International
BIOLOGICAL THREAT REDUCTION

Designing a BSL3 Facility

Sandia National Laboratories

Laboratory Biosecurity and Biosafety

for BSL3 Laboratories

India

Jan 2007

www.biosecurity.sandia.gov

SAND No. 2006-3688C
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for the United States Department of Energy's National Nuclear Security Administration
under contract DE-AC04-94AL85000.

Sandia National Laboratories

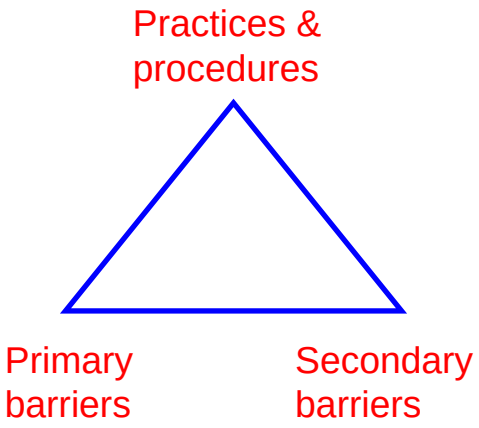
Biocontainment

- Biocontainment is the control of biohazards through
  - Practices & procedures, including administrative controls
    - Good lab practices
    - Written SOPs for research activities, specialized equipment, etc
    - Required training
    - Access requirements
  - Primary barriers (safety equipment)
    - Biosafety cabinets (BSCs)
    - Lab equipment (pipetting devices, waste containers, safety centrifuge cups)
    - Personal protective equipment
  - Secondary barriers (engineering & architectural controls)
    - Building & room construction – the floor plan
    - HVAC issues – directional airflow, filtration
    - Waste treatment

Biosafety Levels

- **Biosafety Levels**
  - **Four biosafety levels provide increasing degrees of protection**
  - **What's the right balance of practices & procedures, primary barriers and secondary barriers?**

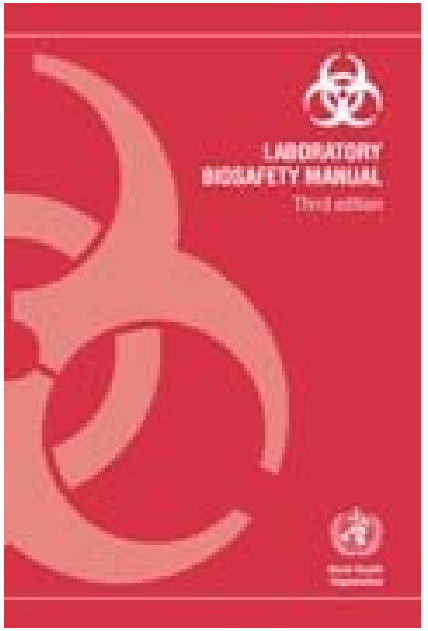
- **Applications:**
  - **Labs (BSL-1, 2, 3, 4)**
  - **(Small) Animal Containment (ABSL-1, 2, 3, 4)**
  - **Large Animal Containment ("BSL-3 AG")**
  - **Plant Containment (BSL-1P, 2P, 3P, 4P)**



Guidance and Regulations

- **Performance-based vs. prescriptive**
  - **A performance approach generally defines what result is intended, leaving how to achieve the result up to the user.**
  - **Prescriptive approaches outline specific requirements that must be done.**

- **WHO Laboratory Biosafety Manual – 3rd edition**



  - **See CD for WHO LBM**

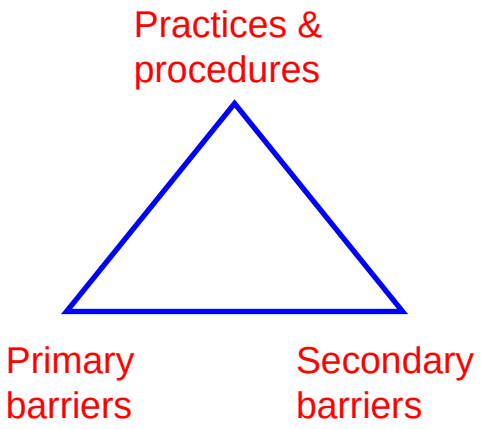
International
BIOLOGICAL THREAT REDUCTION

Planning: Facility Vision

- Where should the facility be located?
- What should the facility do?
- How should it be staffed?
- How will it be supported?
- What is the path to achieving adequate training and resources?
- How should it be linked to existing or planned public/agricultural health authorities in country and internationally?
- How does the facility fit into the country's goals for public/agricultural health and science?
- What is the expected public reaction?
- What support (financial, collaborative, other) will be needed for construction, staffing, training? From where?
- How does the facility see itself contributing to the global scientific community?
- What is the long-term plan to ensure sustainability?

Planning: Risk Assessment is Critical

- Identify biological agents that will be used
- Perform risk assessment
  - Include an evaluation of settings
    - Labs
    - Animal housing
    - Patient care
    - Autopsy/Necropsy
    - Other?
  - And activities:
    - At the macro scale: research, diagnostics, health care, industry, other?
    - At the micro scale: routine manipulations, producing large volumes, aerosolization, animal testing, other?
- Determine biosafety level
  - What degree of biocontainment is necessary to mitigate the risk?



Engineering Controls

- The first and best strategy in biocontainment is to control the hazard at the source
  - If feasible, design the facility, equipment, or process to remove the hazard or substitute something that is not hazardous
  - If removal is not feasible, enclose the hazard to prevent exposure in normal operations
  - Where complete enclosure is not feasible, establish barriers and/or localized controls to reduce exposure to the hazard in normal operations
- Apply before work practices and personal protective equipment are used
- Engineering and other types of controls (including PPE) are NOT mutually exclusive
- Employers may need to use multiple types of controls to prevent employee exposure
- Degree to which engineering controls are required depends on the applicable regulatory framework (incl. guidelines) and a site-specific risk assessment

Containment Barriers

- **Barriers provide protection by:**
  - **Physical separation**
  - **Directional airflow (differential pressure)**
  - **Practices and procedures**
  - **Decontamination**
  - **Filtration**

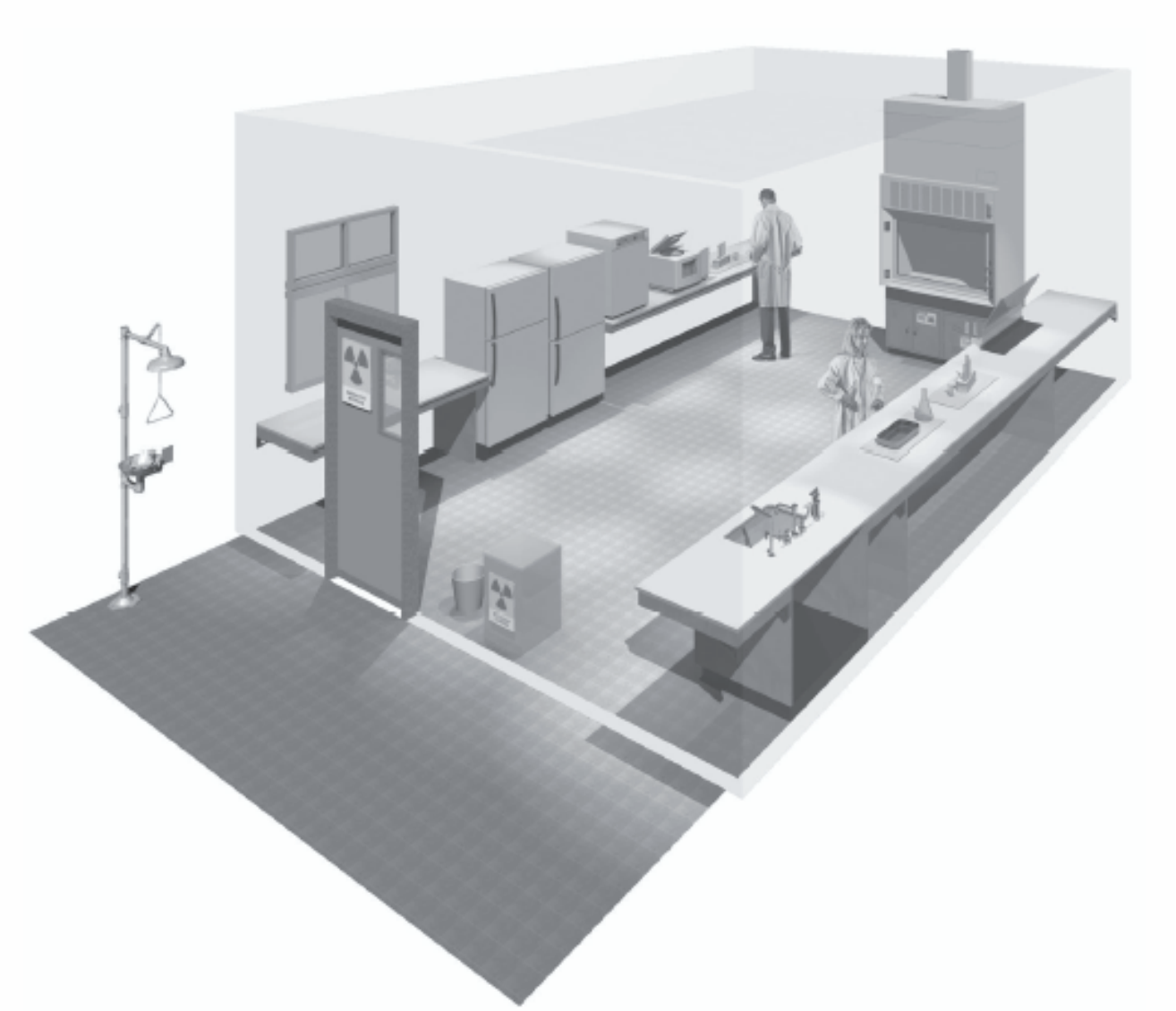
- **Barriers are penetrated by:**
  - **Personnel**
  - **Fluids**
    - **Air, gases, water, drainage…**
  - **Materials**
  - **Products**

Biosafety Level 1: Facility Design

- **Requirements:**
  - **Laboratories have doors**
  - **Sink for hand washing**
  - **Work surfaces easily cleaned**
  - **Bench tops are impervious to water**
  - **Sturdy furniture**
  - **Windows fitted with flyscreens**
- **Other design and construction issues:**
  - **Location – not separated**
  - **Structure – normal construction**
  - **Ventilation – no special requirements**

Easily cleaned and decontaminated

Biosafety Level 1: Facility Design

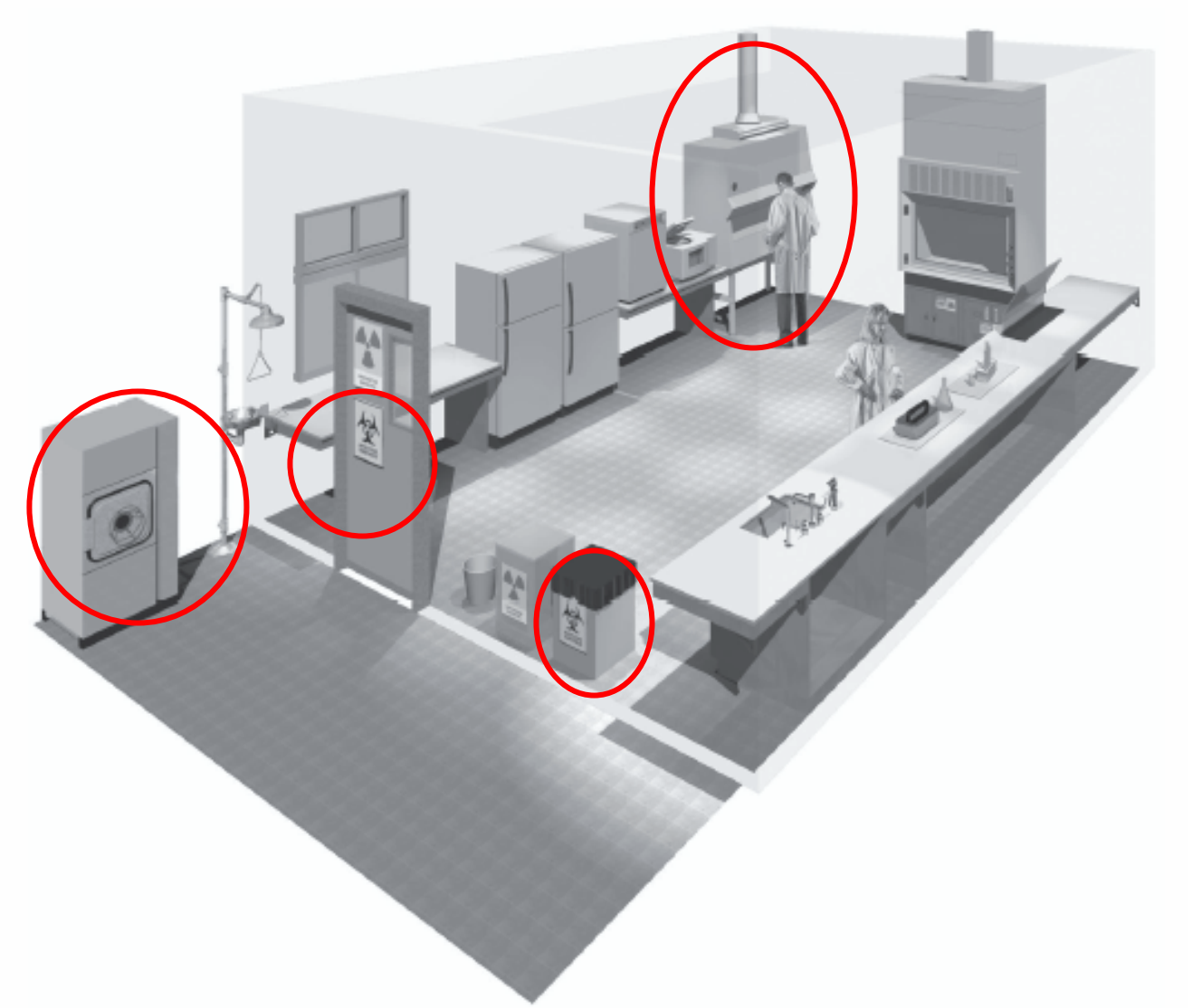


Biosafety Level 2: Facility Design

- **Requirements:**
  - **Laboratories have lockable doors**
  - **Sink for hand washing**
  - **Work surfaces easily cleaned**
  - **Bench tops are impervious to water**
  - **Sturdy furniture**
  - **Biological safety cabinets installed as needed**
  - **Adequate illumination**
  - **Eyewash readily available**
  - **Windows fitted with flyscreens**
  - **Location - separated from public areas**
  - **Ventilation – directional**
    - **Air flows into lab without re-circulation to non-lab areas**

Restricted access
when work in progress

Biosafety Level 2: Facility Design

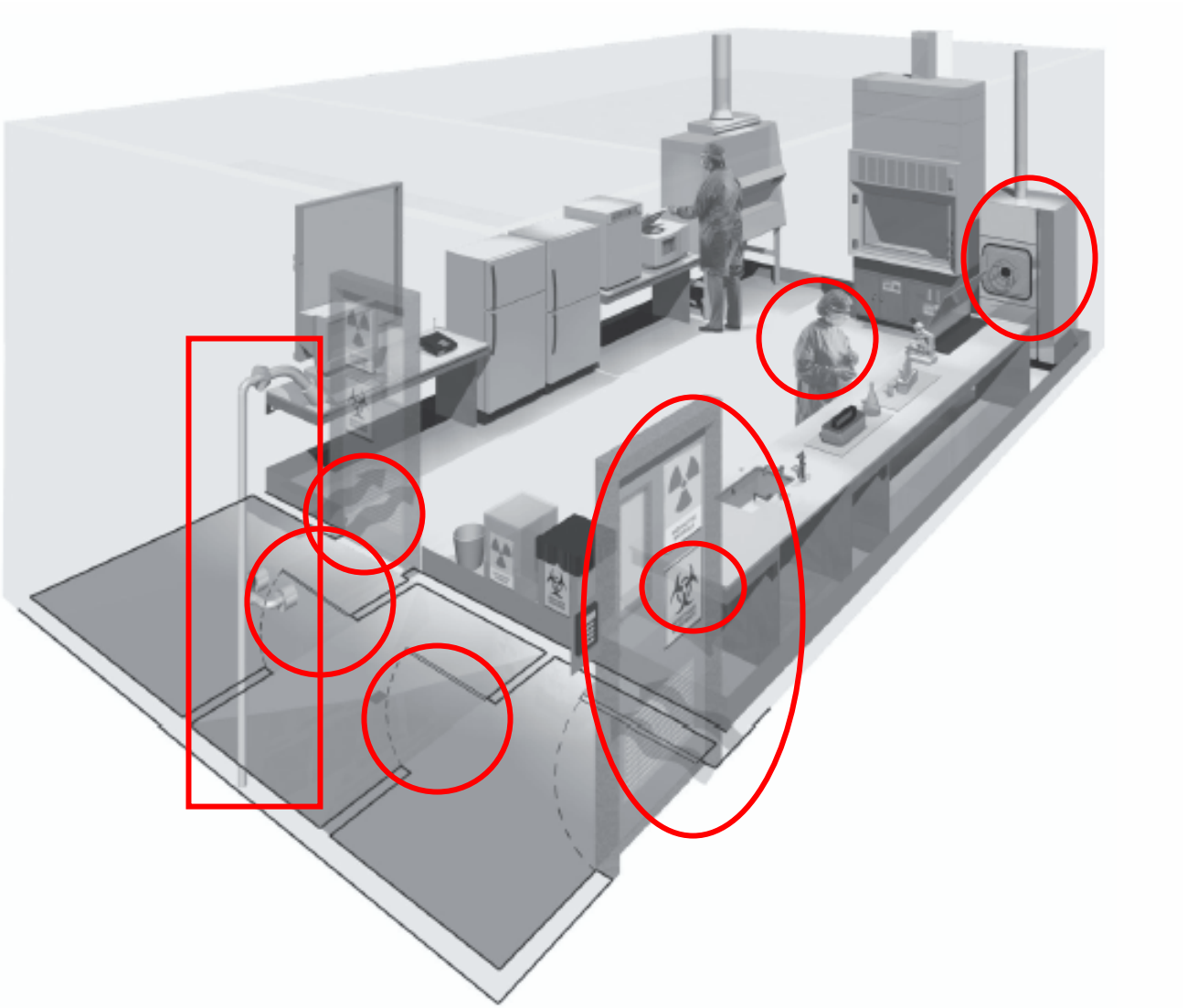


Biosafety Level 3: Facility Design

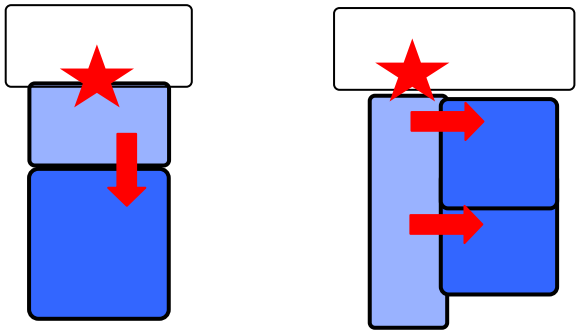
- **Requirements:**
  - **BSL-1 and 2 Facilities PLUS**
    - **Enclosures for aerosol generating equipment**
    - **Room penetrations sealed**
    - **Walls, floors and ceilings are water resistant for easy cleaning**
    - **BSC class II or III to manipulate infectious material**
    - **Separate building or isolated zone within a building**
    - **Directional inward airflow**
    - **Single-pass air**
    - **Double door entry**
    - **BSCs mandatory**
- **Additional requirements depending on work and agents:**
  - **HEPA filtration of the exhaust**
  - **Effluent decontamination**
  - **Personnel showers**

Follow the guidelines, regulations, and site-specific risk assessment for your unique situation!

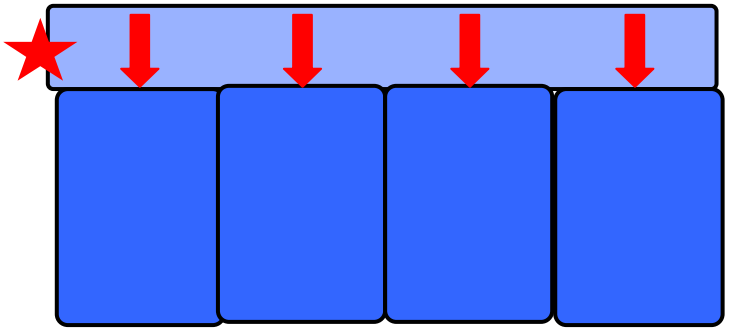
Biosafety Level 3: Facility Design



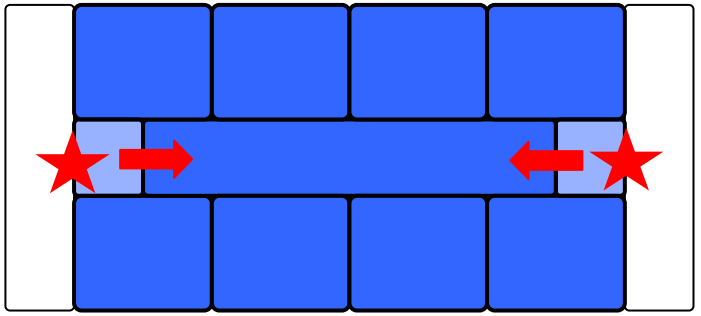
Options for Double Door Entry



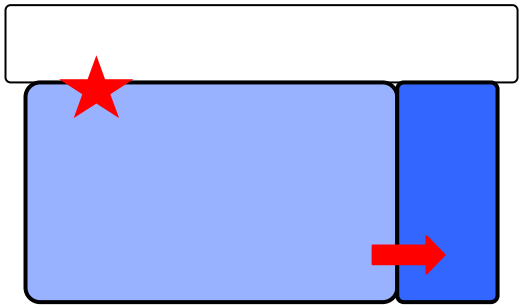
ROOM AS ACCESS ZONE



CORRIDOR AS ACCESS ZONE



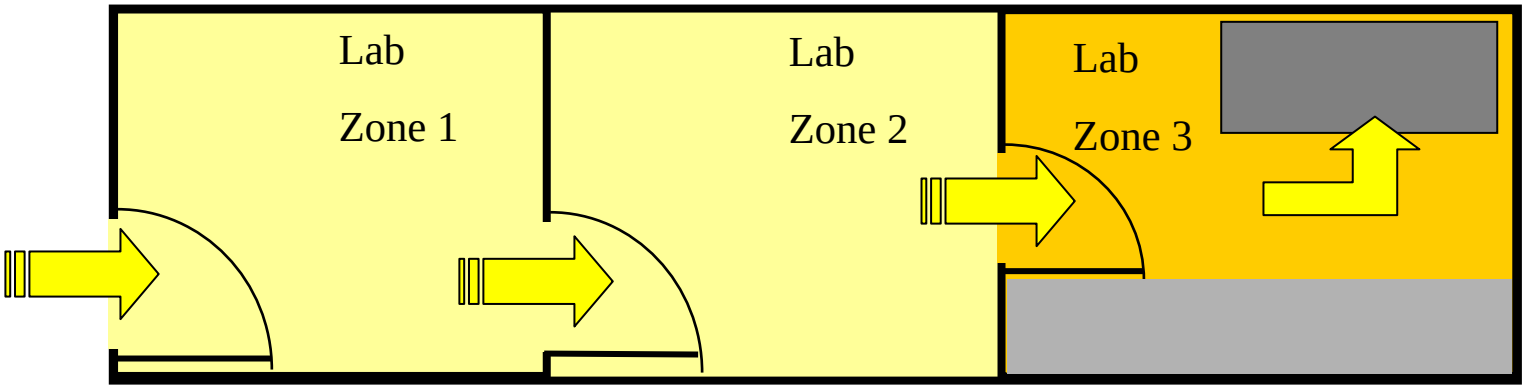
SUITE CONCEPT



LAB AS ACCESS ZONE

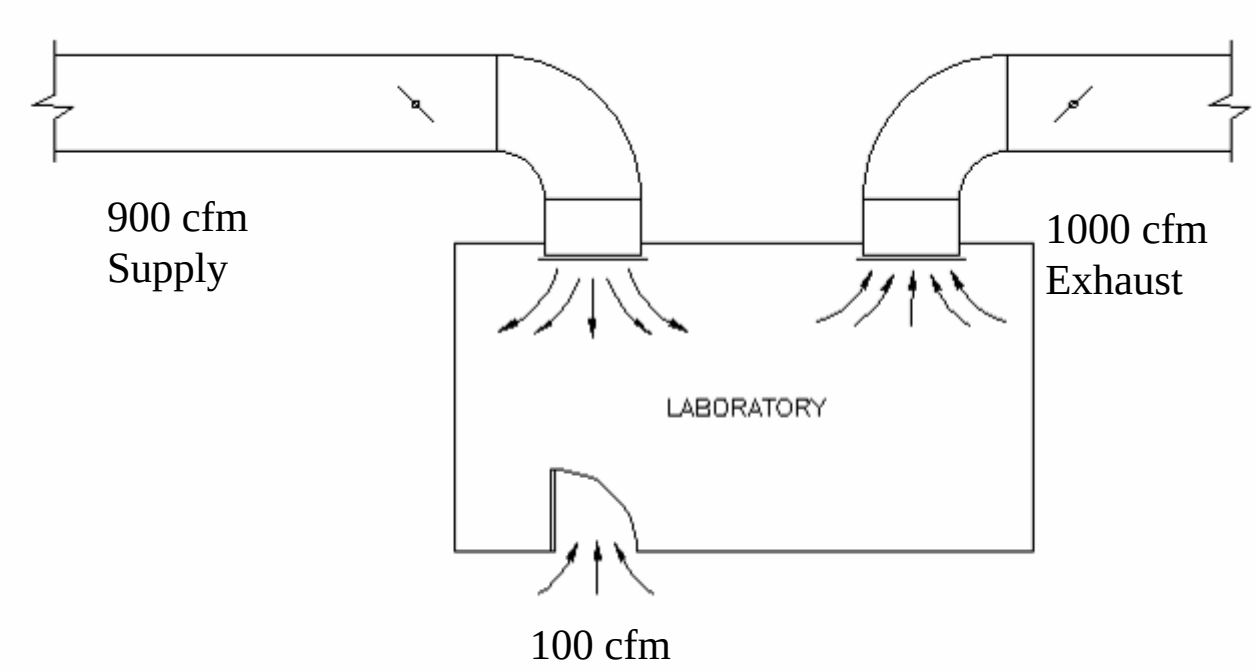
Directional Airflow

- **When Do You Need Directional Airflow?**
- **Airflow Offset Control**
  - **Relies on airflow through doors at all times**
  - **“Leaky Box”**
  - **Provides “Zone Control” of hazards and odors**



Airflow

Airflow Offset Control



"Leaky" Level 3

Heating Ventilation and Air Conditioning Issues

- Pressure monitoring devices at entry
- Smoke test
- HVAC controlled to prevent sustained positive pressurization
- Interlock exhaust/supply
- Alarms for HVAC failure (inside and outside the facility)
- Exhaust air HEPA filtered (sometimes necessary)
- Sealed ductwork
- Backflow prevention on supply air (Damper, HEPA)

The Birth of a New Laboratory

- 1. Planning
  - Define project / team
  - Budget
  - Schedule
  - Owner requirements
    - Goals
    - Functional requirements
    - Codes, Standards, Guidelines
- 2. Design
  - Budget
  - Schedule
  - Design stages
  - Construction documents – drawing and specifications
- 3. Construction
  - Procurement
  - Budget
  - Construction schedule
  - Build
    - Installation and Inspections
    - Startup and testing
    - Training
  - Turnover
- 4. Occupancy
  - Move in
  - Training
  - Periodic testing
  - Go hot

Commissioning

- What: A process to ensure that the completed facility meets the needs of the end user:
  - Safety
  - Security
  - Reliability
- Why: Necessary because all labs are prototypes
  - Layout
  - Functional intent
  - Fit and Finish
  - Systems arrangement
  - Cost
- When: Throughout process – planning, design, construction, occupancy

Commissioning Responsibilities Throughout the Development of a New LAB

- Planning Phase
  - Establish commissioning team
  - Review owner requirements
  - Scope and budget for commissioning
  - Develop plan for commissioning (who, what, where, how, when)
- Design Phase
  - Develop commissioning specifications
    - Process
    - Component verification checklists
    - Systems test forms
    - Integrated systems forms
    - Training
    - Documentation

Commissioning Responsibilities Throughout the Development of a New LAB

- **Construction Phase**
  - Commissioning schedule
  - Complete component verification checklists
  - Develop test procedures
  - Test
  - Oversee resolution of issues
  - Training
- **Occupancy Phase**
  - Warranty review
  - Seasonal testing
  - Oversee resolution of issues
  - Document baseline

Commissioning Test Process

- **Component verification**
  - **Verification that component meets design intent and technical requirements**
- **System test**
  - **Testing to ensure fully functional system under all operational parameters**
- **Integrated system test**
  - **Interdependency of systems and final facility validation**

- **See CD for Websites: Laboratory Commissioning**

Summary

- Risk assessment should determine facility design
- Biocontainment can be achieved through a variety of strategies
  - Balance of primary barriers, secondary barriers, and procedures and practices
- BSL 3 lab builds upon the requirements for BSL 1 and BSL 2 labs
- Every lab is unique – need to ensure lab will work as intended
  - Commissioning
- Designing and building a lab is only the start
  - Must plan for maintenance and long-term sustainability