INTRODUCTION TO THE SEMINAR ON DESIGN & ARCHITECTURE
Gun Wirtanen, DTU National Food Institute

Rådet for Bedre Hygiejne
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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
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Example of Cleanroom Plan

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
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

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.
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

<table>
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<th>ISO classification</th>
<th>Maximum concentration limits (particles/m³ of air) for particles equal to and larger than the sizes shown below</th>
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<tr>
<td>ISO Class 9</td>
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**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

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

- 20 cm clearance for \( \leq 90 \) 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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EHEDG Guideline Doc. 44 – Hygienic Design Principles for Food Factories

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

Coving tiles completed with tiled floor and wall
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 be positioned under the machinery.

- Premises and equipment must be designed, fabricated, constructed and installed according to sound hygienic design 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