THE SANITARY DESIGN WORKSHOP

BEMA

THE SANITARY DESIGN WORKSHOP

Equipment & Plant Design
For Allergen/Pathogen Control in Low Moisture Foods

Part 2:
Food Safety, Product Quality & Sanitary Design Risks

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Sanitary design is integral to food safety.

Orientation and Framing

- *Why sanitary design exists*
- Sanitary design as risk control
- What Risks Addressed ≠ How To

Orientation and Framing

Preventing risks introduced by design

Design Decisions

Sanitation

Enable

Permanently Limit

What Sanitary Design Does and Does Not Do

Does	Does Not
Makes equipment easy to clean correctly	Replace sanitation programs
Prevents design-created failure modes	Eliminate the need for discipline and verification
Supports sustainable food safety and quality outcomes	Guarantee food safety outcomes on its own

Relationships

Design

- Easy or hard to clean

Sanitation

- Sanitation reaches all surfaces with effective methods

FS Outcomes

- Safe

Why Not SSOPs?

Why procedural controls alone are not sufficient?

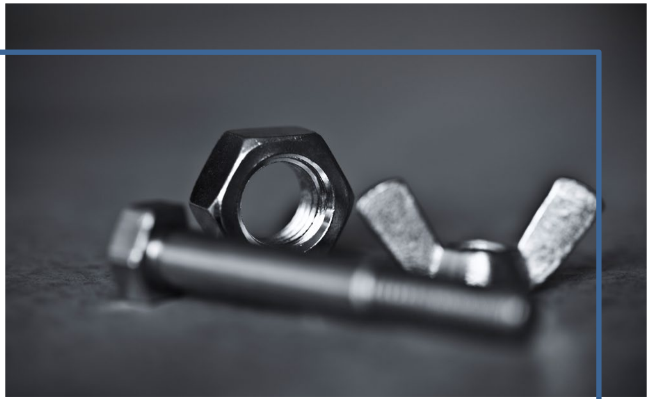
- Procedure cannot overcome every challenge
  - Can’t see it, can’t reach it, can’t clean it
- Procedures are not followed every time by people
  - Variable training, staffing, motivation
- Tools and chemistry can change
  - Too much or too little

You can not sanitize your way out of a poor design

Risk Categories Addressed by Sanitary Design

Microbiological

Chemical



Physical

Risk Categories Addressed by Sanitary Design

Poor design can protect microorganisms from sanitation and inspection

Microbiological

Sanitary design determines whether microorganisms can persist, survive, or be eliminated

Microbiological Risk – The Core Hygienic Design Driver

Sanitary design influences microbiological risk through four key concepts:

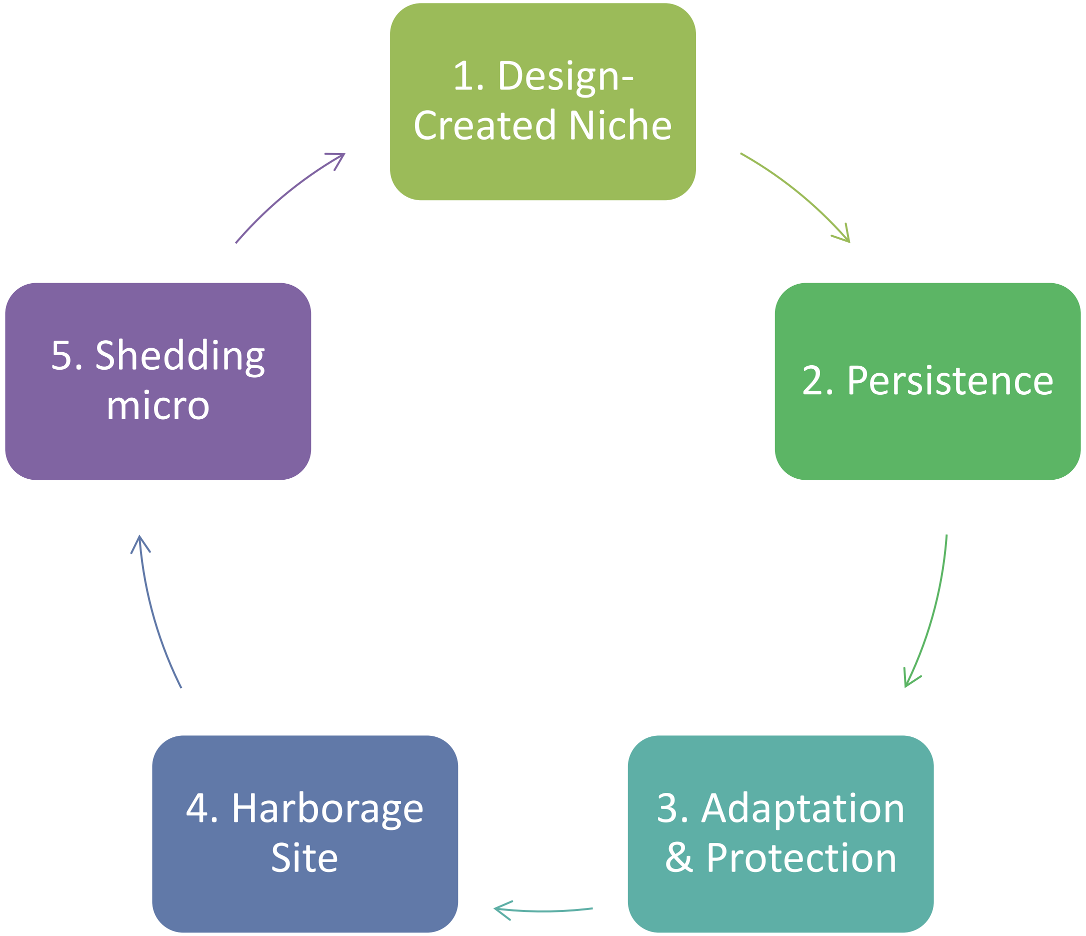
1. Pathogens and Spoilage: Different Outcomes, Same Design Problem
2. Niche → Persistence → Harborage Model
3. Why Corrective Actions Fail When Design Is Poor
4. The Hidden Risk Problem: Accessibility & Inspectability

Pathogens and Spoilage

Different risks. Same microorganisms. Same design problem.

- **Pathogens**: Low numbers can cause serious illness or death
- **Spoilage organisms**: Higher numbers cause product failure and consumer dissatisfaction
- Good sanitary design **limits persistence of *any* microorganism**—reducing both risks

Harborage Model



1. Niche: Protected from sanitation and inspection
2. Persistence: Repeated survival in the same location
3. Adaptation: Increased protection through aggregation or biofilm formation
4. Harborage: Established, difficult-to-remove microbial population
5. Shedding: Overcrowded microorganisms leave the area

What is a niche?

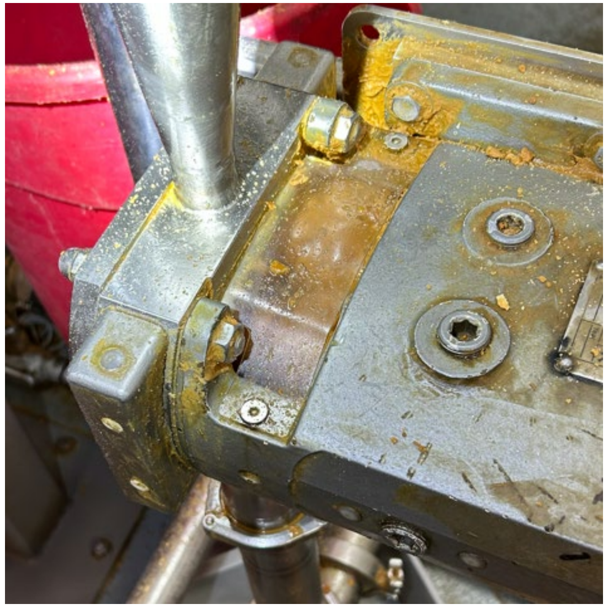
A niche is a location created by poor sanitary design where microorganisms are protected from normal controls.

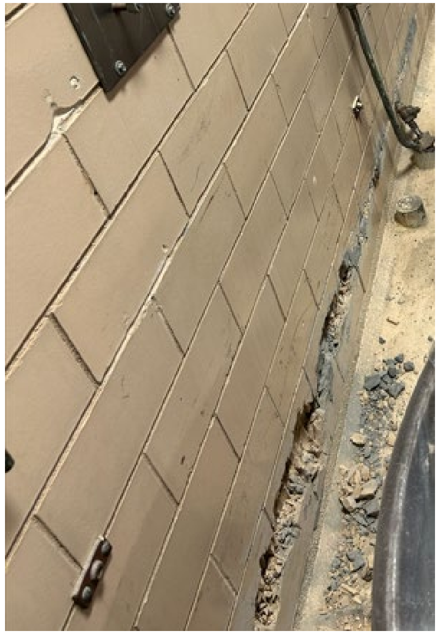
- Protected from sanitation (chemistry, action, or contact is limited)
- Protected from inspection (cannot be easily seen, accessed, or verified)
- Able to remain wet, dirty, or undisturbed long enough to allow survival

How Niches are Created

Niches are created when sanitary design allows surfaces or spaces to escape routine cleaning and control

- Limited access for cleaning, inspection, or verification
- Retention of moisture or product due to poor drainage or geometry
- Surface conditions that trap debris (rough finishes, poor welds, damage)





Persistence vs Growth

Once a niche exists, microorganisms may either persist or grow

- **Persistence**: Low-level survival in the same location over time
- **Growth**: Increasing populations as conditions support multiplication
- **Growth accelerates risk** by increasing resistance, detectability, and impact

Harborage Sites

A harborage site forms when microorganisms persist and adapt within a design-created niche

- Repeated survival allows populations to stabilize or increase
- Protective mechanisms reduce the effectiveness of normal sanitation
- Elimination often requires design change, not more cleaning

Repeated microbiological findings are often a design signal, not a sanitation failure

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Why Corrective Actions Fail When Design Is Poor

- Typical escalation path:
  - More cleaning
  - More chemicals
  - More time
- Why these often fail - sanitary design prevents effective access and control
  - Escalating sanitation does not reach the root cause
  - Chemistry, time, and effort increase—but effectiveness does not
  - Design limitations force extreme or disruptive interventions
- What happens instead:
  - Tear-downs
  - Modifications
  - Gas / heat treatments*
  - Production disruption

* These are extreme measures used when design-created microbiological harborage defeats normal sanitation

The Hidden Risk Problem: Accessibility and Inspectability

Bad sanitary design can hide risk by limiting access for cleaning/inspecting

- Inaccessible areas cannot be reliably cleaned or inspected
- Hidden niches delay detection, allowing problems to persist or escalate
- Lack of visibility undermines confidence in sanitation effectiveness

Risk Categories Addressed by Sanitary Design

Chemical

Chemical Risks Influenced by Sanitary Design

1. What is a chemical risk and how is it different from Micro risk
2. Allergen Carryover as a Design Risk
3. Material Selection: Chemical & Micro Risk Multiplier

Chemical risks matter in sanitary design because sanitation programs optimized for microbiological control may not remove retained chemical residues. Poor design can allow allergens or sanitation chemicals to hang up or degrade materials, turning the cleaning process itself into a source of contamination.

What is a Chemical Risk and Differences

Chemical risks behave differently than microbiological risks and require different design thinking

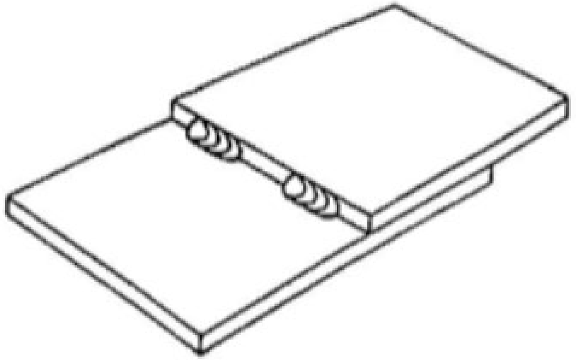
- Microorganisms multiply; chemical hazards persist and transfer
- Poor hygienic design can trap allergens or sanitation chemicals even after cleaning
- In these cases, sanitation chemistry itself can become the source of contamination

Microbiological	Chemical
Living organisms	Residues / substances
Can grow & multiply	Do not grow
Respond to kill steps	Respond to removal & compatibility
Controlled by eliminating niches	Controlled by eliminating retention

Allergen Carryover as a Design Risk

Allergen carryover is often inherited from poor sanitary design

- Dead-ends, poor access, and surface conditions trap allergens
- Cleaning effectiveness is limited by design - “Can’t sanitize allergens”
- Design constraints—not sanitation effort—often drive recurrence



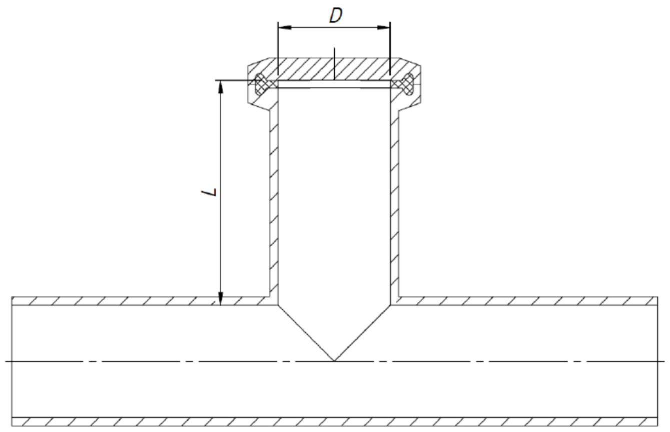
Sanitation Failure ≠ Sanitation Fault

Photos: Credit 3A and OpX

Chemical Residue Retention

Poor sanitary design can cause chemicals to be retained and transferred into product

- Design features can allow sanitation or processing chemicals to hang up instead of self-draining
- Retained chemicals may be released during subsequent production, contaminating product streams
- Inspection and verification are critical because residues may not be visible after cleaning



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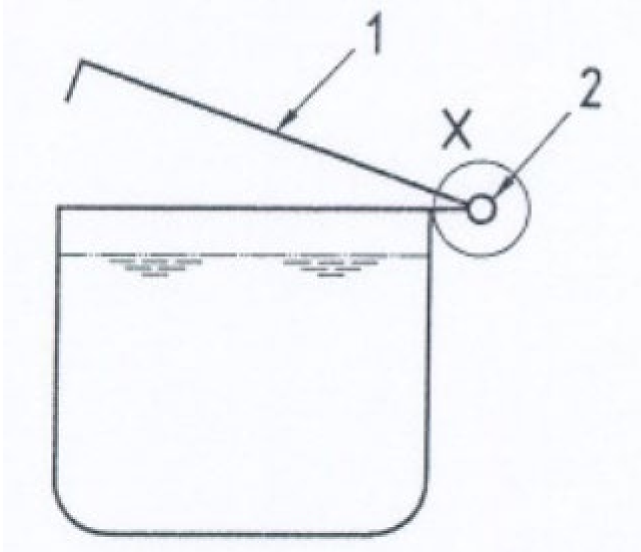
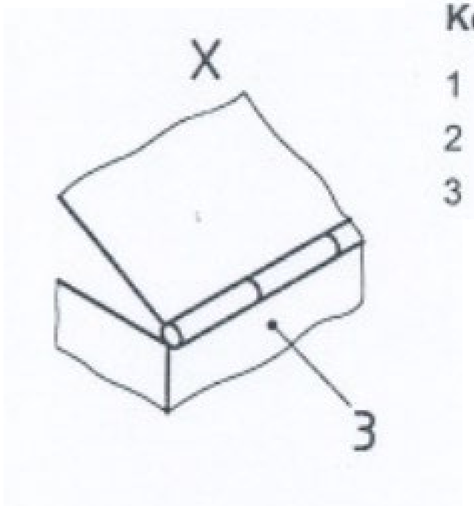
Not to exceed 5" (127 mm)





Key

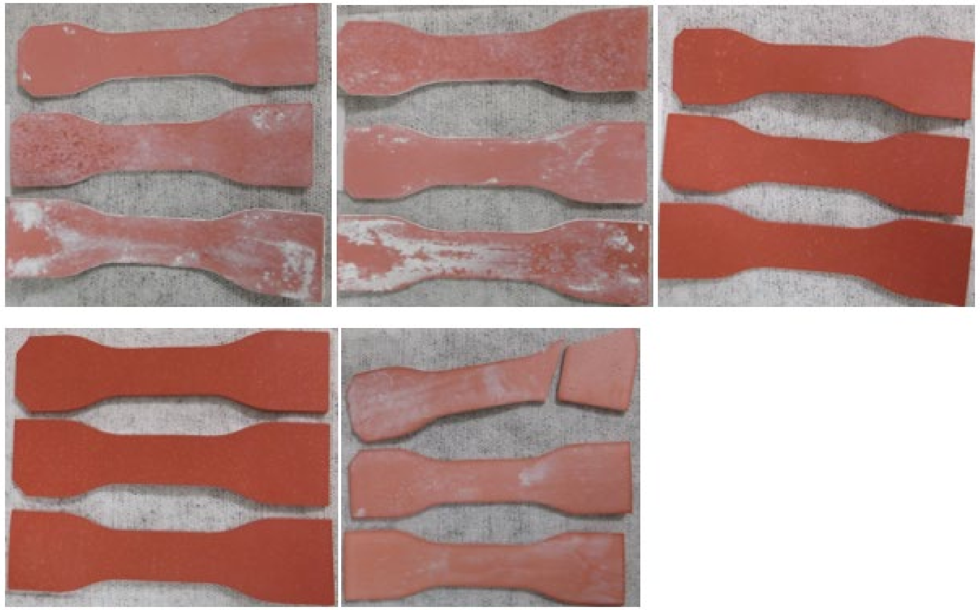
1 Pivoted cover
2 Hinge
3 Head area

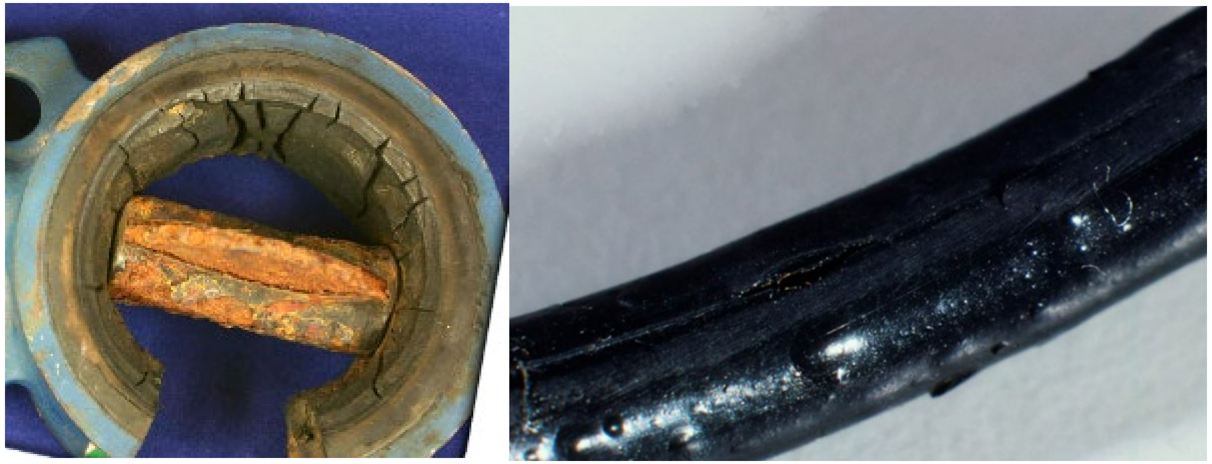
Images: Credit 3A General Requirements and ISO 14159

Material Degradation: Chemical & Micro Risk Multiplier

Improper material selection can create chemical hazards and amplify microbiological risk over time

- Incompatible materials may leach chemicals into food or beverages
- Degradation can create cracks, pits, or rough surfaces that trap product and moisture
- Degraded coatings or materials may detach or dissolve, directly contaminating product





Chemical Attack

Risk Categories Addressed by Sanitary Design

Physical

Physical Hazards & Sanitary Design

Physical hazards are influenced by sanitary design through how equipment fails, wears, and is maintained

In the next few slides, we will discuss:

- **What** physical hazards are and how they differ from chemical and microbiological risks
- **Why** physical hazards belong in hygienic design, not just detection programs
- Designing for **foreseeable** failure to prevent hazards from entering product
- **Cascade** failures, where one design issue leads to multiple downstream risks

What is a Physical Hazard and How Is It Different?

Physical risks involve solid objects entering food due to breakage, wear, or poor design

- Physical hazards do not grow like microorganisms or persist like chemical residues
- Poor hygienic design can introduce or amplify physical risk by allowing parts, welds, or materials to detach and follow the product stream
- Designing for foreseeable failure is critical to controlling physical risk

Good design can determine if a failure is a hazard – or a maintenance issue

Why Physical Hazards Belong in Hygienic Design

Myth	Reality
• Physical hazards are random events managed by detection and maintenance	• Design decisions often determine whether a failure becomes a food safety hazard

WHY THIS BELONGS IN HYGIENIC DESIGN

- Geometry, access, and containment define failure outcomes
- Poor design allows foreseeable failures to enter product
- Hygienic design reduces risk before detection is needed

Designing for “If It Breaks”

If a component fails…

- Where does it go?
- Can it be contained?
- Can it be detected before product contact?

Failure

Contained / drained

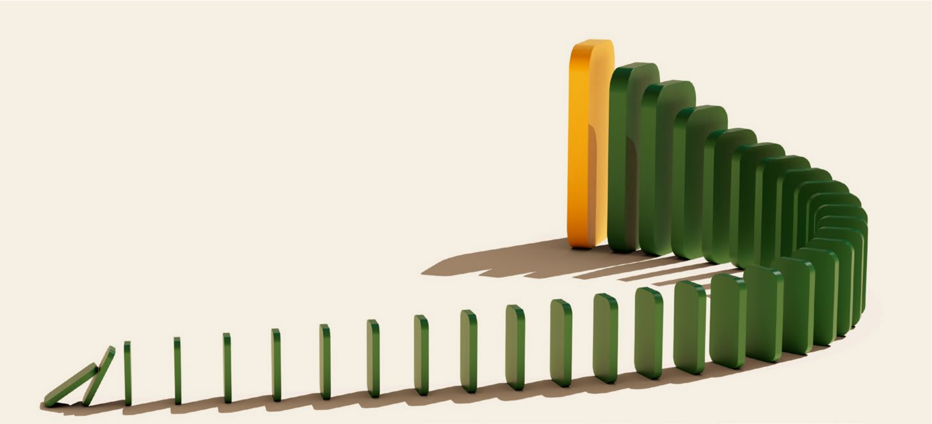
Product Stream

Gravity Paths
Smooth product contact surfaces
Minimizing detachable items
Fastener orientation and retention

Cascade Failures

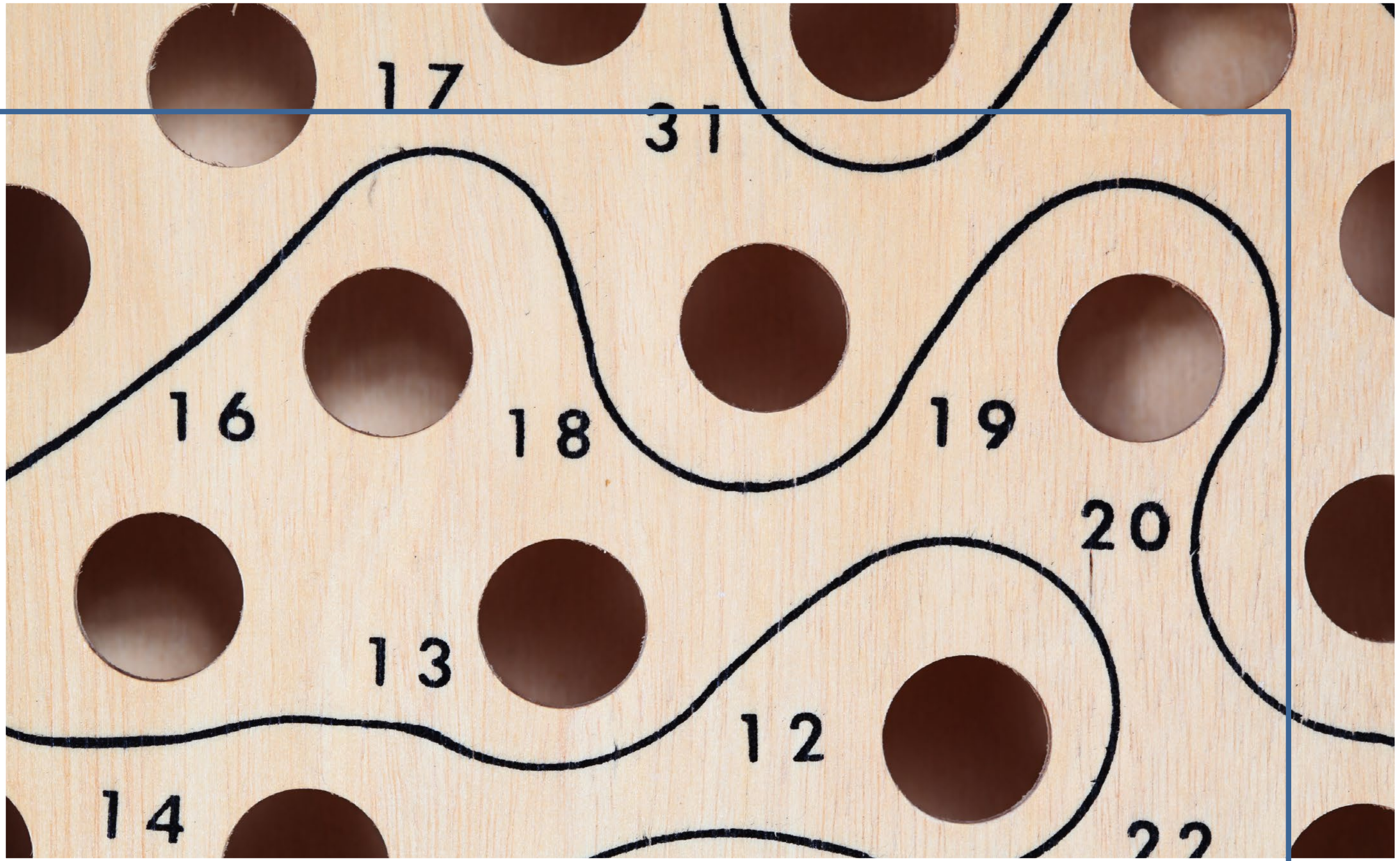
One design failure can trigger multiple downstream risks

- Example cascade:
  - Minor wear, loosening, or breakage occurs
  - Bolt falls into product stream and gets caught in pump
  - Pump drives the bolt into the housing causing metal wear and grooves the housing
  - The bolt is free, but the scored housing is a niche that becomes a harborage point
  - Micro counts start to increase as biofilm starts to develop in the harborage
  - Eventually spoilage complaints increase for that line



Small design gaps can drive disproportionately large consequences

Other Risk Categories: Impacted by Sanitary Design

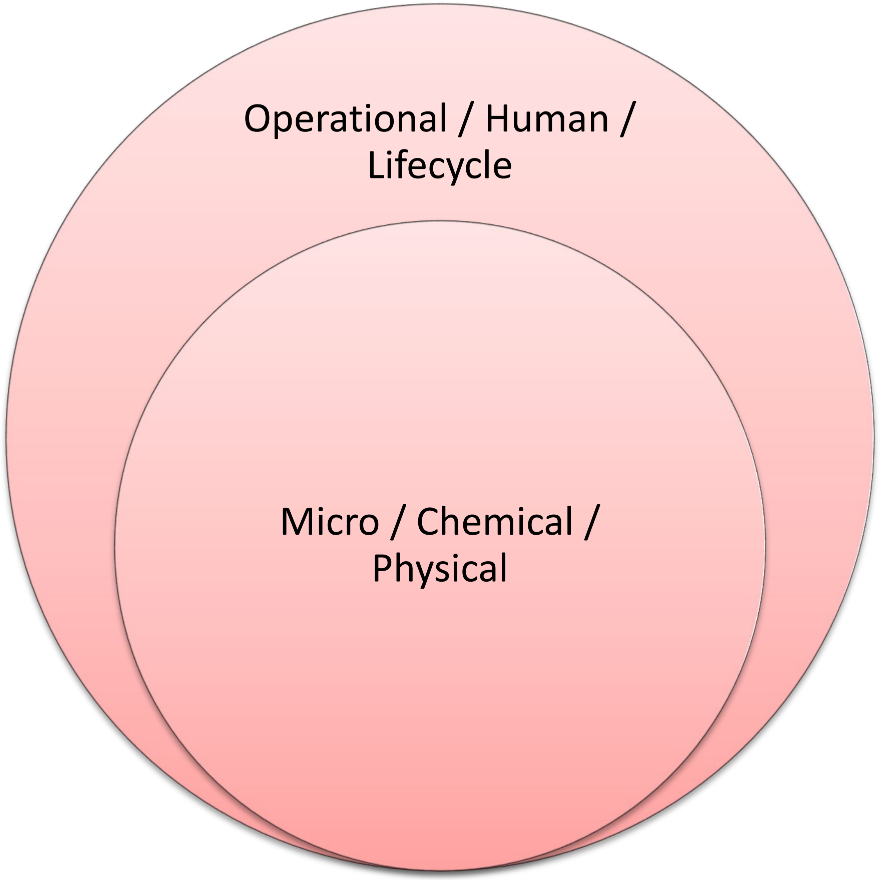


Other Pitfalls

Additional Risks Impacted by Sanitary Design

Successful sanitary design requires balancing core food safety risks with three additional design considerations

- Operational & Reliability Risk
  - Design choices influence uptime, clean-in-place effectiveness, and whether systems perform consistently under real operating conditions
- Human Factors & Behavioral Risk
  - Designs that are difficult to access, clean, or understand increase reliance on workarounds and inconsistent execution
- Maintenance & Lifecycle Risk
  - Equipment changes over time; designs must remain hygienic through wear, repair, and modification



Operational & Reliability Risk

- Designs must function reliably under real operating conditions:
  - Poor reliability drives workarounds, deferred cleaning, or skipped steps
  - Excessive downtime or complexity can undermine sanitation effectiveness
  - Operationally robust designs support consistent control of food safety risks

If a system can't run or clean reliably, hygienic design breaks down.

Human Factors & Behavioral Risk

Design influences how people actually work, not how procedures are written

- Difficult access or awkward tasks increase variability and shortcuts
- Designs that rely on "**heroic sanitation**" are rarely sustainable
- Best designs make the **right behavior the easiest behavior**

Maintenance & Lifecycle Risk

Equipment does not stay "as designed" over its lifetime

- Wear, repairs, and modifications can introduce new sanitary risks
- Inaccessible or fragile designs degrade faster over time
- Hygienic design must remain effective through maintenance and change

Design success is measured over years, not at installation

Balancing Risk Reduction vs Cost, Complexity, and Scale

Reduce the *right* risks

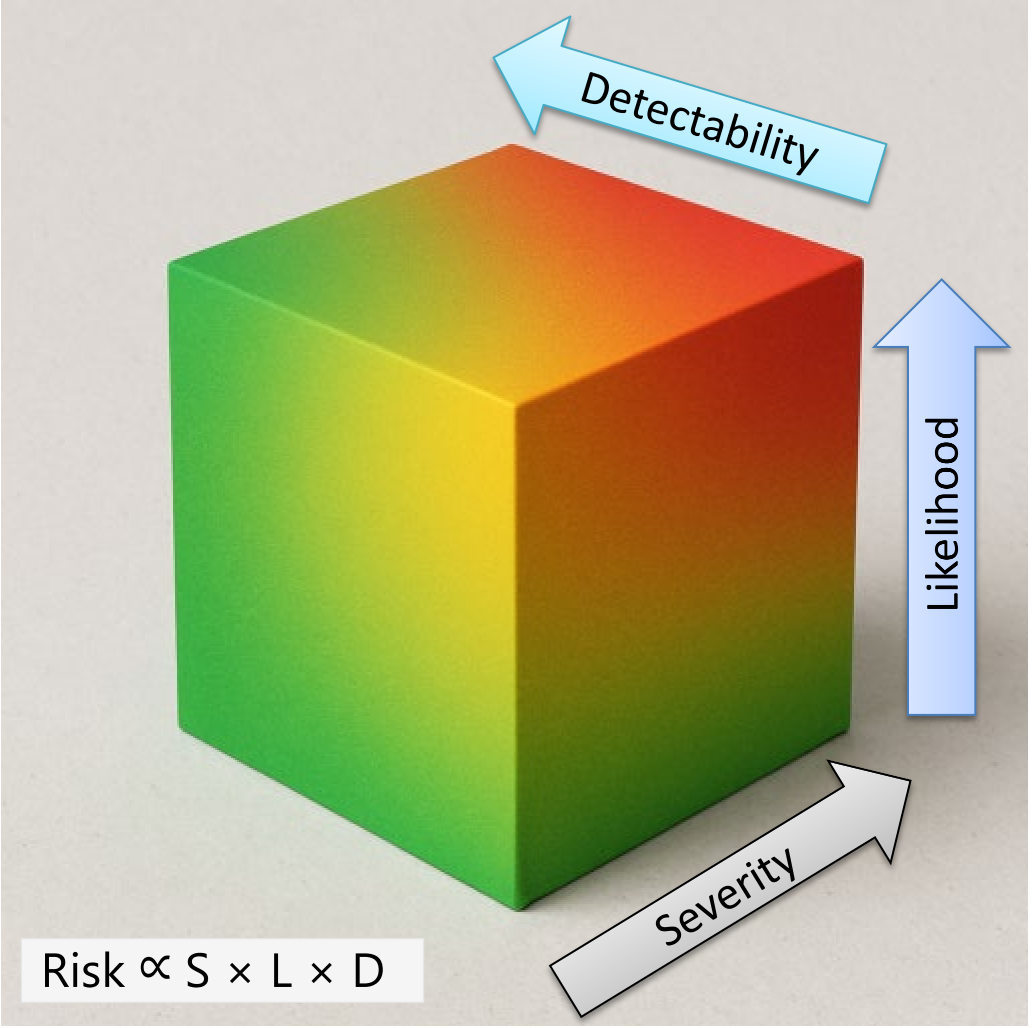
Works in daily operation

Survives maintenance and change

Aligns engineering, sanitation and quality

Balancing Risks: Not All Risks Are Equal

Sanitary design effort should scale with failure risk



High risk → design change	
Medium risk → design + procedure	
Low risk → procedure + monitoring	

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Sanitary design is integral to food safety.

Balancing Risks: The Cost of Over-Engineering

Over-engineering sanitary design can create new risks without improving outcomes

- Excessive design requirements can delay projects and reduce throughput
- Added complexity may shift risk elsewhere in the system
- Capital constraints can limit adoption, leaving higher-risk areas unaddressed

The goal is not the most hygienic asset possible – it is the greatest risk reduction across the system

Balancing Risks: The Cost of Under-Engineering

Under-engineering sanitary design leads to chronic risk and reactive controls

- Persistent findings drive repetitive and ineffective corrective actions
- Issues escalate to increasingly aggressive sanitation and interventions
- Short-term fixes mask design limitations rather than resolving them
- Repeated failures result in loss of confidence, credibility, and trust

Under-engineering turns manageable risks into chronic problems.

What "Balanced" Sanitary Design Looks Like

- Focused on **highest-risk** failure modes
- **Enables** sanitation and avoids creating **chronic** problems
- Operable, maintainable, inspectable
- Developed cross-functionally
- Use structured risk assessment to prioritize and justify decisions

Auditor & Regulatory Risk: Why SD Program?

Regulators and auditors increasingly expect hygienic design to be managed through a defined program

- Audit focus is shifting from isolated findings to program structure and effectiveness
- Hygienic design is now assessed as part of risk management and prevention, not just sanitation execution
- Lack of a defined program increases audit scrutiny and escalation risk

SQF Edition 10 Theme	Auditor Question
FSMS structure and prevention	“Do you manage hygienic design as a program?”

Audit Risks: Emerging Expectations

GFSI benchmarking requirements define what hygienic design programs are expected to include

- Documented hygienic design risk assessment for buildings and equipment
- Multidisciplinary review process across the equipment and facility lifecycle
- Change management for modifications that may impact hygienic design
- Records and evidence demonstrating decisions, actions, and follow-up

SQF Edition 10 Theme	Auditor Question
Risk assessment & change mgmt.	"How do you evaluate and document design risk?"

Audit Risks: Missing Program Elements

Gaps in hygienic design programs create avoidable audit and regulatory risk

- Inability to demonstrate design-based prevention beyond procedures
- Repeated findings when design limitations are treated as execution issues
- Escalation to major non-conformances or reduced audit ratings
- Increased regulatory concern following recurring or systemic failures

SQF Edition 10 Theme	Auditor Question
CAPA & repeat findings	"Why hasn't the design issue been resolved?"

Auditors are no longer just verifying that sanitation is performed — they are verifying that design allows sanitation to be effective.

Closing: Hygienic Design Is a Team Decision

- Hygienic design is not about eliminating all risk
- It is about making deliberate, informed trade-offs
- Best outcomes come from:
  - Engineering
  - Sanitation
  - Quality
  - Operations
  - OEMs

Working closely together

Closing

Hygienic design succeeds when the right risks are reduced, in the right places, at the right time—so sanitation and operations don't have to compensate later.

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