Food Safety
Sanitary Design Facility and Equipment
Foundation For Effective & Efficient Sanitation

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Purpose

Prevent the establishment of soils in a niche (bacteria biofilms, allergenic proteins) or other sites that can lead to contamination of products that will impact product quality and safety.

Recommend a cross functional team meets ongoing to assess existing and future designs to actively assess current and planned controls.
Sanitary Design
Definition
Sanitary Design is the application of design techniques which allow the timely and effective cleaning of the entire manufacturing asset.
Listeria Equation

Controlled Traffic Patterns + GMP's + Clean, Dry Uncracked Floors + Sanitary Design Equip Building + Effective Sanitation Procedures Controls

= Listeria Control
Microbiological Level!

A scratch on a piece of stainless steel acts a harborage point for Listeria.

Courtesy Univ. Wisconsin, Madison
THE “INVISIBLE” BACTERIA

- Salt (120µm, 4724 µ-inch)
- Yeast (5 µm, 197 µ-inch)
- Mold spore (3 µm, 118 µ-inch)
- Listeria (0.5 µm, 19.7 µ-inch)

**Micron (µm)**
- 1/1,000,000 meter
- 39.37 µ-inch

**Micro-inch (µ-inch)**
- 1/1,000,000 inch
- 0.0254 micron
Why Sanitary Design is Important

• As an industry we expect our facilities and equipment to be sanitary and clean, our consumers expect the same.

• Food safety is the number one priority - and cannot not be achieved without equipment and facilities constructed of a sanitary design.

• Belief was that with time and chemicals our sanitation folks could clean any piece of equipment or a facility.
  - Complex designs requiring significant disassembly by tools are susceptible to cross contamination during reassembly.
  - Complex procedural controls are not easily sustained throughout the lifecycle of an asset.
Life Cycle for Equipment in a Plant
Sanitary Design Opportunities

During the 20 year life cycle we will:

• Produce 2 billion meals
  • Train 250 employees on how to clean
  • Introduce and train 80 production supervisors
  • Spend up to 33,000 hours cleaning it
  • Spend 2500 hours doing pre-op inspections
  • Not produce up to 295 Million lbs. of food
  • Generate 15 million gallons of effluent + BOD
  • Generate 78 million lbs of rework
  • Generate 17 million lbs. of inedible waste

• Redesign to improve efficiency
  • Educate management
  • Respond to Consumer complaints
  • Redesign to improve cleaning
  • Potential Product failures
  • Redevelop cleaning procedures
  • High swab counts
FACILITY DESIGN

11 Principles
PRINCIPLES OF SANITARY DESIGN

1. Distinct Hygienic Zones Established In The Facility

Maintain strict physical separations that reduce the likelihood of transfer of hazards from one area of the plant, or from one process, to another area of the plant or process, respectively. Facilitate necessary storage and management of equipment, waste and temporary clothing to reduce the likelihood of transfer of hazards.
Sources of contamination:
- People
- Raw Material
- Ingredients
- Packaging Supplies
- Equipment

Control bacteria Growth

Proper cooling Times

Environmental Testing

Finished Product Testing

Finished product Cooler

RTE Packaging

Palletize

Shipping Dock

Finished product Cooler

RTE Oven Room

RTE Packaging

RTE Oven Room

RTE Welfare Area

RTE Cooler

Wash Room

Office and welfare areas

Raw Welfare Area

Raw Manufacturing

Harvest

Coolers

Receiving

Dry Storage

Inedible Rendering

Maintenance Area

Raw Material Pathogen Load

Cook Temperatures

Key
- Line of Separation
- GMP Force Field
- Listeria Free Zone
- Truck Inspections
- Shipping Control

Good Manufacturing Practices
- Doorway sanitizers
- Handwashing
- Gloves
- RTE Uniform
- Traffic flow

Equipment Design Approval

Separate Welfare areas
2. Control the movement of personnel and materials flows to reduce hazards

*Establish traffic and process flows that control the movement of production workers, managers, visitors, QA staff, sanitation and maintenance personnel, products, ingredients, rework and packaging materials to reduce food safety risks.*
Passive Controls

Passive controls
Rely on administrative procedures, training, and auditing to ensure success

Controls:
- Everything that goes into RTE must be sanitary.
- Trash and trash containers only move out of RTE.
- Controls need to be in place through sanitation and maintenance only shifts.

Active Controls

Magnetic Lock
Access Control Card Reader
Boot Scrubbers

Installed so all employees must pass through them
PRINCIPLES OF SANITARY DESIGN

3. Water Accumulation Controlled Inside the Facility

Design and construct a building system (floors, walls, ceilings, and supporting infrastructure) that prevents the development and accumulation of water. Ensure that all water positively drains from the process area and that these areas will dry during the allotted time frames.
Control room temperature and humidity to facilitate control of microbial growth. Keeping process areas cold and dry will reduce the likelihood of growth of potential food borne pathogens. Ensure that the HVAC/refrigeration systems serving process areas will maintain specified room temperatures and control room air dew point to prevent condensation. Ensure that control systems include a cleanup purge cycle (heated air make-up and exhaust) to manage fog during sanitation and to dry out the room after sanitation.
Loss of Refrigeration can create a major growth opportunity

Time in Which Log Growth Occurs With Temperature Change

<table>
<thead>
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<th>Temperature</th>
<th>Hours</th>
</tr>
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<tbody>
<tr>
<td>16</td>
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<tr>
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<td>180</td>
</tr>
<tr>
<td>463.2</td>
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Temperature x Hours Graph
5. Room Air Flow & Room Air Quality Controlled

Design, install and maintain HVAC/refrigeration systems serving process areas to ensure air flow will be from more clean to less clean areas, adequately filter air to control contaminants, provide outdoor makeup air to maintain specified airflow, minimize condensation on exposed surfaces, and capture high concentrations of heat, moisture and particulates at their source.
6. **Site Elements Facilitate Sanitary Conditions**

Provide site elements such as exterior grounds, lighting, grading and water management systems to facilitate sanitary conditions for the site. Control access to and from the site.
7. Building Envelope Facilitates Sanitary Conditions

Design and construct all openings in the building envelope (doors, fans, louvers and utility penetrations) so that insects and rodents have no harborage around the building perimeter, easy route into the facility, or harborage inside the building. Design and construct envelope components to enable easy cleaning and inspection.
8. **Interior Spatial Design Promotes Sanitation**

Provide interior spatial design that enables cleaning, sanitation and maintenance of building components and processing equipment.
9. Building Components & Construction Facilitate Sanitary Conditions

Design building components to prevent harborage points, ensuring sealed joints and the absence of voids. Facilitate sanitation by using durable materials and isolating utilities with interstitial spaces and stand offs.
Walls at Risk!
Sanitary Doors
10. DESIGN UTILITY SYSTEMS TO PREVENT CONTAMINATION

Design and install utility systems to prevent the introduction of food safety hazards by providing surfaces that are cleanable to a microbiological level, using appropriate construction materials, providing access for cleaning, inspection and maintenance, preventing water collection points, and preventing niches and harborage points.
10.20 Process & sanitary sewers are separated within the building
11. SANITATION INTEGRATED INTO FACILITY DESIGN

Provide proper sanitation systems to eliminate the chemical, physical and microbiological hazards existing in a food plant environment.
Summary

1. An active Facility Design Team can define and rank the facility pathogen control risks by using this process.

2. In existing facilities a risk based action plan will include addressing the “gimmies” or “low hanging fruit” as well as any major redesign needs.

3. This process provides the platform to engage all of the key players in a facility to focus on the “Food Safety” aspect of facility design and maintenance.
Ten Principles of Equipment
Sanitary Design For Ready To Eat Equipment
PRINCIPLES OF SANITARY DESIGN

1. **Cleanable to a Microbiological Level**

   Food equipment must be constructed and be maintainable to ensure that the equipment can be effectively and efficiently cleaned and sanitized over the life of the equipment. The removal of all food materials is critical. This means preventing bacterial ingress, survival, growth and reproduction. This includes product and non product contact surfaces of the equipment.
1. Cleanable to a Microbiological Level (Measurement)

SUPPLIES NEEDED TO COLLECT MICRO SWAB SAMPLES

- Sterile sponges or gauze pads
- Marking pen
- Sterile gloves
- Sterile neutralizing buffer/broth to moisten the sponge or gauze pads
- Whirl-Pak bags
PRINCIPLES OF SANITARY DESIGN

2. Made of Compatible Materials

Construction materials used for equipment must be completely compatible with the product, environment, cleaning & sanitizing chemicals, and the methods of cleaning & sanitation. Equipment materials of construction must be inert, corrosion resistant, nonporous and nonabsorbent.
2. Made of Compatible Materials

6061 Aluminum

Use Aluminum **ONLY** when Necessary.
When Aluminum is used Anodize or applicable process to inhibit corrosion and wear. Inspect Regularly

Avoid Coated Aluminum in Zone 1.

Salt brine corrosion test

Bearings 1, 2, and 8 Thin Dense Chrome plated.
Bearings 3, 5, and 7 are 400 series Stainless Steel.
Bearing 4 is coated.
Bearing 6 is Black Oxide coated

Choose Wisely!
3. Accessible for Inspection, Maintenance, Cleaning & Sanitation

All parts of the equipment shall be readily accessible for inspection, maintenance, cleaning and/or sanitation. Accessibility should be easily accomplished by an individual without tools. Disassembly and assembly should be facilitated by the equipment design to optimize sanitary conditions.
3. Accessible for Inspection, Maintenance, Cleaning & Sanitation
4. No Product or Liquid Collection

Equipment shall be self-draining to assure that food product, water, or product liquid does not accumulate, pool or condense on the equipment or product zone areas.
4. No Product or Liquid Collection
5. Hollow areas Eliminated or Hermetically Sealed

Hollow areas of equipment (e.g., frames, rollers) must be eliminated where possible or permanently sealed (caulking not acceptable). Bolts, studs, mounting plates, brackets, junction boxes, name plates, end caps, sleeves and other such items must be continuously welded to the surface of the equipment and not attached via drilled and tapped holes.
5. Hollow Areas are Hermetically Sealed

Hardware improperly mounted to frame by bolting though sealed tubing!
5. Hollow Areas are Hermetically Sealed
5. Hollow Areas are Hermetically Sealed

If it is not hollow you do not need to keep it sealed!
6. **No Niches**

All parts of the equipment shall be free of niches such as pits, cracks, corrosion, recesses, open seams, gaps, lap seams, protruding ledges, inside threads, bolt rivets and dead ends. All welds must be continuous and fully penetrating.
6. No Niches

Multiple Pulleys
How surfaces are you actually dealing with?

Drive Shaft

Bearing Housing

Spacer

Outer roller

Spacer

Bearing Housing

Drive Shaft
7. Sanitary Operational Performance

During normal operations, the equipment must perform so it does not contribute to unsanitary conditions or the harborage and growth of bacteria.
7. Sanitary Operational Performance
8. **Hygienic Design of Maintenance Enclosures**

Maintenance enclosures (e.g., electrical control panels, chain guards, belt guards, gear enclosures, junction boxes, pneumatic/hydraulic enclosures) and human machine interfaces (e.g., pushbuttons, valve handles, switches, touch screens) must be designed, constructed and be maintainable to ensure food product, water, or product liquid does not penetrate into, or accumulate in or on the enclosure and interface. The physical design of the enclosures should be sloped or pitched to avoid use as a storage area.
8. Hygienic Design of Maintenance Enclosures

View from back side

From This

To This

Previous Design

Sanitary Redesign

Fully Enclosed Supply line
Junction Box

No seal, Located under the product handling equipment.
9. Hygienic Compatibility with Other Plant Systems

Design of equipment must ensure hygienic compatibility with other equipment and systems, e.g., electrical, hydraulics, steam, air, water.
9. Hygienic Compatibility with Other Plant Systems

Clean Out Of Place Tank Example

How will operations and draining the tank impact the surrounding area?

1. Can the drain take the volume?
2. Overrun during drainage safety concerns?
3. Is exhaust needed?
10. Validate Cleaning & Sanitizing Protocols

The procedures prescribed for cleaning and sanitation must be clearly written, designed and proven to be effective and efficient. Chemicals recommended for cleaning & sanitation must be compatible with the equipment, as well as compatible with the manufacturing environment.
10. Validated Cleaning & Sanitizing Protocols

Proven efficacy through microbiological testing ...
PROCESS FLOW CHART FOR DESIGN REVIEW

Manufacturer & Customer Review Equipment Design Against the Checklist Tool → Redesign

Acceptable? (YES)

Third Party Review (optional)

Acceptable? (NO)

Acceptable? (YES)

Purchase and Install Equipment Training and Start-up

Cleanability/ Microbiological Review (90 day)

Acceptable? (NO)

Redesign / Sanitation Control

Acceptable? (YES)

Close Contract
Summary

• Facility and equipment design principles are the foundation for effective and efficient sanitation, food safety, and product quality

• The sanitary design principles need to be part of a defined and institutionalized policy at your site. Its starts before capital is approved.

• It is not just for new equipment
Questions?