

OEL DRIVEN FACILITY DESIGN

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About Arnita Consultants



Arnita Consultants Pvt. Ltd. embodies a brand that is professional, reciprocal and solution-oriented. With **over three decades of experience**, the company communicates a deep commitment to innovation and quality across its **multidisciplinary engineering services**.

We at Arnita are confident in our technical knowledge base stemming from experience of more than **500+ completed projects**, reflecting expertise in sectors like pharmaceuticals, biotechnology, and industrial infrastructure. We emphasize precision, regulatory compliance, and sustainable design, aiming to inspire trust among clients and stakeholders.

With a collaborative approach and adherence to international standards, Arnita positions itself as a reliable partner for complex, large-scale projects.

OEL DRIVEN FACILITY DESIGN

Protection of Product, Operator and Environment

ABOUT OEL

OEL (Also known as OEB/HHC) □ **O**ccupational **E**xposure **L**imit.

Measured as: **µg/day**

OEL Categories

Category	OEL	Effect
G 4	$< 1 \mu\text{g}/\text{m}^3$	very high pharmacologic and toxic effect
G 3b	$< 10 \mu\text{g}/\text{m}^3$	high pharmacologic and toxic effect
G 3a	$< 100 \mu\text{g}/\text{m}^3$	Medium pharmacologic and toxic effect
G 2	$< 1000 \mu\text{g}/\text{m}^3$	low pharmacologic and toxic effect
G 1	$\geq 1000 \mu\text{g}/\text{m}^3$	very low pharmacologic and toxic effect

OEL FACILITIES

- The category from 4 to 5 or to some extent level 3.
- High Potent facilities or Containment facilities



Some of the Aspects of Facility Design

1. Building Concept / Concept Development
2. Environmental Protection
3. Clean rooms
4. Waste handling
5. Operator Protection

CONCEPT DEVELOPMENT

1. Data Collection

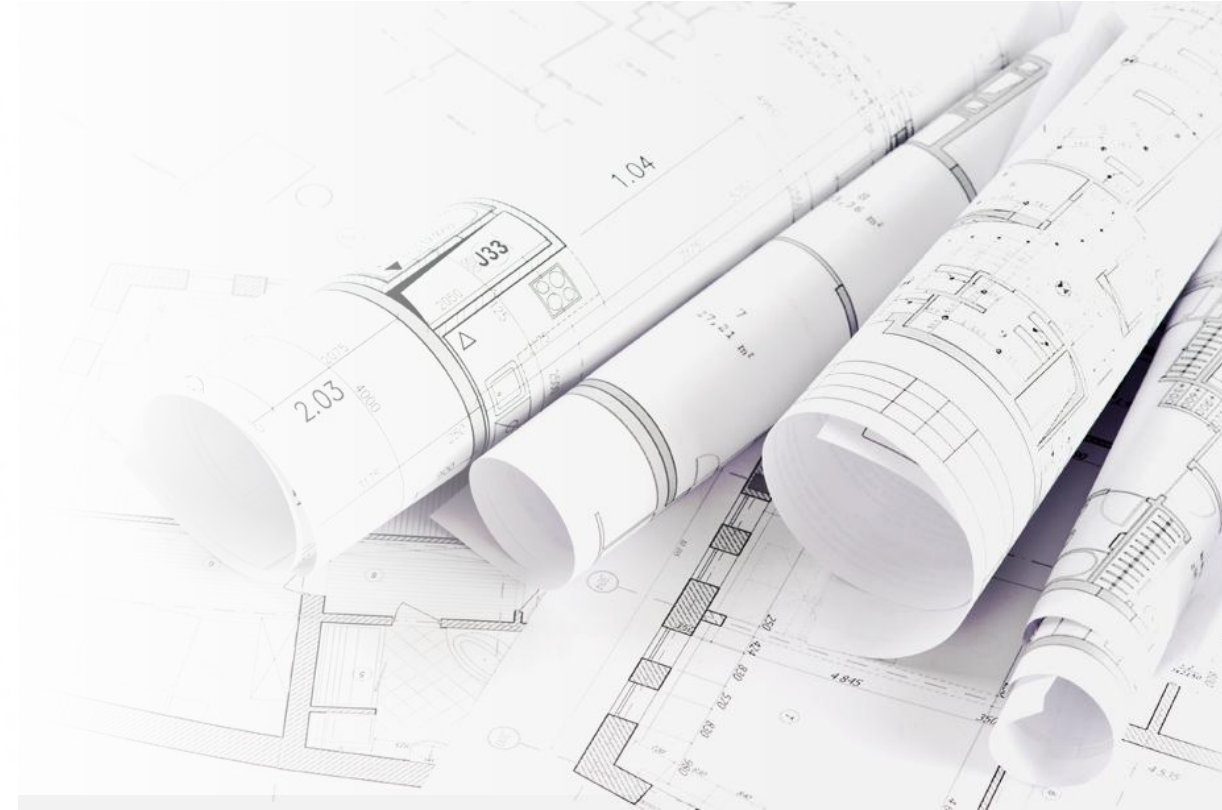
The basis for Concept development is user requirements in terms of :

- a. Dosage form
- b. Volume/ output intended annual/ monthly/ daily
- c. Process steps in the form process flow diagram
- d. OEL based on the potency of substance(s)
- e. HSE requirements
- f. Land size



2. Layout planning

- Inside to outside concept
- Equipment selection
- Space qualification



3. Selection of Containment

Primary Containment:

1. Production Equipment
2. Material handling/ Cleaning
3. Exhaust System

Secondary Containment:

4. Clean rooms
5. Air locks
6. Pressure gradient



3. Selection of Containment

Primary Containment:

- A. Isolators
 - Drum Docking System
 - Rapid Transfer Ports (RTP)
 - Split Valves System
- C. Safety Cabinet



3. Selection of Containment

Secondary Containment:

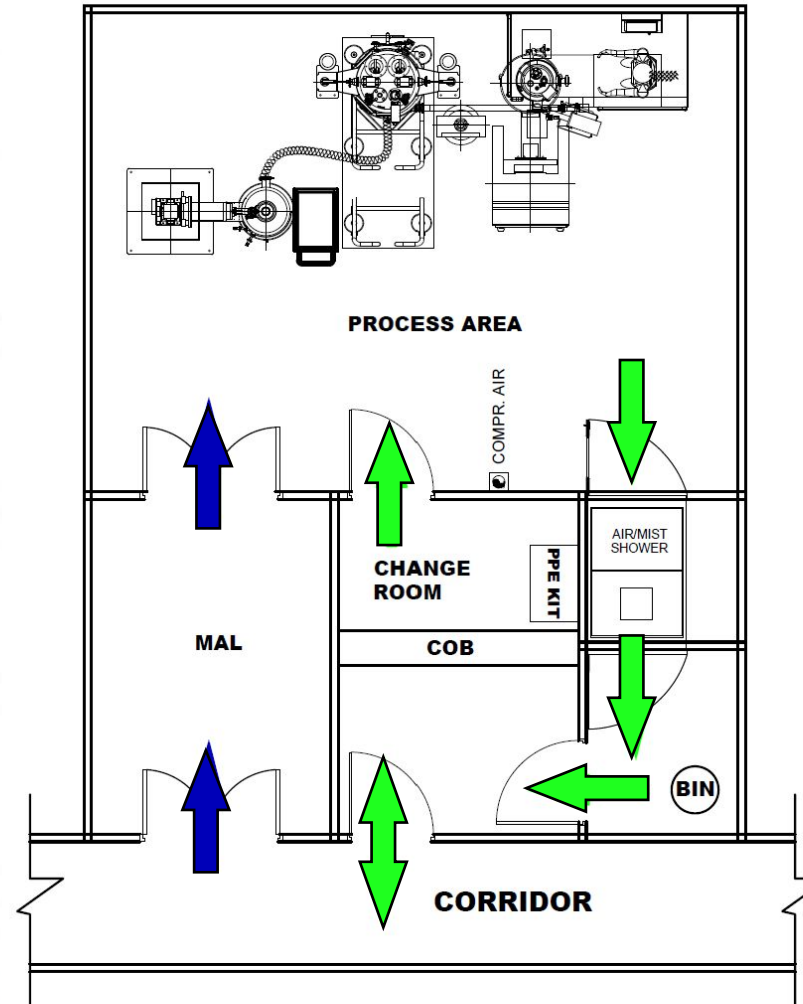
- a. Room concept
- b. Flow of material
- c. Flow of personnel
- d. Room layout
- e. Pressure gradient
- f. Air locks
- g. Emergency concept
- h. Decontamination
- i. Movement of Dirty Equipment
- j. Waste disposal



ROOM CONCEPT

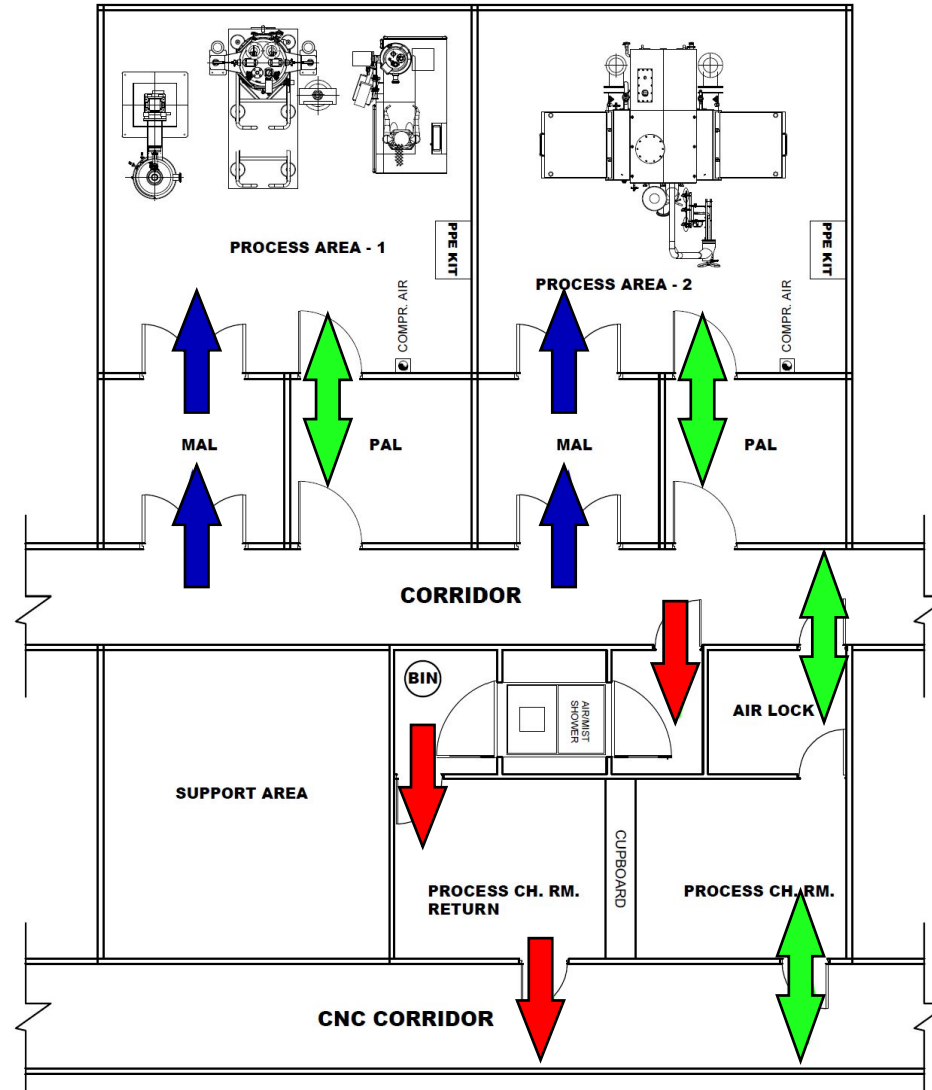
- Process Equipment
- Material handling
- Operation space
- PPE
- Breathable air supply
- Escape route



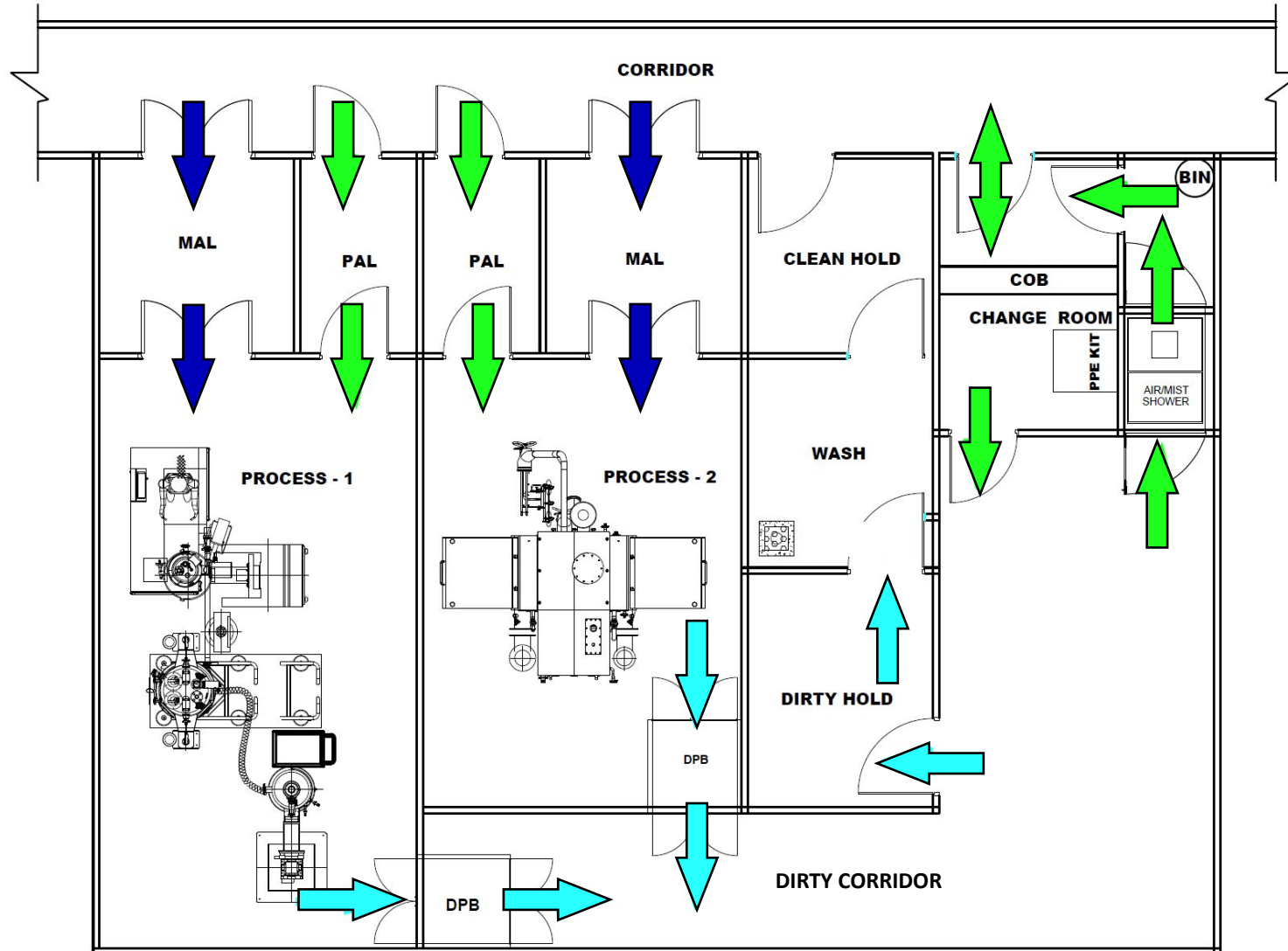


LEGEND

- ↔ MAN MOVEMENT
- ↔ MATERIAL MOVEMENT



TYPICAL ROOM LAYOUT



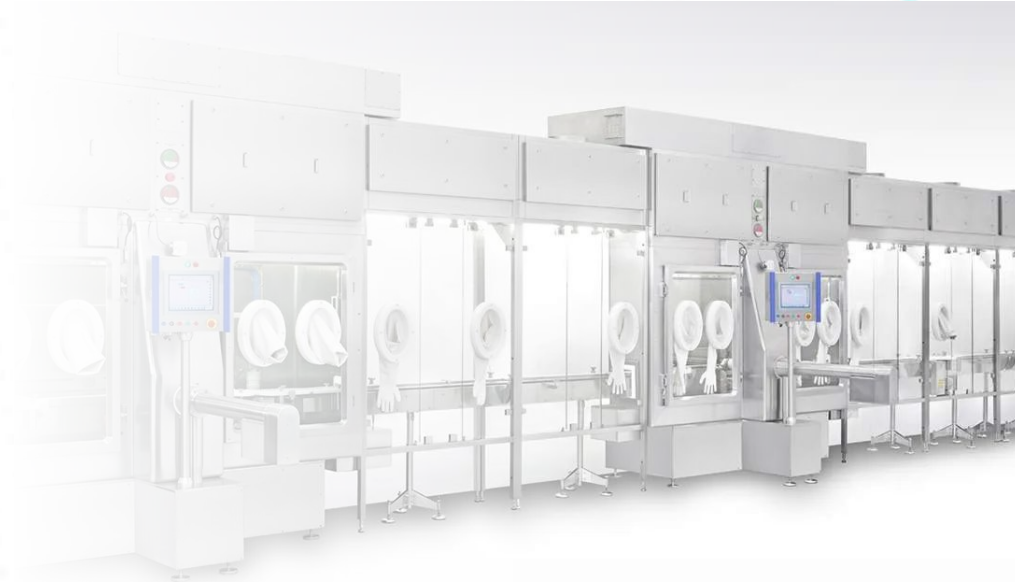
LEGEND

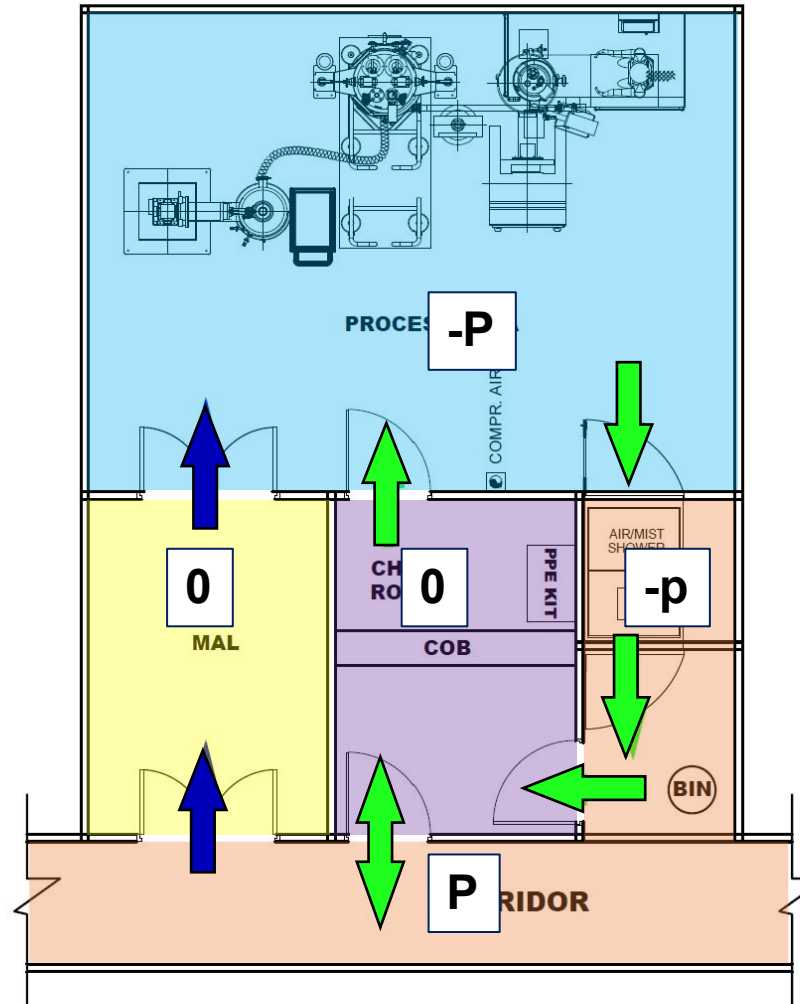
- ↔ MAN MOVEMENT
- ↔ MATERIAL MOVEMENT
- ↔ DIRTY EQUIPMENT MOVEMENT

ENVIRONMENTAL PROTECTION

1. Pressure Cascade Concept

- Negative pressure in Workspaces.
- Maintain constant negative pressure and validate 24/7.



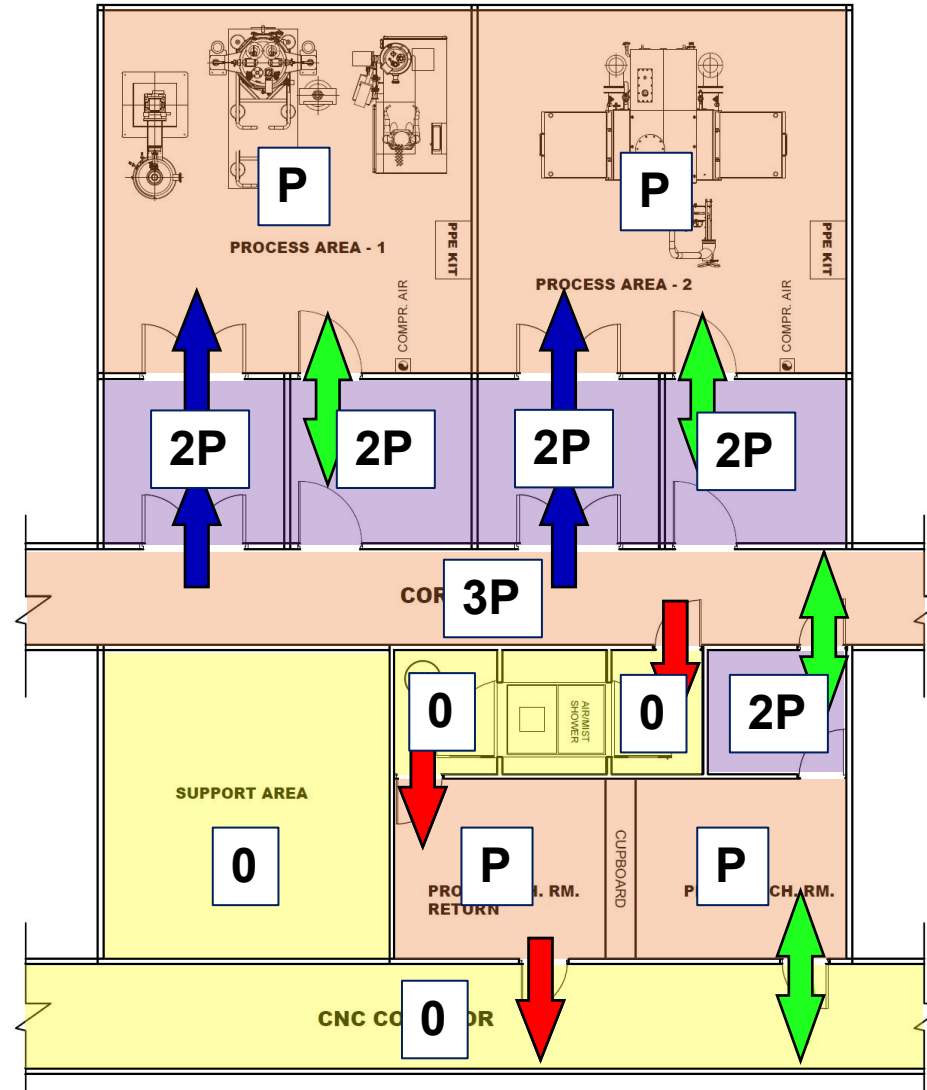


LEGEND

- ↔ MAN MOVEMENT
- ↔ MATERIAL MOVEMENT

OPEN HANDLING

TYPICAL ZONING DIAGRAM



LEGEND

- MAN MOVEMENT
- MATERIAL MOVEMENT
- EMERGENCY MAN MOVEMENT

ENVIRONMENTAL PROTECTION

- Local Extraction Ventilation
- Filter Change Protocol (BIBO)
- System Interlocks
- Construction of ventilation system
- Airflow Isolation
- Exhaust System Requirements
- Pressure Control
- Safety Measures



CLEAN ROOMS

Clean room Classification:

- ISO 8
- ISO 7
- ISO 5



2. Construction of Clean rooms:

- Airtight Construction
- Minimized Joints
- Cleanability
- Ceiling Design
- Fixture Integration



2. Construction of Clean rooms:

- Ceiling Access
- Filter & Lighting Access
- Minimal Installations
- Accessory Cleaning Protocol
- PPE Air Supply



WASTE HANDLING

1. Solid Waste

2. Liquid Waste



Handling Of Dirty Equipment/ Waste

- Limit Movement Of Dirty Equipment/ Tools
- Washing Areas Shall Be Close To The Source
- Segregated Path For The Movement Of Dirty Equipment
- Use Of PPE Kits During The Washing Of Contaminated Tools/ Dirty Equipment
- Use Of Washing Stations To Limit The Exposure To Operator.



DECONTAMINATION

- Solid waste – decontamination shall preferably close to the source.
- Decontamination room near dispensing room for decontamination of waste generated post dispensing.
- Waste generated in manufacturing area can be decontaminated in a common room within manufacturing department.
- Liquid waste
- Decontamination method.



OUR TAKE-AWAYS

- OEL
- Containment
- Process Equipment
- URS
- Entire life cycle of installation.
- Cleaning
- Repair and Maintenance
- Waste handling
- Decommissioning

Thank you.

Any questions?