Hygienic Design for Manufacturing Facilities & Equipment

DENNIS GROUP

Agenda

- Hygienic Design for Facilities
- Hygienic Design for Equipment
- 3rd Party Industry Standards

Hygienic Designs for Facilities

What is Hygienic (Sanitary) Design?

Design techniques applied to buildings, equipment, and processes to enhance cleanability to a microbiological level and help mitigate food safety risks.

Easy to clean, controls pathogens, & allows for less downtime for cleaning.

Hygienic Designs Are Directly Related to Regulations

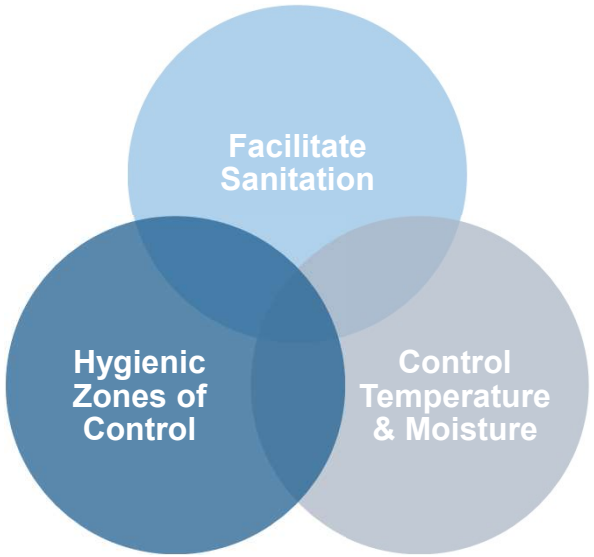
21 CFR Part 117 cGMP Categories

- Personnel
- Plant and grounds
- Sanitary operations
- Sanitary facilities and controls
- Equipment and utensils
- Processes and controls
- Warehousing and distribution

The regulation does not provide specifics.

+ Material characteristics
+ Equipment/ utility characteristics
+ Environmental characteristics

3 Themes of Sanitary Facility Design



Hygienic Zones of Control:

+ In order to eliminate cross contamination, define areas with different sanitary needs delineated by physical separations.

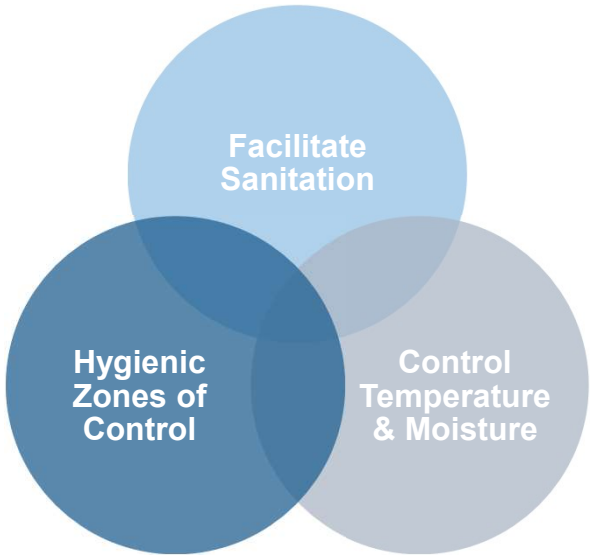
Control Temperature and Moisture:

+ By controlling water accumulation, room temperature and humidity, and air flow and quality, to prevent the survival, harborage, growth, and of microorganisms.

Facilitate Sanitation:

+ The facility should be easily cleanable to a microbiological level.

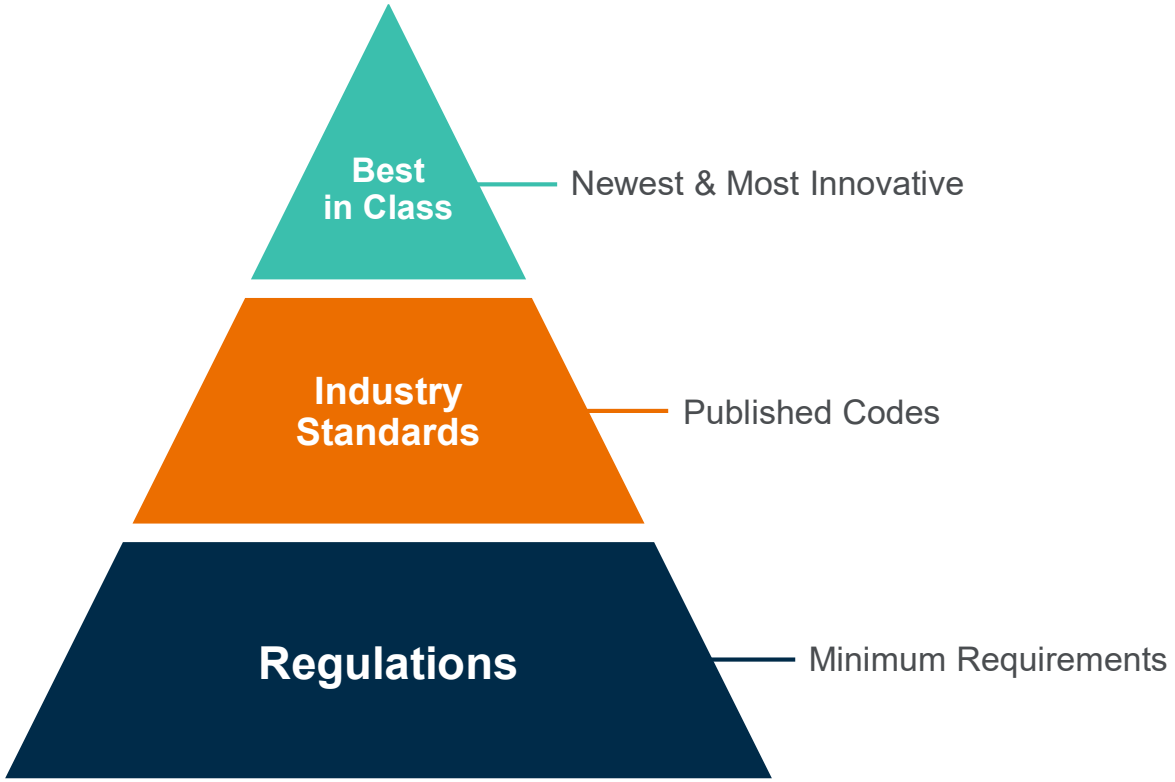
Sanitary Design Principles



North American Meat Institutes Sanitary Design Principles

1. Define Distinct Hygienic Zones
2. Control Flow of Materials & Personnel
3. Control Water Accumulation
4. Control Temperature & Humidity
5. Control Air Flow & Quality
6. Site Elements Facilitate Sanitation
7. Building Envelope Facilitates Sanitary Conditions
8. Interior Spatial Design Facilitates Sanitation
9. Building Components & Construction Facilitate Sanitation
10. Design Utility Systems To Prevent Contamination
11. Sanitation Integrated Into Facility Design

Levels of Hygienic Design



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Hygienic Zones of Control

Hygienic Zoning

Why is hygienic zoning important for facility design?

- Defines a space based on product risk
- Sets the baseline for sanitary design within each space
- Dictates the materials of construction within a space
- Assists with control of food safety hazards by controlling & maintaining hygienic zones
  - Easy to clean designs – reduction of threaded, nut/bolt connections
  - Stops the spread of pathogens from area to area
  - Reduces allergen cross contact
  - Limits the opportunity for cross contamination
  - Materials selected to last and reduce harborage zones

Hygienic Zone Classifications

Hygienic Zoning – the classification of rooms within a facility based on the food safety risk to the product

GMP High Care	GMP Medium Care	GMP Standard Care	Non-GMP/Utility
Any area with exposed ready to eat finished product.	Production spaces located before a kill step.	Areas in which raw materials and product is not exposed to the environment or foreign contaminates	Areas where no food production, packaging, or storage is occurring

Wet Clean Vs. Dry Clean

Maintaining Hygienic Zones

How does the facility maintain hygienic zones?

+ Reduce crossovers within the facility layout
+ Reduce traffic traveling through different hygienic zones
+ Separate raw and RTE
+ Separate unique allergens
+ Manageable path of travel

1/21/2025

Flows to Consider

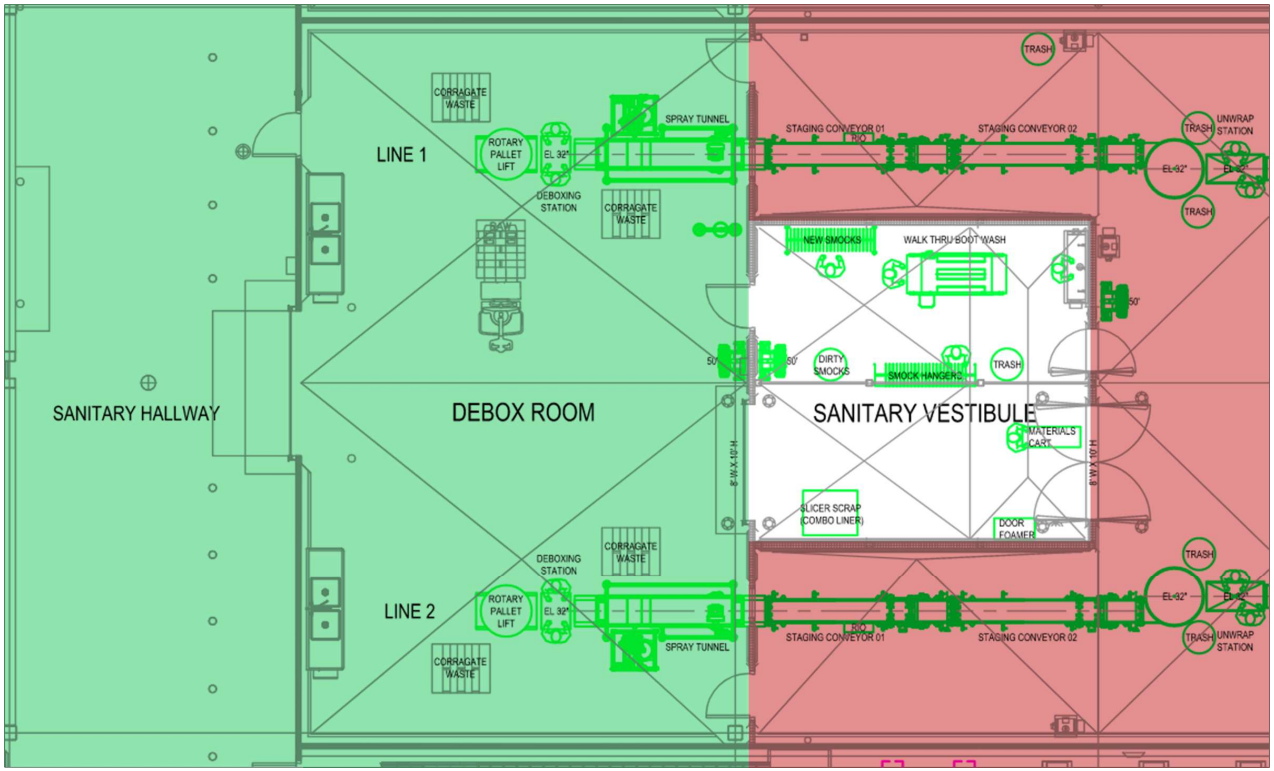
Material Flows	Personnel Flows	Alternate Flows *For Construction*
+ Raw ingredients, product, waste + RTE product + Allergens + Rework + Primary Packaging + Secondary/Tertiary Packaging + Waste	+ High Care personnel + Medium & Standard Care personnel + Management, QA, & Maintenance	+ Contractors + Materials for construction + Waste

Reduce Traffic Traveling Through Different Hygienic Zones

Sanitary vestibules or **transition zones**:

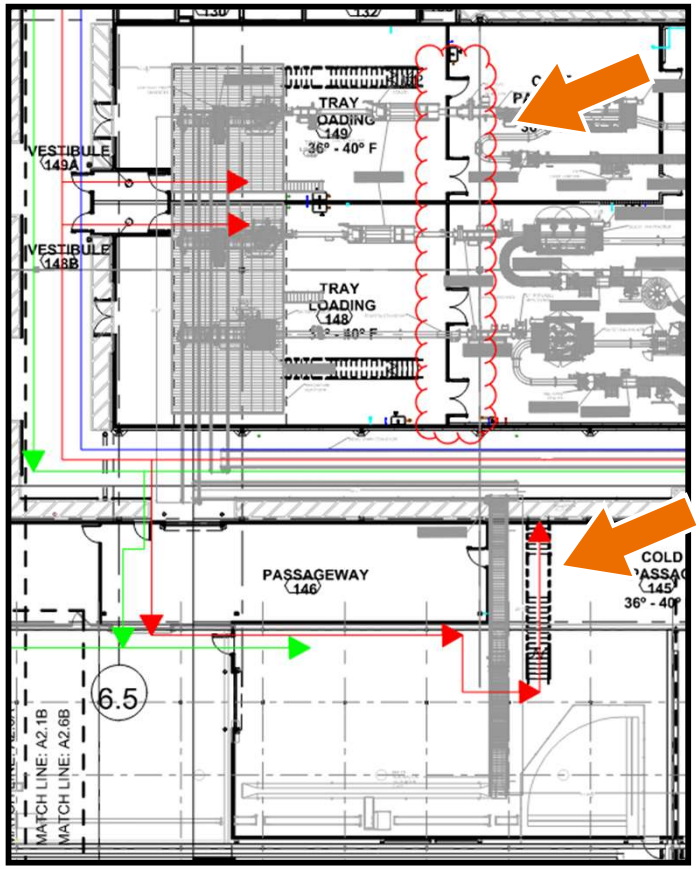
- Reduce environmental pathogens entering high care
- Controls floor conditions
  - Foot traffic
  - Wheel traffic
- Promotes good employee hygiene
  - Handwashing
  - Gowning
  - Gloves

Reduce Traffic Traveling Through Different Hygienic Zones



Reduce Traffic Traveling Through Different Hygienic Zones

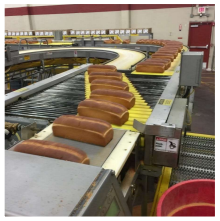
! SANITARY VESTIBULES CAN BE BYPASSED



Separate Unique Allergens

Storage

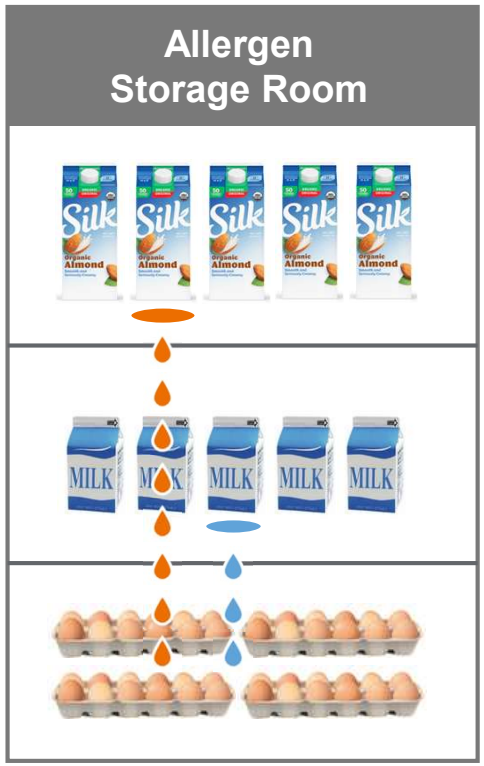
Handling



Processing

Allergens in Storage

What's wrong with this design?



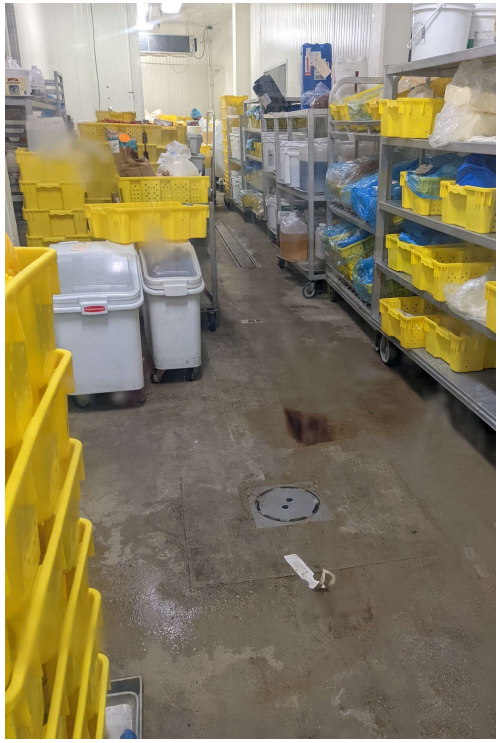
Damage to almond milk may contaminate **both milk & eggs**

Damage to milk may contaminate the **eggs**

Allergens in Product Handling

Secondary Ingredient Handling

- Where do the allergens go after the warehouse?
  - Supersack/ Bulk bag unloading stations
  - 50lb bag unloading stations
  - Drum pumps
  - Secondary totes and buckets
  - Directly to production lines
- How to control?
  - Employee practices
  - Separation or separate equipment
  - Color coding of scoops and containers
  - Portable or permanent dust collection systems



Allergens in Processing

Equipment, Conveyance, Rework, & Waste

- What is the allergen profile of the production line?
  - Shared equipment?
  - Cleanability?
- Are there walls between production lines?
  - For dusty processes or cleaning during production, this may be required.
- What is the path of travel?
  - Conveyance
  - Rework
  - Waste
- Is there adequate storage?

Sanitary Design Principles

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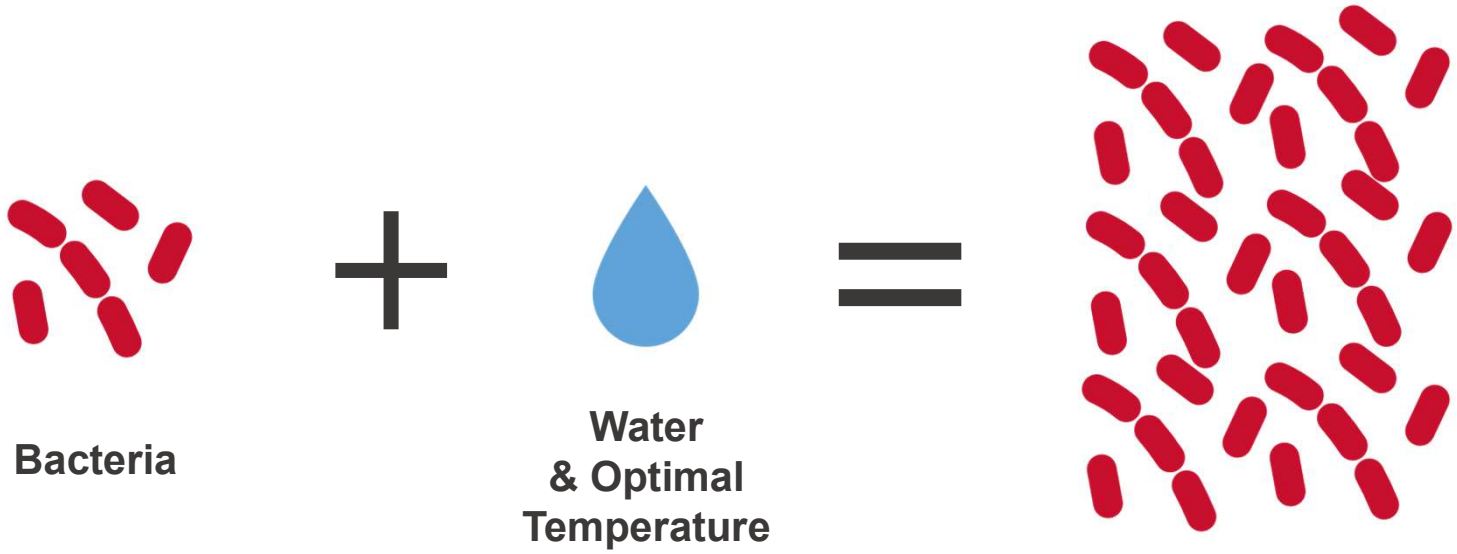
Control Temperature & Moisture

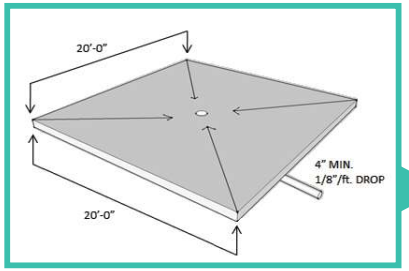
Why Control Temperature & Moisture?

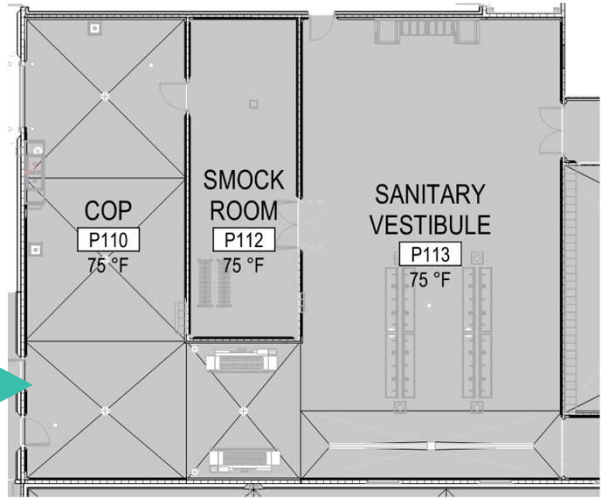


Designs to Reduce Water Accumulation

Flooring Features – Drain Design

- Floor is sloped to drain
- Equipment discharges are piped to drains with air gap
- Cleanable
- Suitable size for space
- Process waste lines are not connected to our sanitary waste lines





Photos from: https://foodsafedrains.com/

Trench Drain

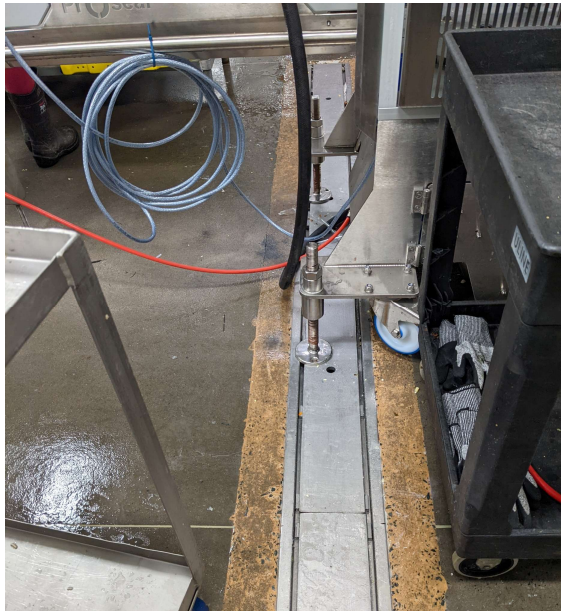
Slot Drain

Spot/Area Drain

Drain Considerations

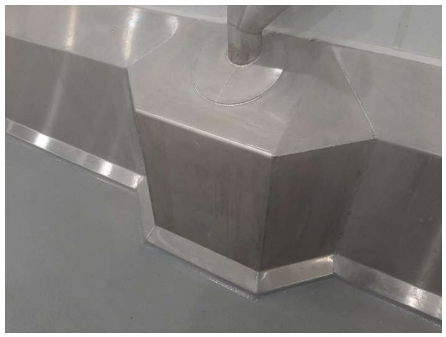
Do you see clogged piping?

Can it be accessed for cleaning?



Designs to Reduce Water Accumulation

Flooring Features





Designs to Reduce Water Accumulation

Reducing Flat Surfaces

Hover to magnify image or click to enlarge

Photo from: HyShed by Hoffman

Condensation Control

Condensation Control

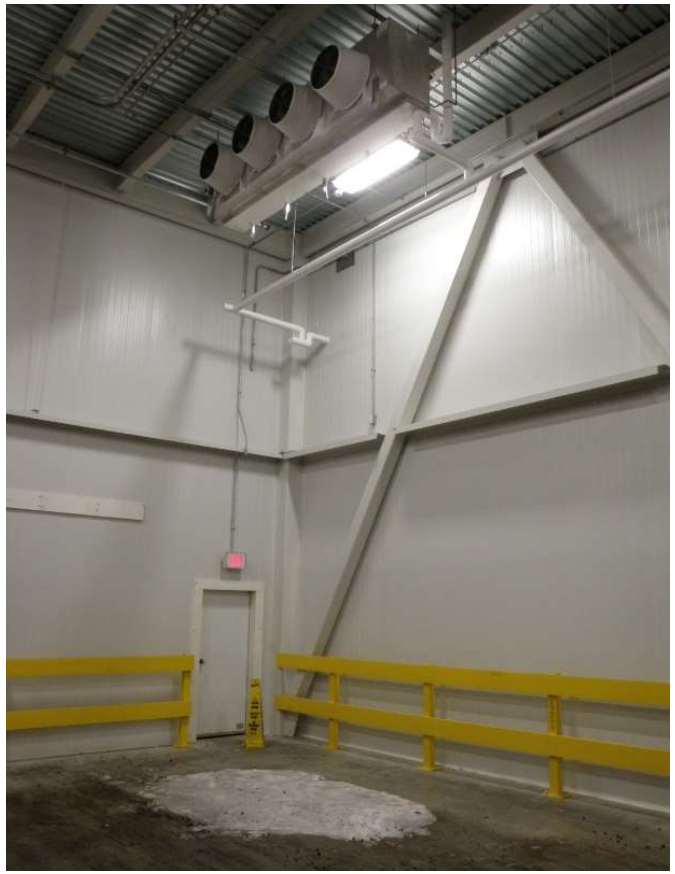
Beware of frost

- Freezing inhibits growth of bacterial or viral pathogens
- Improper process
- Poorly constructed or not maintained

Condensation & HVAC

Several factors affecting air handling units:

+ Lack of preventative maintenance
+ Doors being left open
+ HVAC not designed for space



Air Quality Considerations

Ways to spot check air quality during an inspection

- HVAC, Blower, Pneumatic, & Dehumidification systems
  - What is their preventive maintenance schedule for air filter changing and ask for the work orders showing the last 3 times they have been changed.
  - Look for signs of mold, mildew, or dust on the units
  - Air testing results
  - Mold complaints
- Where is air or steam introduced to the process?
  - Culinary steam (3A SSI standard)
  - Are sterile air filters at point of use? Ask for the work orders showing the last 3 times they have been changed.
  - Are air guns being used for cleaning?
  - Are there any compressed air or gas leaks?
  - Air testing at source and point of use

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Facilitate Sanitation

Building Envelope Facilitates Sanitary Conditions

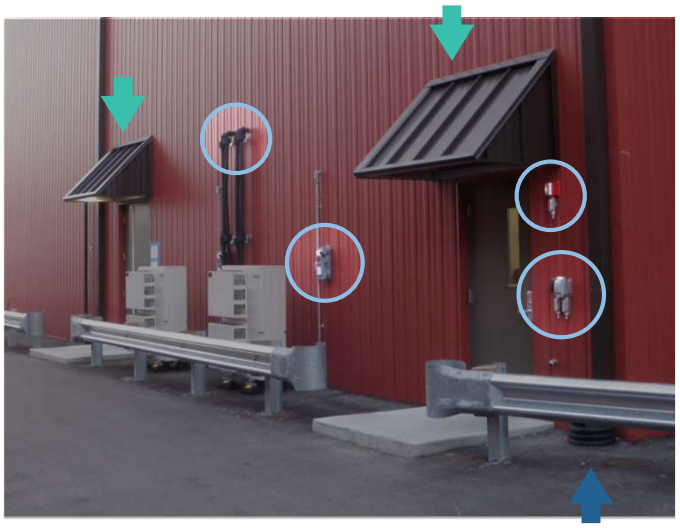
Exterior Elements

+ Design and build 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 build building envelope components to enable easy cleaning and inspection.

Entrance canopies sloped to prevent nesting & water accumulation

Roof sloped and drained off exterior of building

All voids were filled & sealed to prevent water damage and pest entry



Interior Spatial Design Promotes Sanitation

Spatial Design

FDA 21 CFR 117.20 Plant and Grounds

"…aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food, food-contact surfaces, or food-packaging materials with clothing or personal contact."

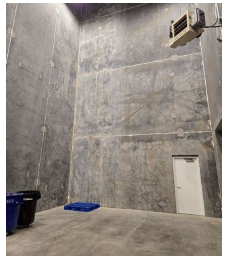
Building Materials

Common Materials Found in Food Production Areas

Building Components	Preferred Materials
Flooring	MRF, Vitreous Tile, Dairy Brick, Sealed Concrete, Epoxy Coated
Walls	IMP, Vitreous Tile, Precast Concrete, CMU
Ceiling	IMP, Prefabricated concrete, Drop ceilings
Doors	Solid metal or plastic (not hollow), No wood, No Glass
Light Fixtures	Shatter resistant bulbs, flushed mounted preferred
Interior Windows	Lexan panels flush mounted or pitched sill







What options are available for food manufacturers to use in their infrastructure?

Options for support materials

Strut

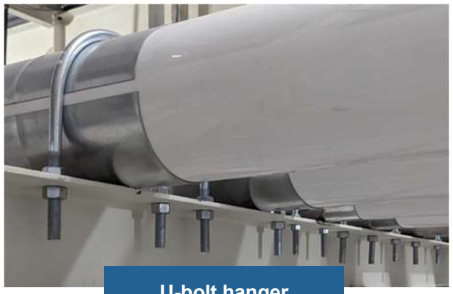
Pipe

HSS

Angle

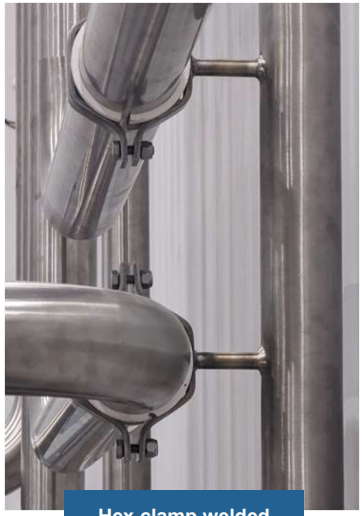
Options for Hangers/Attachments

How do we support and hang pipes?



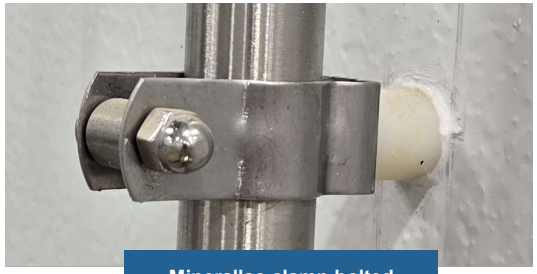
U-bolt hanger attached to I beam

Behringer clamp welded to HSS



Hex clamp welded to pipe

Syntiro Zero Puddle Hanger attached to equipment



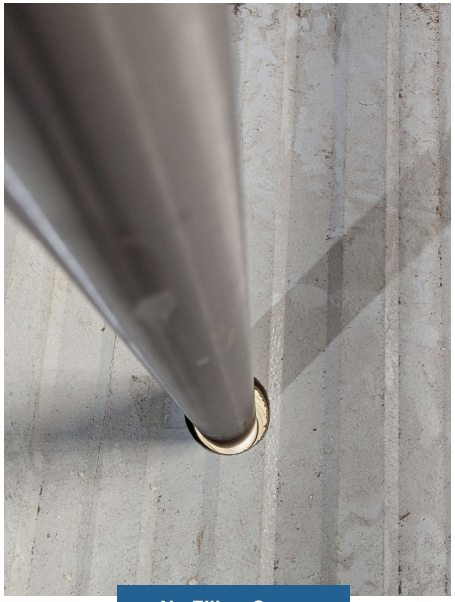
Minerallac clamp bolted to IMP wall with spacers

Options for Penetrations

How do I cut through the walls and ceilings?

Pipetite

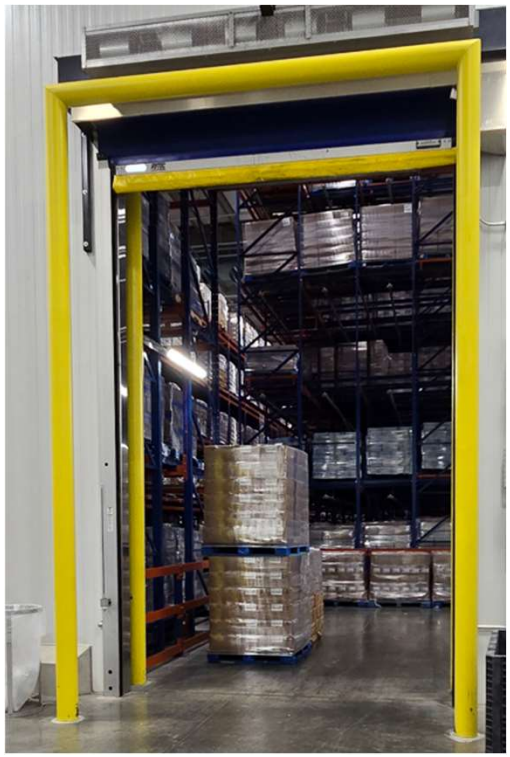
Escutcheon Plate



No Fill or Cover

Options for Barriers

Painted metals vs. stainless steel

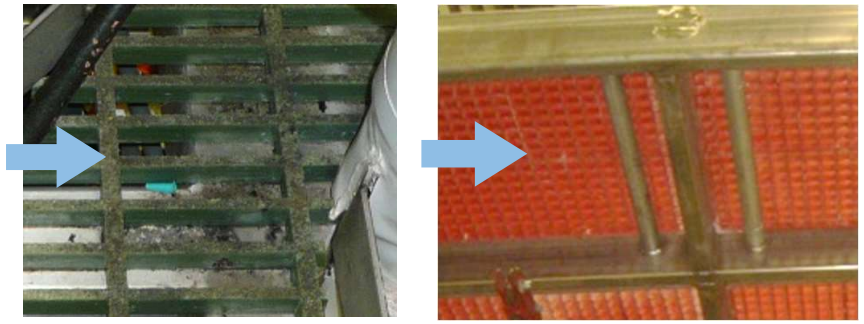


Options for Working Platforms

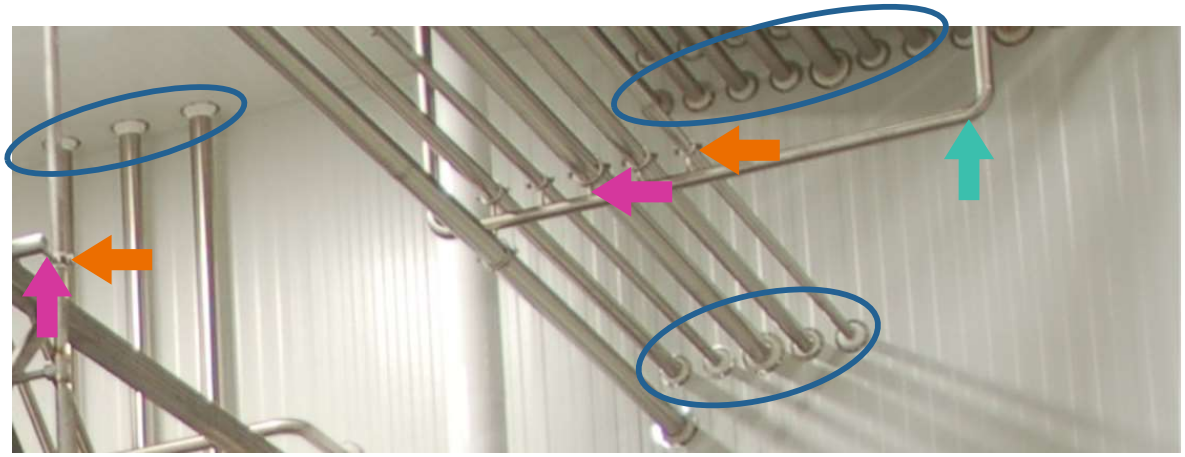
- Use materials suitable for wash-down
- Avoid debris collection
- Slope horizontal surfaces whenever possible
- Use solid decking above open product and slope to drain

Handrails continuously welded & ground smooth. Kick plates welded to handrails above deck.

Grating supported by pipe can drain better and prevent microbiological growth



Is Construction Suitable for the Hygienic Zone?



STAINLESS STEEL

HSS/PIPE

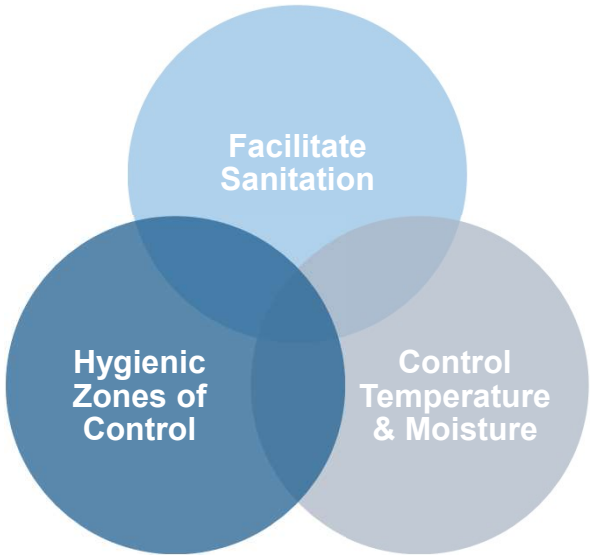
SMOOTH ROD

PIPETITE

HEX

MATERIALS OF CONSTRUCTION	HYGIENIC ZONE DESIGNATION						
	GMP HIGH CARE DRY	GMP HIGH CARE WET	GMP MEDIUM CARE DRY	GMP MEDIUM CARE WET	GMP STANDARD CARE DRY	GMP STANDARD CARE WET	NON-GMP/ UTILITY
ACCEPTED SUPPORT MATERIAL:	GALVANIZED STEEL	STAINLESS STEEL	GALVANIZED STEEL	STAINLESS STEEL	PRIMED CARBON STEEL	STAINLESS STEEL	PRIMED CARBON STEEL
TRAPEZE TYPE:	HSS / PIPE	HSS / PIPE	ANGLE	ANGLE	ANGLE	ANGLE	STRUT
SUPPORT RODS:	SMOOTH ROD	SMOOTH ROD	SMOOTH ROD	SMOOTH ROD	SMOOTH or ALL-THREAD	SMOOTH or ALL-THREAD	ALL-THREAD ROD
PENETRATION TYPE:	PIPETITE	PIPETITE	ESCUTCHEON PLATE	ESCUTCHEON PLATE	ESCUTCHEON PLATE	ESCUTCHEON PLATE	
CLAMPS:	HEX	HEX	HEX	HEX	TRADE SPECIFIC	TRADE SPECIFIC	TRADE SPECIFIC
SPECIALIZED COMMENTS:							

Summary



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Hygienic Designs for Equipment

Steps for Reviewing Equipment

1. Define Product Contact & Non-Product Contact Surfaces
2. Determine Cleaning Methods
3. Determine Approved Materials of Construction
4. Evaluate for Food Safety Hazards

1. Determine Product Contact & Non-Product Contact Surfaces

Product Contact Surfaces

+ Most controlled area is where the product can touch
+ Consider all angles
+ Must meet regulatory requirements for these surfaces.

Non-Product Contact Surfaces

+ Includes all remaining parts of the equipment
+ The closer to product contact, the higher the sanitary requirements

2. Determine Cleaning Methods

How will the equipment be cleaned?
What chemicals will be used?
How easy is it to clean after install?

Cleaning Methods	Made to be Cleanable	Installed to be Cleanable
+ CIP System	+ Accessibility	+ Access
+ COP Sink	+ Spacers	+ Clearances
+ Dry Clean	+ Disassembly requirements	
+ Wet Clean	+ Cleaning Time	
+ Manual Clean	+ Niches	
+ Tunnel Washer	+ Reassembly	

3. Determine Materials of Construction

+ Choose materials based on operational environment and intended use.
+ Materials must maintain its characteristics during the life of the equipment and not become a source of contamination.
+ Food contact surfaces & equipment must meet regulatory requirements.

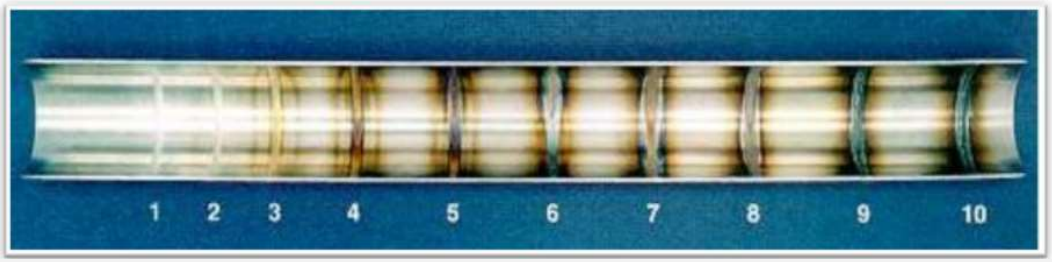
Smooth	Impervious	Free of cracks and crevices
Nonporous	Nonabsorbent	Non-contaminating
Nonreactive	Corrosion resistant	Durable
Maintenance free	Nontoxic	Cleanable

3. Determine Materials of Construction

Metals	Applications
Stainless Steel	Preferred metal for food contact surfaces because of its corrosion resistance and durability.
Cast Iron	Occasionally used for frying and cooking surfaces
Aluminum	Baking trays, cooking surfaces
Copper, Brass, & Bronze	Primarily used in brewing and piping for air/water in non-wash areas.
Titanium	Used in highly corrosive environments, high acid products, or high salt products (tomato processing)
Carbon Steel	Never use as a food contact surface
Galvanized Steel	Never use as a food contact surface

3. Determine Materials of Construction

All welds should be ground & polished to a minimum #4 finish.



From the AWS D18.1/D18.2 standards for austenitic stainless steel piping in food & dairy

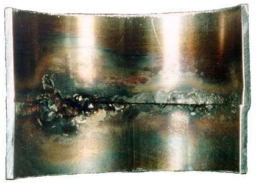
A series of orbital welds on the ID of a 316L stainless steel tube

These welds were purged on the ID with argon gas containing oxygen as a contaminant ranging in concentrations from 10 ppm (sample 1) to 25,000 ppm (sample 10).

Sample numbers greater than four have typically been considered unacceptable.

NOT ACCEPTABLE

This weld is "sugared"



Manual weld taken from an operating plant. This weld has defects which include lack of penetration, misalignment, a huge crevice, and discoloration due to poor ID purge.

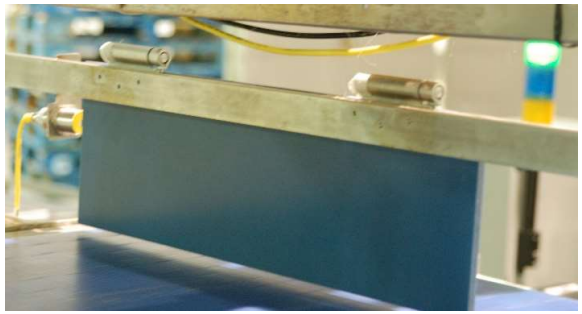
ACCEPTABLE

for food, dairy, & beverage

An orbital weld on 316L electropolished stainless steel. The weld is fully penetrated with a uniform crevice-free inner weld bead with good alignment. The ID was purged with argon containing 8 ppm of oxygen which resulted in slight discoloration.

3. Determine Materials of Construction

Non-Metals	Applications
Plastics *(Nylon, UHMW, Polyethlyene)*	Gaskets, seals, scrapers, tools, conveyor belts ***Food Grade formulas only***
Ceramics	Membrane filtration
Glass	Inspection windows, dial covers, optical sensors ***Always use plastic options first***
Rubbers/Elastomers *(Nitrile, Silicone, EPDM)*	Gaskets, seals ***Food Grade formulas only***



3. Determine Materials of Construction

COMMON MATERIAL FAILURES		
METAL	**PLASTIC**	**ELASTOMERS**

+ Galling
+ Corrosion
+ Surface Wear
+ Mechanical Failure
	+ Mechanical Failures
	+ Thermal Failures
	  + Extreme heat = melts
	  + Extreme cold – brittle & cracks
	+ Chemical Failures
	  + Solvents
	  + Ozone
	+ Environmental failures
	  + UV
	  + Heat
	  + Pollution
		+ Over compression
		+ Chemical degradation
		+ Swelling
		+ Heat aging
		+ Tears & crevices
		+ Ozonolysis & Oxidation

^ https://www.elastoproxy.com/rubber-gaskets-fail/
< https://www.plasticexpert.com/learn/c900-pvc-pipe-failure/

4. Evaluate Design for Food Safety Hazards

Consider

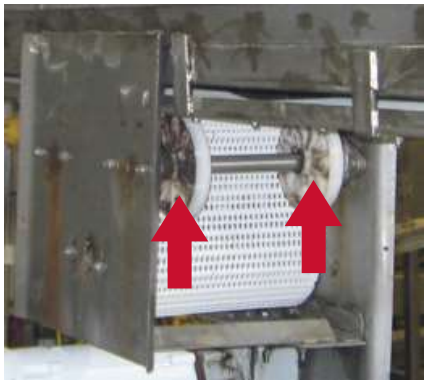
+ **Biological** – Opportunity for water build up & bacterial growth?
+ **Chemical** – Does machine oil have opportunity to get into product stream?
+ **Physical** – Metal on metal risk? Bolts used rather than welds?

Eliminate sources of hazards

+ Flat surfaces
+ Ledges
+ Niches
+ Hollows
+ Rough surfaces
+ Corrodible
+ Permeable

Biological Hazards

Physical Hazards



3rd Party Standards

“Approved” Equipment & Products

Examples

Is This Construction Suitable for High Care?

✓ Equipment in good condition

✓ Drop ceiling is in good condition

X Peeling paint and corrosion

X Floor coating is damaged

X Drains in poor condition & clogging in some areas

Is This Construction Suitable for High Care?

X **Production environment has not been cleaned at an adequate frequency**

X **Signs of condensation**

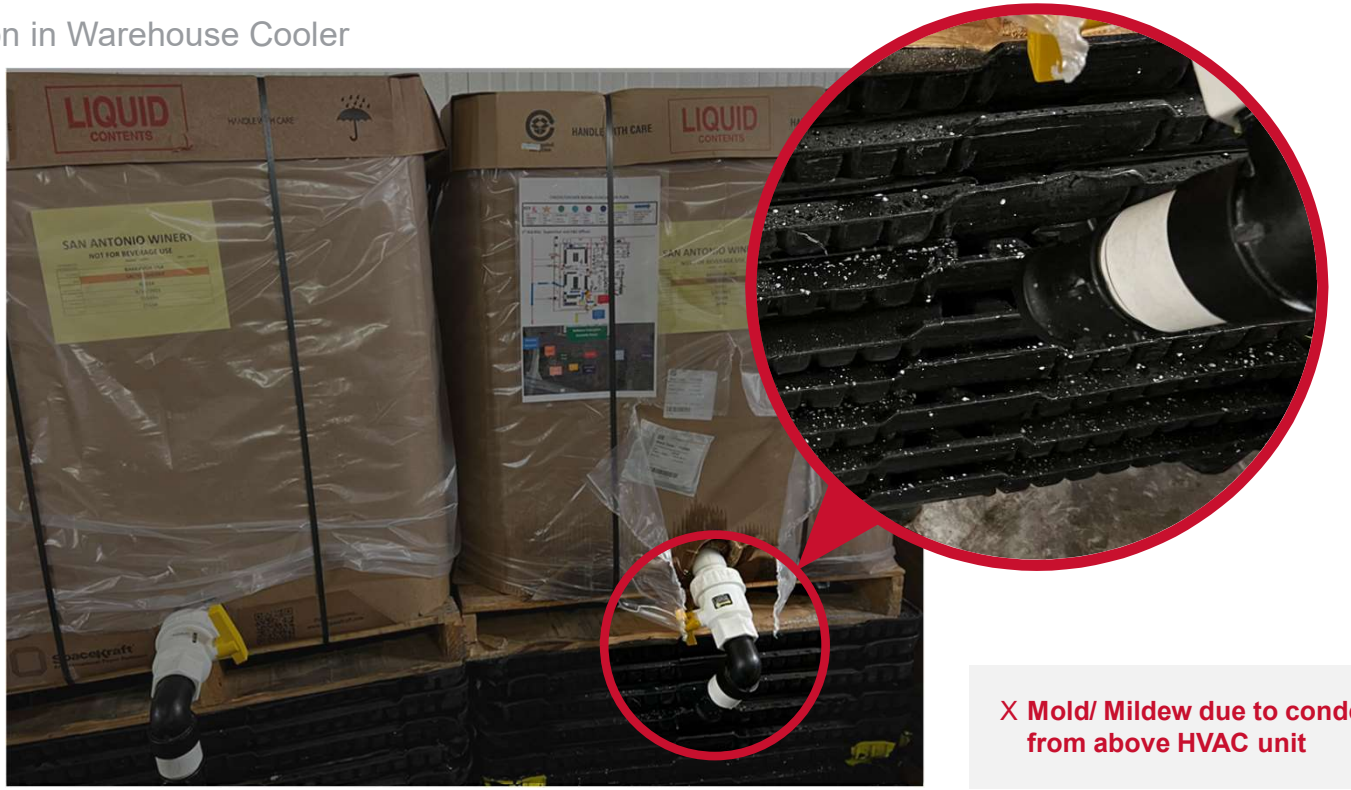
Is This Construction Suitable for Medium Care?

- X Cockroach present in a raw processing area
- X Cheapest design installation options utilized*
  - X Struct support with channels and holes
  - X Plastic controls cabinet without a pitched top, discolored from sanitation chemicals
  - X Rust on the washer
- X Many painted elements within a washdown space

*The cheapest materials can be used if they are maintained.

Is This Construction Suitable for Standard Care?

Condensation in Warehouse Cooler



X Mold/ Mildew due to condensation from above HVAC unit

Is this Suitable for the Exterior of a Food Plant?

Have you asked someone other than a FS&Q Manager about these GMPs?

- X **Overgrown vegetation – ants, rodent activity**
- X **Poor water drainage flooding into dry warehouse**
- X **Storing new equipment outside – introduction of biological hazards, pest activity**

Thank You!

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