Laboratory Design and the Industrial Hygienst

Ali Mohammadian, MspH, CIH, SDAIHA President
Genmark/Roche - Director - Sites, SHE, Security & Sustainability

Picture and Bio

https://www.linkedin.com/in/m-ali-mohammadian-cih-msph/

is a Certified Industrial Hygienist (CIH) with extensive experience in security management, EHS management, Facilities Engineering and Management, as well as Real Estate and Sustainability. He holds an MS in Public Health (Industrial Hygiene) from San Diego State University and a BA in Biology from Lawrence University. He has been a Certified Industrial Hygienist since 2015.

Ali has been with Genmark since 2019 and in current role is Director (Head): SHE, Security, and Sites (SSO & SEO) at GenMark Diagnostics, Inc., a Roche Company, since March 2022.

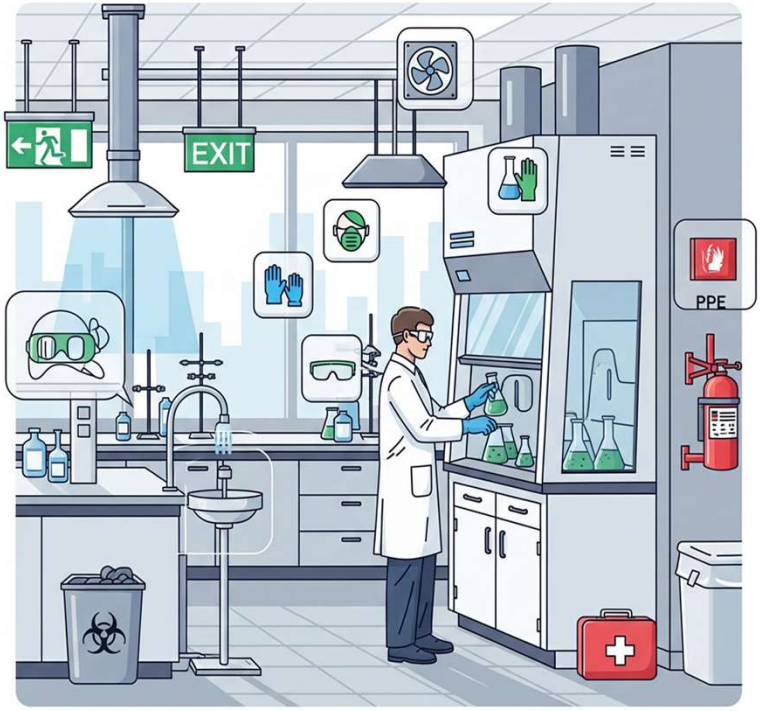
Prior to GenMark, Ali has over 20 years of experience in EHS with various organizations including Self-Employed Consultant (SaFEhs), Lab Fellows, Medtronic, Kasai Consulting, Environmental Engineering Firms (Arcadis and Project Resources Inc), and Cornell University.

Ali is also involved in community leadership, serving on the Board of Trustees for the Fleet Science Center, as President of the San Diego - American Industrial Hygiene Association (SDAIHA) from 2024-Present, and as a San Diego Squared Mentor in 2025. As well as a Partner in Stolen Roots Winery. His hobbies include snowboarding, yoga, ceramics, food, and wine.

Disclaimer

The views expressed in this presentation are my own and do not necessarily reflect the views or opinions of Roche/Genmark.

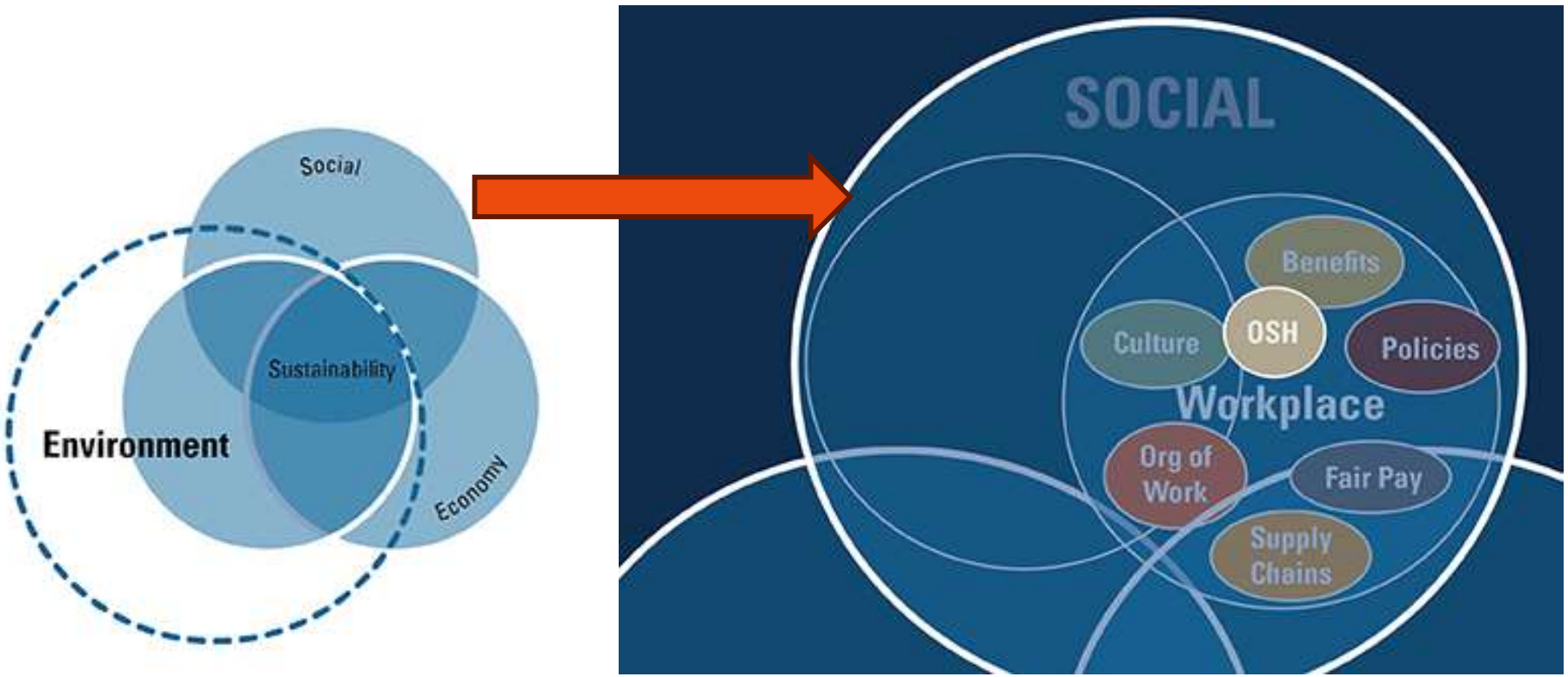
Presentation Summary



- Industrial Hygiene is vital in laboratory design process.
- Anticipate, recognize, evaluate, and control all workplace hazards.
- Design must consider user requirements and regulatory needs.
- Prioritize engineering controls and plan for future flexibility.
- Continual environmental monitoring ensures facility success.

Workplace → “Lab” → Clean Room

Holistic Approach to Workplace Focusing on “Lab” Design

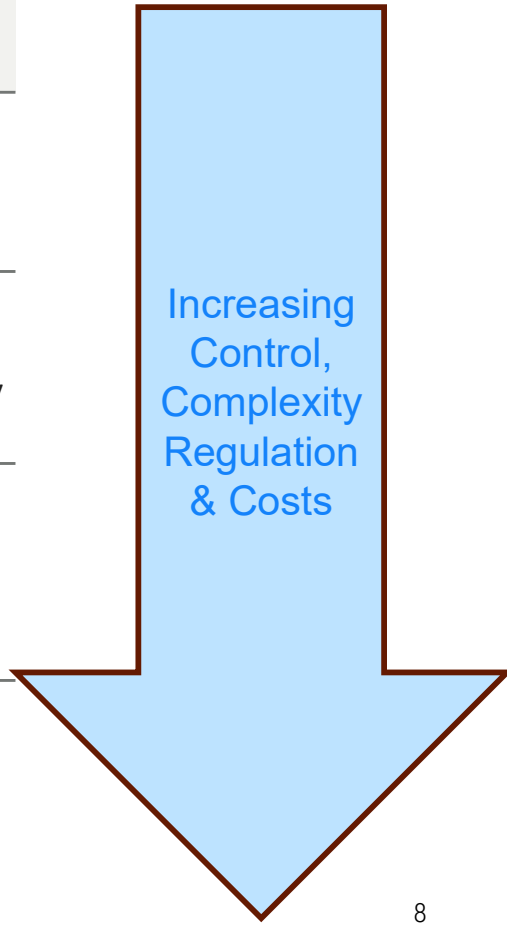


What is a “Lab”

- Purpose: Labs are designed to **provide controlled conditions for scientific work**, ranging from educational experiments to advanced research and medical diagnostics.
- Types: There are various types of labs, each with specialized equipment. Examples include:
  - Chemistry labs: Used for chemical experiments and analysis.
  - Biology labs: Focus on living organisms and biological processes.
  - Physics labs: Investigate physical phenomena like mechanics and electricity.
  - Medical labs: Perform diagnostic tests on patient samples like blood and tissue.
  - Educational context: In a school or university setting, a "lab" often refers to a hands-on class where students practice skills, collect data, and apply concepts learned in lectures.
  - Medical context: A medical lab test involves a healthcare professional analyzing a sample from a patient to help diagnose illnesses and monitor their health.
  - Or a Mix of all of the Above……

Various Types of Controlled Environment Rooms (CER)

SPACE TYPE	PURPOSE	CHARACTERISTICS	Control Requirements
Lab	General research, education, and non-regulated testing	Basic equipment, often open access, minimal documentation	Basic safety protocols, general organization, Lab Notebook
GLP Lab (Good Laboratory Practice)	Non-clinical health and environmental safety testing	Structured protocols, comprehensive documentation, equipment calibration	Strict adherence to GLP regulations, quality assurance, data integrity
Controlled Not Classified	Activities requiring some environmental control but not strict classification	Defined control parameters (e.g., temperature, humidity), restricted access	Monitoring of defined parameters, personnel training, cleaning procedures
GMP Clean Room (Good Manufacturing Practice)	Manufacturing and processing of products, especially pharmaceuticals, requiring contamination control	Highly controlled environment, classified by particle count (e.g., ISO or EU GMP grades) Controlled Particles	Strict GMP adherence, regular validation, rigorous environmental monitoring, gowning procedures,



Clean Room Classification

ISO 14644-1 Cleanroom Standards | Cleanroom Classifications

Class	Maximum Particles/m³						FED STD 209E equivalent
	≥0.1 um	≥0.2 um	≥0.3 um	≥0.5 um	≥1 um	≥5 um	
ISO 1	10	2					
ISO 2	100	24	10	4			
ISO 3	1,000	237	102	35	8		Class 1
ISO 4	10,000	2,370	1,020	352	83		Class 10
ISO 5	100,000	23,700	10,200	3,520	832	29	Class 100
ISO 6	1,000,000	237,000	102,000	35,200	8,320	293	Class 1,000
ISO 7				352,000	83,200	2,930	Class 10,000
ISO 8				3,520,000	832,000	29,300	Class 100,000

Clean Room – Air Change Rate, Airflow Type and Gowning

Cleanroom Features by ISO Class

ISO Class	Air Change Rate (per hour)	Typical Airflow Type	Personnel Gowning Requirements
ISO 1	500–750+	Unidirectional (Laminar)	Full suit, goggles, gloves, respirator
ISO 2	480–720	Unidirectional	Full suit, goggles, gloves
ISO 3	400–600	Mostly unidirectional	Full gowning, hair cover, gloves
ISO 4	300–450	Mixed airflow	Full gowning with coverall and gloves
ISO 5	240–360	Mixed with laminar zones	Gown, face mask, hair net, gloves
ISO 6	90–180	Non-unidirectional	Hair net, lab coat, gloves
ISO 7	60–120	Non-unidirectional	Smock, shoe covers, hair cover
ISO 8	10–25	Non-unidirectional	Minimal: hair net, basic lab attire
ISO 9	<5	Standard HVAC	No special gowning

Is a GMP Clean Room a Lab?

- No. But there is Overlap.
- In this Presentation the use of **“Lab”** will be used to refer to the Controlled Environment Rooms (including a traditional laboratory to Clean Rooms)
- The User Requirements as well as the hazards present determine the degree of control and Monitoring needed

Why “Lab” Design for an Industrial Hygienist or EHS Professional?

Why should an IH be interested in Lab Design?

Let's start with the Definition:

Industrial Hygiene is the **science** and **art** of **anticipating**, **recognizing**, **evaluating**, and **controlling environmental factors** and **stresses** in the **workplace** that may cause sickness, impaired health, or discomfort among workers or the community.

It involves using scientific principles to protect and enhance the health and well-being of people by **managing chemical, physical, biological, and ergonomic hazards**. OSHA ref

Laboratory Design & Environmental Monitoring

- User Requirements -
  - Processes, Chemistry, Biologicals - Controlling Hazards
  - Utilities - process gases, water
  - Research, Development, Manufacturing, GXP considerations
  - GXP
- Pressurization Strategies
- BMS vs 3rd Party Verification
- Particle Count Requirements - Viable and Non-Viable

Key reasons for an IH to be interested in Lab design

- Hazard control:
  - A primary responsibility of an IH is to control workplace hazards.
  - Lab design is the most effective way to do this by incorporating engineering controls at the outset, such as proper ventilation, chemical storage, and emergency equipment placement.

- Compliance:
  - Effective lab design helps ensure compliance with safety and environmental regulations. This includes planning for necessary safety features from the initial stages of a project.

- Accident prevention:
  - A well-designed layout reduces the likelihood of accidents by establishing clear traffic flow, providing sufficient space, and ensuring emergency exits are accessible.

- Health and well-being:
  - Design elements like proper lighting, noise, ergonomic workstations, and air quality management and other stressors contribute to the long-term health and comfort of lab personnel, which can improve concentration and morale.

Key reasons for an IH to be interested in lab design

- Flexibility for the future:
  - Laboratories need to adapt to new technologies and research methods. IHs should advocate for flexible designs with modular components and adaptable infrastructure to accommodate future changes without compromising safety.

- Productivity and efficiency:
  - A logical layout with dedicated spaces for different tasks, from bench work to support and office areas, improves workflow and efficiency. This reduces wasted time and movement, allowing for more productive work. Ergonomic concerns.

- Integration of equipment:
  - Planning for the placement and integration of specific equipment, such as sensitive or large instruments, is crucial for both safety and performance

- Deep understanding of how the building works

IH – Anticipating Hazards

Anticipating - Defining Scope

How will this Controlled Space (Lab/MFG) be used?

- Defining Scope
- Primary Purpose
- Secondary Purpose
- User Groups
  - Primary User Groups
  - Secondary User Groups
  - Support Groups
- Processes
- Adjacencies – what other groups or processes need to be collocated ?
- Future use
- Assemble an SME Team –
  - Identify Key Personnel to work with
  - Ask Questions and Requests for information

Anticipating – Request “The Lists”

Chemical lists

- Fire Code Compliance (Hazardous Materials Inventory System) by Control Area

Biohazardous lists

- Biologicals, Select Agents - R

Waste Generated Lists

Equipment lists

Process Flow Diagrams

High Pile Storage Reports (Warehouse Spaces)

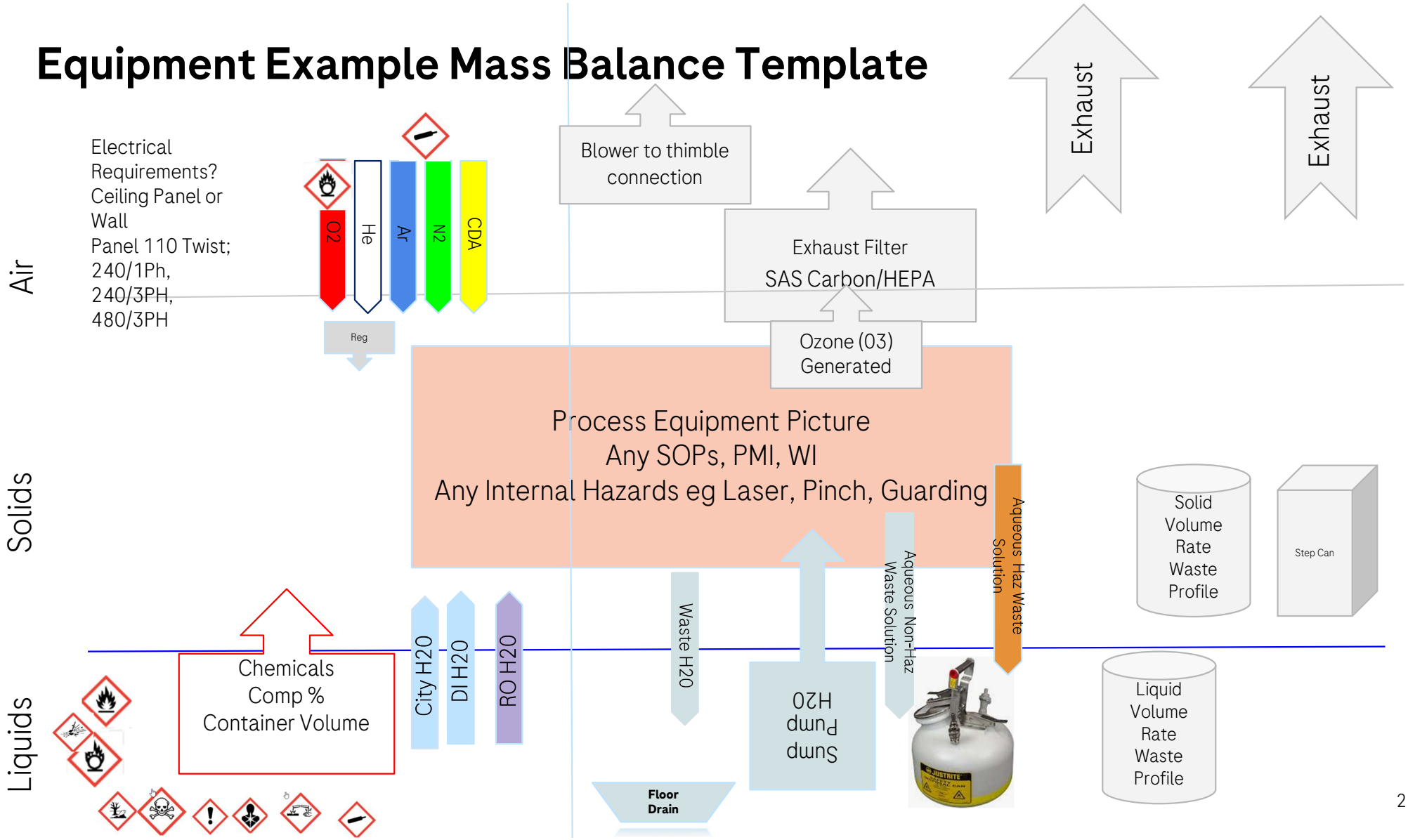
Asbestos Reports – If any renovation work is being performed

Anticipating: Equipment List & Information Requirements

- Equipment Information
  - Make
  - Model
  - Serial Number
- Utilities
  - Electrical Services
  - Natural Gas
  - Process Gases/CD Air/Vacuum
    - Flow
    - Pressure
    - Vacuum
  - Water (City, DI, RO, etc)
    - Flow
    - Pressure
  - Data Cabling
  - WiFi

- Equipment Information
  - Operational Range
    - Temp
    - Relative Humidity
  - Dimensions
  - Weight
  - Vibration
  - Lighting requirements
  - Heat Loads

Equipment Example Mass Balance Template



Anticipating: Chemical Inventory - HMIS Reporting & Detailed Information

California (State) Fire Code Categories

- Combustible Fibers
- Compressed Gases - Inert
- Combustible Liquids
  - II, III-A, III-B
- Corrosives
- Cryogenic Fluids
- Explosives
- Flammable Gases
- Flammable Liquids
  - I-A; I-B; I-C
  - FL1C/CL2 FL1C OR CL2: Cannot distinguish by information provided in SDS
- Flammable Solids
- Highly Toxics
- OP Organic Peroxides
  - Unclassified Detonable
  - OP1-5 Organic Peroxides I-V
- Oxidizers 1-4
- Oxidizer Gas, Gaseous
- Pyrophorics
- TX Toxics
- UR1-4 Unstable Reactives 1-4
- WR1-4 Water Reactives 1-4
- Aerosols

- Floor Plans
- Chemical Name
- CAS #
- SDS (Actual Copy or Link)
- Composition %
- Container Information
  - Size
  - Type
  - Unit of Measure
- Location
  - Stored
  - Used
  - Room/Floor
  - Control Zone
- Storage Type
  - Cabinet
  - Haz Cab
  - Cold Temp Unit
- In-Use Status
  - Open or Closed

User Requirement Specifications

- Request all User Requirement Specifications for the “Lab”
- Critical Parameter User Requirements
  - Facilities/Utility URS
  - Process URS
  - Equipment URS
- If these do not exist, you may find some of the “Lists” will provide information which to create URS
- These will for the Basis of Design – by the Architect
- These will be used in the Commissioning & Qualification of the new “Lab”
  - These can be used to set Alert Levels and Warning Alarms for Environmental Monitoring

User Requirement Specification (GxP)

- User Requirements Specification (URS) is a
  - formal document that details the functional, operational, and regulatory requirements for equipment, facilities, utilities, or computerized systems.
  - The foundation for design, procurement, and validation activities, ensuring that the final product meets the user's needs and is compliant with regulations.

User Requirement Specification (GxP)

Key functions of a URS

- **Defines user needs**: The URS translates the user's requirements and business needs into a clear, written specification that is easy for designers and vendors to understand.
- **Guides design and procurement**: It provides the necessary criteria for engineering, quality, and operations departments to select and purchase equipment or systems that meet the specific needs of the process.
- **Forms the basis for validation**: The URS is the starting point for all subsequent validation activities, such as Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ). It is used to verify that the installed and operating equipment meets the initial requirements.
- **Ensures regulatory compliance**: By defining how the system must meet regulatory expectations, the URS is a critical document for demonstrating compliance during audits and is often a mandatory requirement in regulated industries.
- **Prevents scope creep**: By setting firm boundaries for the project, a well-documented URS helps prevent the project from expanding beyond its original goals.

Other Sources of User Requirements:

Regulatory requirements (not an exhaustive list)

- Global - EU, Individual Country Requirements
- Federal - EPA, FDA, Fed OSHA, NFPA,
- State - DTSC, CUPA, CalOSHA, Stormwater, Fire Code, Building Code
- County/Region - Air Pollution Control Board, Water Board
- City - Industrial Waste Water, Fire Department (Prevention), Business License, Permitting,
- Internal Policies: Global EHS, Quality, Regulatory, Purchasing Policy, Internal Approvals

IH – Recognizing Hazards

Recognition

Reviewing the information provided….. **recognize hazards** based on what is provided.

- Chemicals
  - HMIS report compared against Maximum Allow Quantities (MAQs)
  - Screening Inventories against
    - Prop 65 (if in California or planning on selling a products here)
    - TSCA
    - Substance of Very High Concern (SVHC), a chemical substance identified under the European Union's REACH regulations
    - Industrial Wastewater Discharge Permits
    - Precursor List (DEA & State DEA)
  - OSHA & State OSHA Carcinogen lists
  - OSHA Named Regulations

Recognition

Reviewing the information provided….. **recognize hazards** based on what is provided.

- Equipment List
  - Machine Guarding, LOTO – Hazardous Energies, Ergonomic Concerns
- Wastes/Emissions produced –
  - Was this in the HMIS report
  - Where the the waste discharge to?
  - Are there emissions produced?
- Biologicals -
  - What Risk Groups are present?
  - Attenuated vs Viable or Patient Samples?

- The Identification of any hazards must be further evaluated.

IH – Evaluating Hazards

Evaluating

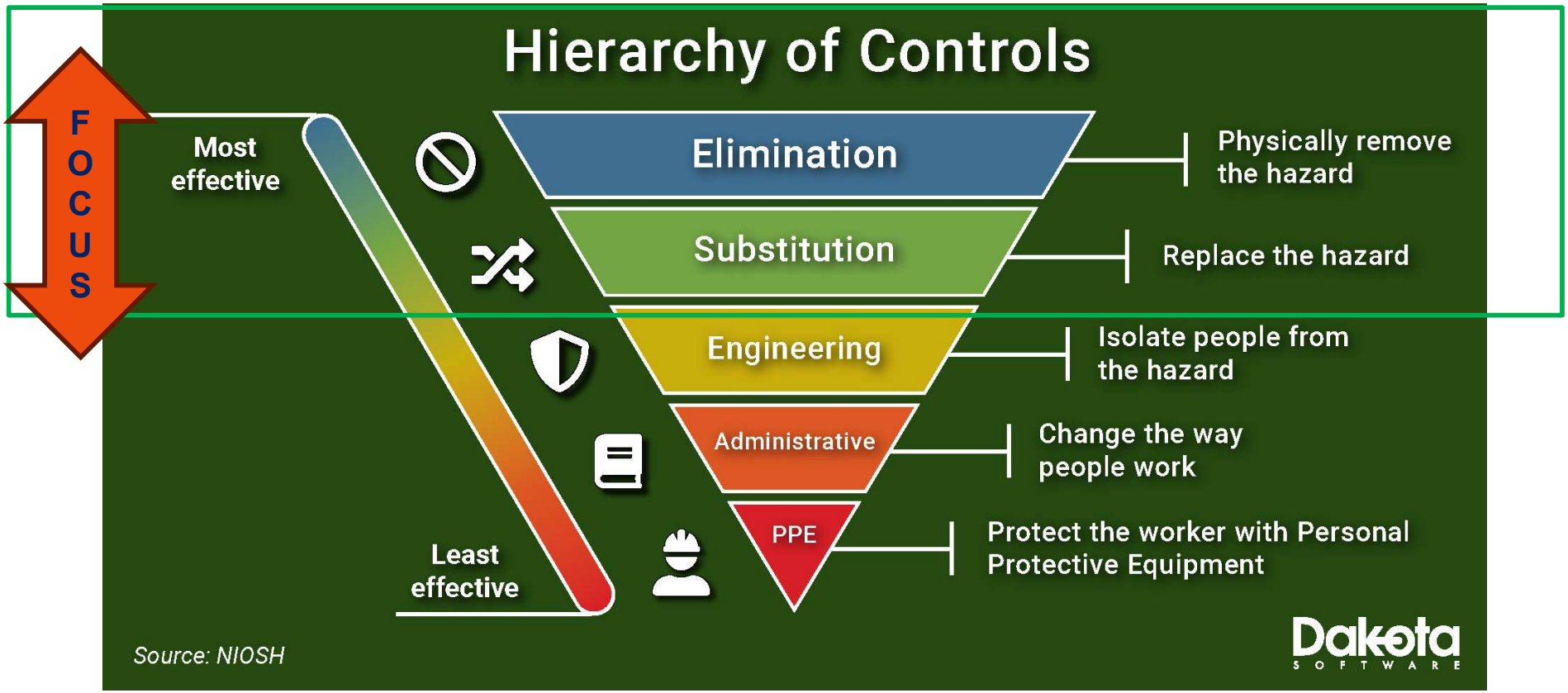
- Assessments – Review or Conduct New
  - Existing Risk Assessments
  - Existing Exposure Monitoring Results
  - Job Hazard Assessments
  - Equipment Safety Assessments
  - Entirely new building or green build? – Phase 1 ESA

- Be Curious – Will the usage of these recognized hazards the same process, scaled up, or entirely different use case?

  - If it is a new process or scale up you will need a general idea of the SOP or Lab Procedure

IH – Controlling Hazards

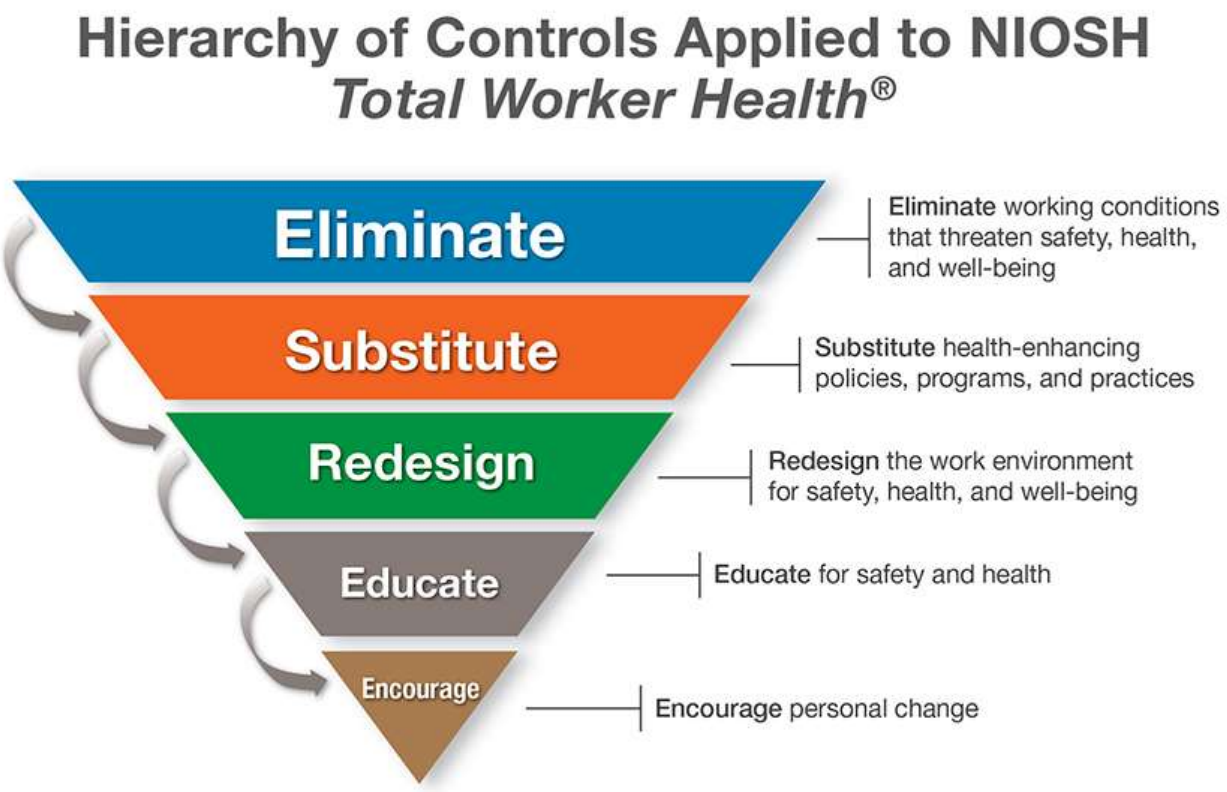
Controlling – Designing and Redesigning the Workplace



Controls – General Tips for Success

- BE INVOLVED EARLY – Get a Seat at the Table
- Create the Inputs to the Construction Project:
  User Requirement Brief and the Basis of Design
- Be Present during the Early Concept Design, Scoping Design and throughout project
- Mutual Education and Understanding
  - Conversations about the hazard, understanding the processes,
  - Respectfully challenge the User Requirements:
    - Why does this user requirement exist, and what the end user is trying to accomplish.
- **Legacy answer - this is always how we've done it**

Controlling



Suggested Citation: NIOSH [2016]. Fundamentals of total worker health approaches: essential elements for advancing worker safety, health, and well-being. By Lee MP, Hudson H, Richards R, Chang CC, Chosewood LC, Schill AL, on behalf of the NIOSH Office for Total Worker Health. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health. DHHS (NIOSH) Publication No. 2017-112.

Controlling

WARNING – There are a few times the Construction team will seek an IH's opinion:

- Fume Hood Solvent LEL calculations
  - Timing – HMIS report just prior to Building Permit submittal
- Questions from the Fire Prevention Department
  - Timing – After Building Permit Submittal
- Asbestos report – They will ask if you can take samples
  - Timing – Just prior to Building Permit Submittal
- Mold found during construction

TIP BE CONTROLLING and INSERT YOURSELF IN THE PROCESS

Controls - Elimination

- Focus on Elimination – Design out

- Example - Working from heights -— Falls, ladders, etc
  - Consider maintenance & repair activities and access to mechanical systems
    - is the system serviceable where the MEP Engineer located Mechanical Equipment?
    - Can the systems be ground level or in a mechanical room?
    - Can elevated walking surfaces be added to eliminate the temporary ladders and lifts
  - Example – Sodium Azide is on the chemical inventory. Upon inquiry the company no longer uses this chemical in their process. Eliminate it.

Controls - Substitution

Substitute

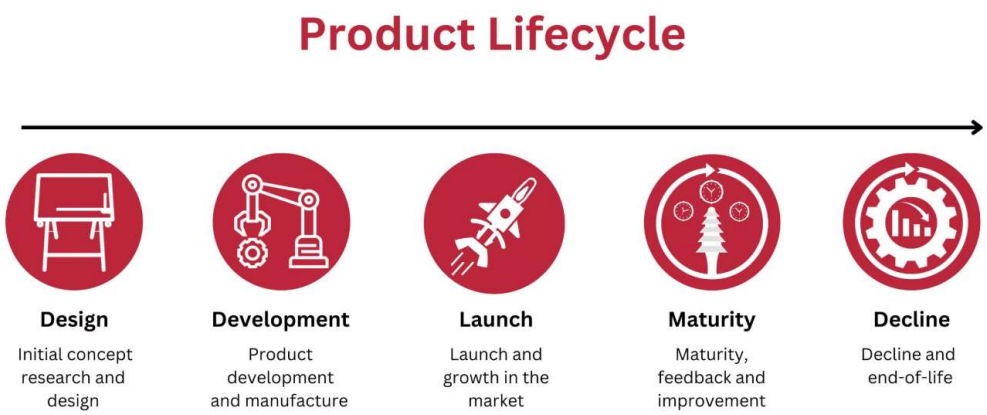
- Replace unsafe, unhealthy working conditions or practices with safer, health-enhancing policies, programs, and management practices. These should improve the culture of safety and health in the workplace. Mutual Understanding

Enablers

- Mutual Education –
  - Understand the User Processes
  - Users should strive to understand your Role
- Chemical Substitution - What is green chemistry? - it is best to document this conversation
  - Example – What are some Alternatives to Methylene Chloride?
- Rethink the processes with the End Users and the Subject Matter Experts

Other Considerations: Ease of Change vs Product Stage

- Understanding of where in the Product Life Cycle may make change more possible.



- Changes are become increasingly harder to implement as the product matures
  - Design, Research → Development → Maturity

Planning for Success by Planning for Failure

Even in the Best Maintained Facilities Equipment can Fail….Business Continuity, Redundancy, & Early De

- Early Detection - Continual Environmental Monitoring
- Quick Response - enabled by Action Limits
  - Engineered preferred to Human
- Redundancy - Equipment, Tie-ins, spare critical equipment

Controlling – Containment Options

Biosafety and Containment - Primary vs Secondary Containment

Feature	Primary Containment	Secondary Containment
Purpose	Protects Personnel from exposure to hazard	Protects the environment outside the lab
Key Elements	• Safety equipment • good microbiological techniques	• Building structure, • airlocks, • specialized ventilation, • HEPA filters in exhaust systems, • handwashing stations
Examples	• Biosafety cabinets, • sealed containers, • PPE (gloves, coats, respirators)	• Facility design • Operational practices

Biosafety Cabinet Classification

Class I BSC

Protection: Personnel & environment, No product protection
How It Works: Air is drawn into the cabinet through the front opening and filtered before being exhausted
Best For: Laboratories handling low-risk biological materials, such as teaching labs or procedures that generate aerosols (e.g., microbiological research with non-hazardous agents)

Class II BSC

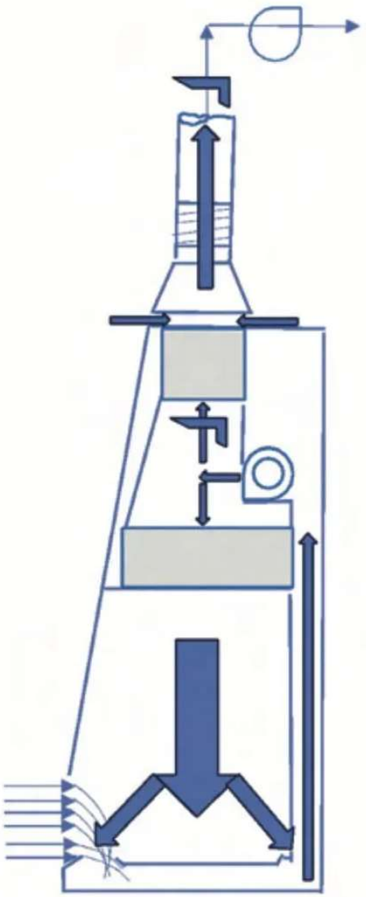
Protection: Personnel, Environment, Product
How It Works: HEPA-filtered downward airflow protects the product, while inflow protects the user. Exhaust air is also HEPA-filtered
Best For: Clinical, diagnostic, and pharmaceutical labs working with BSL-2 and BSL-3 pathogens (e.g., *HIV, Salmonella, Toxoplasma)*
Types of Class II BSCs:

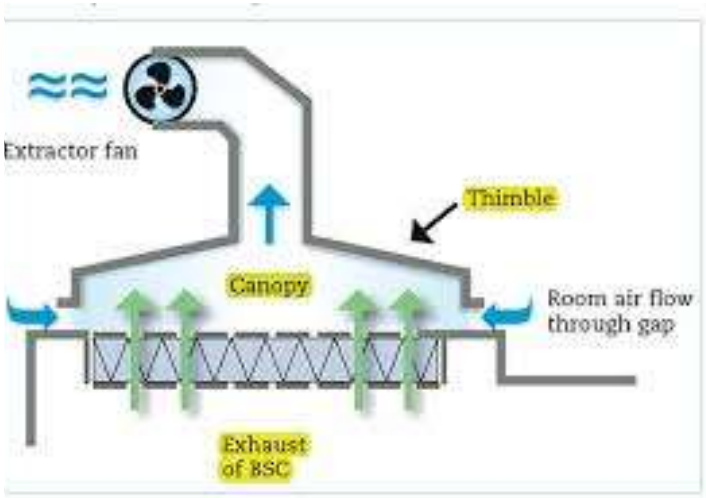
- *A1 & A2:* Recirculates most air inside; limited chemical handling
- *B1 & B2:* Higher exhaust rates; suitable for handling hazardous vapors

Class III BSC

Protection: Maximum protection for personnel, environment, and product
How It Works: A gas-tight enclosure where workers operate through attached gloves. All air is fully exhausted through HEPA filtration, preventing any exposure.
Best For: BSL-4 containment, used for handling dangerous and exotic pathogens like *Ebola, Marburg virus*

Figure 1: Class II, Type A2 Vented Biological Safety Cabinet





BSC Class II A2 with Thimble (Canopy) Connection

- Flexible
- Less complicated to Balance a Room
- Air Gap
- Can use for some hazardous materials

BSC Class II Type A2 with Thimble vs B2

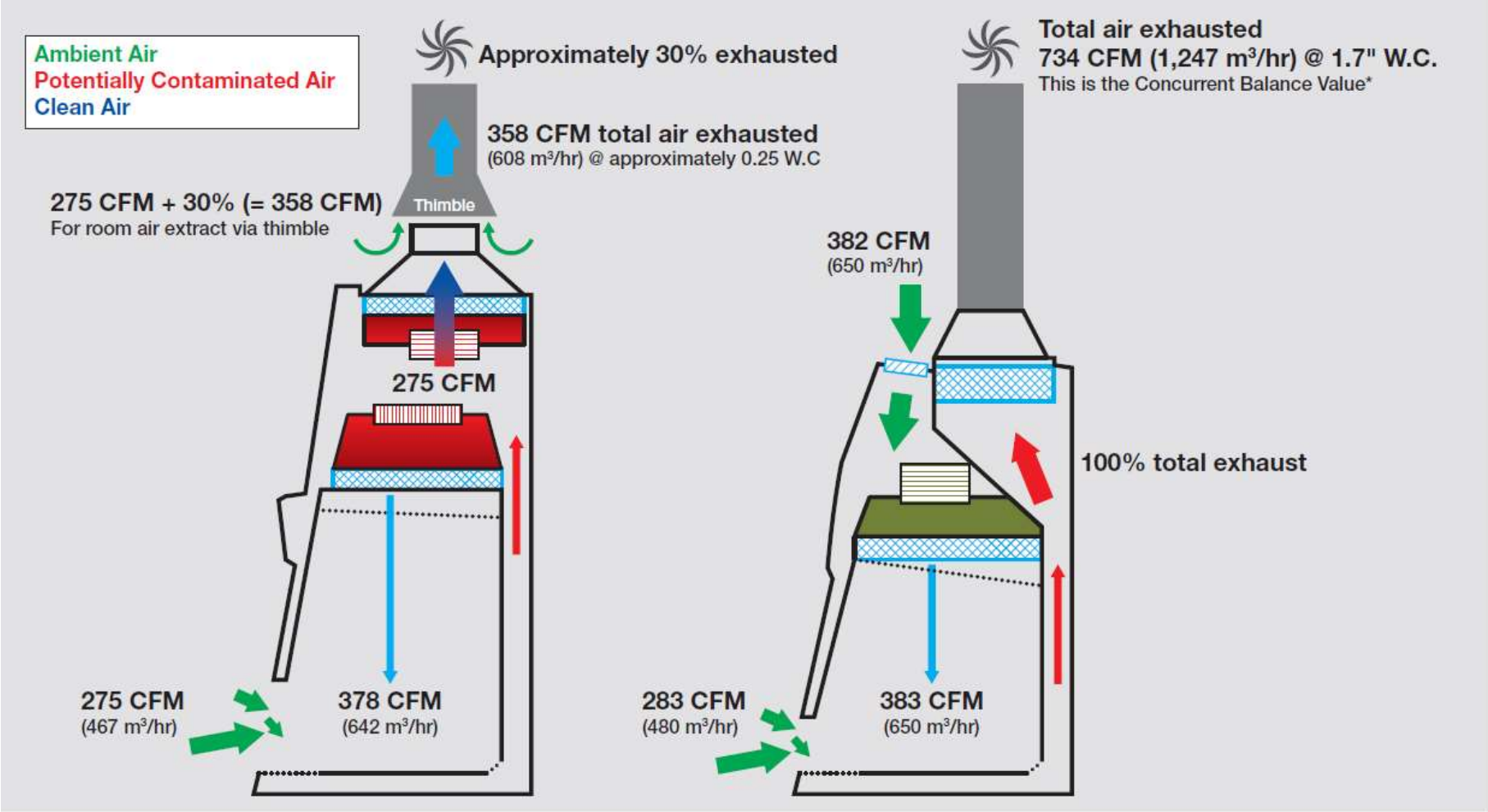


Figure 4. Thermo Scientific Type A2 BSC (thimble) and Thermo Scientific Type B2 BSC.

BSC Class II Type A2 with Thimble vs B2

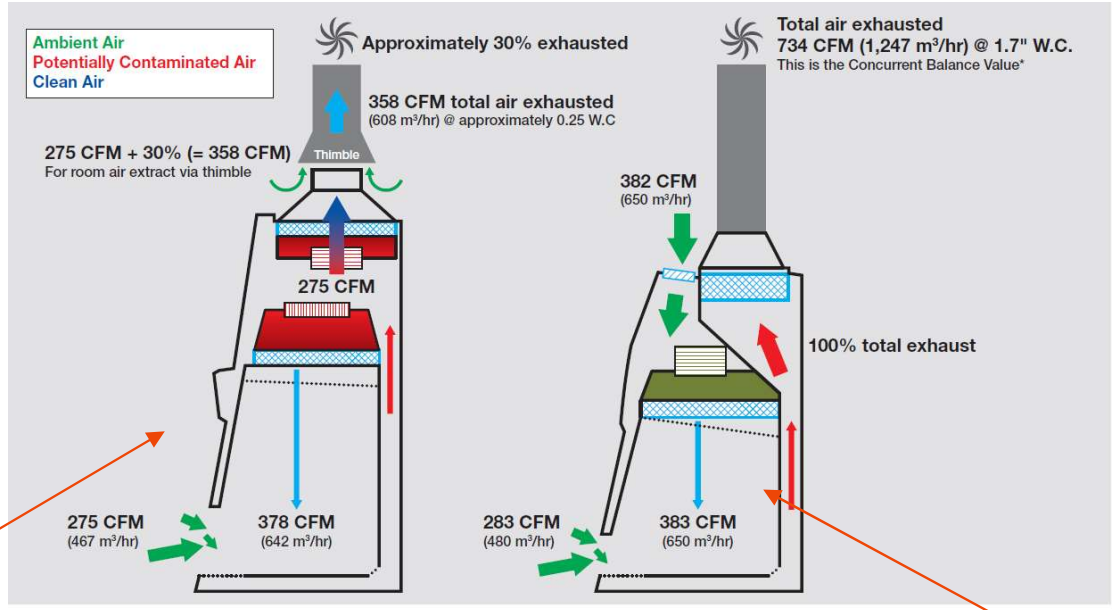


Figure 4. Thermo Scientific Type A2 BSC (thimble) and Thermo Scientific Type B2 BSC.

A2 with Thimble Primarily for microbiological agents at BSL-1, 2, and 3; can be used for **minute quantities** of volatile chemicals if vented outside via thimble.
Can be off a common Exhaust Brand

B2 Suitable for larger volumes of volatile and toxic chemicals, as well as radionuclides
Prefer Dedicated Exhaust per B2

Other Ventilation to consider

- Ventilated Balance Enclosures
- Fume Hoods
- Canopy Hoods
- Snorkel
- Specialized equipment ventilation requirements
  - Supply and Exhausts
  - Eg rotovap
- Make Up Air (you will need to condition)
  - Single Pass
  - Recirculation
- Heat Loads
- Future needs

It is not all about worker safety...also think product safety

- Outside Enironmental Particulate Contamination Control
- Indoor Enironmental Particulate Control - From the people or processes within the room
  - Hair/Dander/Make-up/ Clothing/ microorganisms (Viruses, bacteria, etc)
- Process to Process Contamination
- eg - Amplicon, microorganisms that are incompatible, enzymes

“Clean Room” vs Biocontainment

Feature	“Clean Room”	Biosafety Containment
Primary Purpose	To control the environment by eliminating contaminants like dust and airborne particles to protect a product.	To protect personnel, the environment, and the product from biohazards like infectious agents.
Main Concern	Preventing contamination from entering the space.	Preventing the escape of dangerous biological material.
Key Technologies	High-efficiency particulate air (HEPA) filtration, controlled airflow, and strict protocols.	Biosafety cabinets with HEPA filtration, negative pressure rooms, containment devices, and personal protective equipment (PPE).
Examples of Use	Pharmaceutical manufacturing and microchip fabrication.	Handling viruses, bacteria, genetically modified organisms, and other infectious agents.
Combined Use	A containment facility can be a cleanroom, but with additional controls to handle specific hazards	A cleanroom may be a component of a biosafety facility, with its clean environment being part of the overall safety strategy.
Airflow Direction and Pressure Cascade	Out & Positive Cascade	Inward – Negative Cascade or Positively Pressurized Anteroom – Negative Interior

Pressure Cascades – What is your Application?

- Cleanrooms: To prevent contamination of sensitive products in industries like pharmaceuticals and microelectronics.
- Biocontainment laboratories: To prevent the escape of infectious diseases or hazardous biological agents.
- Pharmaceutical manufacturing: To maintain sterility in aseptic processing areas and protect products from contamination.
- High-potent compound handling: To contain aerosols and dust from highly potent or hazardous materials, protecting both the product and the operators.

Pressure Cascades – How does it work

- Pressure differentials: The core principle is establishing a difference in air pressure between adjacent rooms or zones. This difference is managed using HVAC systems.
- Directional airflow - Containment:
  - Positive pressure: In cleanrooms, higher pressure in the critical zone pushes clean air outwards through doors and other openings, preventing contaminants from entering.
  - Negative pressure: In containment areas like BSL-3 labs or high-potent handling rooms, lower pressure draws air inward, ensuring any contaminants, such as aerosols or hazardous substances, are pulled into the room rather than escaping.
- Airlocks: These are a common application of pressure cascades. Personnel or materials pass through a series of airlocks, each with a progressively different pressure, creating a barrier against contamination during transfers

Airlock Design – Positive Pressurizations

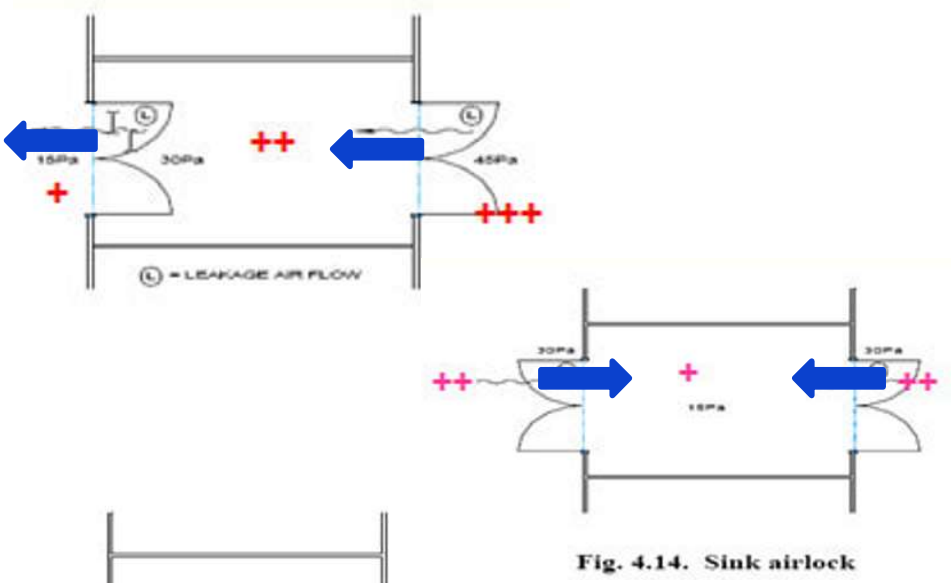


Fig. 4.14. Sink airlock

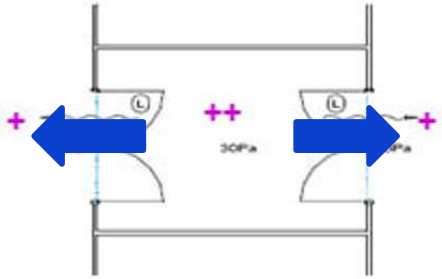
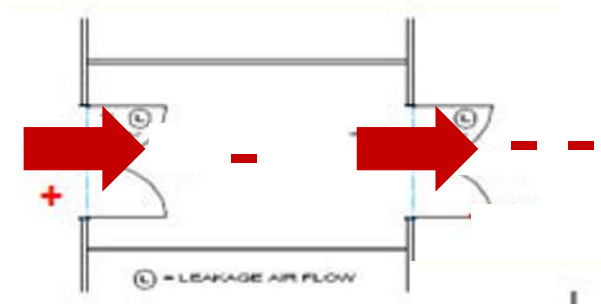


Fig. 4.15. Bubble airlock

- Cascade Airlocks: Feature progressively increasing pressure from the outer to the inner area, allowing airflow from the clean area to the less clean area, minimizing contamination risks.
- Sink Airlocks: Have lower pressure than the adjoining rooms, containing contaminants and preventing their escape into cleaner areas.
- Bubble Airlocks: Maintain higher pressure within the airlock compared to both adjacent rooms, preventing contaminants from entering from either side.

Airlock Design – Negative Pressure Containments



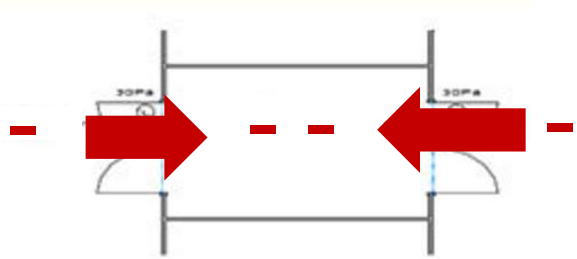


Fig. 4.14. Sink airlock

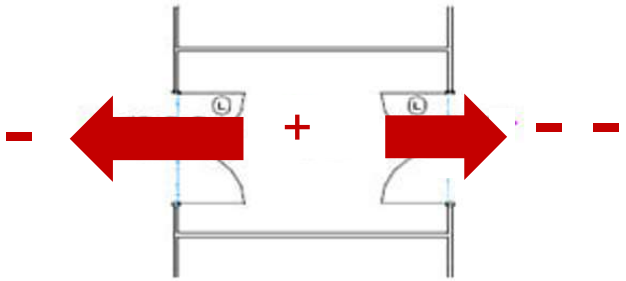


Fig. 4.15. Bubble airlock

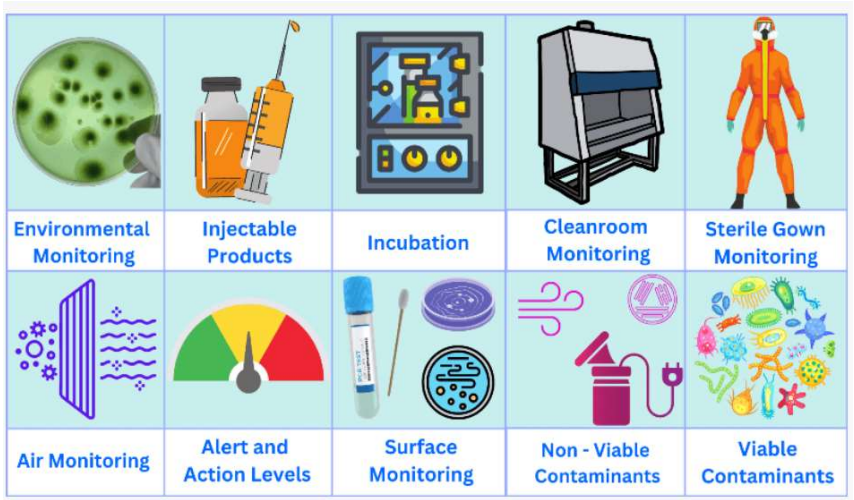
- Cascade Airlocks (Negative): Decreasing Pressure into the workspace for containment
- Sink Airlocks: Have lower pressure than the adjoining rooms, containing contaminants and preventing their escape into cleaner areas.
- Bubble Airlocks: Maintain higher pressure within the airlock compared to both adjacent rooms, preventing contaminants from entering from either side.

Other Considerations to Maintain Control of the Space

- Security
  - Access Controls
  - Airlock/Mantraps
  - Unidirectional flow
  - CCTV
  - Training Requirements to gain Access
- Signage
  - Door Signage –
    - Owner,
    - Emergency Numbers,
    - Prop 65 Warning,
    - Hazard Signage (GHS)
    - Biosafety Signage
    - NFPA Diamonds
    - PPE Requirements
- Gowning Procedures
  - Access Controls
  - Airlock/Mantraps
  - Unidirectional flow
  - CCTV
  - Training Requirements to gain Access
- Cleaning Procedures
  - Do not for get the Janitorial Closet
  - Where is the Mop water dumped
  - Do you need separate sets of cleaning equipment?–

Environmental Monitoring to Ensure Health of “Lab”

Environmental Monitoring



- Definition: Environmental monitoring is the process of measuring the following to ensure a controlled environment is performing to design:
  - Particulates - microbial (Viable) and Non-Viable particulate quality,
  - **Temperature**
  - **Humidity**
  - **Pressures**
  - Other Critical User Requirements (Gas Pressure)

- This monitoring is crucial for both Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP)

Environmental Monitoring – Continual Monitoring to ensure “Lab” is constant

Parameter	Frequency	Type	Features
Temperature	Continual	Digital - Wired/Wireless	▪ Validated, ▪ Expandable System ▪ Datalogging with cloud storage ▪ Multiple Alert Levels, ▪ Multiple Groups ▪ Multiple Call Trees, SMS, emails ▪ 21CFR Compliant ▪ Calibrated with traceable standards
Relative Humidity	Continual	Digital - Wired/Wireless	
Differential Pressures	Continual	Digital – Wired/Wireless	
Particle Non-Viable	As Needed, Routine Sampling	Portable and Handheld	Datalogging WiFi Connectivity Long battery life

Summary & Take Home

- “Lab Design” provides an Industrial Hygienist with the unique opportunity to have a holist understanding of the processes in the “lab” and to intervene early to design for the health and well-being of the employee’s and community by eliminating, substituting, and engineering hazards.
- This is a long and highly detailed process
- Mutual understanding of the End User’s goals and processes and the IH’s goals to provide the healthiest Workplace is necessary.
- Typical request for IH involvement from the construction teams is too late in the process for the IH to make a deep and lasting impact.
- Early & continual involvement from the IH is necessary to achieve these goals.
- An IH’s role in Lab Design to Support Safe Science brings life-saving healthcare products to the market to improve lives while having minimal impact to our employees and the environment.

?