Case Study: New Food Plant Safety Plan

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2017 May 02

Why is it important and what are we trying to prevent?

- On May 7, 2015, the U.S. Food and Drug Administration released the findings from recent inspections at the Blue Bell production facilities in Brenham, Texas (CDC)
- CDC estimates that approximately 1600 illnesses and 260 deaths due to listeriosis occur annually in the United States[1]. (CDC)
-  (CDC)

Listeria Monocytogenes

 (CDC)

Escherichia Coli (E. coli)

Regulatory is holding business accountable for what they know and when they know it

ConAgra fined $11.2M for salmonella peanut butter

USA Today

Roger Yu
5/20/2015

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ConAgra Grocery Products will plead guilty and pay $11.2 million in fines for shipping contaminated peanut butter that was linked to a salmonella poisoning outbreak in 2006, the Justice Department said Wednesday.

In their agreement, ConAgra Grocery, a subsidiary of ConAgra Foods, admitted that its Peter Pan and private label peanut butter products were contaminated with salmonella, leading to more than 700 cases identified nationally until 2007 by federal health officials.

ConAgra will pay a criminal fine of $8 million for a misdemeanor violation of the federal Food, Drug and Cosmetic Act — the largest fine ever in a food safety case — and forfeit assets of $3.2 million.

"No company can let down its guard when it comes to these kinds of microbiological contaminants," said DOJ principal deputy assistant attorney Ggeneral Benjamin Mizer, in a statement. "Salmonellosis is a serious condition, and a food like peanut butter can deliver it straight to children and other vulnerable populations."

FROM T

(Yu)

Some construction techniques are problematic

Factory floor repairs

(unknown)

Harborage points create areas in the plant that are impossible to clean, and detect failures. are

Serious issues waiting to happen.

Examples include
Dairy Tile,
Block walls
Fiberglass dairy board

How do Pathogens move through a facility?

- Hands

(Duncan)

- Wheels

Feet

(Unknown2)

Build to the standards and document the process

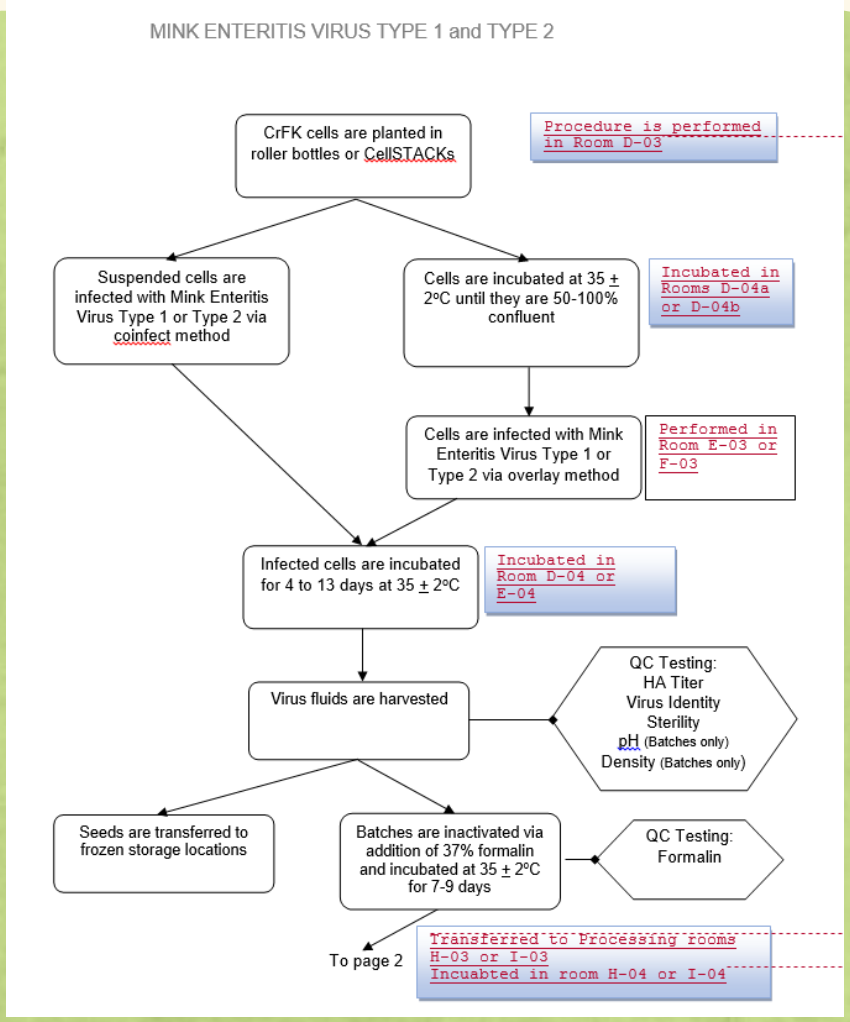
- What is Global Food Safety Initiative?
- SQF
- BRC
- International Featured Standard
- FSSC 22000
- GLOBAL Good Agriculture Practices
- Best Aquaculture Practices (BAP)
- Global Markets Programme
- Canada GAP

Pick a appropriate standard

EMMI Project objectives

- Product: Gruyere
- Open curing rooms
- Design- regulatory outcome
  - Quality First
  - Building controls behavior
  - Standardize and simplify
  - Food Safety and Food defense

First document your HAACP flow process
You know your process best!



What is your process flow and the steps involved in manufacturing your process?

Document any critical information

Temperatures
Flow rates
Volumes
Run rates etc.

Based up your process flow start your HACCP flow chart

Product description:	**Pasteurized Semi- and Hard cheese**
Intended use:	**Specialty, Retail and Foodservice applications (human consumption)(ready to eat)**
File location	**HACCP plan located on BabtecDOK (document control system)**
Product specifications	**Gruyere, Raclette, Swedish Fontina, Fontiago, , GranQueso - See product specifications for specific types**
Method of Distribution:	**Products distributed commercially through Distribution Center**
Date:	**Signature of HACCP Team Leader:**

Analysis of each stage of the process:

Process stage Number on flow sheet	Definition of risk[1]						Action to control hazard/reason for risk definition	Risk: [2] CCP/ oPRP/ LR	*Tolerance/ limit values* +/-	Monitoring (continuous monitoring criteria)	Corrective measures and responsibility	Method of verification
	Processing error	Foreign body	Microorganisms	Pests	Allergens	Residues						
	** N/A designation Risk is not possible at this step											
1	Provided products											
							No Risk	LR	NA	NA	NA	NA
2	Order											
							No Risk	LR	NA	NA	NA	NA
3	Raw milk control											
	F5						Errors controlled further in process	LR	NA	NA	NA	NA
		F5					Addressed in Step 7	LR	NA	NA	NA	NA
			B1				Raw milk can be contaminated with Listeria, Salmonella or other pathogenic bacteria.	LR	None, present after Step 17	Is controlled by step 17 (Pasteurization)	NA	NA
				F5			Addressed in Step 4 to Step 7	LR	NA	NA	NA	NA

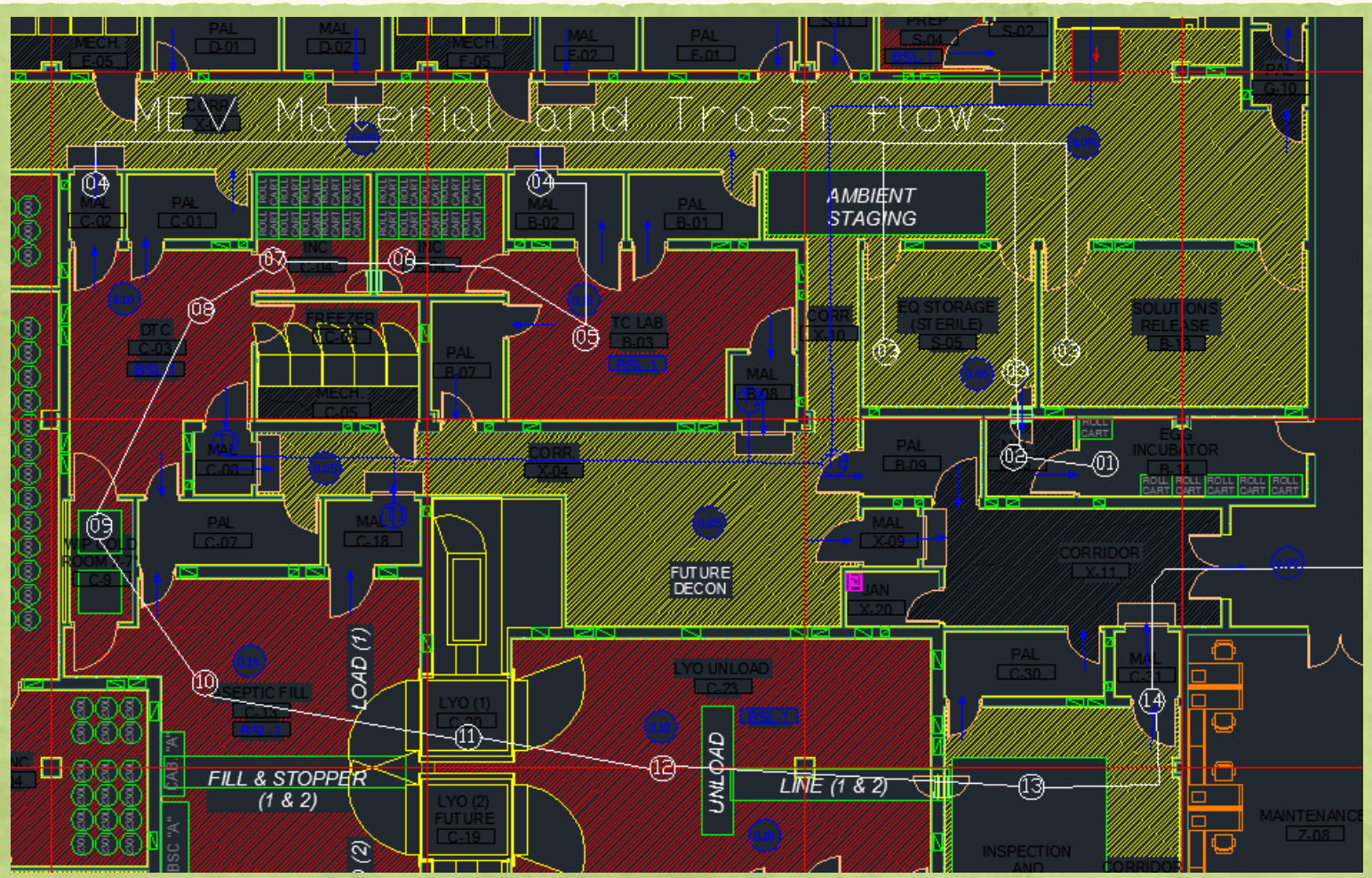
1) Definition of risk according to checklist / HACCP-relevant risk in food
2) Risk = according to CL HACCP - decision tree / CCP = Critical control point / oPRP = operational Prerequisite Program / LR = low risk

Outline your HAACP analysis and perform your initial risk analysis.

How will you control each of the risks in the process?

What risks can you design out, or significantly reduce?

Map your process flow on plan



Map your people, product and trash flows.

Change paths to minimize or eliminate Cross Contact Potentials.

Use Lean principles

Review your standards, and document how you are going to comply.

Food Defense Self–Assessment Checklist for Slaughter and Processing Plants

Outside security

1. What food defense measures does your Plant have in place for the exterior of the building..
   - Are the plant's grounds secured to prevent entry by unauthorized persons (e.g., by locked fence, gate or entry/exit doors)?

     Yes. All plant doors are electronically secured with company controlled key fobs. Both Employee and Visitor entrances have multi door entry system (two doors must unlock to gain access)

     - **Main Plant Building Plant level (A-2.30)**
     - **Door and window Schedule (A-2.32)**
   - Is there enough lighting outside the building to properly monitor the plant at night/early morning?

     Yes, Parking lot lighting, Building parameter lighting and outside surveillance cameras are installed.

     - **Building drawing Site layout (C-1.02)**
   - Do emergency exits have self-locking doors and/or alarms?

     Yes, All exterior doors self-lock with controlled access or alarms.

     - **Building drawing Site layout (C-1.02)**
   - **Exterior of the facility is marked with signs stating it is under video surveillance and doors are alarmed. Exterior of plant also is marked with Unauthorized Personnel prohibited signs warning**

2. Are the following secured with locks, seals, or sensors when unattended (after hours/weekends) to prevent entry by unauthorized persons?

   - Outside doors

Use the standards to define expectations and control the resulting outcome.

Establish design criteria early with the stakeholders

Make sure the building will match your critical process and regulatory needs.

This living document will explain the concept and execution of the project , and provide the necessary information when the plant Quality Personnel are responding in an audit.

Use Zoning Control and protect your facility– EMMI Example

In this example

Green- Zero Risk
Yellow – low Risk
Red – High Risk

Have the Building Control Employee Behavior and reinforce your Food Safety Program

In this example

68 Surveillance cameras

28 security doors controlled by job description

Visible air pressurization indication

Reduce the amount of required ongoing training by standardization and restricting behavior

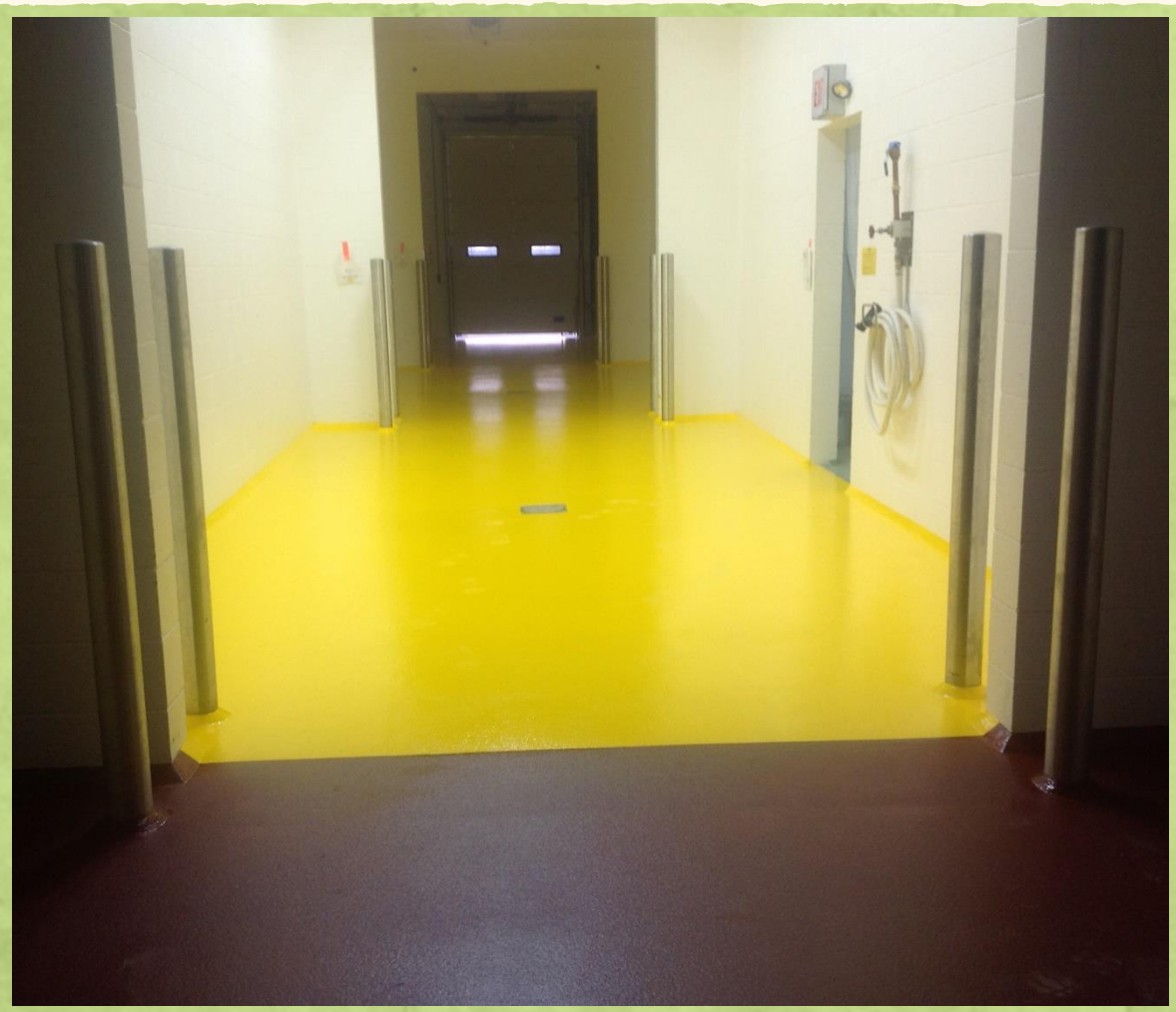
Build in Hygiene Transition Zones into your traffic flow map

In this example

Green- Zero Risk
Yellow – low Risk
Red – High Risk

Remember:
Hands
Feet and
Wheels

Recommend using color where ever possible



In this example

Green- Zero Risk
Yellow – low Risk
Red – High Risk

Use visuals with meaning

Standardize chemical usage, and water temperatures

Pre-diluted chemicals are delivered to the factory floor

Water Hose drops have temperatures preset from a circulation loop

Simplify your SOP's in each step possible.

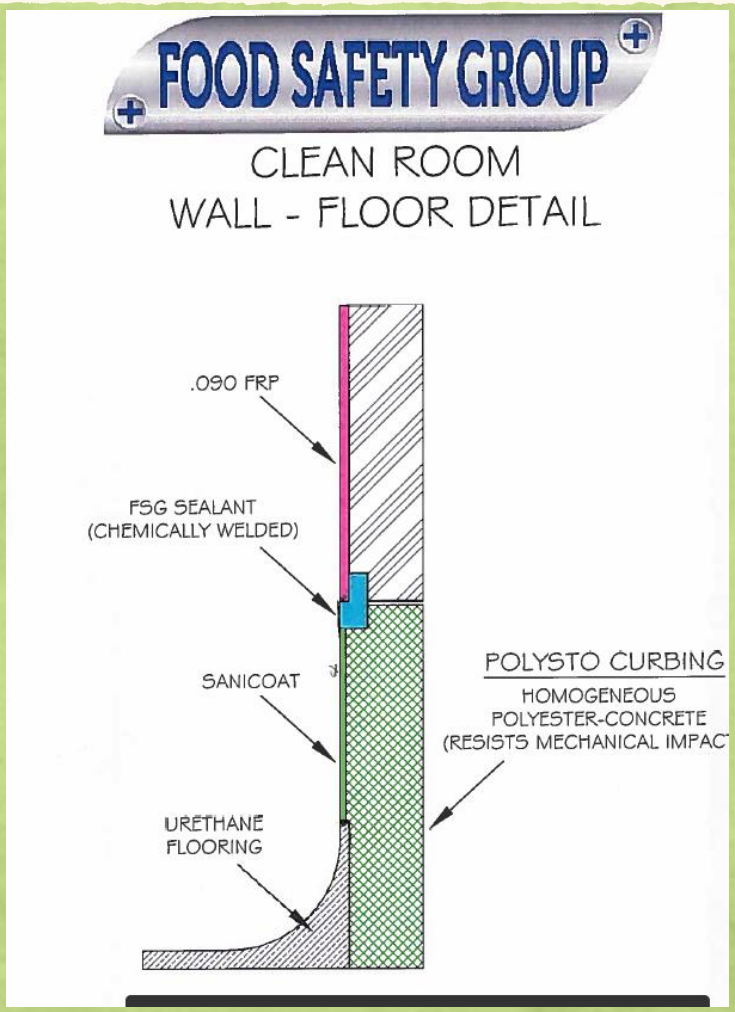
Use Proper Insulation and HVAC controls to Prevent Condensation.

Pay attention to foundations, Types of insulation and heat transfer spaces between occupied spaces.

Avoid condensation in High Risk areas.

Only use non moisture absorbing materials to avoid mold creation.

Eliminate harborage points and long term maintenance



Review all finishes for current and future harborage points

Require Permanent seamless construction where ever possible

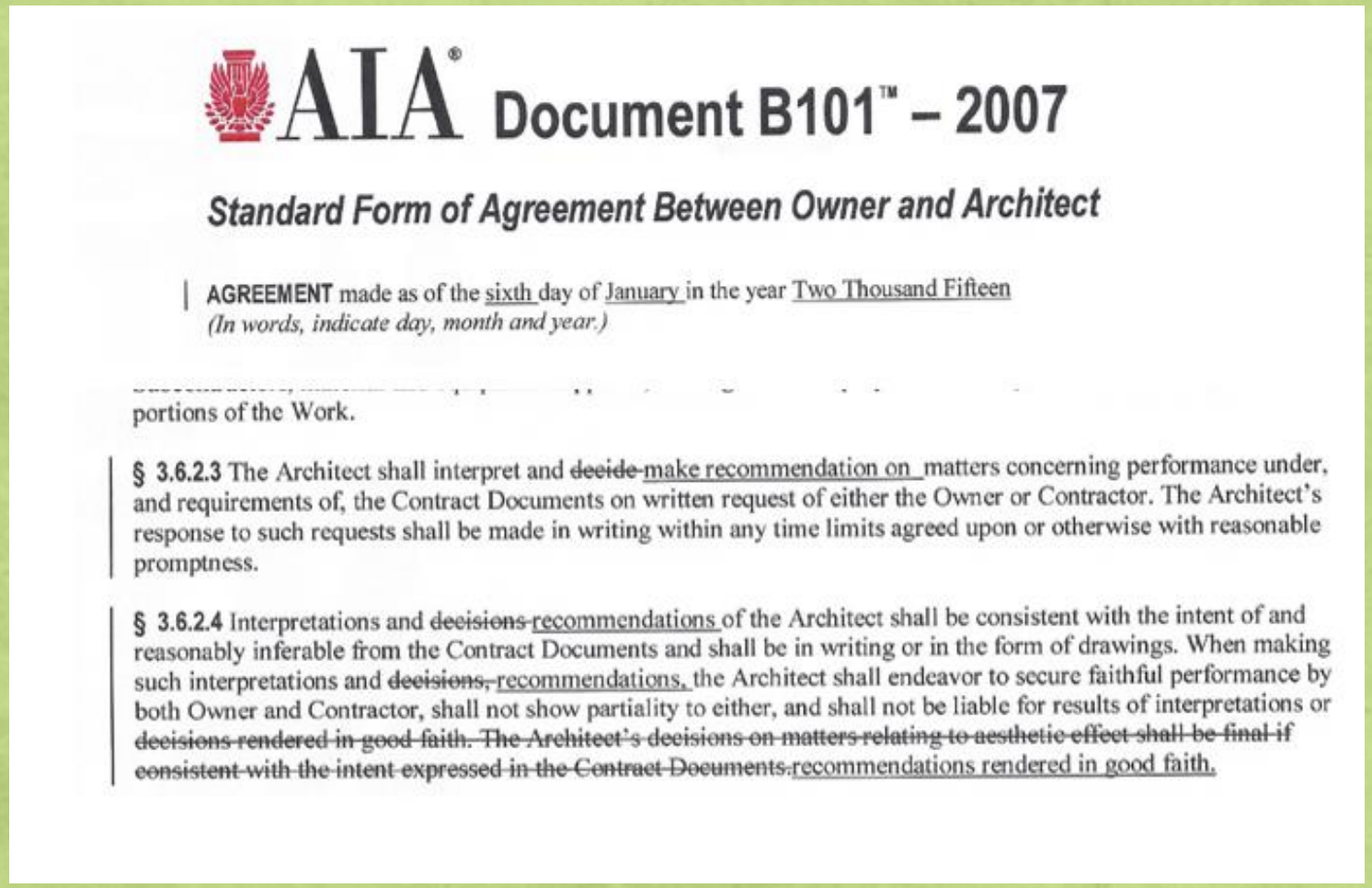
- No Caulk in product areas
- Pay close attention to the following:
  - Door Frame to wall, and floor junctions
  - Equipment supports
  - Window frames
  - Electrical and mechanical penetrations
  - Process and sprinkler piping penetrations

Process piping should be floor supported not building supported (buildings move)

Control the construction process by documenting expectations early in the project

- Most opportunities have very little to no cost impact
- Details established prior to the bidding process controls project costs.
  - You are in your most powerful position of negotiation
  - Forces the sub contractors to be efficient.
  - Significant reduction in post contract change orders (expensive)

Make sure your quality process is in place prior to entering contracts.



AIA® Document B101™ – 2007

Standard Form of Agreement Between Owner and Architect

AGREEMENT made as of the sixth day of January in the year Two Thousand Fifteen
(In words, indicate day, month and year.)

portions of the Work.

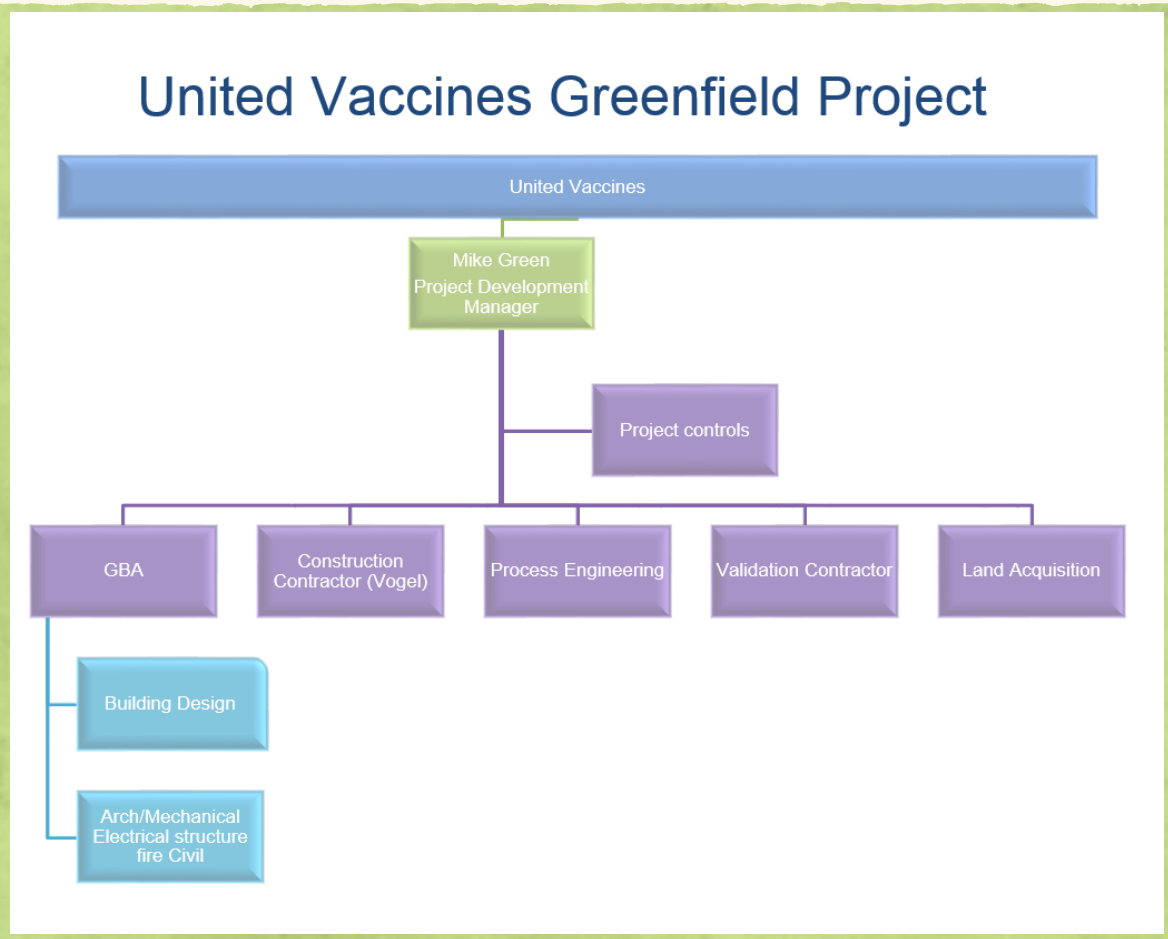
§ 3.6.2.3 The Architect shall interpret and ~~decide~~ make recommendation on matters concerning performance under, and requirements of, the Contract Documents on written request of either the Owner or Contractor. The Architect's response to such requests shall be made in writing within any time limits agreed upon or otherwise with reasonable promptness.

§ 3.6.2.4 Interpretations and ~~decisions~~ recommendations of the Architect shall be consistent with the intent of and reasonably inferable from the Contract Documents and shall be in writing or in the form of drawings. When making such interpretations and ~~decisions,~~ recommendations, the Architect shall endeavor to secure faithful performance by both Owner and Contractor, shall not show partiality to either, and shall not be liable for results of interpretations or ~~decisions rendered in good faith. The Architect's decisions on matters relating to aesthetic effect shall be final if consistent with the intent expressed in the Contract Documents.~~ recommendations rendered in good faith.

Find the right person, internal or external that has enough knowledge to protect the owner and ensure a good regulatory outcome.

Change the contracts to have that champion have the power of final decision.

Project Organizational Chart example



Recommendations during the project construction phase

- Watch closely as foundations, exterior walls construction for compliance with your final objectives. (Cracks, gaps, insulation etc).
- Start your Pathogen monitoring program early. No later than when the shell of the building is enclosed.
  - Know if you have a problem on the site don't be complacent.
- Your presence will show you are vested in the outcome.
- As the interior walls start being constructed, walk your traffic patterns (people, product and trash)
- Nearing completion the monitoring of the finishes will take more time. Be picky about the details.

EMMI Regulatory Results

Implemented FSSC22000

Results of the first pass Audit.

0 Majors
8 minors (all predicted)

All minors SOP related and none procedural

EMMI facility Results

Emmi project completion:

- $46 Million dollar 80,000 sq. ft.
- "State of the Art" GFSI food manufacturing facility for EMMI (FSSC22000)
- 2.3% Change orders

Speaker Back Ground --- Mike Green

- 26 years project management
- 8 years Operations Director experience
- Mechanical Engineering training
- Food and Pharma experience
- Certified Six Sigma Black belt
- Certified Quality Auditor

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Credits

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