

Process Integration for Hygienic Design

3-A SSI Education Program

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Process Integration for Hygienic Design

Got the Equipment ...
it's 3-A ...
Now What?



What's the Goal?

Operate a facility that produces safe and wholesome food!

Today's Focus

- Plant Design
- Equipment Installation, Operation & Maintenance

Salt (120 μ m, 4724 μ -inch)

Yeast (5 μ m, 197 μ -inch)

Mold spore (3 μ m, 118 μ -inch)

Listeria (0.5 μ m, 19.7 μ -inch)



FDA 483's – FDA feedback that conditions may lead to adulterated food.

Common Themes

Plant Design

- Proper **precautions to protect food**, food-contact surfaces, and food-packaging materials from contamination...because of deficiencies in plant design.
- Effective measures are not being taken to **exclude pests** .
- Facility is designed such that employees processing young cheeses must pass through the packaging area where aged, ready-to-eat cheese is packaged.... **Traffic patterns**
- **Moisture and condensation** issues which can contaminate food
- **Drainage** system back-up

GMP's

- Employees in contact with food, food-contact surfaces, and food-packaging materials were not maintaining adequate personal cleanliness.
- Improper use of hair nets and gloves
- Employees scratching head with out rewashing hands

Sanitation

- Failure to conduct cleaning and sanitizing operations **properly and frequently** as necessary.
- Procedure used for cleaning and sanitizing has **not been shown to be adequate**

NAMI Facility Design Principles

Guide for Plant Design



- ✓ PRINCIPLE 1: DISTINCT HYGIENIC ZONES ESTABLISHED IN THE FACILITY
- ✓ PRINCIPLE 2: PERSONNEL & MATERIAL FLOWS CONTROLLED TO REDUCE HAZARDS
- ✓ PRINCIPLE 3. WATER ACCUMULATION CONTROLLED INSIDE FACILITY
- ✓ PRINCIPLE 4. ROOM TEMPERATURE & HUMIDITY CONTROLLED.
- ✓ PRINCIPLE 5. ROOM AIR FLOW & ROOM AIR QUALITY CONTROLLED
 - 3-A 612-00 Environmental Air Quality
- ✓ PRINCIPLE 6. SITE ELEMENTS FACILITATE SANITARY CONDITIONS
- ✓ PRINCIPLE 7. BUILDING ENVELOPE FACILITATES SANITARY CONDITIONS
- ✓ PRINCIPLE 8. INTERIOR SPATIAL DESIGN PROMOTES SANITATION
- ✓ PRINCIPLE 9. BUILDING COMPONENTS & CONSTRUCTION FACILITATE SANITARY CONDITIONS
- ✓ PRINCIPLE 10. UTILITY SYSTEMS DESIGNED TO PREVENT CONTAMINATION
 - 3-A 604-05 Supplying Air Under Pressure, 3-A 609-03 Method of Producing Culinary Steam
- ✓ PRINCIPLE 11. SANITATION INTEGRATED INTO FACILITY DESIGN
 - 3-A 605-04 Permanently Installed Product and Solution Pipelines and Cleaning Systems



Facility Design

Exterior... from the lot line in
Focus: pest, dirt and dust control

Plant Exterior

- Solid, smooth, minimize gaps and nesting spots

Exterior Lighting

- Minimize... but meet code
- Insects are readily attracted to UV-A and UA-B in the spectrum range 300 and 420 nm generated by electric arcs or lamps like mercury-vapor lamps.
- LED lighting can produce virtually no UV

Access ways

- Paved and well drained and maintained

Exterior Landscaping

- Minimal close to building



Facility Layout

Plant must be designed to prevent contamination of food

Separation and Traffic Patterns

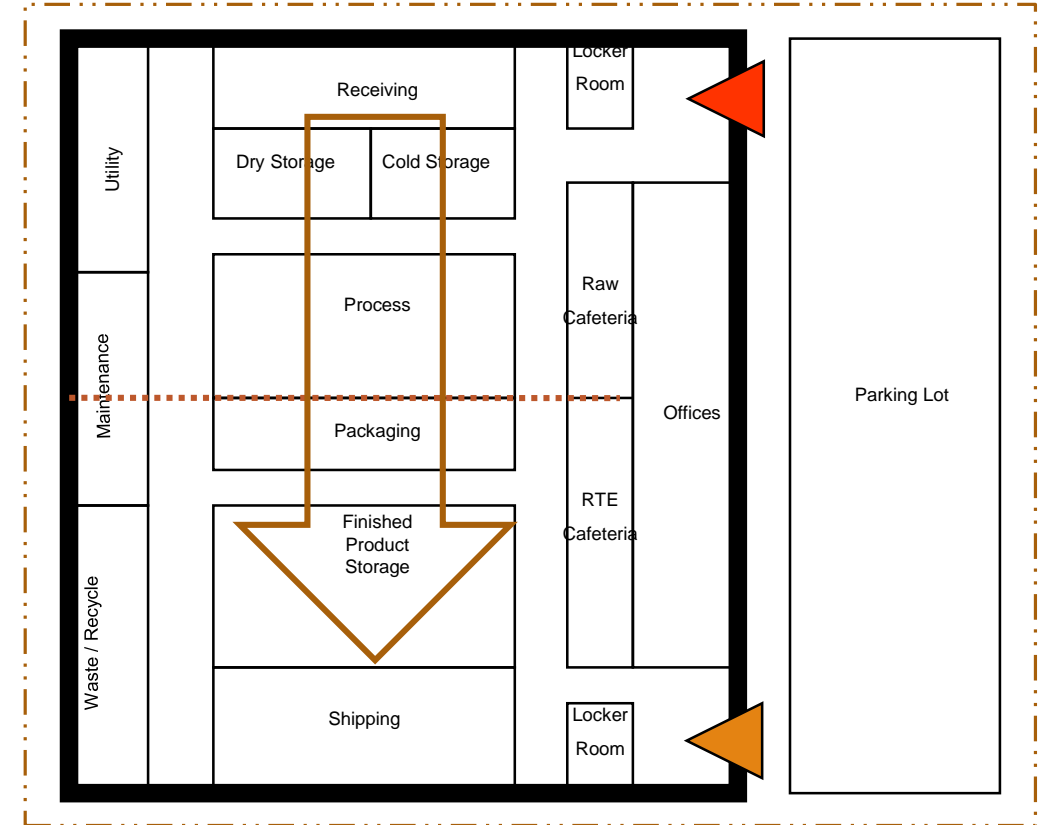
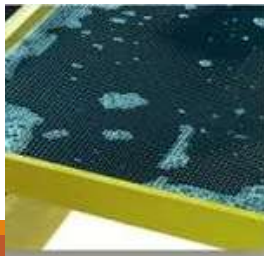
- Raw and RTE workers
- Sanitation, Maintenance, Management, Quality Assurance
- Visitors and Contractors
- Products, ingredients, rework, and packaging materials
- Portable equipment storage and use

Processes. Is there a process kill step?

- Can personnel pass across Raw/RTE areas?

Foot Cleaning

- Scrubbers, foot baths and foamers

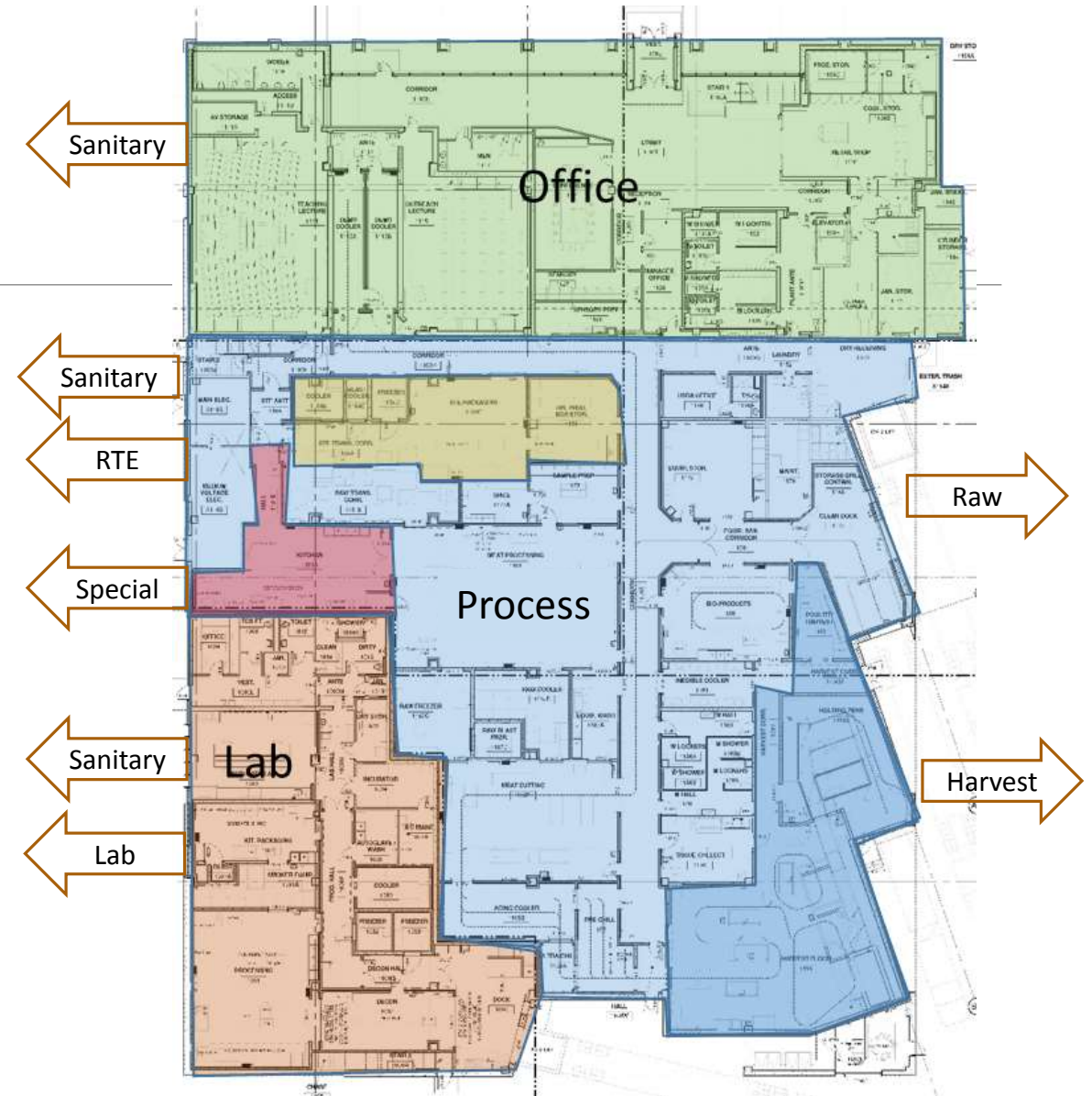


Facility Design

Drainage outfalls

Separate outfalls for

- RTE Process
- Raw Process
- Special or Batch Process
- Sanitary



Sanitation Planning

Key understanding for facility design

Define initial approach and chemistry along with the process design and development

Room and equipment design follow with sanitation plan in mind.



Sanitation Equipment and Chemistry Plan

Pre-construction

Equipment

Application	Description	Water Supply			Compressed Air	
		Temperature (°F)	Pressure (PSI)	Flow (GPM)	Pressure (PSI)	Flow (SCFM)
Rinse	Strahman M-750TG w/ M-70 nozzle	140	40	5 - 6	-	-
Soap Foam Station	EcoLab Commander 4411LP	100 - 140	50 - 100	2 - 4	40 - 90	3 - 5
Sanitizer Station	EcoLab Mikro Spray J-6	100 - 140	20 - 60	3 - 5	-	-
Portable Foamer	Ecolab Foam-it 25	100 - 140	-	. ¹	40 - 80	5 - 10
Doorway Foamer ²	Ecolab Ecocare	cold	50 - 100	2 - 4	40 - 90	3 - 5

Water supply

Hardness target not to exceed 3.5 grains per gallon for all sanitation use.

Chemical Use

Chemical	Type/Application	Dilution	East	West
Advantis FC	Foam Cleaner	2-5 ounces per gallon of water	Room and Equipment	
HD Acid LC-30	Acid Foam Cleaner	2-4 ounces per gallon of water	Equipment	Equipment
Vortexx	Peroxyacid-based Sanitizer	1 ounce per 3-6 gallons of water	Room and Equipment	-
Boost 3200/3201	Foam Disinfectant	12.8 ounces per gallon of water	Micro Issue ³	Room and Equipment
Principal	Non-foaming cleaner for CIP & spray cleaning	none	Spray Cleaner	-
Ster-Bac Quat	Quat Sanitizer	1 ounce per 2.5-4 gallons of water	Doorway Foamer	
Boost FT	Powdered Floor Sanitizer	Straight	Floors as necessary	
Pathways Solid Drain Sanitizer	Quat Rings	Straight, placed in drain	Drains (4" or 8" dia ring)	
Lift RT	Floor Cleaner	1.3-6.4 ounces per gallon of water	Hallways and Docks	

Room Temperatures During Sanitation?

A challenging balance. . . Cool and Dry

Key considerations

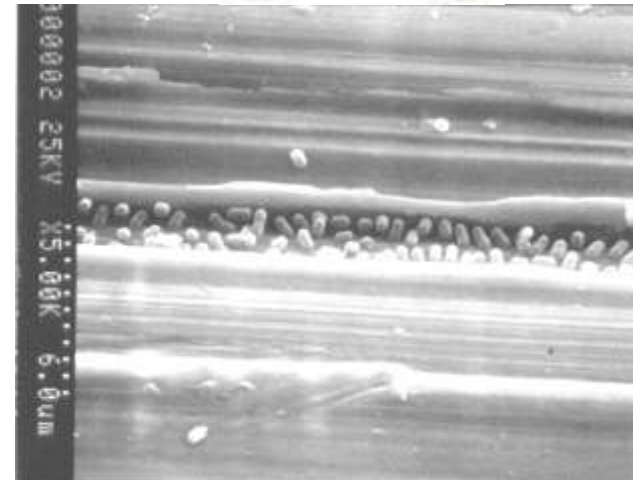
- Microbiological – manage growth of microbes thru temperature and moisture
- Return **room and equipment** back to operating conditions
- Physical impact to room – expansion and contraction
- Sanitor vision and well-being

Maintain

- Maintain room to no higher than 10 - 12 degrees above normal operations temperature, but never exceed 50 degrees

Fluctuate

- Allow warmer temperatures with 100% make up... allows for quicker humidity removal.



Facility Design

Keep it simple

Inert

Non porous

Non absorbent

Cleanable

Sealed Joints

Absence of Joints



Facility Design

Refrigeration and HVAC

Design Requirements

- Operation Conditions
- Sanitation Conditions

Equipment Considerations

- 3-A 612-00 AP Plant Environmental Air
- Air Supply...relatively clean & odor free
- Filter efficiency
- Air flow – “clean to dirty”
- Minimize Duct, Welded
- Minimize equipment in room
- Access and clean-ability



Facility Design

Drains

- Stainless Steel, 4 inch (10 cm) minimum size
- Loose-set traffic grate & removable, perforated, collecting basket
- P– trap welded to drain. Minimum water seal of 3 inches. Proper venting
- Integral trap drains are not preferred.
- Equipment placement must allow for easy access to floor drains for cleaning.
- Grease Traps.....outside!



Facility Design

Walls and penetrations

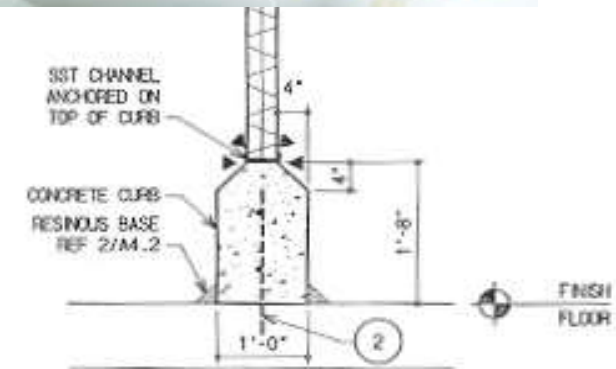
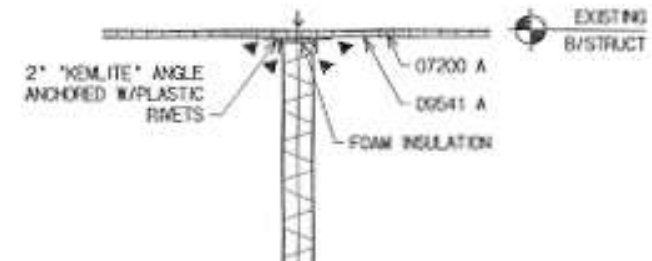
Flat and Smooth

- resistant to process and sanitation conditions as well as wear and moisture.
- solid, not hollow, easily cleanable

Joints - Maintained

Penetrations

- Minimized and Sealed!
- Warm vs. Cold room
 - Insulation to prevent condensation
- Electrical
 - Foam filled conduit
 - Insulated exterior



Facility Design

Floors

- Heavy Loads such as fork lift and trolley traffic
- Process and cleaning chemicals including strong acids and bases
- Suitable for process conditions including hot or cold process water draining across floor
- Need to be cleanable, smooth yet slip resistant
- Thermal Shock – expect at least 6 sanitations per week with a maximum temperature 140°F – 180°F
- Impact of regular dropping of pallet loads and combo bins
- Abrasion due to high traffic, dragging of items across floor, coarse product on floor
- **Short repair times due to 7 day per week operation**
- **Initial and Repair Cost \$\$\$**



Facility Design

Ceilings, Utilities and Lighting

Avoid ceiling joints over product

Lighting

- 30 – 50 fc **non shadowing** lighting
- Inspection – CRI +80
- Recessed, Ceiling Mount or Pendant?
- Shadows from drops, ducts cooling units

Utilities

- Utilize interstitial space as much as possible
- Overhead utilities – never over product!
- Proper sealing & insulation

R1	
R2	
R3	
R4	
R5	
R6	
R7	
R8	
R9	
R10	
R11	
R12	
R13	
R14	
R15	



Plant Design

Construction & Remodeling

Assure contractors understand

- Plant GMP's
- Traffic patterns

Consider if contractors can use common areas

Temporary enclosures

- Water and dust proof
- Ventilation
- Durable for length of installation



Equipment Installation

Welding

- Attend the “Hygienic Welding: How Do You Know When It’s Right?” session
- Train and develop welders



Equipment Installation

Passivation

- **Thorough chemical cleaning** of the stainless steel food contact surfaces and **render surfaces inert** (non-reactive) and protected from corrosion by the formation of a passive surface film composed of **chromium oxide and nickel oxide**
- All **newly installed** and **repaired** stainless steel food contact piping, food contact tanks, CIP piping, CIP tanks, and food contact equipment shall be cleaned and passivated prior to use.



Equipment Installation

Equipment Access

A sufficient amount of space must be allowed around equipment for:

- Operator Access
- Material Supply and Removal
- Maintenance
- Safety
- Sanitation



Equipment Installation

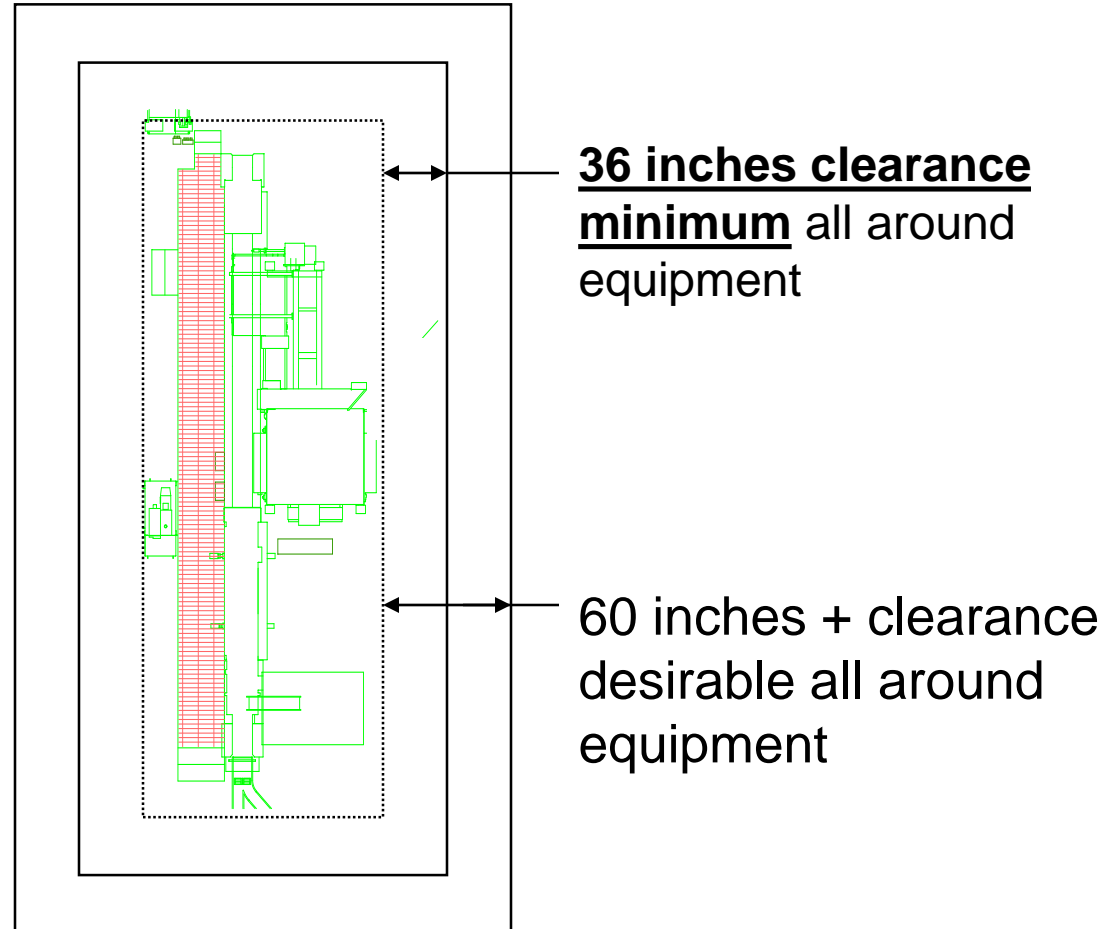
Equipment Access Guidelines

Minimum Clearance **Under** Equipment

< 36" wide	8"
36" - 60" wide	12"
60" - 84" wide	18"
> 84" wide	24"

Minimum Clearance **Over** Equipment

< 36" - 84" wide	24"
> 84" wide	30"





Equipment Installation

Self Draining Installation



Equipment Installation

Electrical

Electrical equipment is at high risk for infestation due to many openings for dust/food/moisture to enter. Insects can easily access warm area for insects to lay eggs

Conduits

- Ideal: only penetrate bottom of enclosure in wash down areas.
- Acceptable: Side penetration of enclosures
- All penetrations are to be gasketed to seal enclosure in wash down areas.

Wall mounting minimum stand-off clearance

- 1" for boxes smaller than 6" x 6"
- 2" for boxes smaller than 12" x 18"
- 3" for boxes smaller than 24" x 24"
- 4" for boxes greater than 24" x 24" or boxes to have open back or be sealed to wall at joint (review with owner)

Floor mounted panels must have a minimum of 6 inch sanitary legs or be set on a 6 inch housekeeping pad. Panel must be sealed to pad.



Equipment Installation

Exhaust and Process Drains

Steam emitting equipment...Exhausts

- Adequate exhaust to remove steam
- Condensate management
- Room air balance, air back flow prevention when off
- Discharge location and drainage
- Cleanable

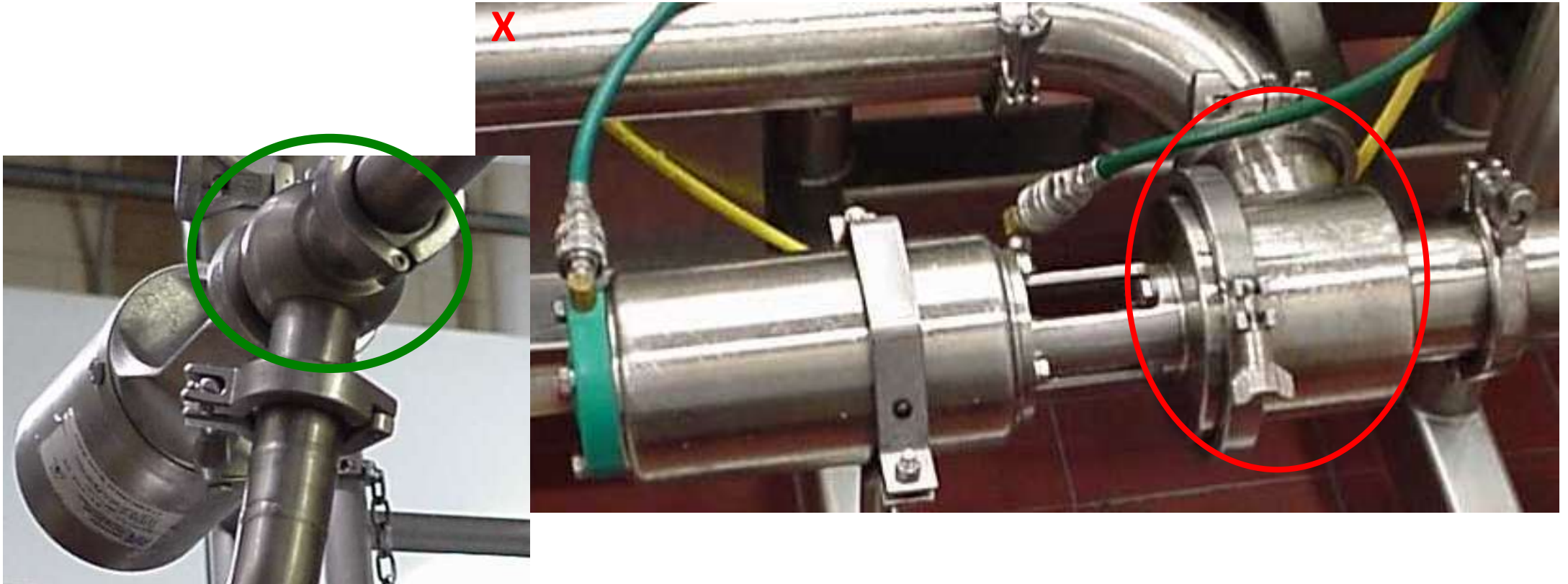
Water emitting equipment...Drainage

- Adequate capacity to remove all water without contaminating floor
- Air Gap



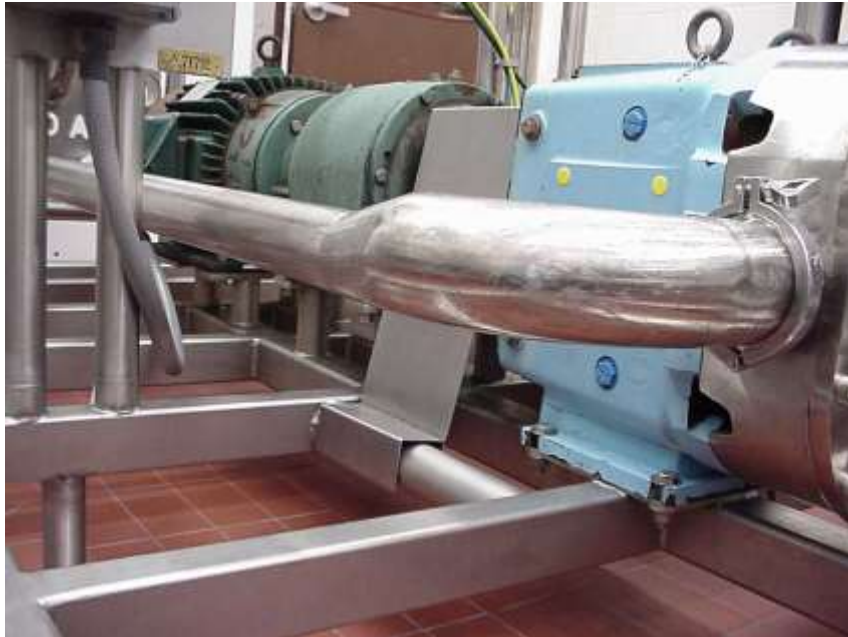
Equipment Installation

Valve Installation



Equipment Installation

Piping



Equipment Operation

Processes used must be shown to maintain a sanitary condition

Operation as intended....

- Product, temperatures

Cleaned as intended

- CIP vs. COP/manual
- Cleaning chemicals, temperatures and durations
- Cart or basket for removable parts
- reassembly

Cleaning process validated and verified

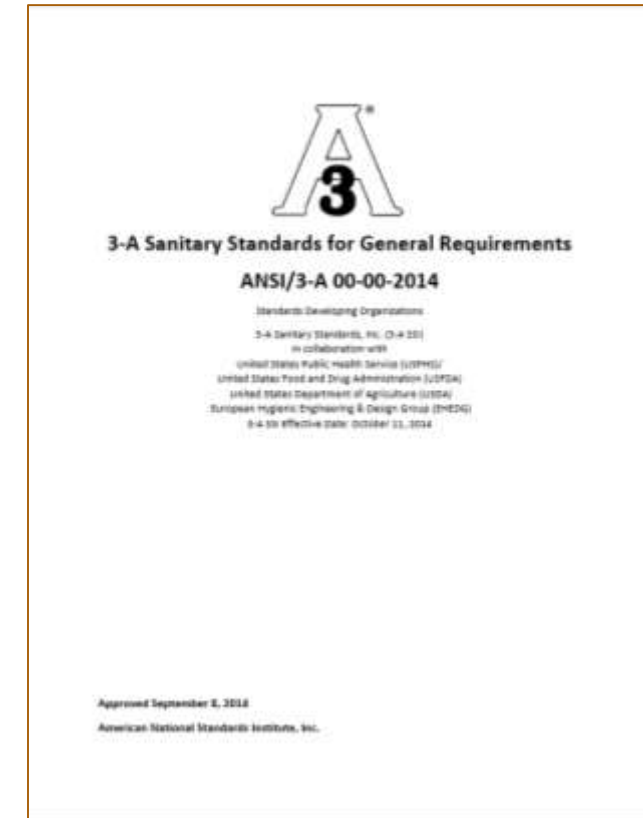


3-A Standards

not just for equipment manufactures...

The goal of 3-A SSI is to protect consumable products from contamination and to ensure that all product surfaces can be mechanically (CIP) cleaned or easily dismantled for manual cleaning.

- 3-A SSI: develop sound standards
- Manufacturer: design & construct equipment
- Operator: install, operate and maintain equipment
- Regulatory: Inspect based on Standards



Equipment Operation

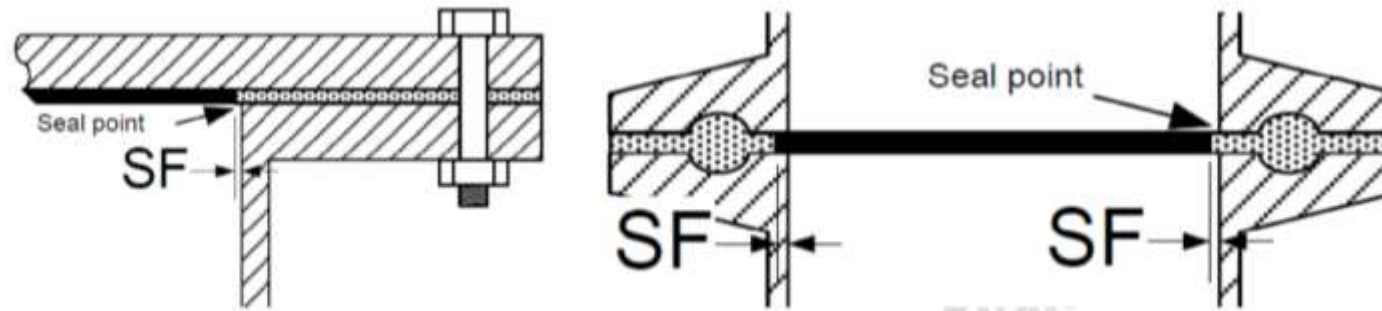
Pre-Op inspection using 3-A 00-00-2014

Product Contact Surface	Pre-Op
D1 – Surface	<ul style="list-style-type: none">• Inspect that surfaces retain surface and conformational characteristics
D1.2.1 Plastic and Rubber	<ul style="list-style-type: none">• Inspect for damage• Replace with materials that meet physical and chemical requirements.• 3-A SSI Replacement Parts and System Component Qualification Certificate (RPSCQC)
E1.1 – Surface finish	<ul style="list-style-type: none">• Ra < 32 μ in. Repair to meet original finish
E1.1 – Welded, Braised or Soldered Joints	<ul style="list-style-type: none">• Inspect joints for pits, cracks or deterioration. dye test
E1.3 – Surface Treatments Mechanical, electro polishing...	<ul style="list-style-type: none">• Inspect that surfaces retain original surface characteristics

Equipment Operation

Pre-Op inspection using 3-A 00-00-2014

Product Contact Surface	Pre-Op
E2.1.1.2 – Interference fits	<ul style="list-style-type: none">• Dye test for fit
E2.1.1.3 – Bonded joints of rubber and Plastic	<ul style="list-style-type: none">• Inspect for continuous and mechanically sound bond.
E2.2, E7 – Non-permanent joints and Gaskets	<ul style="list-style-type: none">• Assure gasketed joints are installed and tightened as designed...substantially flush interior



Substantially Flush (SF) = 1/32" (0.794 mm) maximum

Equipment Operation

Pre-Op inspection using 3-A 00-00-2014

Product Contact Surface	Pre-Op
E3.1 Coatings	<ul style="list-style-type: none">• Free of delamination, pitting, spalling, blistering
E4 COP Cleaning	<ul style="list-style-type: none">• COP/Manual – all product contact surfaces inspected.
E5 Draining	<ul style="list-style-type: none">• Surfaces shall be self draining
E6 Dead Ends	<ul style="list-style-type: none">• Assure no dead ends greater than 2X nominal diameter or 5 inches• Remember probe diameter is subtracted from the pipe diameter
E8-E14	<ul style="list-style-type: none">• Special attention during cleaning and inspection to exposed threads, perforated surfaces, coil springs, shafts and bearings

Equipment Operation

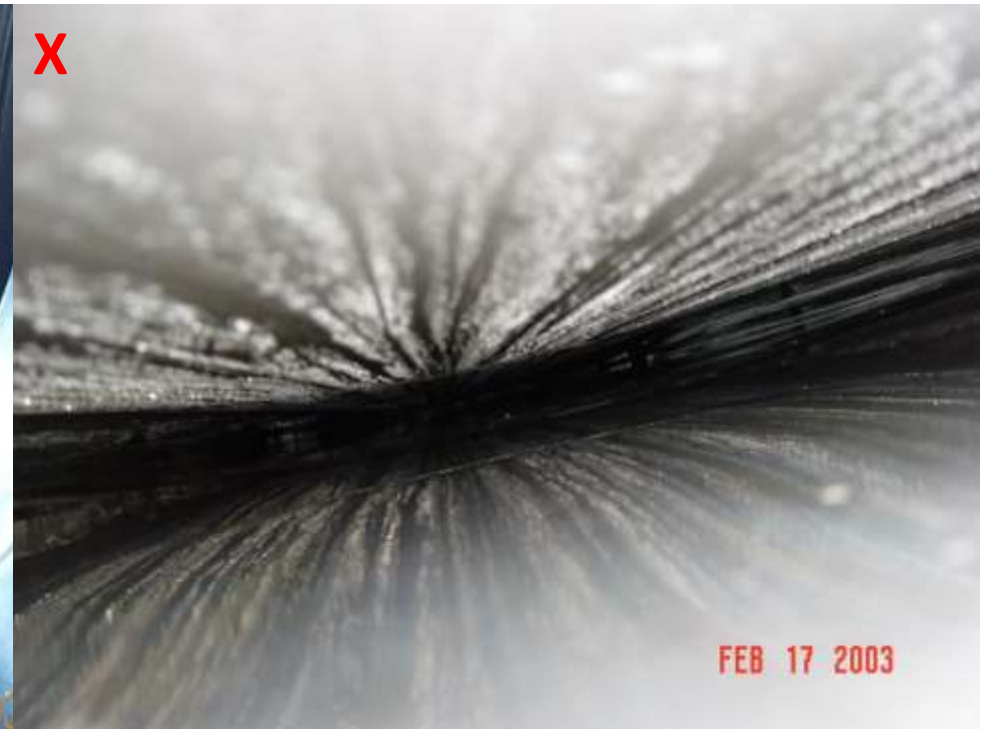
Pre-Op inspection using 3-A 00-00-2014

Product Contact Surface	Pre-Op
E14 Openings and Covers	<ul style="list-style-type: none">• Insure deflectors, seals and guards are properly installed and aligned
Non product	
F4 Cleaning	<ul style="list-style-type: none">• Check for soil and contamination. Remove any pooling water
F7 Service Piping	<ul style="list-style-type: none">• Braided coverings may not be used• Piping minimized and remote from product contact zones• Pneumatic exhaust piped away from equipment• Worm type hose clamps not used

Pre-Op findings....



no CIP coverage on bottom of tubes



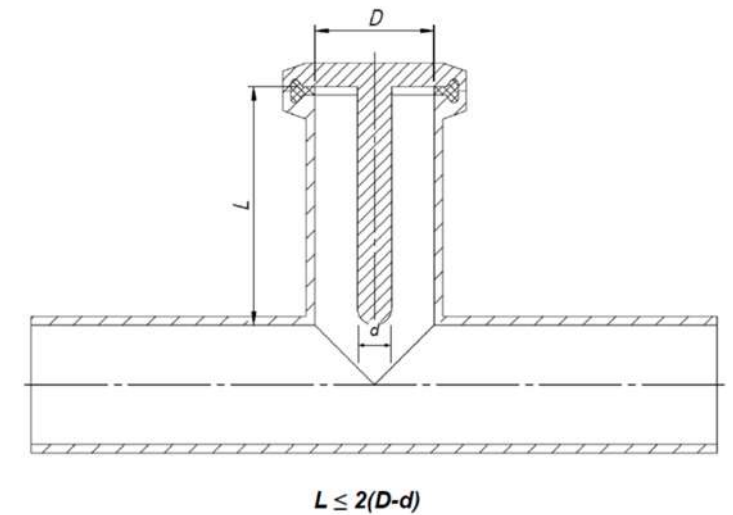
Silo vent, no CIP coverage

Pre-OP Findings

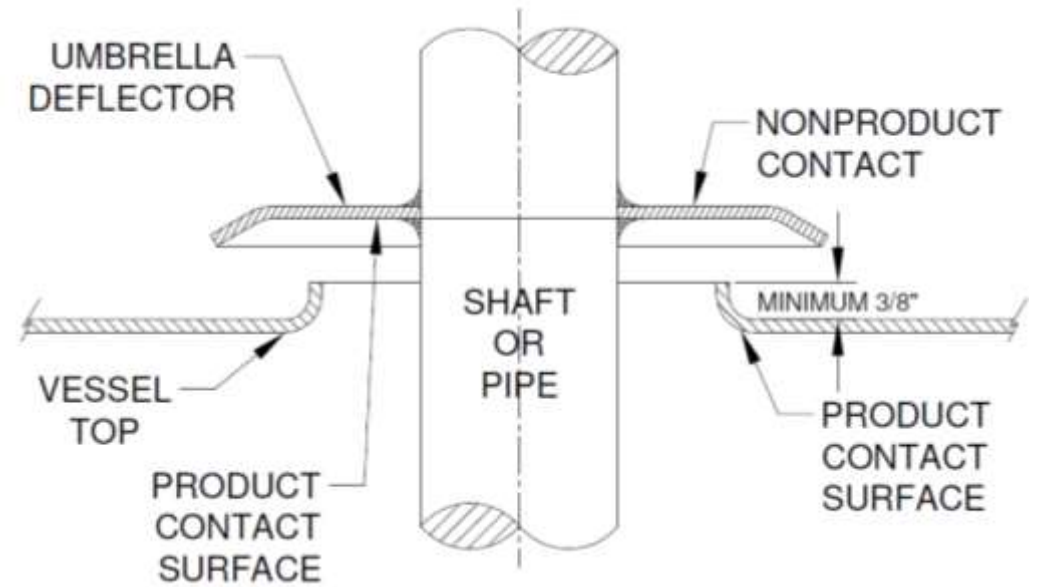


E6.1 Assure no dead ends greater than 2X nominal diameter or 5 inches

Pre-OP Findings



Pre-OP Findings



E14 Openings and Covers

Equipment Operation

Plant Sanitary Design Team

- Review **product formulation** projects
 - Changes in density, viscosity, inclusions, process temperatures,
- Review **productivity** projects
 - Changes in product flow, worker traffic, packaging material
- Review **maintenance** practices
 - Changes in maintenance frequencies, repair materials
- **Audit equipment and practices** to original or approved condition.

Equipment Operation

Additional Thoughts

- Training and qualification
 - Operator
 - Quality
 - Sanitation
 - Maintenance
- Vendor quotes – do they provide the right Sanitary Design for your product, sanitation method, maintenance capability?

Closing Thoughts

Plant and Process Design

- Build in proper precautions to protect food, food-contact surfaces, and food-packaging materials from contamination

Training and execution

- Employees trained and consistently follow GMP's
- Operators well trained on equipment operation and troubleshooting
- Operate, maintain and clean as designed

Sanitation

- Procedure used for cleaning and sanitizing is Validated and Verified
- Rigorous pre-ops for sanitary conditions

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AMI Facility Design Principles

PRINCIPLE 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.

PRINCIPLE 2: PERSONNEL & MATERIAL FLOWS CONTROLLED TO REDUCE HAZARDS

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

PRINCIPLE 3. WATER ACCUMULATION CONTROLLED INSIDE 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.

PRINCIPLE 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.

PRINCIPLE 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.

AMI Facility Design Principles

PRINCIPLE 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.

PRINCIPLE 7. BUILDING ENVELOPE FACILITATES SANITARY CONDITIONS

Design and construct all openings in the building envelope (doors, louvers, fans, 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.

PRINCIPLE 8. INTERIOR SPATIAL DESIGN PROMOTES SANITATION

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

PRINCIPLE 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.

PRINCIPLE 10. UTILITY SYSTEMS DESIGNED 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.

PRINCIPLE 11. SANITATION INTEGRATED INTO FACILITY DESIGN

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