A Guide to Improve Cleanliness Levels for Critical Products
Glaeser Group – Quick Facts

Pioneer and Expert in Technical Cleanliness

- **Own Cleanlabs in key regions**
  - first CleanLab in Germany (2002)
  - CleanLab in the US (2010)
  - CleanLab in China (2015)
  - CleanLab in Mexico (2018)

- **Manufacturer of Extraction Cabinets**
  - since 2010
  - ACM range for small to medium components
  - RiuS range for medium to large components
  - special solutions on request

- **Member of the industrial alliance TecSa/TecSa 2.0**
  - developer of VDA19/19.1 standard

- **Inspector ISO16232 training**
  - 2 day course (in accredited lab)
  - theory and practice
  - case studies, exam, certificate
Cleanliness Challenges

For manufacturers of critical products in Automotive, Aerospace, Optics, Electronics......
Cleanliness Inspection vs Assembly Cleanliness


- **Parts are cleaned after production**
  control of cleanliness in accordance to industrial standards (ISO16232/VDA19.1), OEM or tier 1 specifications

- **Reaction chain if failing limits**
  1. control of analysis conditions and analysis equipment
  2. extraction of additional components / inspection lots
  3. escalation strategy (typically stated in client-supplier-relationship, e.g. asking for additional analysis or extended analysis
  4. if no compliance: process observation / improvement
     “Technical Cleanliness in Assembly” (VDA19.2)

- **Aim of Assembly Cleanliness**
  1. prevent additional particle contamination at sensitive areas
  2. remove particles which cannot be avoided
  3. protect components and assemblies from cross-contamination by the environment

Assembly Cleanliness focuses on processes after cleaning with technically clean, finished products (own produced or supplied parts)

Pre-Condition: existing cleanliness specification with limits
Processes influencing Technical Cleanliness
Designing a Clean Assembly Facility

Sequence Diagram for Planning

- Requirement: Cleanliness specification
- Cleanliness specification fulfilled
  - No: Final cleaning of system possible?
    - No: Process chain analysis
      - Process optimization using guideline
        - No: Cleanliness specification fulfilled
          - Yes: Measure implemented in assembly and environment
    - Yes: Assembly in conventional production with final cleaning
      - No: Assembly in conventional production
Designing a Clean Assembly Facility

Structure of influencing factors

- **Aim and approach**
  - as clean as necessary, but not as possible
  - from the inside to the outside

- **A particle source is more critical**
  - the closer it is to the component
  - the longer the component is exposed to it
  - the more function critical particles are to be created

- **Group in direct and indirect particle sources**
Designing a Clean Assembly Facility

Conception

- Do we need clean areas?
- In which cleanliness grade is the clean area to be graded?
- Which measurements are required for which clean area?
- Which particles are critical?
  - size from ..... to ........
  - density from ..... to ........
  - form / shape / dimensions
  - nature of particles (conductive, abrasive, hard, ....)

Task:
- Prevent the generation of particles which are not permissible according to the cleanliness specification
- Remove particles which are not permissible according to the cleanliness specification
- Design of processes and facilities by planner
  (F Assembly equipment)
- D Logistics (inner packaging)

Verification of measures relevant to cleanliness:
G Measuring cleanliness factors
Designing a Clean Assembly Facility

Process Chain Analysis

Determination of real weak points

No summation

Bringing Cleaning to Machining
Assembly-Equipment

Basics

- **Assembly Equipment**
  - robots
  - machines
  - manual work-stations
  - assembly stations

- **Parameters**
  - process
  - material
  - design
  - flow-rate
  - wear
  - maintenance
  - cleaning

- **View from in(side) to out(side)**
Assembly-Equipment

Cleanliness Strategies

• **Avoid particle creation**
  - design of mating-parts and –parameters
  - low-wear equipment components

• **Avoid particle transfer (cross-contamination) via**
  - feeders, carrier/boxes, staff, environment, …

• **Protect the product from contamination**
  - enclosure of particle creating components
  - cover above the products
  - place particle sources below the product

• **Remove critical particles**
  - assembly- integrated cleaning components and equipment-components

• **Avoid moving equipment**
  - no grippers, linear axle…. above open sensitive component-surfaces

• **Use easy-to-clean design**
  - no in-accessible corners, edges, outstanding screw-heads
  - open design to minimize particle collection

• **Avoid lacquered surfaces**
  - (wear of lacquer particles)
  - stainless steel for mechanically heavy impacted areas

• **Equipment design rules**
  - few and/or permeable horizontal surfaces (e.g. perforated sheets)
  - control air draft of fans or pneumatic cylinders away from components
  - keep supply wires / pipes outside the process-area
  - place fittings, hinges at outside
  - close open profiles
Assembly-Equipment

Cleanliness Strategies

- **Work station design rules**
  - **no mixed tasks**
  - clear separation of workplace from environment and assembly work
  - assure good illumination without dazzling effects/shade
    - particles can be easier detected
  - feed material in from the back or side of the station, best not by the worker
  - do not handle above components while reaching for tools – define movements
  - hang tools and assembly aides up at defined places
  - provide redundant tools to avoid reaching over components
  - use trays for tools, fixtures and component parts with minimal surface, with open bottom
  - do not place supply boxes, component holders and dispensers below the work area (side/above)
  - use solid shelves to protect containers below
  - use grid bottom in containers

- **Housing design rules**
  - for protection either of the environment or the interior of the equipment
  - airflow with integrated filtered air
  - use acrylic glass or flexible curtains
  - fix lids, covers, doors in a way that particles do not drop inside while opening

- **Define downtime and storage rules**
  - empty conveyer / protect components?

- **Use separate areas for rework / bring reworked parts only back in required cleanliness condition**
Assembly-Equipment

Cleaning in Assembly

- **Assembly integrated cleaning**
  - removal of particles immediately after generation
  - final cleaning of components in function test station
  - keeping equipment clean to avoid displacement
  - sufficient cleaning efficiency
  - if possible directly without additional handling
  - without adding cycle time
  - e.g. manual suction via vacuum-systems
  - integrated compressed airflow / suction systems
  - brushing systems with integrated suction
Environment
Definition of Clean Area

A Clean Area is a room or portioned area of a room which has been constructed for the manufacture, assembly, and storage of components and systems and for which appropriate measures have been taken to achieve and maintain surface cleanliness.

- **Cleanliness grade (CG)**
  classification of a clean area

- **CG’s come with**
  recommendations for logistics, packaging, dress-codes, handling recommendations....
## Environment

### Classification of Cleanliness Levels:

- **CG-0** conventional production
- **CG-1** cleanliness area
- **CG-2** conventional room
- **CG-3** cleanroom

<table>
<thead>
<tr>
<th></th>
<th>Uncontrolled Zone</th>
<th>Cleanliness Zone</th>
<th>Cleanliness Room</th>
<th>Cleanroom</th>
</tr>
</thead>
<tbody>
<tr>
<td>separation by floor markings, partitions, ceiling curtains</td>
<td>O</td>
<td>X</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>separation by fixed walls with ceiling</td>
<td>O</td>
<td>O</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>regulation of material movement</td>
<td>O</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>regulation of personnel movement</td>
<td>O</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>air filtration incl. conditioning</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>X</td>
</tr>
</tbody>
</table>
Environment

Aerosol-Diagram for cleanliness level

Examples of materials:

- \( \rho \) (aluminum) = 2.7 g/cm\(^3\)
- \( \rho \) (steel) = 7.8 g/cm\(^3\)
- \( \rho \) (polystyrene) = 0.02-0.09 g/cm\(^3\)

400 \( \mu \)m
Environment
Operative Measures

• Marking of clean areas

• Determination of:
  - control measurements (e.g. monitoring with particle traps)
  - appointee in charge of cleanliness

• Specification of:
  - suitable packaging material
  - dress-code

• Regulation of structural alteration measures, setting-up procedures, repair work and other intervention (in respect of cleanliness)

• Keeping areas clean:
  - cleaning plans for rooms, work stations and production equipment (Who? When? How?)
  - avoid un-controlled blow-off or sweeping (better vacuuming or wet wipes)
  - IMPORTANT: qualified cleaners and suitable cleaning equipment
  - Ancillary effect: sensitization of staff / credibility towards clients / image enhancement

• Staff:
  - provide clear rules of conduct
  - access to clean areas only for qualified staff!
Logistics
Packaging as the most important factor

Packaging should be based on the character of parts and components with focus on cleanliness specification/limits, position on critical surfaces, geometry & weight as well as material and surface conditions.

• **Principle**
  the more sensitive the surface of the parts to pack, the more important is the fixation of the parts in order abrasion of particles

• **Critical:**
  - paper / cardboard / wood / metal
  - reusable / pool systems
Logistics
Handling Concept for Cleanliness Areas (CG 1-3)

Outer packaging has no defined cleanliness condition and cannot be brought into areas with cleanliness requirements:

Pass-through and reload concepts required
## Staff

### Duties towards Technical Cleanliness & Mindset

<table>
<thead>
<tr>
<th>Staff group</th>
<th>duty</th>
</tr>
</thead>
<tbody>
<tr>
<td>Management</td>
<td>• Represent</td>
</tr>
<tr>
<td></td>
<td>• Provide resources</td>
</tr>
<tr>
<td>Planer</td>
<td>• Define quality targets</td>
</tr>
<tr>
<td></td>
<td>• Develop measures and implement them</td>
</tr>
<tr>
<td>Assembly worker</td>
<td>• Consequent operation according to trained concepts</td>
</tr>
<tr>
<td>machine operator</td>
<td>• Commitment to quality targets</td>
</tr>
<tr>
<td>Logistic staff</td>
<td></td>
</tr>
</tbody>
</table>

**Qualification of staff is required**

- ✓ Notice
- ✓ Understand
- ✓ Implement
- ✓ manage / be able

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**Parts Cleaning Conference**

**Bringing Cleaning to Machining**
## Staff

### Functions in respect of Technical Cleanliness

<table>
<thead>
<tr>
<th>Human as</th>
<th>Process</th>
<th>Example</th>
<th>Example measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Actuator</td>
<td>Activities which can generate particles</td>
<td>Press-fitting of components or operation of an handling unit</td>
<td>Instruction to avoid particle generation or description of cleanliness-compatible handling</td>
</tr>
<tr>
<td>Transmitter</td>
<td>Particle displacement by use of clean as well as contaminated equipment</td>
<td>Contact with contaminated outer packaging or staying in areas with lower cleanliness level</td>
<td>Avoidance of mixed activities</td>
</tr>
<tr>
<td>Source</td>
<td>Activities within the assembly-area</td>
<td>Primary: hair, skin scales, skin oil, sweat, microorganism (e.g. saliva), cosmetic (skin cream, nail polish, facial powder...) Secondary: wear of clothing (e.g. fluff)</td>
<td>Specific dress-code, reduction of staff presence to a minimum</td>
</tr>
<tr>
<td>Remover</td>
<td>Targeted cleanliness-procedure</td>
<td>Removal of particles from functional surfaces, cleaning of workplace and equipment</td>
<td>Work instruction</td>
</tr>
</tbody>
</table>
Staff
Dress Concepts

- Wear only inside the clean area and avoid contact with sensitive component surfaces and environment
- Store protective clothing at clean area
- Clean reusable clothing regularly
- Replace damage items due to risk of increased fluffs / fibers displacement
- Use different colors for areas with different responsibility
- Gloves: choose suitable material and replace as frequent as necessary
Assembly Cleanliness

Summary: Risk-Analysis

• Observe the different influencing factors for cleanliness, where and how could particles be created, released or transferred

• Are those particles critical
  - how are those particles transferred to sensitive areas
  - how can those be avoided, blocked, removed

• Analysis of the process steps / equipment / components / parts / auxiliary media / tools / storage areas ....
  - analyze step by step – best already while planning the set-up

• Know where you stand – support your risk analysis by
  - checking experience / observation by staff
  - measure each step of process and evaluate
  - determine measurements, implement them and constantly control the process by cleanliness analysis in order to evaluate and understand the effect

• METHODS OF TECHNICAL CLEANLINESS INSPECTIONS (VDA 19.1 / ISO 16232) TO VERIFY IMPROVEMENTS
  - any measure by assembly cleanliness need to be controlled by cleanliness inspection to assure effects
  - support cause studies and process optimization with standard analysis and / or extended analysis
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- Technical cleanliness inspections
- Extraction equipment and accessories
- Training for "inspector technical cleanliness" (ISO16232)
- Training for "designer technical cleanliness" (Assembly Cleanliness)
- Consultancy and advise