Food Safety Equipment Design Principles

NORTH AMERICAN MEAT INSTITUTE

Protein PACT
For the People, Animals & Climate of Tomorrow

FOUNDATION FOR MEAT & POULTRY RESEARCH & EDUCATION

Purpose

Optimal Food processing equipment & infrastructure designs are critical in reducing the risk of contamination of food products by pathogens, spoilage organism's and foreign material. By continuously Improving hygienic design expectations and performance criteria it will promote industry-wide awareness, and drive food safety cultural improvements that will further work toward reducing food plant contamination events and recalls.

Goals:

- 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
- Prevent the occurrence of foreign material in meat and poultry products due to equipment & infrastructure design challenges
- Recommend establishing a cross functional team to assess existing and future design risk: determine if design modification (s) will eliminate risk (s), establish design management practices: PEC, PIC, PM maint, etc.

Sanitary Design Definition

Sanitary Design is the application of engineering techniques which allow the timely, effective, and safe cleaning of the entire manufacturing asset

<u>Design Motivations- What does the end user care about?</u>

"Safe, Clean, On-Time"

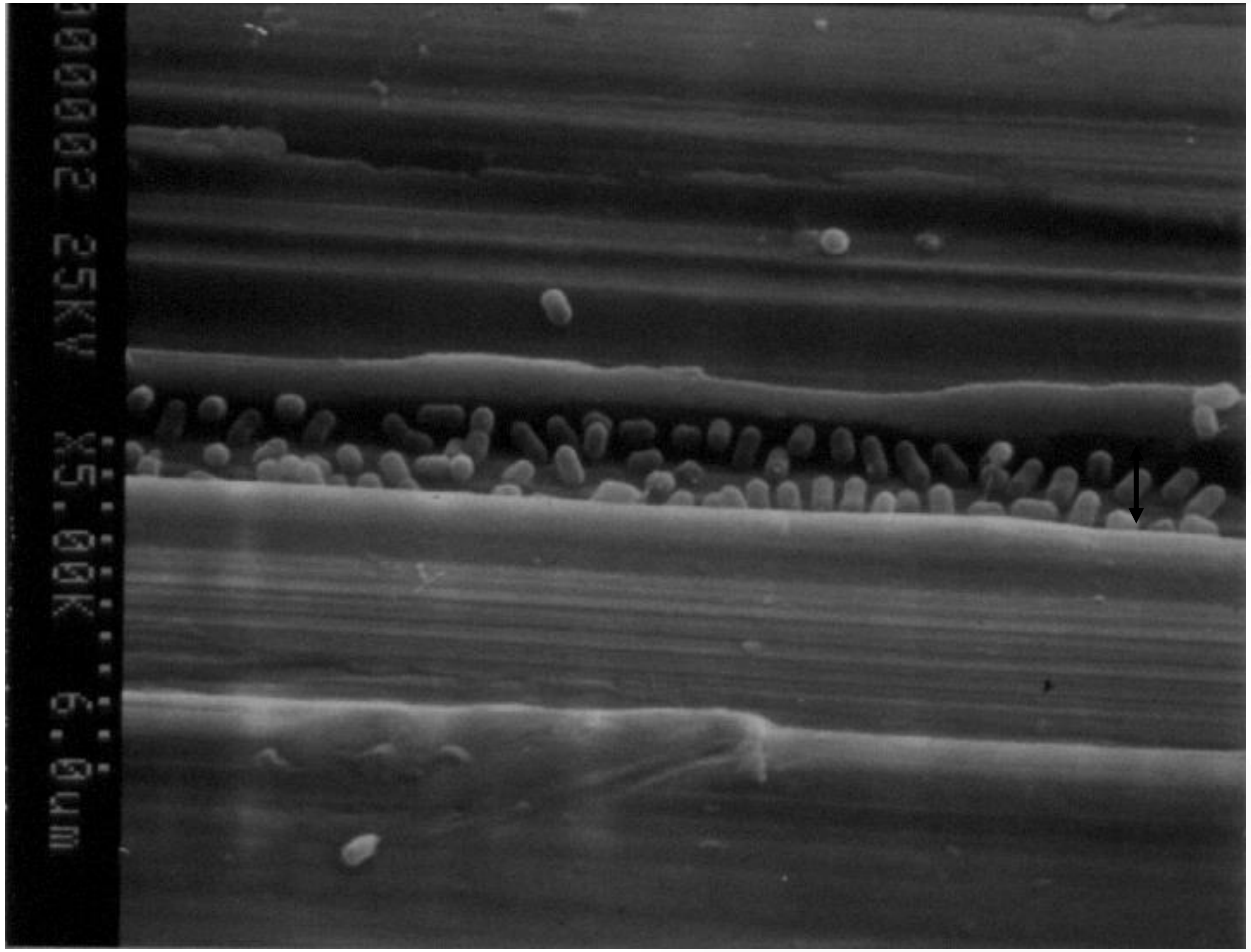
✓Promotes Employee Safety ✓Consistent Cleaning Effectiveness & Efficiency: Sanitation Friendly ✓Pathogen & Product Spoilage Control ✓Insect & Allergen Control ✓Eliminates Chemical & Extraneous Material Risk ✓Maintains a Sanitary Food Manufacturing Environment ✓Maintenance Friendly	**✓Less Resources Needed to Clean and Maintain ✓Promotes Production Efficiency ✓Promotes Product Yield: Keeping Food Residues and Moisture off Environmental Surfaces ✓Long Term Sustainability: Control Cost & Profitability- Keep Plants Open and People Employed**

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

Why Sanitary Design is Important

- As an industry, we expect our facilities and equipment to be sanitary and clean and our consumers expect the same.
- Food safety is the number one priority and cannot not be effectively achieved without equipment and facilities constructed in a sanitary manner.
- Original belief was that with sufficient 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 management controls are not easily sustained throughout the lifecycle of an asset.

Demonstrate control…
What does it take?

- All equipment has some type of Sanitary Design (SD) flaws that overtime can create harborage points deep inside equipment that will eventually affect product contact surfaces, and surrounding environmental areas in the processing environment
  - Similar with Infrastructure designs (even with good designs): If not properly monitored, cleaned at the correct frequency, and maintained

- **Numerous food manufacturers:** have discovered routine cleaning practices are not enough to ensure long-term hygienic conditions can be maintained (equipment & infrastructure)

- Can result in a variety of food safety, and quality issues:
  - Microbiological: food safety (pathogen), poor shelf life (spoilage)
  - Allergens: food safety
  - Foreign Material: food safety
  - Pest Control: food safety
  - Design promotes product quality issues

Must be Manage with difficult to sustain Periodic Equipment & Infrastructure Cleaning (PEC, PIC), & Maint PM's

Life cycle for equipment in a plant – Optimize and build an E&E Design

I have to clean this for the next 20+ years?
What were they thinking?

2022

2042

During the 20-year life cycle we will:

- Produce 20 billion portions
- 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

A better design will make safer food more efficiently over the next 20 years

Proactively we will need to:

- Redesign to improve effectiveness
- Educate management on risks
- Spend capital to reduce risks
- Redesign to improve cleaning
- Redevelop cleaning procedures

Designing it right will avoid a redesign

NAMI FACILITY & EQUIPMENT DESIGN TASK FORCE

Hormel Foods

THE STELLAR GROUP

Sara Lee

Middough Consulting Inc.
ARCHITECTS • ENGINEERS • CONSTRUCTORS

Hatfield

HENDON REDMOND
Engineers . Architects . Consultants

BAR S

Mc CLIER

Carter Burgess

Tyson

KRAFT

ConAgra Foods

THE HASKELL COMPANY
AMERICA'S DESIGN-BUILD LEADER®

Land O'Frost
What Great Taste Is All About™

JOHN MORRELL

HIXSON
ARCHITECTURE ENGINEERING INTERIORS

RAM
MARKET SOLUTIONS, INC.

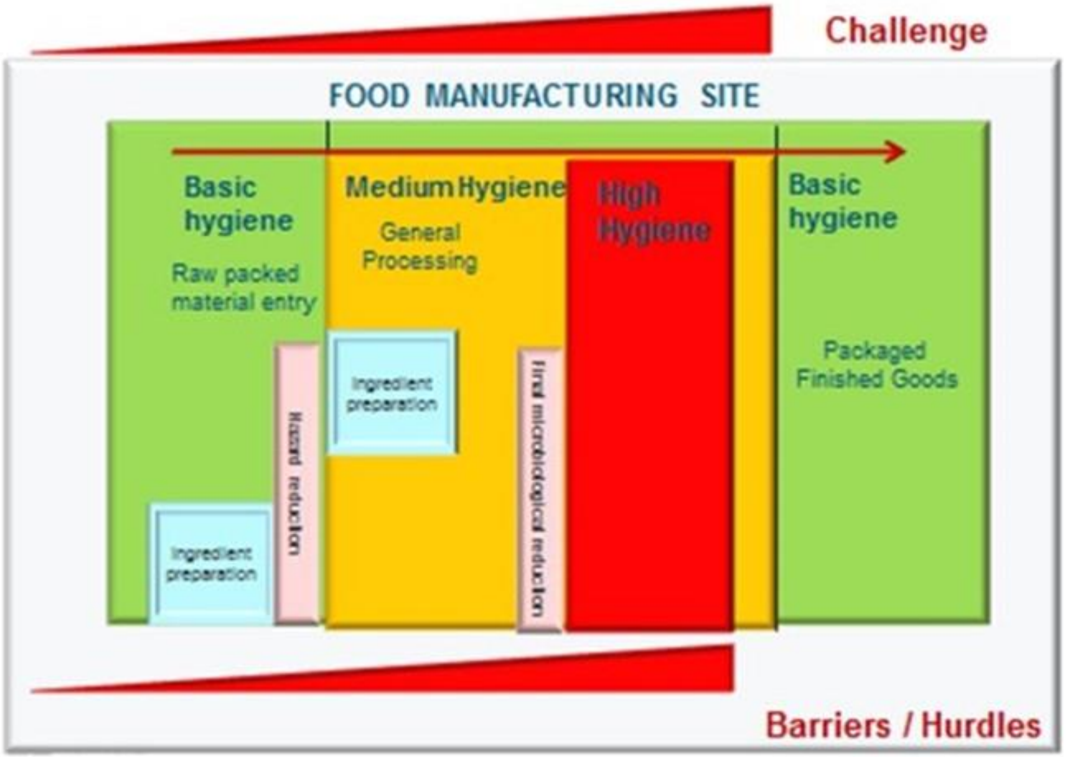
FACILITY DESIGN

11 Principles

PRINCIPLES OF SANITARY DESIGN

1. Distinct Hygienic Zones Established In The Facility

Maintain <u>strict physical separations</u> 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.



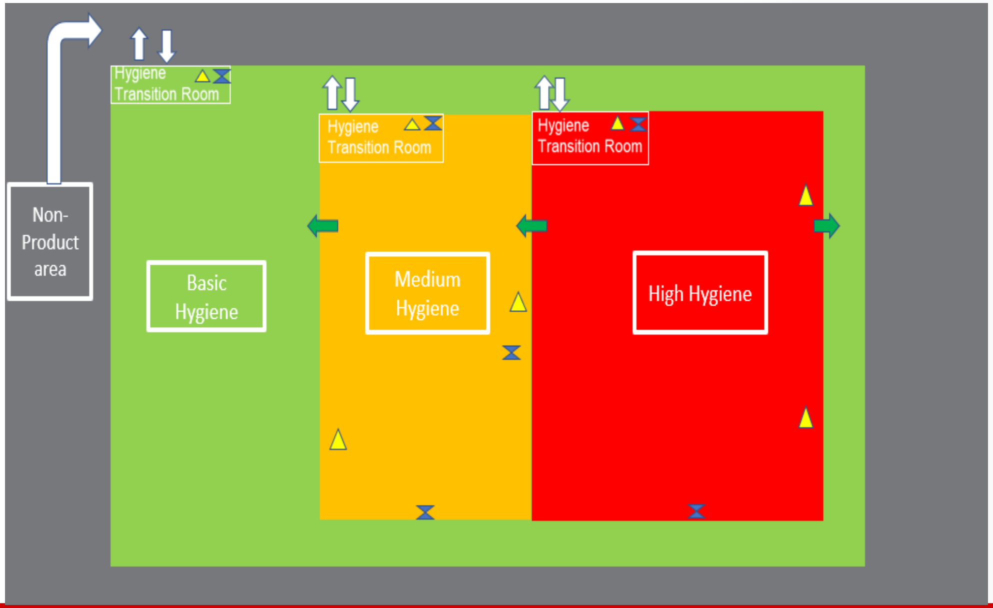
Hygienic Zoning refers to the division of the facility using <u>barriers</u>, <u>hurdles</u> and <u>practices</u> to minimize the risk of cross-contamination from the environment, personnel, and/or other materials or sources:

- HVAC -Pressurized air
- Drain system separation
- Controlling water run off
- Waste handling
- Cross functional traffic: foot & wheel
- GMP support & storage areas
- Employee welfare areas
- Cleaning systems: CIP, COP
- Cross functional Tools

PRINCIPLES OF SANITARY DESIGN

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.



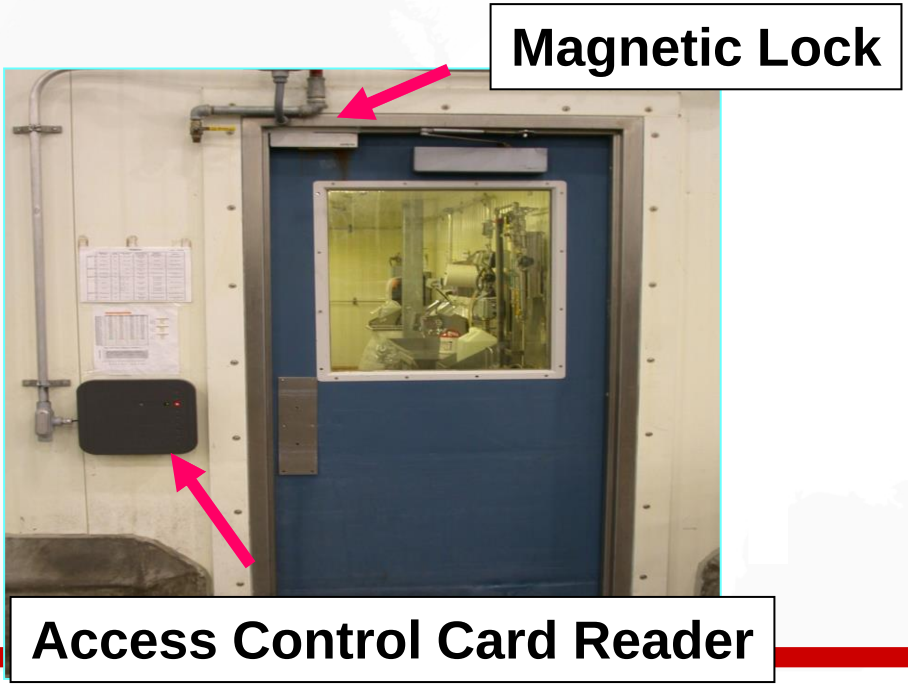
Passive Controls

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

Active Controls

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.



Lessons Learned "Listeria do not honor either orange or yellow barrier lines"

Boot Scrubbers

Installed so all employees must pass through them

PRINCIPLES OF SANITARY DESIGN

3. Water Accumulation Controlled Inside the Facility

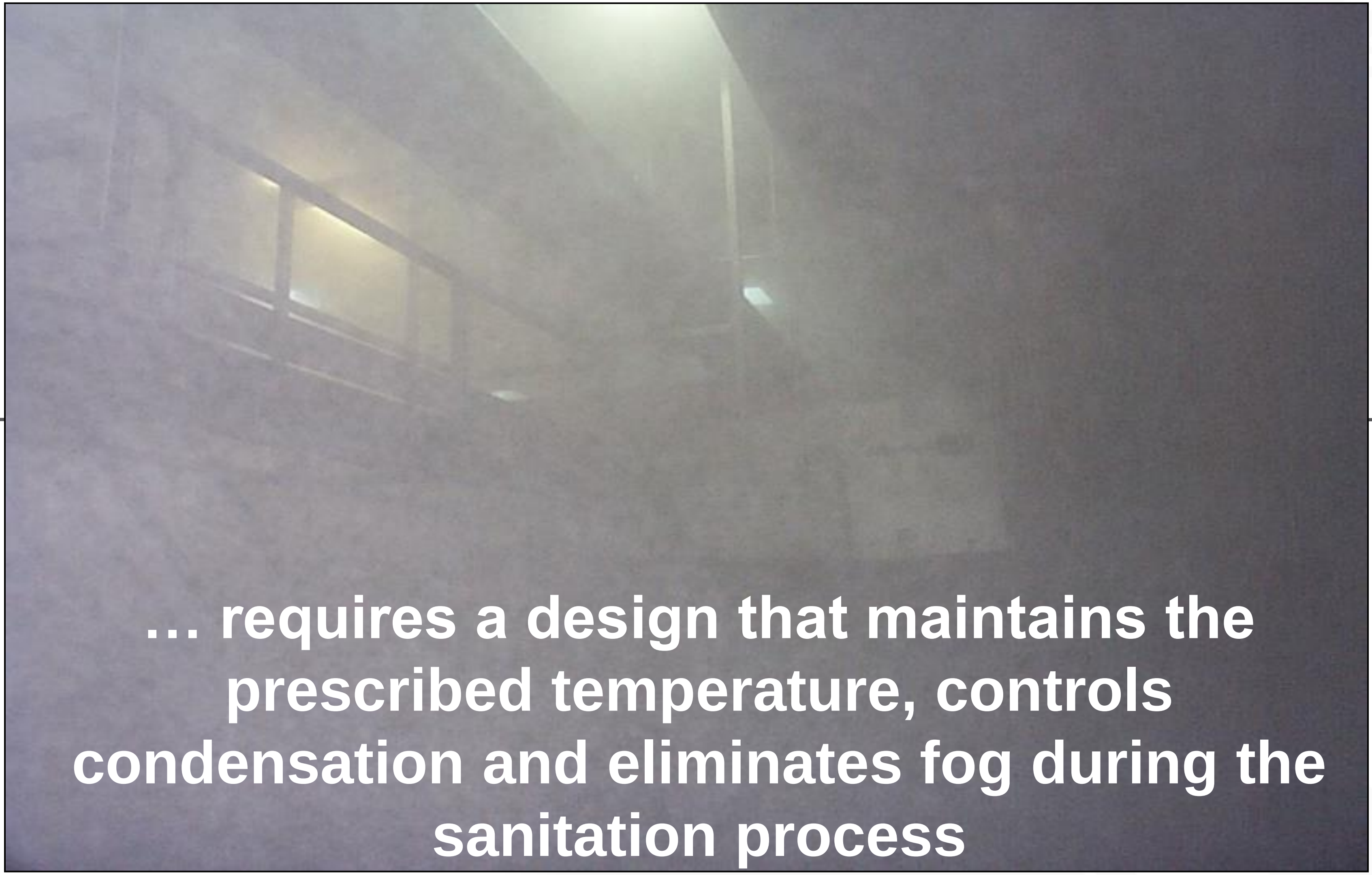
Design and construct a building system (floors, walls, ceilings, and supporting infrastructure) that prevents the development and accumulation of water. Ensure that all water positively drains from the process area and that these areas will dry during the allotted time frames.

PRINCIPLES OF SANITARY DESIGN

4. Room Temperature & Humidity Controlled

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.

HOW TO CLEAN TO A MICROBIOLOGICAL LEVEL?



… requires a design that maintains the prescribed temperature, controls condensation and eliminates fog during the sanitation process

PRINCIPLES OF SANITARY DESIGN

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 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.

PRINCIPLES OF SANITARY DESIGN

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.

PRINCIPLES OF SANITARY DESIGN

8. Interior Spatial Design Promotes Sanitation

Provide interior spatial design that enables cleaning, sanitation and maintenance of building components and processing equipment

PRINCIPLES OF SANITARY DESIGN

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!

Wet cleaned GMP room on the opposite side of illustrated wall

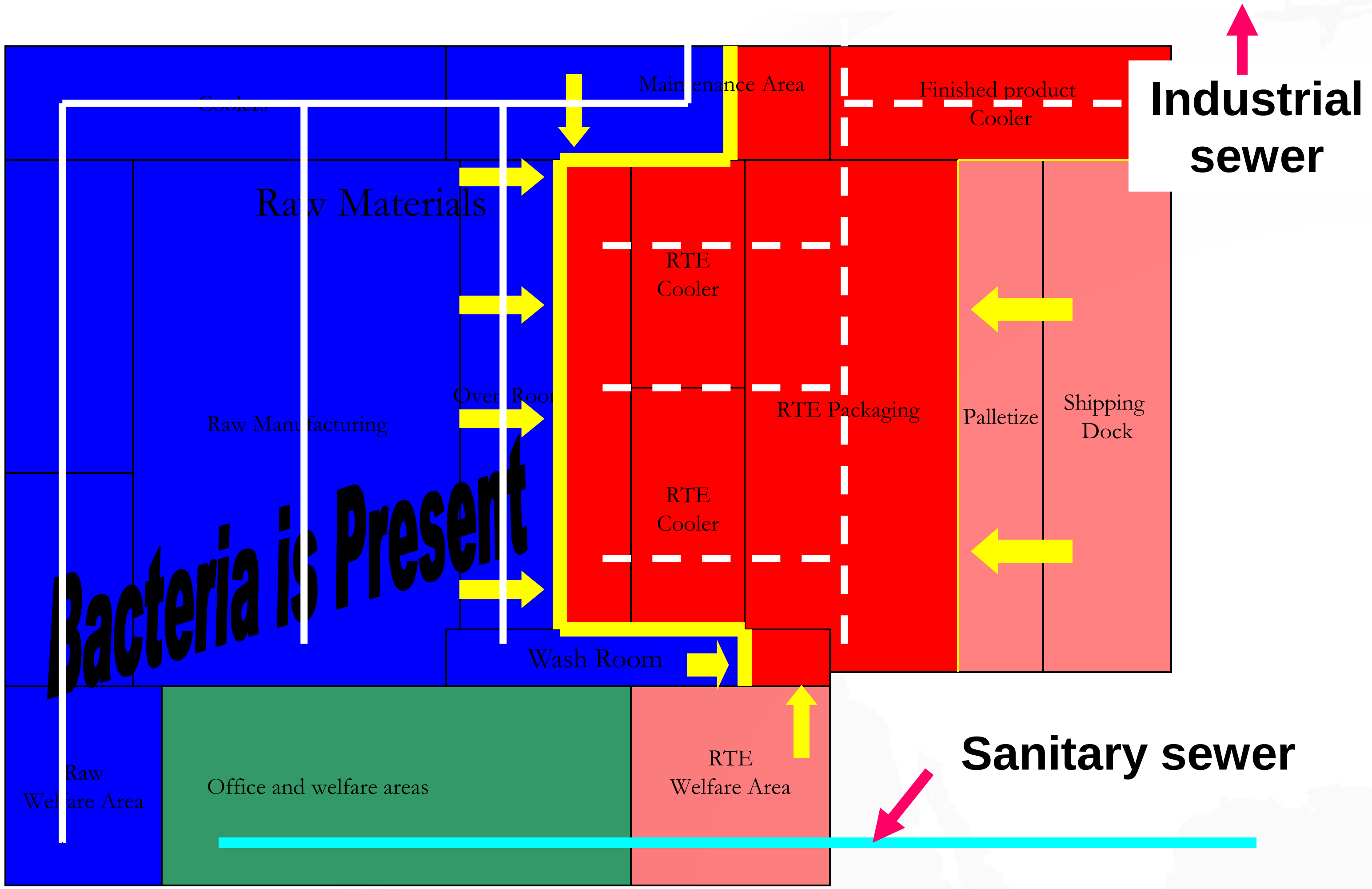
Sanitary Doors

PRINCIPLES OF SANITARY DESIGN

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

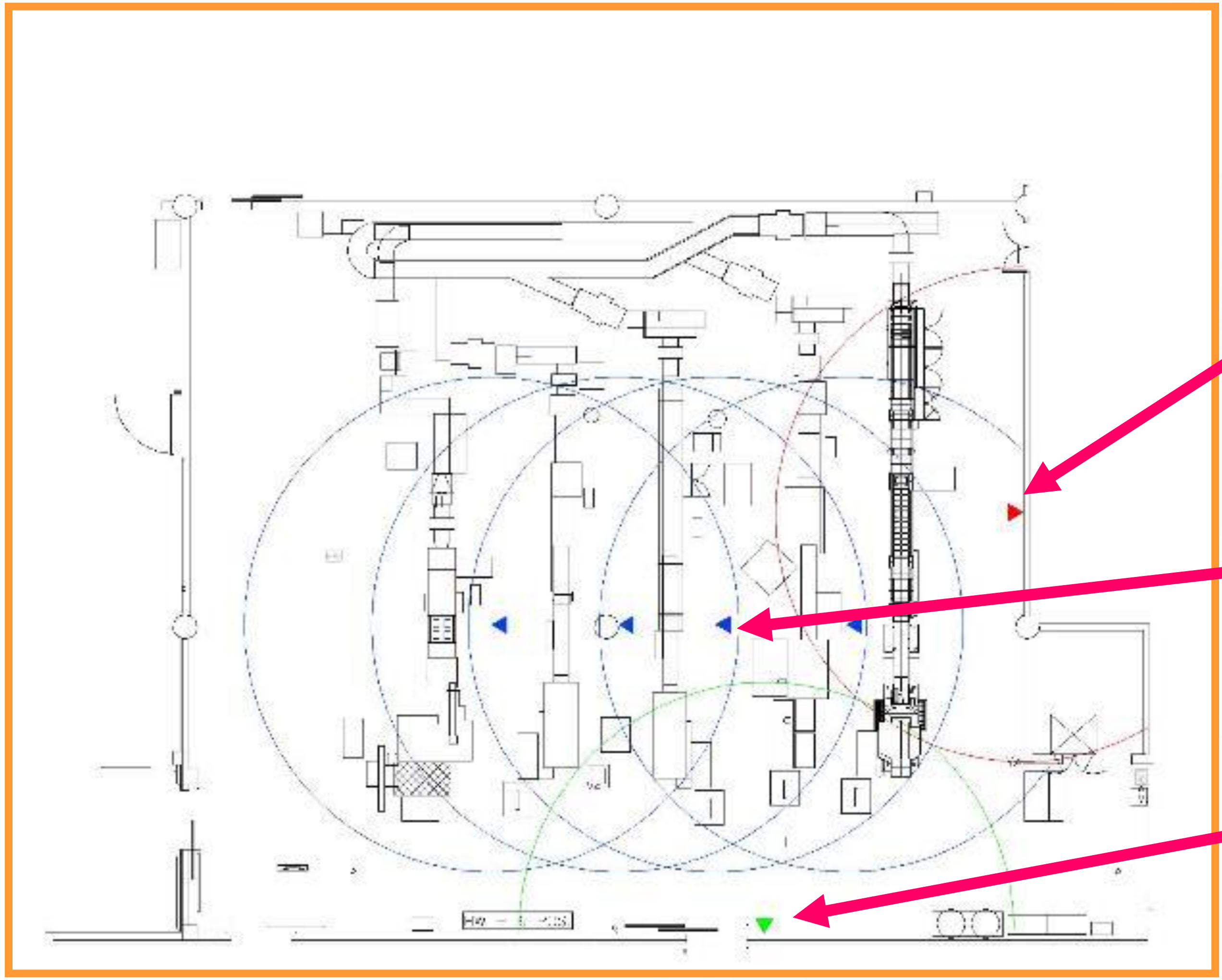


PRINCIPLES OF SANITARY DESIGN

11. SANITATION INTEGRATED INTO FACILITY DESIGN

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

11.2 Location of hose stations are sufficient & hose lengths are long enough to ensure all points are accessible without draping or carrying hoses across process equipment



Poor position

Best Positions

Good position

RISK ANALYSIS MATRIX

Likely Occurance of a Hazard if No Action is Taken				
	HIGH			Highest Risk Area ("The Vital Few") First Priority
	MEDIUM			
	LOW	Least Risk Area (Lowest Priority)		
		LOW	MEDIUM	HIGH
		Severity of Risk if Hazard Occurs		

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.

PRINCIPLES OF FOOD SAFETY DESIGN

Ten Principles of Food Safety Design

Expanded the Equipment Hygienic Design Principles to Include FM Prevention

2020-2021:

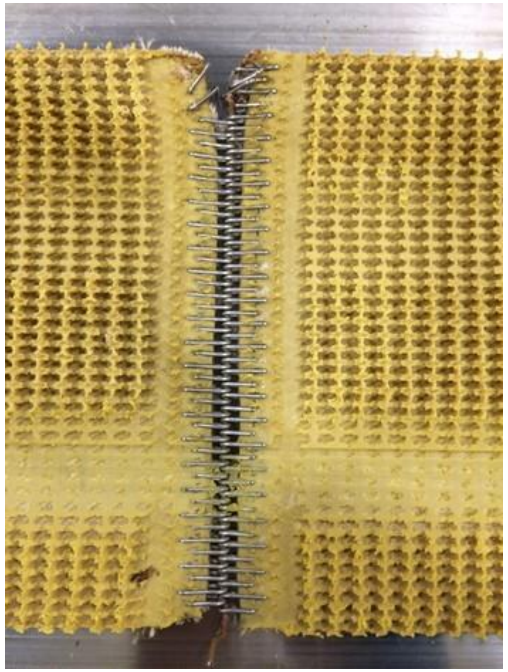
- In response to increased foreign material issues & industry recalls impacting food safety:
    - NAMI formed a Food Safety Equipment Design Task Force (FSEDTF) that was tasked to develop operational guidelines for controlling, and preventing foreign material (FM) contamination within meat manufacturing plants

- **8/2021:** FSEDTF releases (a third version) Equipment Sanitary Design Principles:
    - FSEDTF: expanded upon existing principles and updated HD checklist to include designing out foreign material risk
    - The FSEDTF team is made up of equipment manufacturers which includes collaboration with meat and poultry processing companies, certifying organizations and government officials

PRINCIPLES OF SANITARY DESIGN

1. Made of Compatible Materials

Construction materials used for equipment must be robust and compatible with the product, environment, chemicals, and sanitation methods



Surfaces: made of materials which are degradation (wear) resistant, non-toxic, non-absorbent & comply with regulations

Incompatible materials can create risk over time:

- Physical hazard - material breaking off and ending up in product
- Microbial Hazard – creating an uncleanable surface that can harbor microbes
- Chemical Hazard – surface can become uncleanable, which can result in ineffective rinsing or removal of allergens
  - Other Examples: lubricants, hydraulic fluid, cleaners & disinfectants, boiler water additives, compressed air (oil)

1. Made of Compatible Materials

- Utilize Stainless steel grades: 304, 316 (must be appropriate for use).
- Materials not used include wood, enamelware, uncoated aluminum, uncoated anodized aluminum, cloth belts, etc. (Anodize or applicable process to inhibit corrosion and wear).
- Plated, painted, and coated surfaces are not used for food contact surfaces or above the product zone areas

Salt brine corrosion test

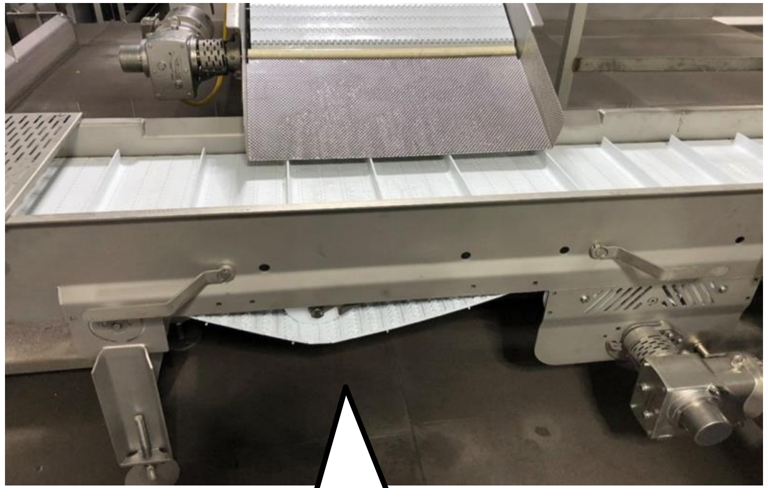
- Bearings 1, 2, and 8 Thin Dense Chrome plated.
- Bearings 3, 5, and 7 are 400 series Stainless Steel.
- Bearing 4 is coated.
- Bearing 6 is Black Oxide coated

Choose Wisely!

PRINCIPLES OF SANITARY DESIGN

2. Accessible for Inspection, Maintenance, & Sanitation

Equipment and parts shall be readily accessible for inspection, maintenance, and sanitation; without the use of tools.



Surfaces in the product zone readily accessible for sanitation and inspection. **Any Risk?**

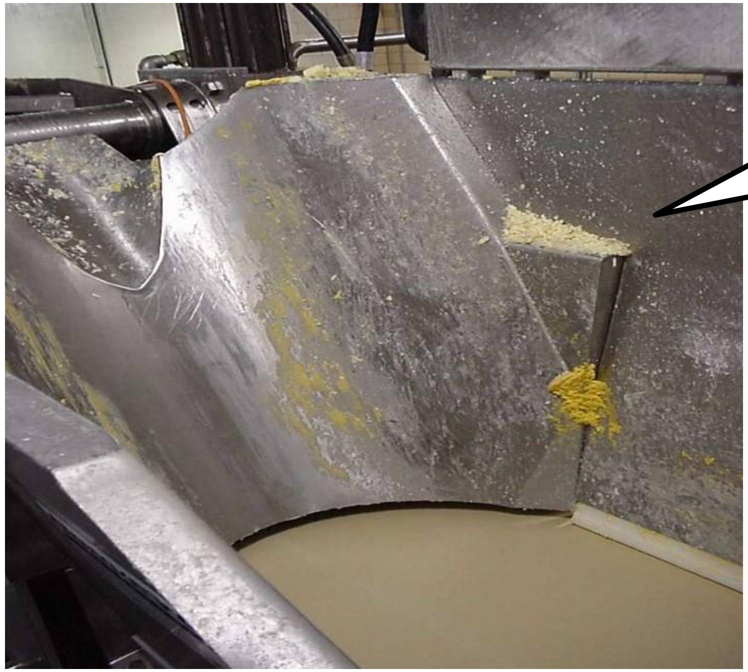
Accessibility challenges promote risk due to ineffective and/or inefficient task completion:

- Sanitation
- Maintenance
- Inspections (cleanliness, FM)

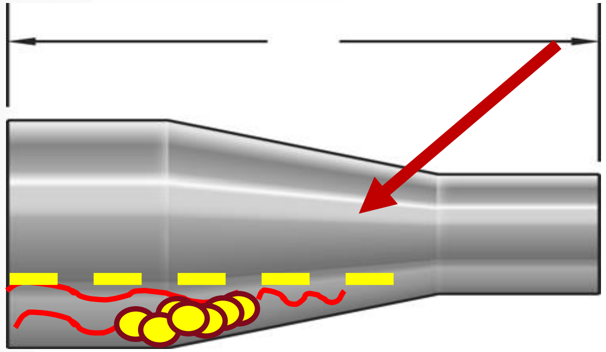
PRINCIPLES OF SANITARY DESIGN

3. No Product, Liquid, or Other Material Collection

Equipment should be self-draining to assure that product, liquid (which can harbor or promote the growth of bacteria), and other materials do not accumulate, pool, or condense on the equipment.



Accumulating Soil: may promote quality, & shelf-life challenges?

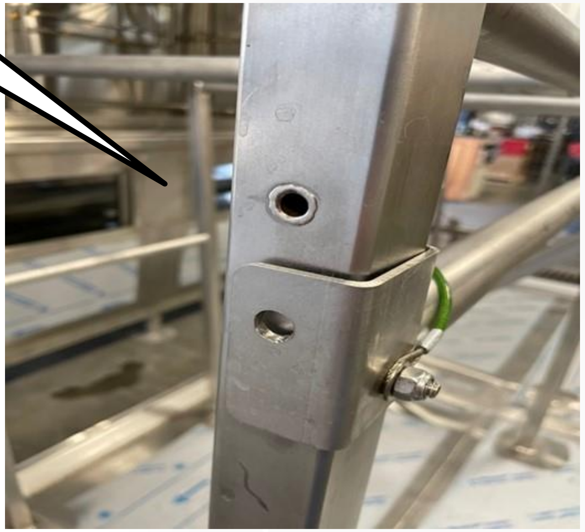


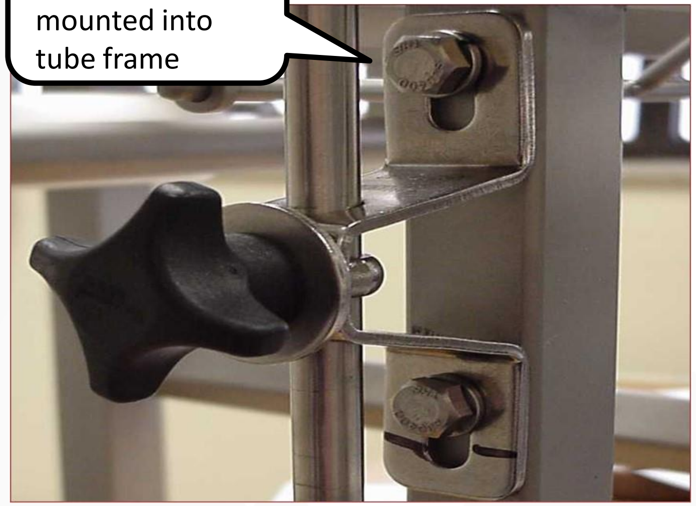
Dead end pipe:
Any Risk?

PRINCIPLES OF SANITARY DESIGN

4. Hollow Areas are Hermetically Sealed

Hollow areas of equipment such as frames and rollers are eliminated wherever possible or permanently sealed. Bolts, studs, mounting plates, brackets, junction boxes, nameplates, end caps, sleeves, and other items must be continuously welded to the surfaces, not attached via drilled and taped holes.



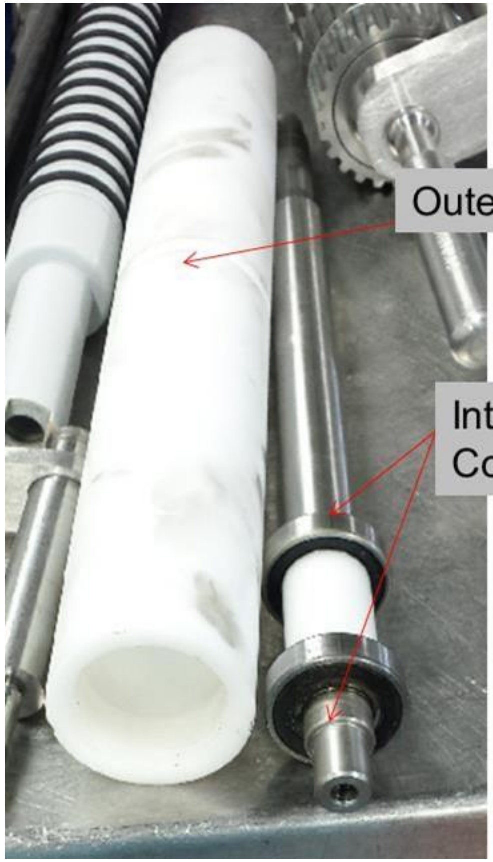


4. Hollow Areas are Hermetically Sealed

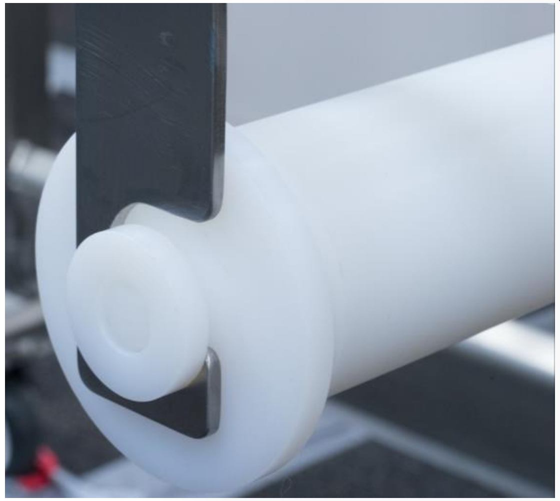
Solid frame members: round, sloped with angles or bends

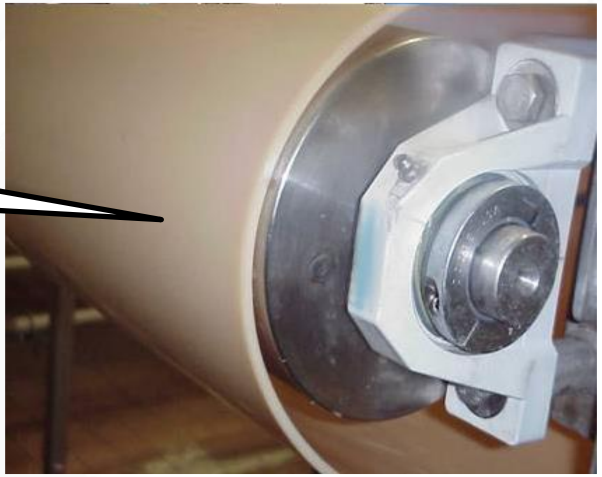
Solid L Channel: can present soil and moisture collection points- if installed horizontally in a manner to provide a ledge

4. Hollow Areas are Hermetically Sealed

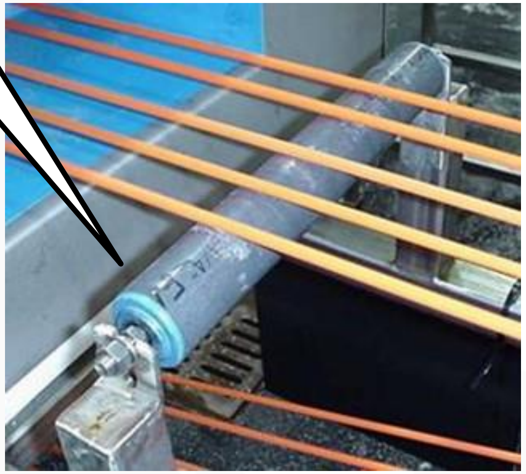


Sealed hollow or solid roller





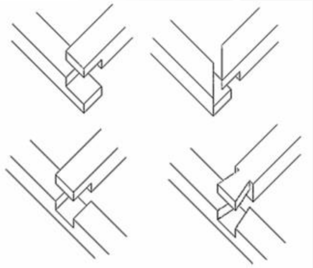
Non-hermetically sealed hollow roller



PRINCIPLES OF SANITARY DESIGN

5. No Niches

Equipment parts should be free of niches such as pits, cracks, corrosion, recesses, open seams, gaps, lap seams, protruding ledges, inside threads, bolt rivets, and dead ends.



- Niches are protecting the microbial population from routine sanitation practices, allowing the population to develop and potentially cross-contaminate (Z1 and / or exposed food).
- A 'lap joint' describes joining two pieces of material by overlapping them without a hermetic seal.

PRINCIPLES OF SANITARY DESIGN

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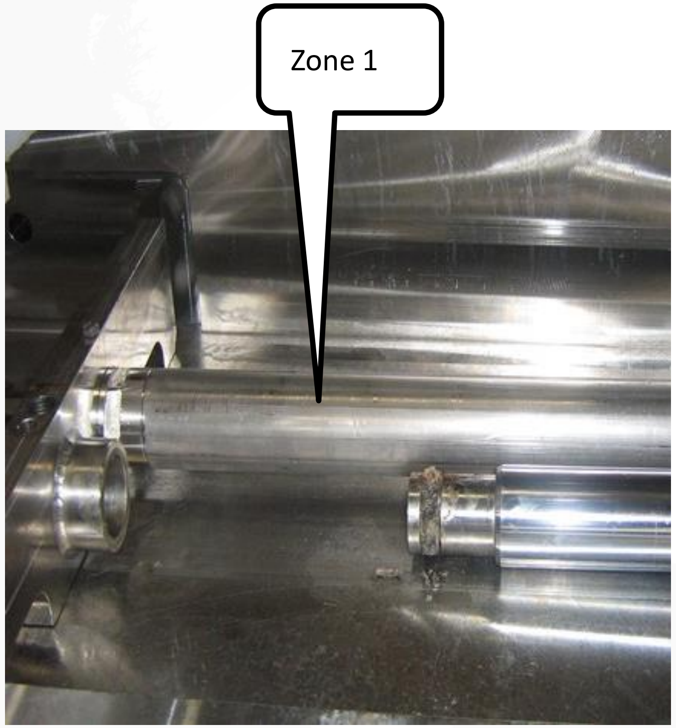
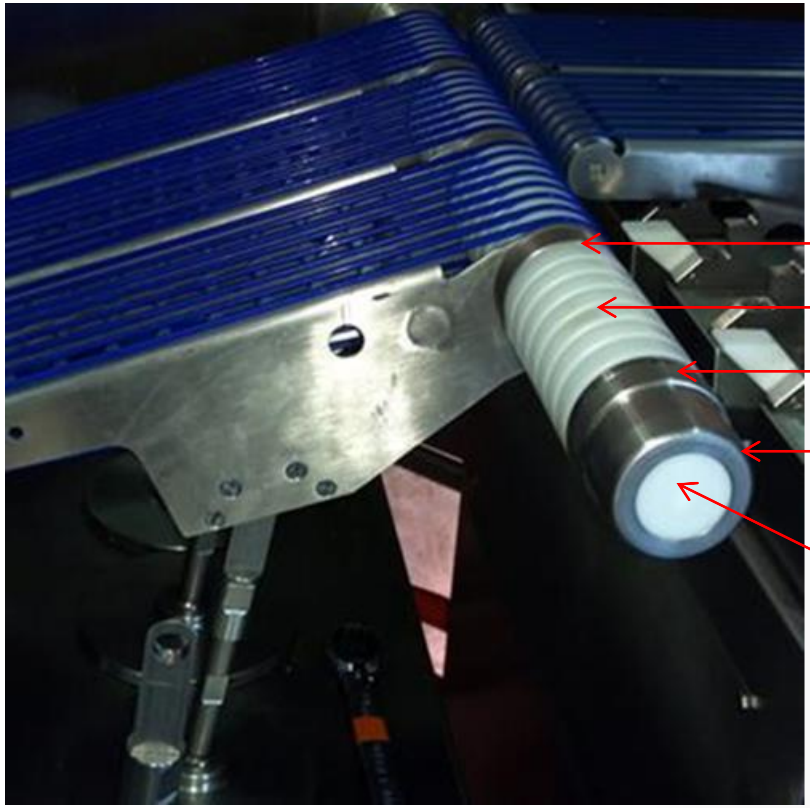


How many surfaces are you actually dealing with?



Spacer

Outer roller

Spacer

Bearing Housing

X 4

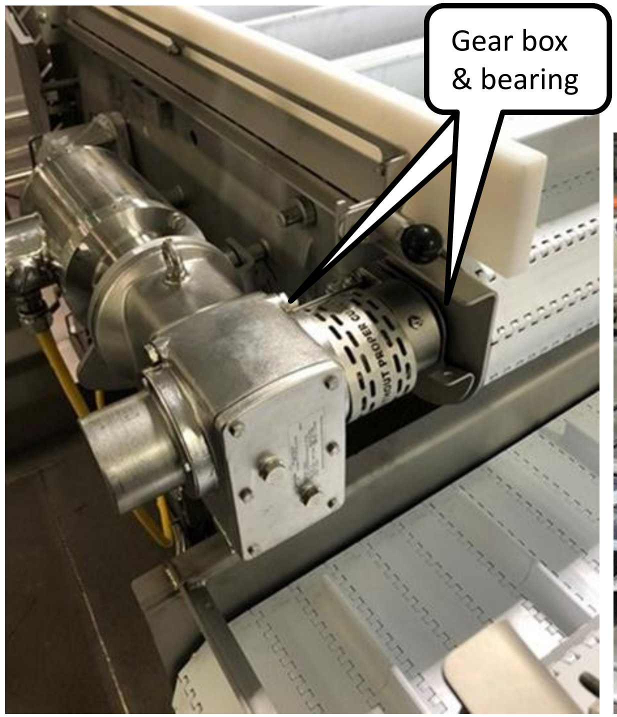
Drive Shaft

PRINCIPLES OF SANITARY DESIGN

6. Operational Performance

During normal operations, the equipment must perform so it does not contribute to unsanitary conditions; the harborage and growth of bacteria; or the creation of foreign material.

- During operation, equipment surfaces should not promote product quality challenges due to soil buildup, or moisture / product liquid purge

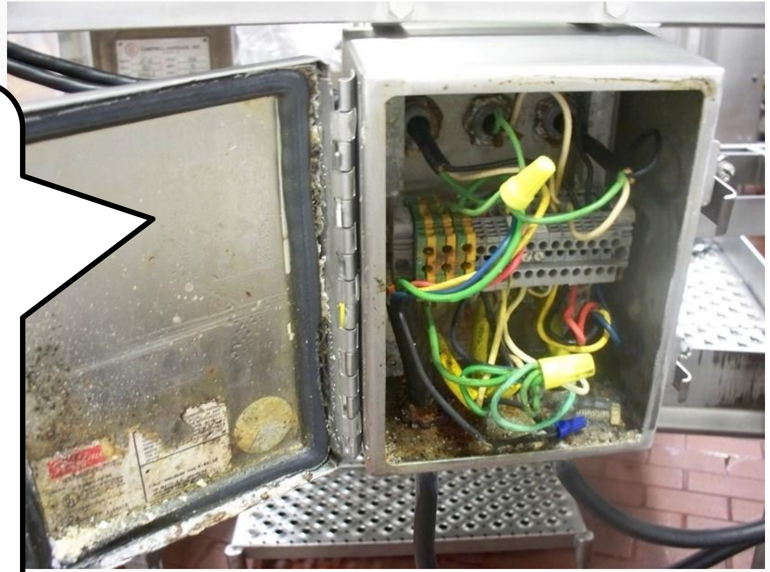


PRINCIPLES OF SANITARY DESIGN

7. Maintenance Enclosures

Maintenance enclosures and human machine interfaces such as push buttons, valve handles, switches and touchscreens, must be robust to ensure integrity and designed to prevent product residue or water penetration or accumulation. Enclosures should be sloped or pitched to avoid use as a storage area or residue accumulation point.

Enclosure needs: sloped top, 365-degree access, non-porous & cleanable door seal, sanitary interior hinge, and IP rated for the environment- including sanitation



PRINCIPLES OF SANITARY DESIGN

8. Compatibility With Other Plant Systems

Equipment that requires additional sub systems, such as exhaust, drainage, or automated cleaning systems, does not create food safety design risk because of the soil load, operational conditions, or standard sanitation operating procedures.

Understanding the Decision

Impact on plant KPI's (*Safe, Clean, & On-Time*)?

Engineering/Maintenance

Profitability/Operations

FSQA/Sanitation

Understanding the Decision

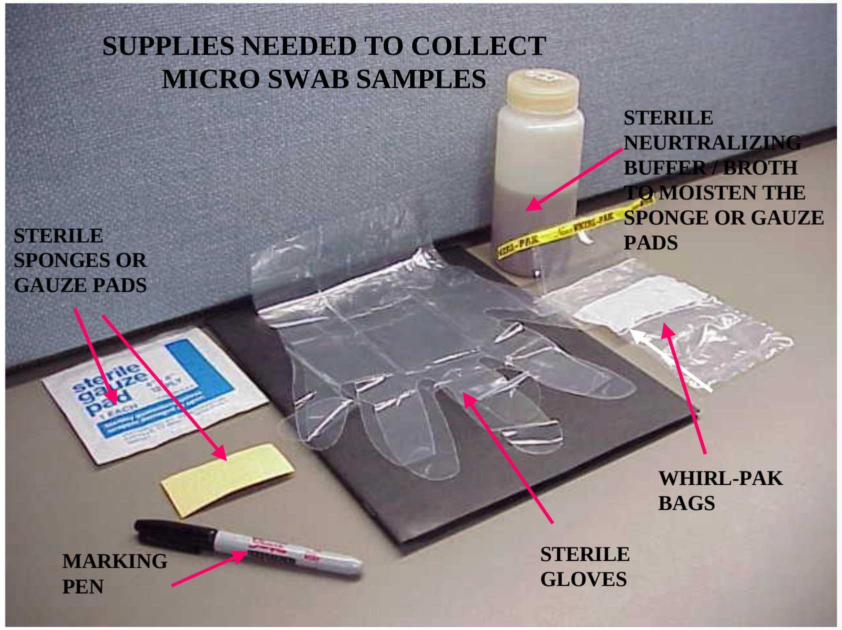
If a design principal is being compromised: the full implication and work around needs agreed upon before moving forward

How do we manage this?

PRINCIPLES OF SANITARY DESIGN

9. Cleanable to a Microbiological Level

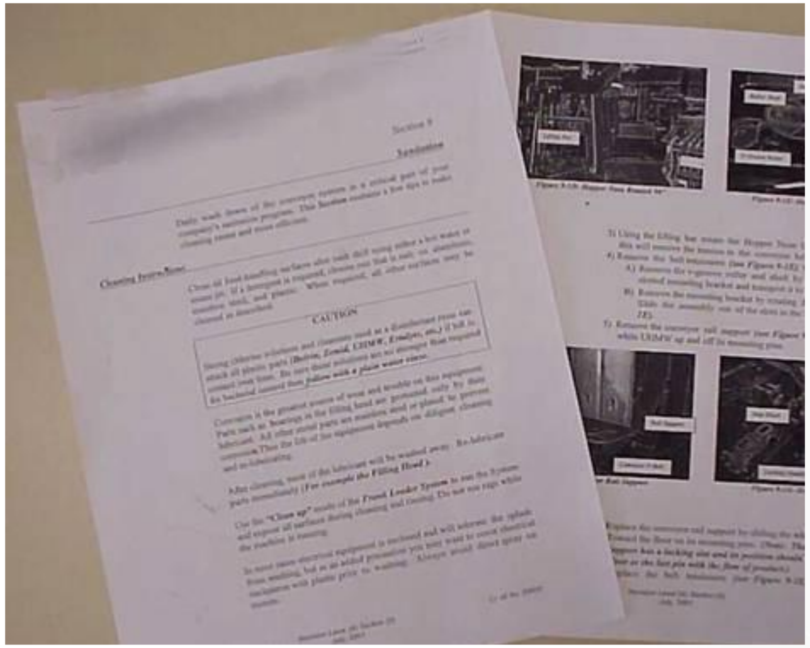
Food equipment must be constructed to ensure effective and efficient cleaning over the life of the equipment with minimal degradation. The equipment should be designed to prevent bacterial ingress, survival, and growth, as well as preclude introduction or accumulation of allergens, chemicals, or foreign material, on both product and non-product contact surfaces.



PRINCIPLES OF SANITARY DESIGN

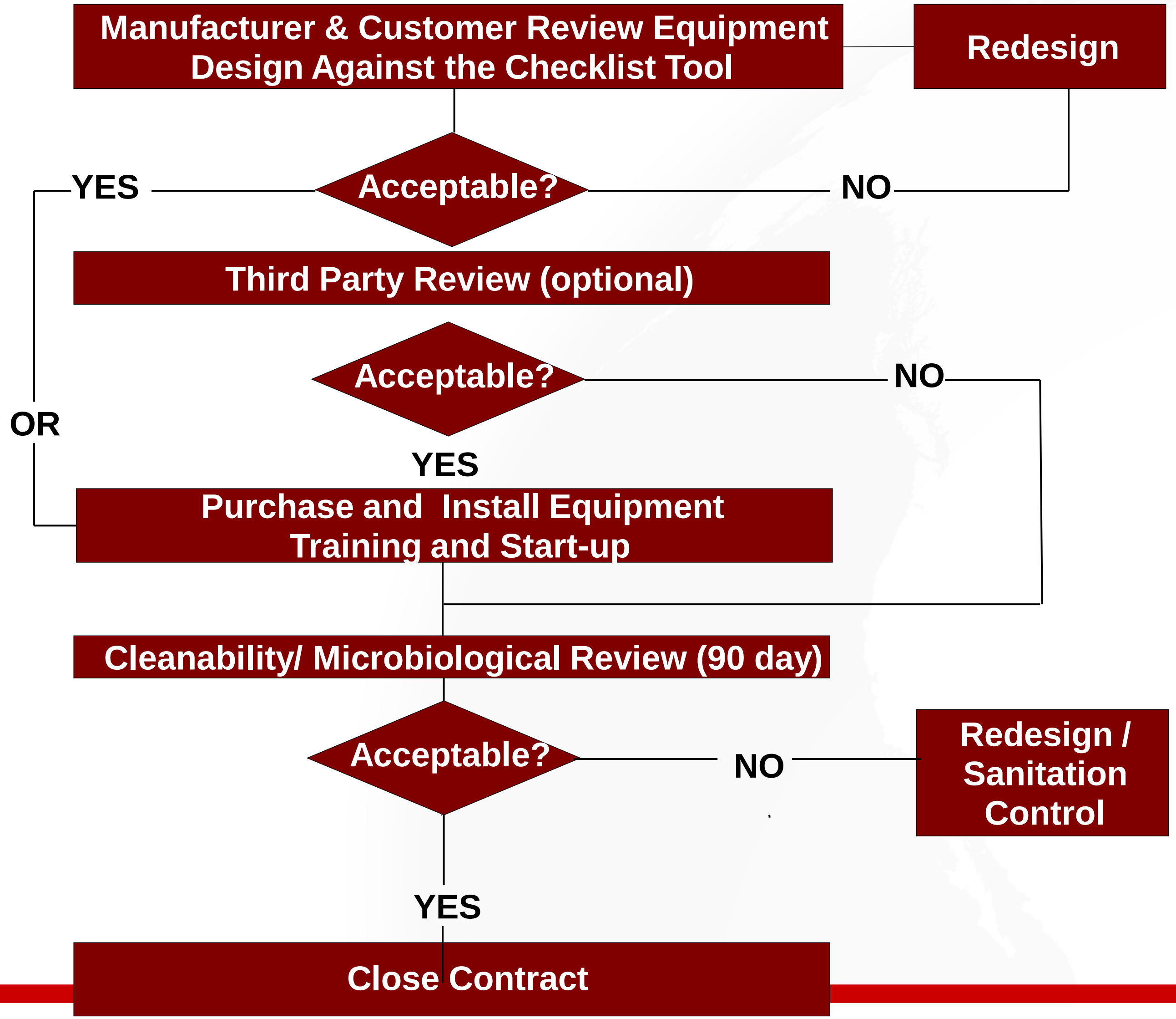
10. Validated Sanitation Protocols

Procedures for sanitation must be clearly written, designed and proven effective and efficient. Chemicals and procedures recommended for cleaning and sanitation must be compatible with the equipment and the manufacturing environment to prevent damage.



- Components are capable of withstanding sanitation procedures through the respective lifetime of the equipment or each component.
  - Routine Sanitation
  - PEC: steam pasteurization temps (thermal shock), ClO2 or Ozone fumigation, Bio-film & disinfection chemistries, etc.
- The need for periodic deep cleaning beyond routine sanitation is minimized.
- Written cleaning procedures: all routine & PEC (deep clean) practices have been built along with corresponding images to capture consistent
- Must use data to demonstrate process control: pre-op findings, micro data, allergen data when applicable

PROCESS FLOW CHART FOR DESIGN REVIEW



Utilizing Principles of Food Safety Design

Guard with welded shield

Principles of Food Safety Design

	Reference (principle eqipment/utilities/building / Cip tab)	Notes / observation	Pictures	Control: PSS, Repair, Modify/Replace, or CAPEX	CHIPS Yor N	Type PSS Critical/ non-critical	Evidence: SOWI, Work Order, other
1	5.4, 5.5, 5.7	5.4 Inproper welds creating lap joint between guard and welded L bracket. 5.5 Lap joint does not meet the required spacing. 5.7 Welds are not continuous and smooth. Modify or redesign splash guard. Until redesign is complete plastic guards must be removed during every sanitation cycle.		Modify / re-design	yes	PSS critical clean	

Key Take-Aways

1. Facility and equipment design principles are the foundation for effective and efficient sanitation, food safety, product quality, and maintaining brand reputation : Reduces Risk & Business Exposure
2. Build a holistic business case for improving equipment & infrastructure Hygienic Design (new & current)
   → Understanding design risk and total cost of ownership is critical (PEC, PM maint, daily sanitation)
3. Use a cross functional team approach for new design reviews:
   → Leverage subject matter experts (in-house and externally), involve OEM's (before capital is approval and during all project stages)
4. Managing current Hygienic Design limitations using the plant's MSS system:
   - Takes leadership, and a strong food safety culture
   - Requires ongoing focus, resources, and commitment to manage design risk
   - Cross functional team approach for legacy design reviews: goal eliminate process risk, and improve E&E.

Investment in Hygienic Design is one of the most important legacies you can leave to your company, customers and consumers

Questions?