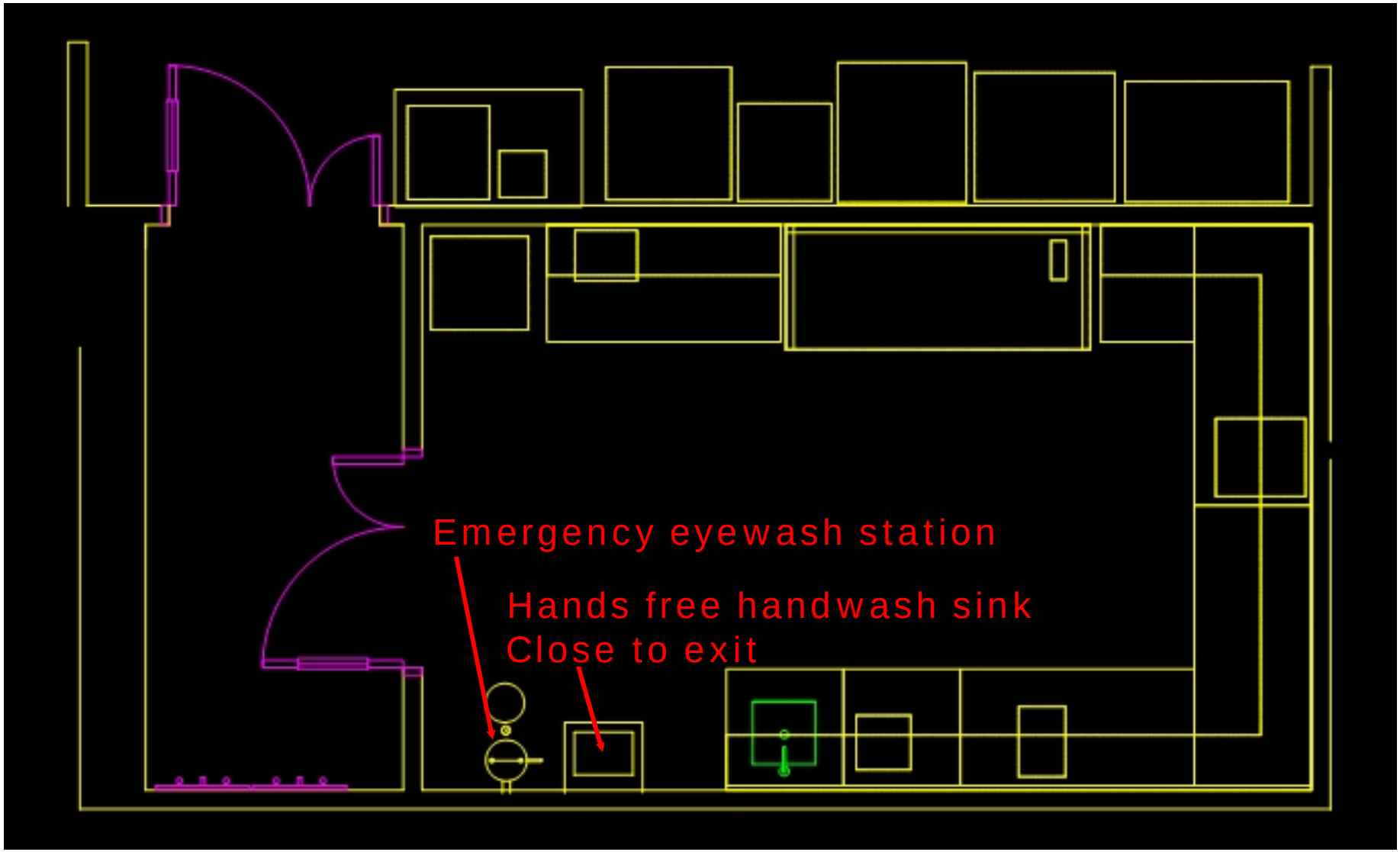
Handwashing

- Design Ideas
  - Look at having a hands free handwash sink adjacent to all exit doors to remind staff to wash hands before leaving
  - Include other handwash sinks in areas where staff can easily be contaminated or if they are a long distance (more and 25’) from available dedicated handwashing sink.
  - Utilize wall hung lavatories instead of countertop sinks to indicate that they are not to be used for “dirty” work.
    - It is too easy to use any adjacent sink to pour off a specimen and as workloads change and space is

BSL3 – Minimize Contamination

- Must have handwashing sink.
  - Must be hands-free or automated
  - Locate near the exit door
  - If two zones must be a handwash sink in each
- Eyewash station must be available

Handwash sink



Emergency eyewash/ flood showers

- OSHA
  - Utilizes ANSI standards
  - Facilities for quick drenching or flushing of the eyes and body shall be provided within the work area for immediate use if there is a possibility of exposure to injurious corrosive material.
- HHS/AIA
  - Shall include emergency shower, eye-flushing devices…

Emergency eyewash/ flood showers

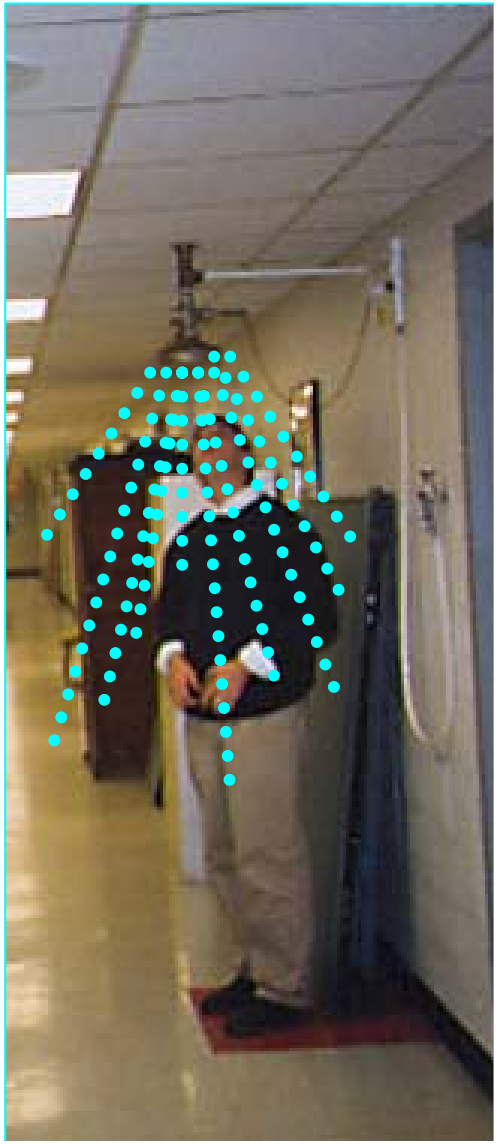
- NFPA 99
  - Where eyes or body can be exposed to injurious corrosive materials, suitable fixed facilities shall be provided within the work area
  - Fixed eye baths shall be designed and installed to avoid injurious water pressure.
- CAP
  - Is there an emergency eyewash within 100’ or 10 sec travel distance from every area where hazardous chemicals or biohazards are

Emergency Eyewash

- water remains on without use of hands (hands to hold open eyes)
- goes from off to on in one second or less
- large and easy to operate controls
- delivers 0.4 gal. of water per minute
- water nozzles 33 to 45 inches above floor
- checked and flushed weekly

Emergency Shower

- opens in one second
- water remains on without use of hands
- delivers 30 gal. of water per minute
- easy to locate and accessible controls
- head at 84” from floor
- adjustable water supply
- checked and flushed weekly



Personal Safety; Emergency Shower

- Good to place some sort of special marking on floor to designate shower area.
- Can be used if clothes catch fire.

Cleanliness

- CAP
  - Are workbenches and sinks decontaminated each day of use, and the effectiveness checked at least monthly?
  - Are work areas clean and well maintained?
  - Are floors, walls, and ceilings clean and well-maintained?

BSL2 - Ventilation

- No specific requirement on ventilation systems by CDC.
  - Should consider inward flow of air without recirculation to spaces outside of the laboratory.

BSL3 - Ventilation

- A ducted ventilation system is required
  - Directional airflow into lab from clean areas towards contaminated areas (front to back)
    - Under failure conditions the airflow will not be reversed
  - Must be able to verify directional air flow
    - Visual monitoring device provided at entry with audible alarms
  - Exhaust air not recirculated to any other area.
  - Exhaust air to be dispersed away from air intake or occupied areas
    - If cannot be done, then must be HEPA filtered.

BSL3 - Ventilation

- Primary containment of Biohazards
  - Whereas biological safety cabinets are the primary safety barrier the lab room is considered to be the secondary safety barrier.
    - Inward directional air flow is optional for BSL2, but required for BSL3
    - At BSL3 (and 4) exhaust air must be directly exhausted since it is considered potentially contaminated. Called dedicated single pass exhaust system.
    - BSL3 exhaust going through HEPA filter is optional, but required in BSL4.

Ventilation

- Air changes
  - HHS/AIA
    - Minimum air changes per hour 6 for lab spaces except Glasswashing & Sterilizing which are at 10
  - Design recommendation
    - Clinical Pathology at 10 to 12
    - Anatomic Pathology at 12 to 15
- Directional airflow
  - Prevents aerosols from moving out of the lab into other areas of the building
  - Design; Create all lab areas as negative

Ventilation

- Supply air
  - Can be supplied from clean areas or from outside.
  - Cannot be supplied from other laboratory testing areas.

Ventilation

- Exhaust air
  - US Department of Health and Human Services
    - all air exhausted directly to outdoors, no air recirculated by means of room units.
      - Note that hospital laboratories are “Pathology” labs – Surgical Pathology and Clinical Pathology, not “General”
    - Areas with contamination or odor problems shall be exhausted to the outside and not recirculated to other areas
  - ASHRAE
    - For most laboratories 100% ventilation will be used, with the recirculated air being zero

Ventilation

- Exhaust air
  - NFPA 45; Fire protection in labs using chemicals
    - Lab ventilation systems shall be designed to ensure that chemicals originating from the lab shall not be recirculated. Release of chemicals shall be controlled by enclosures or captured to preventing any flammable and/or combustible concentrations of vapors from reaching any source of ignition.
    - Air exhausted from laboratory hoods and other special local exhaust systems shall not be recirculated
    - Air exhausted from laboratory work areas shall not

Ventilation

- Exhaust air
  - OSHA 1910.1030
    - A ducted exhaust-air ventilation system shall be provided. This system shall create directional airflow that draws air into the work area through the entry area. The exhaust air shall not be recirculated to any other area of the building, shall be discharged to the outside, and shall be dispersed away from occupied areas and air intakes.
  - OSHA 1910.1000
    - Air contaminants in clinical labs include methanol and xylene

Ventilation

- CAP
  - Are examination and storage areas adequately ventilated by an exhaust fan or fume hood to remove noxious fumes and odors?
  - Is ventilation adequate for the workload and types of procedures performed in the laboratory?

Ventilation

- Formaldehyde
  - OSHA
    - Limits of exposure
    - Adverse health effects that range from mild to life-threatening. A particular danger is development of olfactory fatigue.
    - Particular problems in histology and pathology labs
    - Known carcinogen – increase risk of cancer in nose, sinuses and lungs.
    - Engineering controls to keep levels below specified PELs. (cannot exceed 0.75 ppm in 8 hours). Monitoring is required, usually through personal devices

Ventilation

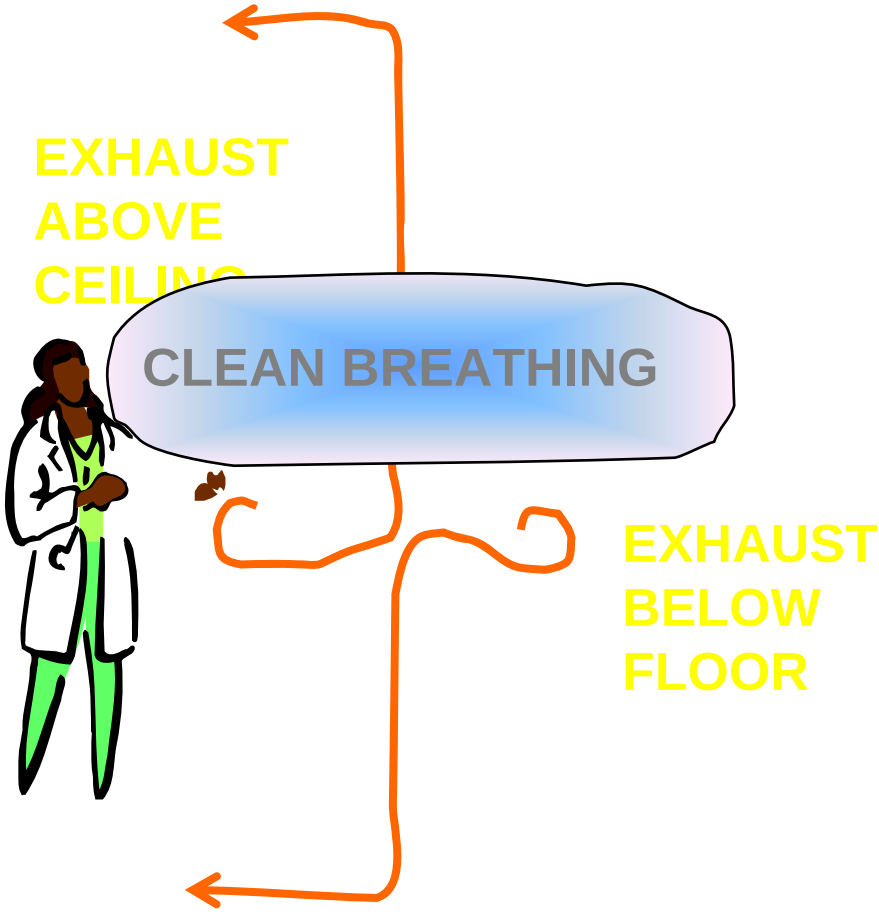
- Xylene
  - OSHA
    - Exposure established at 100 ppm over 8 hours
    - Potential to be carcinogenic
    - Personal monitoring should be done

Ventilation

- Formaldehyde & Xylene
  - CAP
    - Are vapor concentrations maintained below the following maxima?
      - Formaldehyde; 0.5 ppm over 8 hours, 2.0ppm 15min
      - Xylene; 100ppm 8 hours, 150ppm 15 min
    - Vapor concentrations must be monitored in all areas where these reagents are used

Formalin and Xylene

- Most important to remember that the fumes are heavier than air!



BSL2 – Biosafety Cabinets

- BSC's installed in best location to protect from air fluctuations that can affect operation
  - No interference from air supply and exhaust ducts
  - Away from doors, operable windows
  - Away from heavily trafficked areas
  - Procedures involving infectious materials that could generate aerosols should be done in a BSC

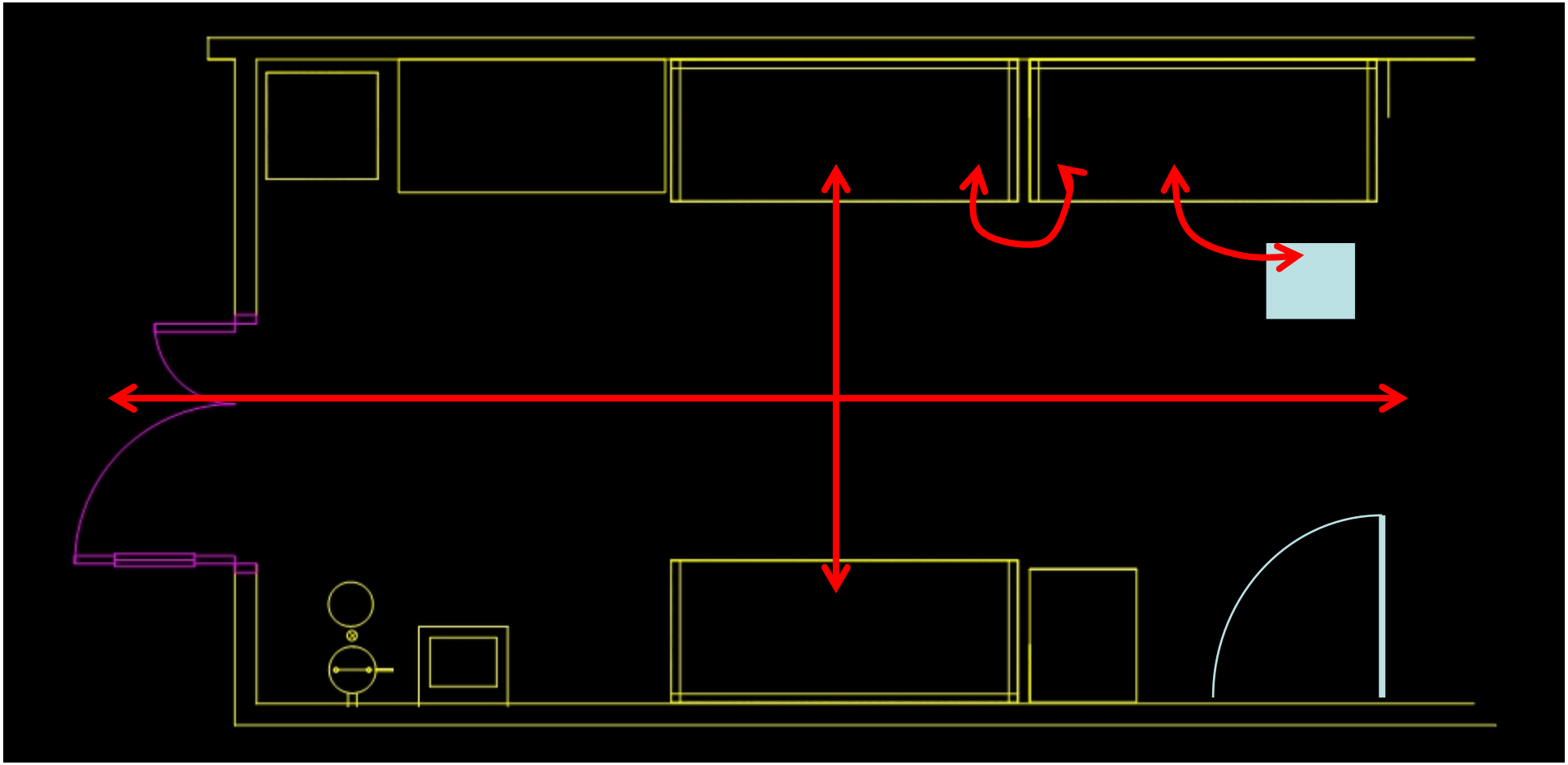
BSL3 – Biosafety Cabinets

- BSC's installed in best location to protect from air fluctuations that can affect operation
  - No interference from air supply and exhaust ducts
  - Away from doors, operable windows
  - Away from heavily trafficked areas
- Class II can be re-circulated into lab as it is HEPA filtered
- Can also be connected to lab exhaust system by thimble or hard connection.
- Procedures involving manipulation of infections materials must be conducted within a BSC or other containment device.

Biosafety Cabinets

- Biosafety Cabinets
  - Compromised by
    - Poor location
    - air currents
    - decreased airflow in the hood
    - leaking filters
    - crowded work surfaces
    - Poor user techniques

Biosafety Cabinet



Biosafety Cabinets

- CAP
  - Does the biologic safety cabinet meet minimum requirements for work?
    - Exhaust air from a class I or class II biological safety cabinet must be filtered through HEPA filters. Air from Class I and IIB cabinets is hard-ducted to the outside. Air from Class IIA cabinets may be recirculated within the laboratory if the cabinet is tested and certified at least every 12 months. It may be exhausted through a dedicated stack that protects against backflow of air from adverse weather conditions or through the building exhaust air system in a manner (e.g., thimble connection) that avoids any interference with the air balance of the biological safety cabinet or building exhaust system.

BSL3 – Other possible criteria

- Enhanced protection may be required by other agencies
  - Ante room for equipment storage
  - Dress-in, shower-out capabilities
  - Gas tight dampers for lab isolation
  - Lab effluent decontamination
  - Final HEPA filters for lab exhaust air
    - Gas-tight isolation dampers around HEPA filters
    - Decontamination ports
    - Bag-in/ bag-out capability

BSL1 – Furniture/Finishes

- Decontaminate work surfaces after working or any spills with appropriate disinfectant
- Decontaminate all cultures, stocks and other potentially infections materials before disposal with an effective method. This can be outside of immediate lab as long as it is secured for transport per regulations

BSL1 – Furniture/ Finishes

- Bench space for work
- Furniture should be capable of supporting anticipated loads and uses.
- Spaces between furniture should be accessible for cleaning
- Designed so they can easily be cleaned
  - Again has implications for general traffic and those areas that are open to the testing area. As along as the air is shared the same precautions should be met.

BSL2 – Furniture/Finishes

- Decontaminate work surfaces after working or any spills with appropriate disinfectant
  - Ensure that casework can withstand disinfectant and lots of cleaning.
    - Stainless steel – not always a good option if cleaning with bleach as it will rust.
    - Open “wounds” in countertops and casework that expose wood can make it impossible to truly clean.
  - Counters should not be so cluttered that they cannot be cleaned appropriately – ensure enough space.
- Bench tops impervious to water, resistant to heat, organic solvents, acids, alkalis, and

BSL2 – Furniture/Finishes

- Designed so they can easily be cleaned
  - No carpeting or fabric is allowed as it cannot be easily cleaned/ decontaminated.
  - Chairs must be covered with a non-porous surface that can easily be cleaned and decontaminated.
- Lab should be easily cleaned
  - Carpets and rugs are not permitted.
  - Spaces between furniture should be accessible for cleaning
  - Chairs covered with non-porous material

Easily cleaned

- Use cork
  instead of cloth

BSL2 – Furniture/Finishes

- Bench space for work
  - Provide appropriate countertop areas for the work that is being done in the space. Should be cleanable surfaces.
  - Need to determine amount of space needed for work
    - Base on equipment, work to be done, procedures.

BSL2 – Furniture/Finishes

- Furniture should be capable of supporting anticipated loads and uses.
  - Need to be impervious to water, resistant to heat, solvents, acids, alkalis and other chemicals
  - Verify weights of equipment to ensure that weight requirements can be met.
- Spaces between furniture should be accessible for cleaning

BSL3 –Furniture/ Finishes

- Easily cleaned and decontaminated
  - Carpets and rots not permitted
  - Seams, floors, walls and ceiling surfaces should be sealed
  - Spaces around doors and ventilation opening should be capable of being sealed

BSL3 – Furniture/ Finishes

- Floors must be slip resistant, impervious to liquids, and resistant to chemicals
  - Consideration should be given to seamless, sealed, resilient or poured floors with integral cove bases.
- Walls should have sealed smooth finish
- Ceilings should be the same as the walls.

BSL3 – Furniture/ Finishes

- Furniture should be able to support anticipated loads and uses
  - Must be able to clean spaces between furniture and equipment
- Bench space for sufficient for work
- Bench tops impervious to water, resistant to heat, organic solvents, acids, alkalis, and other chemicals.
- Chairs must be non-porous

Design - Furniture/ Finishes

- Utilize casework that is made for the 24/7 hard and wet work that is done in Pathology labs.
  - Use flexible systems with ability to adjust up and down and reconfigure without construction. Labs change on average of once every 2 months.
  - Suspended cabinets are great as you can clean under them and don’t have spaces where dirt and bacteria can gather for years.
  - Ensure it can withstand weights of equipment which could easily be 300 pounds

Design - Furniture/ Finishes

- Do not use anything that could harbor bacteria or chemicals
  - Casework should be sealed – no exposed particle board, plywood….
  - Chairs should have cleanable surfaces – NO fabric
  - Do not utilize cloth bulletin boards – use cork instead

Design - Furniture/ Finishes

- Flooring Issues
  - 24/7 work
  - Staining
  - Standing
  - Slipping
  - Weights
  - Sliding heavy objects around
  - Vibration
  - Cleanability

Design - Furniture/ Finishes

- Flooring Options
  - BSL 1 and 2
    - Recycled rubber flooring (not all rubber flooring so must be very careful)
    - VCT
  - BSL 1, 2 and 3
    - Sheet vinyl
    - Poured epoxy

Space

- CAP
  - Is sufficient space available so there is no compromise in the quality of work or safety of personnel?
  - Is there adequate space for instruments, storage, administrative, technical and clerical work?
  - Is there adequate space for accession of potentially biohazardous specimens?

Ergonomics

- OSHA
  - Voluntary Guidelines
  - Hearing/noise exposure – 1910.95
    - Hearing conservation program whenever noise exposures equal or exceed an 8 hours TWA of 85 dBA.
- CAP
  - Is there a documented ergonomics program to prevent musculoskeletal disorders through prevention and engineering controls?
  - Does the laboratory have a policy to protect personnel from excessive noise levels?

Special Practices

- BSL 1
  - Sign must be posted to note biohazard.
  - Effective pest program
  - Lab windows that open must be fitted with screens
- BSL 2 – BSL1 criteria PLUS
  - Lab windows that open must be fitted with screens, but it is best if they do not open.
  - Animals and Plants should not be in the lab
- BSL 3 – BSL1 and BSL2 criteria PLUS
  - All windows must be sealed shut

BSL Levels -Recombinant DNA

- DNA that has been created artificially. DNA from two or more sources is incorporated into a single recombinant molecule.
  - Used to provide enough material for analysis in PCR (polymerase chain reaction)
- From NIH Guidelines for Research Involving Recombinant DNA Molecules
  - If you are funded by or in an institution that receives NIH funds for other projects you must comply.

BSL2 -Recombinant DNA

- Risk groups – 2; those associated with human disease which is rarely serious.
  - Chlamydia
  - Clostridium species
  - Escherichia coli
  - Neisseria species
  - Salmonella species
  - Staphlococus aureus
  - Streptococcus species

BSL2 – Recombinant DNA

- Risk group 2 – Parasitic
  - Giardia
  - Ascaris lumbricodes
- Viral
  - Hepatitis A, B,C,D and E
  - Epstein Barr
  - Herpes
  - Human Papilloma viruses
  - Measles
  - Mumps
  - Parainfluenza

BSL3 – Recombinant DNA

- Risk group 3
  - Associated with serious or lethal human disease for which preventive or therapy may be available
    - Mycobacterium tuberculosis
    - Creutzfeldt-Jacob
    - HIV

BSL Levels -Tissue Cultures

- Are a potential risk for infectious agents
  - Examples of HIV, Hepatitis B and C
  - Also evidence of transplantation of human tumor cells to health recipients
- OSHA interprets exposure to bloodborne pathogens to include human cell lines.

Bioterrorism - Biosecurity

- Events to determine importance
  - Anthrax attack in Oct 2001
  - Public Health Security and Bioterrorism Preparedness and Response Act of 2002
  - Expansion of US Select agent regulations in Dec 2003
- Definition
  - “intentional use of microorganisms, or toxins derived from living organisms, to produce death or disease in humans, animals, or plants”
  - Protection of microbial agents from loss, theft, diversion or intentional misuses

Bioterrorism/ Biosecurity

- Risk and threat assessment
- Facility security plans
- Physical security
- Data and electronic technology systems
- Personnel security policies
- Policies regarding accessing the lab
- Specimen accountability
- Receipt of agents into the lab
- Transfer of agents from the lab
- Emergency response plans
- Report of incidents, injuries and security breaches.

Security

- The lab must be isolated from public areas
  - In the event of a suspected bioterrorism sample the lab staff should not be disturbed – needs to be able to perform work.
- Specimens could be utilized as weapons
  - Drug resistant Salmonella, Listeria and M. Tuberculosis

Security

- Access control recommendations
  - Consolidate lab work areas as much as possible.
  - Separate from public areas of the building
  - Lock all select agent areas when unoccupied
  - Lock all freezers, refrigerators, cabinets and other containers where select agents are stored
  - Limit cleaning, maintenance and repairs to when authorized employees are present and can serve as escorts and monitors

Security

1. Must limit access to the facility
2. Locking files, refrigerators, freezers, incubators
    1. Chain of Custody
    2. Possible Bioweapons
3. Entrance doors locked
4. HEPA filters on exhaust
5. Glass breakage sensors at windows
6. Alarm sensitive areas
7. Personnel IC for security areas

Bioterrorism - Biosecurity

- Started by determining of you have anything that could be considered a risk.
- Physical security is to prevent removal of the agents for “non-official” purposes.
  - Review building and premises, labs and storage areas
- Access should be limited to authorized and designated employees based on need.
  - Should include all areas such as entrances, freezers, refrigerators, incubators….
- Options to limit access
  - Locked doors
  - Card key system

Bioterrorism

ORGANISM	HANDLING	CULTURING
Anthrax	BSL-2	BSL-3
Botulism	BSL-2	BSL-2/3
Plague	BSL-2	BSL-3
Tularemia	BSL-2	BSL-3
Brucellosis	BSL-2	BSL-3
Hemorrhagic Fever	BSL-4	BSL-4
Smallpox	BSL-4	BSL-4

Bioterrorism - exposure

- If exposed to Anthrax
  - Shower in BSL3 area – take off outer clothing (i.e. lab coat)
    - Requires that you have an emergency flood shower
  - Shower in separate room – take off all clothing
    - Requires that there is a shower available such as a locker area.
    - Should be as close as possible to Micro lab to minimize contamination of surroundings as staff member moves from one area to another.

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