INTRODUCTION TO THE SEMINAR ON DESIGN & ARCHITECTURE

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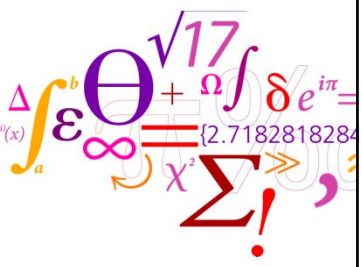

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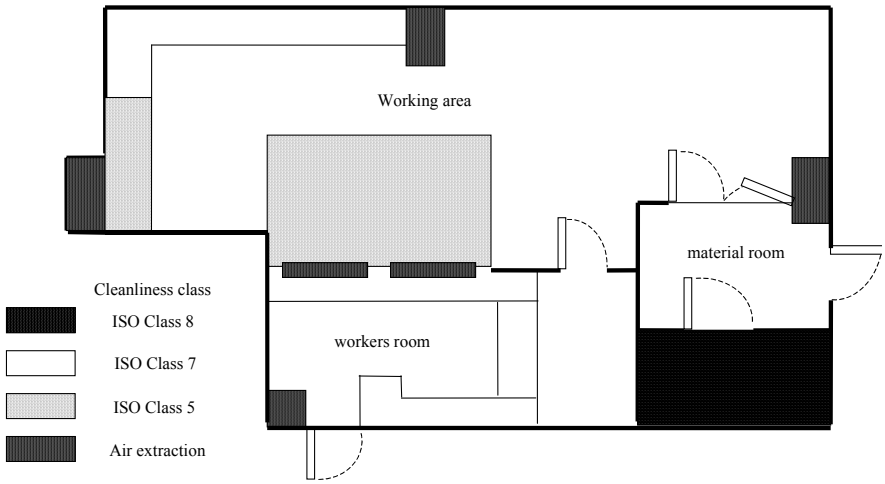
CLEANROOM TECHNOLOGY IS USED IN

- **ULTRA CLEAN AREAS**
  e.g. in production of intravenous solutions

- **CONTROLLED PROCESSES**
  e.g. in operation theatres

Example of Cleanroom Plan



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DEFINITION OF CLEANROOM

- The aim of cleanroom is to protect processes (or products) from air contaminants
- The cleanroom class should be chosen according to the activity
- Important factors are air related e.g. air distribution, air flow & pressure differences

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Important in Cleanroom Design

- Choosing materials of ceiling, walls and floors
- Places of doors
- Places of equipment
- Material flows
- Maintenance routes
- Places for changing clothes
- Routes for personnel

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DEFINITION OF CLEANROOM

- Standard ISO 14644-1:1999 "Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness" defines cleanroom as a room in which the concentration of airborne particles is controlled, and which is constructed and used in a manner to minimize the introduction, generation, and retention of particles inside the room, and in which other relevant parameters e.g. temperature, humidity, and pressure, are controlled as necessary.

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DISTURBANCES AFFECTING THE AIR FLOW

- **Disturbances affect laminar air flow much, because contaminants tend to accumulate in swirls.**
- **The air flow can be disturbed by**
  - **physical barriers and moving objects**
  - **persons**
  - **other air flows**

Cleanroom classes according to standard ISO 14644-1:1999

ISO classification	Maximum concentration limits (particles/m^3 of air) for particles equal to and larger than the sizes shown below					
	0.1 µm	0.2 µm	0.3 µm	0.5 µm	1 µm	5 µm
ISO Class 1	10	2				
ISO Class 2	100	24	10	4		
ISO Class 3	1 000	237	102	35	8	
ISO Class 4	10 000	2 370	1 020	352	83	
ISO Class 5	100 000	23 700	10 200	3 520	832	29
ISO Class 6	1 000 000	237 000	102 000	35 200	8 320	293
ISO Class 7				352 000	83 200	2 930
ISO Class 8				3 520 000	832 000	29 300
ISO Class 9				35 200 000	8 320 000	293 000

EHEDG Guideline Doc. 44 – Hygienic Design Principles for Food Factories Good Building Design:

- **protect against** physical (e.g. dust particles) , chemical (e.g. poisonous gases) and biological (e.g. insects) **contamination**
- **have as few** personnel entries and exterior **openings as possible**; security and fire escapes are still needed
- have solid doors with **self-closing mechanisms**
- **physical internal walls separating departments** from each other
- **reduce cross-contamination by segregation of various flows** e.g. products, personnel, equipment, waste and air

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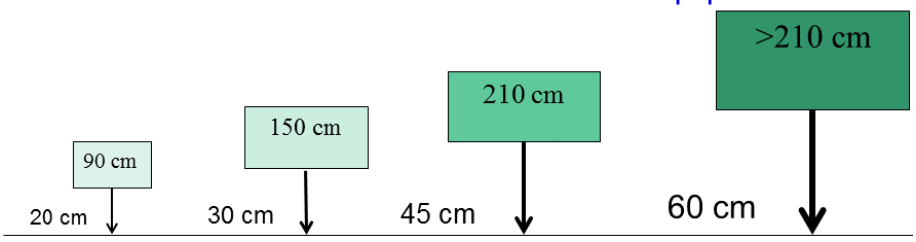
EHEDG Guideline Doc. 44 – Hygienic Design Principles for Food Factories

For cleaning and maintenance purposes **a minimum clearance under and between equipment as well as from the wall** is suggested:

- 20 cm clearance for ≤ 90 cm sized equipment
- 30 cm clearance for 90 – 150 cm sized equipment
- 45 cm clearance for 150 – 210 cm sized equipment
- > 60 cm clearance for > 210 cm sized equipment



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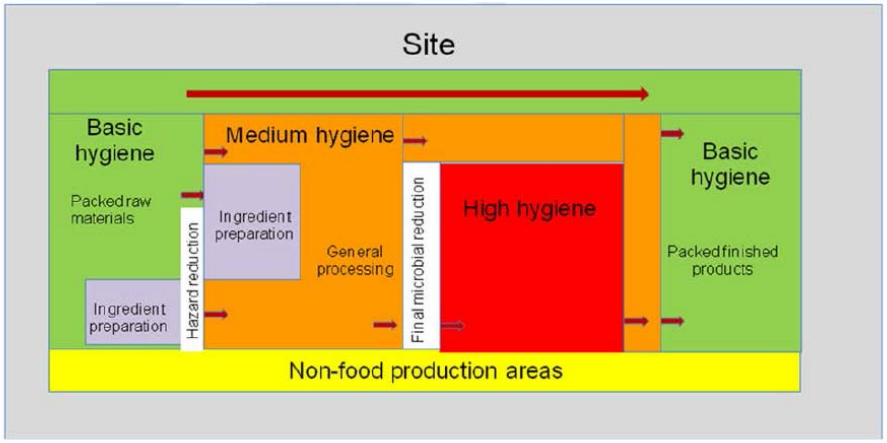

Figure 7.1.1 - Schematic representation of food manufacturing zones showing potential routes of product flow dependent on the product's need for microbiological protection from the manufacturing environment.

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Material transport through hatches with two doors – one in the processing area and one in the hygienic area – which should be interlocked i.e. only one door can be opened at one time

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EHEDG Guideline Doc. 44 – Hygienic Design Principles for Food Factories

The joints between the crash bar and the floor must be rounded out and sealed with a food safe sealant.

EHEDG Guideline Doc. 44 – Hygienic Design Principles for Food Factories

Coving tiles completed with tiled floor and wall

EHEDG Guideline Doc. 44 – Hygienic Design Principles for Food Factories

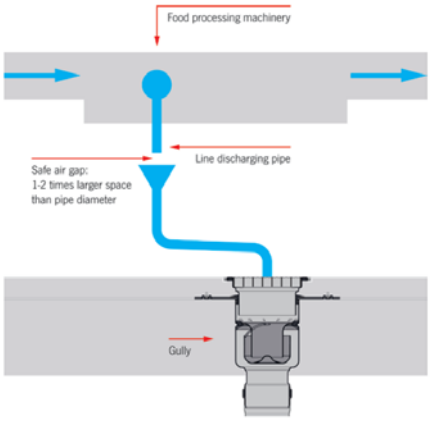

Figure 8.7.1 - Tundish or funnel directly connected to drain gully grating

The gap is essential to avoid cross contamination and backflow from the drainage to the machine. To be fully accessible for cleaning and inspection, drains should not ne positioned under the machinery.

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EHEDG Guideline Doc. 44 – Hygienic Design Principles for Food Factories

- **Premises and equipment must be designed, fabricated, constructed and installed according to sound hygienic desing principles**
- **Hygienic design provides defence against**
  - **internal factory hazards e.g. easy to clean and no harbourage sites**
  - **external factory hazards e.g. deliberate contamination**
- **Hygienic design provides hygienic conditions via best practices and structure rigidity**

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