MAY 9–12, 2022

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Internal Audits

Beyond Checking the Box

Your Presenters

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Internal Audits Beyond Checking the Box

"Audit Significance" Jen Fernan – J&J Snack Foods Corp.

Agenda

- Why audits are important
- Audit categories
- Audit frequency
- Tools to aid in the audit process
- Auditor qualities

Importance of Audits

- Verification activities
  - Ensure compliance to requirements
  - Verify we are following programs as stated:
    - Checks completed every 30 minutes
    - Or approximately every 30 minutes
  - Can be specific to a function, process, or production step
  - Can audit documents, site requirements, programs, or performance
  - Verify corrective action effectiveness

Importance of Audits

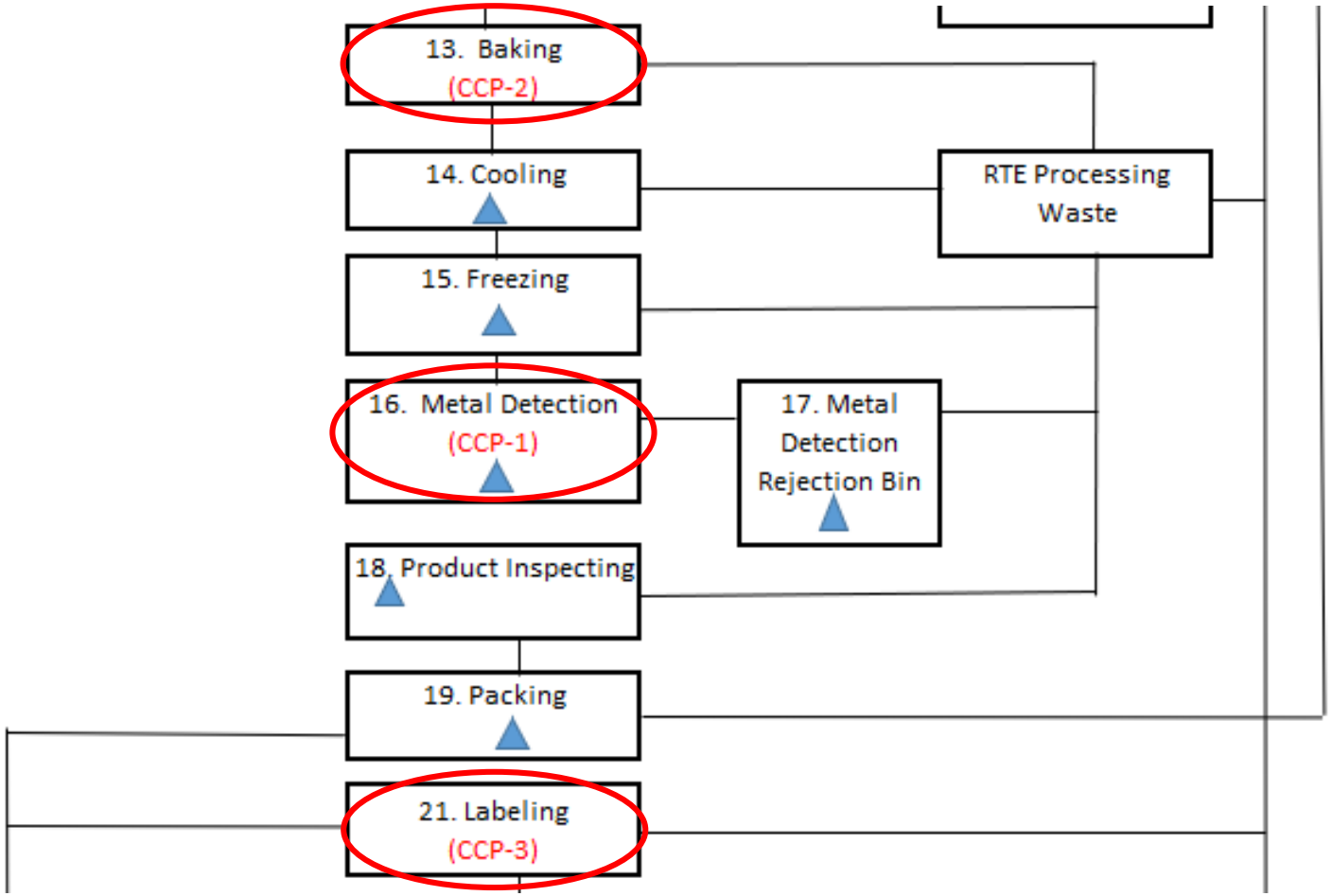
- Identify gaps
  - Program gaps and deficiencies to mitigate issues and minimize risk
  - Adherence to written programs (e.g., SSOPs)
  - Can’t fix what you don’t know is broken

Types of Audits

- GMP observation audits
- Process audit vs. larger program audits (e.g., metal detection process vs. foreign material control program)
- Sanitation audits – e.g., individual SSOP or MSS completion
- Data audits – e.g., trending EMP/PEMP, record reviews, net weight program
- CCP monitoring audits

Observation, Interview, Record review

Frequency of Audits



- Frequencies for audits should be risk based
- If a process step is considered a CCP, should it be audited with a greater frequency?

Frequency of Audits

	GLASS, PLASTIC, AND CERAMIC INSPECTION LOG					PROD-20
	Created:	11/10/2008		Revised:		8/28/2020
DATE:				INSPECTED BY:		
	LOCATION/ITEM	QUANTITY	MATERIAL TYPE	RISK LEVEL low to high (1-5)	BROKEN OR MISSING	CORRECTIVE ACTION
	PRODUCTION ROOM					
1	Lights	14	Plastic	2		
2	Batch Controller	2	Plastic	3		
3	Low crator cover	2	Plastic	3		
4	Paper Stand cover	2	Plastic	3		
5	Water Flow meter	2	Plastic	3		
6	Vitaline cover	8	Plastic	3		
7	Brine Pressure gauges	7	Plastic	3		
8	Ingredient feeder cover	1	Plastic	5		
9	Covers below filler	4	Plastic	4		
10	Stick insertor cover	8	Plastic	5		
11	COP tank cover	1	Plastic	3		
12	Sink cover	1	Plastic	2		
13	Flavor Tank cover	4	Plastic	3		

- Should glass and plastic be audited based on use and handling, RLTO?

Product Contamination:	
Unlikely to Occur	1
Could Occur	2
Somewhat Likely to Occur	3
Likely to Occur	4
Extremely Likely to Occur	5

Tools to aid in the process

- The five senses – sight, sound, smell, touch, taste (quality audits)
- Camera
- Flashlights
- Black lights

Tools to aid in the process

- Audit Checklists

Glass & Brittle Plastic Self Inspection

Check Sheet

Employee Names: _____

_____

Date: _____ Time: _____ AM / PM (circle one)

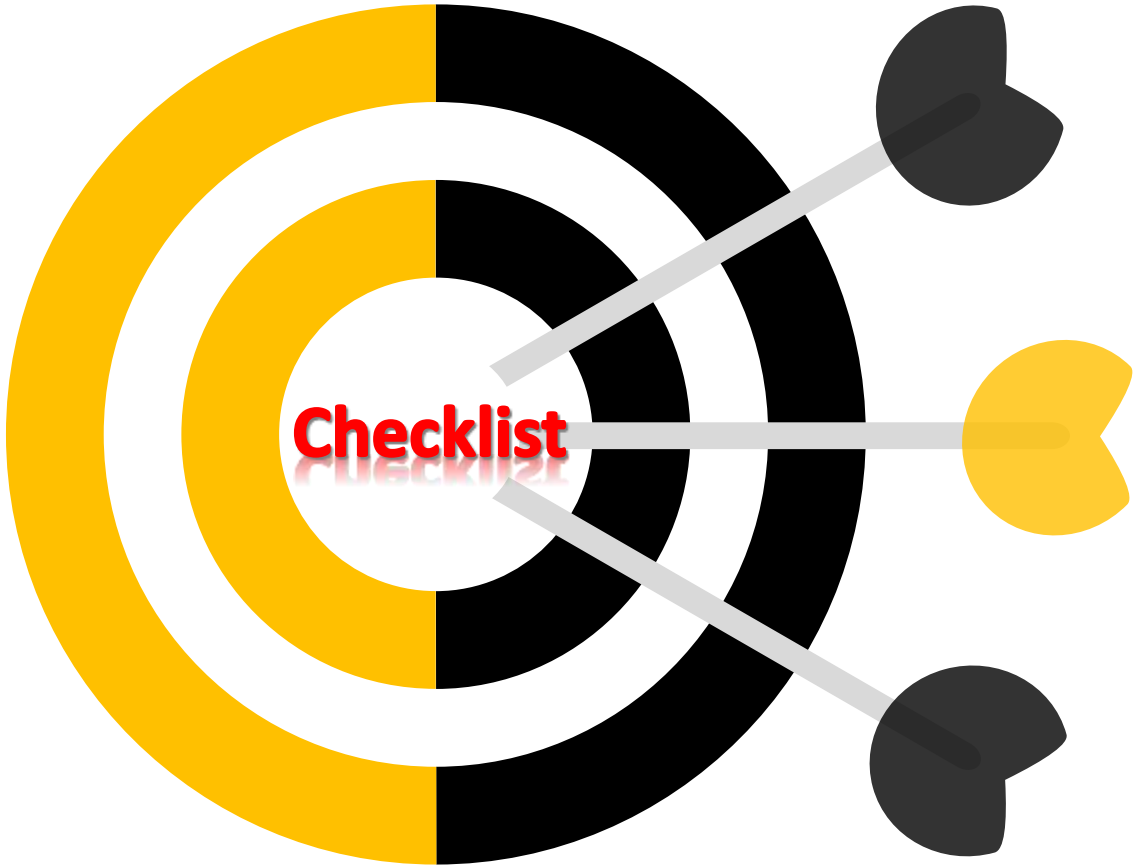
A = Acceptable **U = Unacceptable**

Production area	A	U	Issue	Corrective Action

MONTHLY GLASS,PLASTIC AND CERAMIC INSPECTION LOG				
Created:		11/10/2008	Revised:	3/2/2021
DATE:			INSPECTED BY:	
	LOCATION AND QUANTITY	MATERIAL	BROKEN / MISSING?	CORRECTIVE ACTION
	PRODUCTION ROOM			
55	3 way sink ceiling cover	Plastic		
56	Big brine pump cover	Plastic		
57	Broom hooks - 9	Plastic		
58	Brooms / brushes	Plastic		
59	chart recorder covers - liquifier - 2	Plastic		
60	chart recorder covers - Stack Freezer -	Plastic		
61	Batch Controller - liquifiers -1	Plastic		
62	Eyewash station	Plastic		
63	Digital case counters - 2	Plastic		
64	Incline conveyor / strip curtains	Plastic		
65	color buckets	Plastic		
66	Cup ceiling cover	Plastic		
67	Cup machine PLC - 1	Plastic		
68	Stick machine PLC - 1	Plastic		
69	Cup machine - metal detector control	Plastic		
70	Cup machine batch controller	Plastic		
71	Pressure Gauges - Old 603 - 9	Glass		
72	Air dryer behind Old 603	Plastic		
73	Pressure Gauges - New 603 - 9	Glass		
74	Pressure Gauges - 403 - 9	Glass		
75	403 - Flavor Tanks, Batch controller	Plastic		
76	Ingredient feeder covers - 2	Plastic		
77	exit lights	Plastic		

Tools to aid in the process

- Checklist



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Internal Audits Beyond Checking the Box

"Connecting the Dots" Mike White – J&J Snack Foods Corp.

Internal Audits?

We speak “Gemba” in Operations (Ops, Logistics, Maintenance)…but wait, what is that?

現場 (GEMBA) means – “The real place”

AKA:
Where the action is!
Where the “magic” happens!
Where the rubber meets the road!
Where the real work happens ☺

Gemba walks provide managers/supervisors a simple means of supporting overall Continuous Improvement for all functions

Who: Managers, supervisors, leaders, future leaders, anyone that can add value

Where: Choose one value stream – a simple means of noticing key issues

When/how long: Daily, should take between 15-45 minutes

What: It's important to have a clear and obvious focus, don't look for everything or you'll likely accomplish nothing. Have the "right" tools (flashlight, camera, means to document)

Why: If done regularly, with clear stated intentions, it will consistently demonstrate commitment and support of the continuous improvement process and overall management commitment to Food Safety

The Powerful GEMBA walk lies in:

1. Asking open ended questions about observed conditions-not a time to performance manage

2. Knowing the current state and really try to grasp it - don't immediately change any process; seek the truth

3. Being a very "active" listener and having a learning attitude

4. Publicly sharing what you learned during the Gemba Walk

5. Following up – monitoring the process

But shouldn't quality do this? Why Operations?

The Gemba walk provides Managers and Supervisors a simple means of supporting overall Continuous Improvement for all functions

Who – Managers, Supervisors, Leaders, future leaders, anyone that can add value.

Where – Chose one value stream. This is a simple means of noticing key issues.
When/how long – Daily! Depending on size of site/value stream, this should take between 15-45 minutes.

What – It's important to have a clear and obvious focus. Don't look for everything or you'll likely accomplish nothing. Have the "right" tools (flashlight, camera, means to document)

Why – If done regularly, with clear and focused intentions, it will consistently demonstrate commitment and support of the continuous improvement process and overall management commitment to Food Safety.

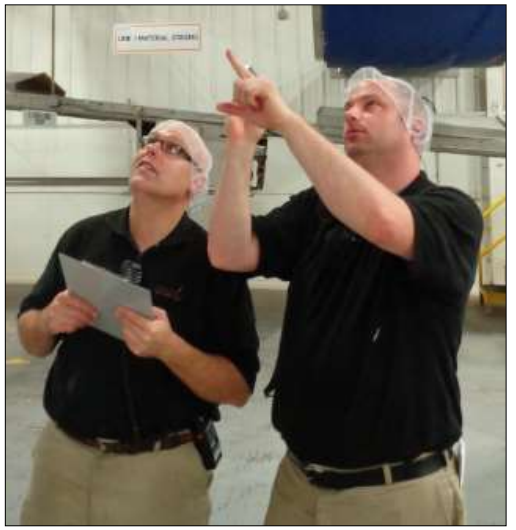
The Powerful GEMBA walk lies in:

1. Asking open questions to the team about observed conditions and routine to perform/practice manage
2. Know the current state and really try to grasp it-don't immediately change any process; seek the truth
3. Being a very "active" listener and having a learning attitude
4. Publicly sharing what was learned during the Gemba Walk
5. Following up and monitoring the process

But shouldn't quality do this? Why Operations?

But shouldn't quality do this? Why Operations?

If your plant has 100 total employees, roughly 80% work in operations and only 5% work in quality. Your chances to "win" increase by 16 times by getting the Operations team involved in the process.



5 Steps to an effective GEMBA Walk-TPPOF Method

1. TEAM-Identify, train and prepare the team
2. PLAN-Have a plan/schedule
3. PROCESS-Follow the value stream and focus on the process (not people)
4. OBSERVE-While walking in teams, ask questions and document observations (don't suggest changes during a walk unless an immediate people or food safety issue). This is a great time to connect and build rapport with your team.
5. FOLLOW UP- share with employees and return to GEMBA

Identify, train and prepare the team

Who: Bring in your leadership superhero's-build your culture!

Train: Repetition makes perfection…the more you walk, the more you learn and the more opportunities you identify; walk together

Prepare: talk before you walk. What should we focus on? Have a theme

Have a plan/schedule

	Monday	Tuesday	Wednesday	Thursday	Friday
Week 1	Line 1	Line 2	Line 3	Line 4	Warehouse
Week 2	Maintenance	Receiving	Line 1	Line 2	Line 3
Week 3	Line 4	Warehouse	Maintenance	Receiving	Line 1
Week 4	Line 2	Line 3	Line 4	Warehouse	Maintenance
Week 5	Receiving	Line 1	Line 2	Line 3	Line 4
Week 6	Warehouse	Maintenance	Receiving	Line 1	Line 2
Week 7	Line 3	Line 4	Warehouse	Maintenance	Receiving
1st shift					
2nd shift					
3rd shift					

Follow the value stream and focus on the process (not people)

Items to look at:

- People safety
- Food safety
- GMPs
- Housekeeping
- Standards
- 5S

Ask questions and document observations

don’t suggest changes during a walk unless an immediate people or food safety issue

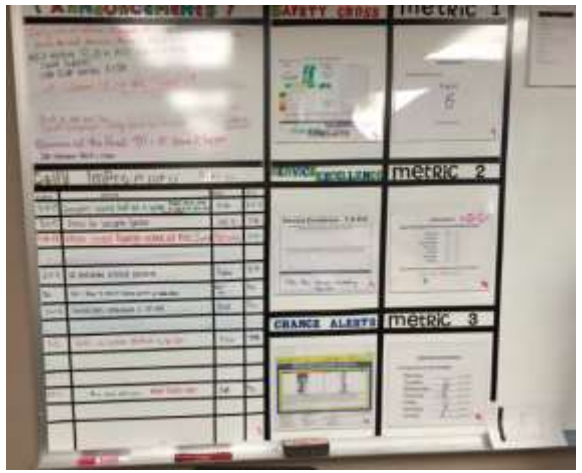
FORM Action Item List		NUMBER	
APPROVED BY M. White	REVISION NUMBER 02	REVIEWED BY M. White	REVIEWED DATE 10/01/2018

Site: Chicago Dogs Corp
Department: Line 3
Last Updated: 5/1/2022
Owner of List: M. White

No.	Observation	Task	Who	Due	Actual Done	Result / Status
1	Tarps dirty in mixing	Review SSOP	Sanitation Manager	6/1/2022		
2	Incorrect colored scoop used for wheat WIP	Review process for tool storage	Quality Mangager	6/15/2022		
3	Hot dogs falling off conveyor near spiral freezer	Analyze loss point to correct	Operations Manager	7/1/2022		
4	Condensation observed at spiral freezer exit	condensation	Maintenance Manager	6/15/2022		
5	3 employees not observed wearing beard nets properly	Review GMP training and retrain	Operations Manager	6/1/2022		
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						

Follow Up

Go public!...share with employees and return to GEMBA



	Monday	Tuesday	Wednesday	Thursday	Friday
Week 1	Line 1	Line 2	Line 3	Line 4	Warehouse
Week 2	Maintenance	Receiving	Line 1	Line 2	Line 3
Week 3	Line 4	Warehouse	Maintenance	Receiving	Line 1
Week 4	Line 2	Line 3	Line 4	Warehouse	Maintenance
Week 5	Receiving	Line 1	Line 2	Line 3	Line 4
Week 6	Warehouse	Maintenance	Receiving	Line 1	Line 2
Week 7	Line 3	Line 4	Warehouse	Maintenance	Receiving

KEEPIN' IT FRESH

- Involve all levels of the organization
- Don't miss a day
- Make it simple
- Make it fun!

Keep your foot on the gas pedal…as soon as you let up, they will too

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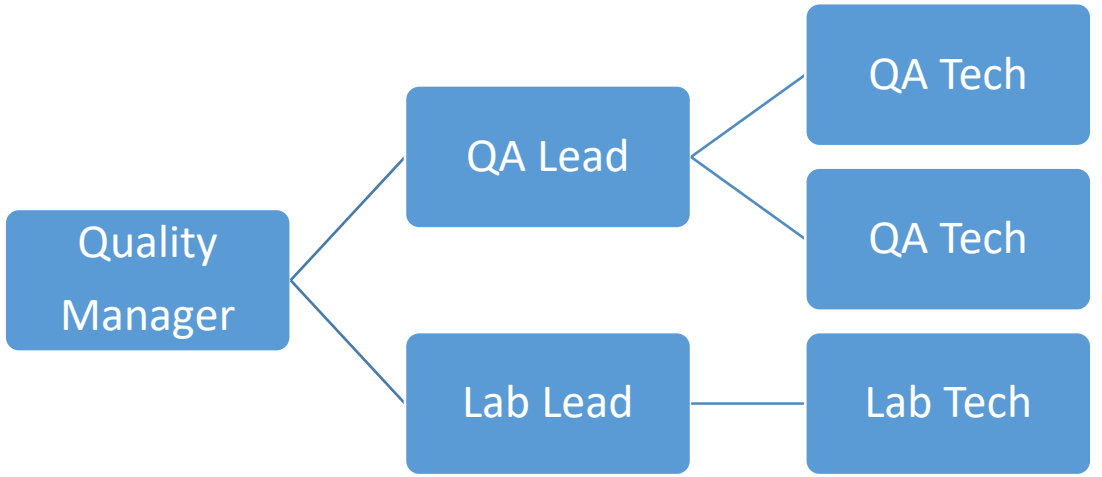
Internal Audits Beyond Checking the Box

“FSQ is not the sole Owner” Joe Meyer – Kerry

Who Owns Internal Audits & Auditing?

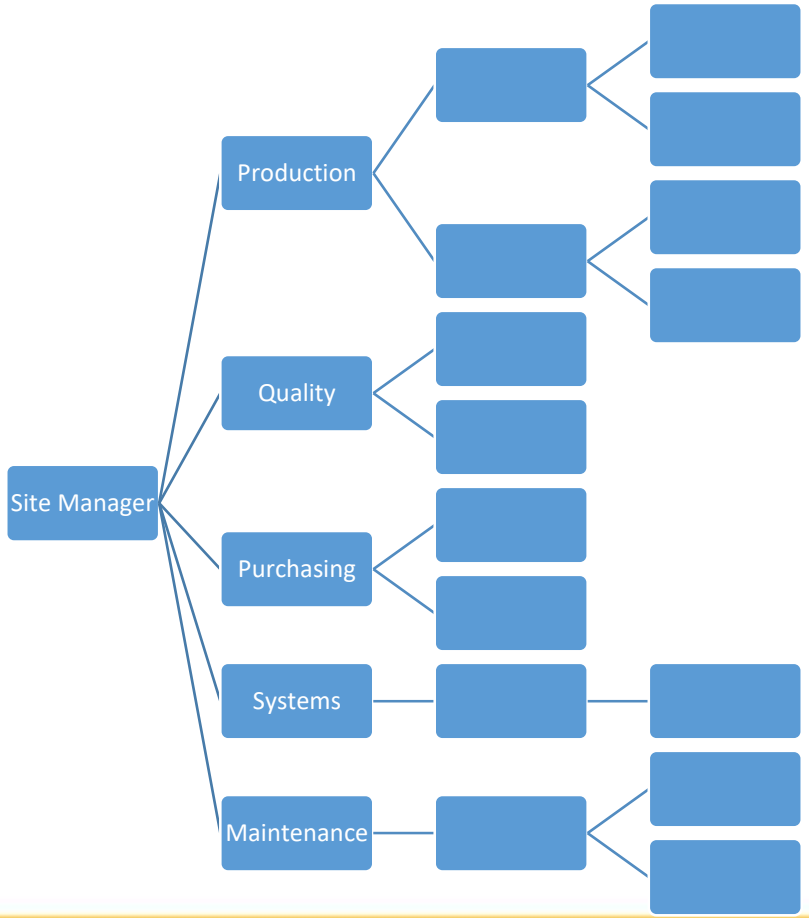
Sharing Internal Audit Ownership

- Internal audits and auditing can be overwhelming if taken on by FS/QA alone
- Limited resources
- Can become stale



Sharing Internal Audit Ownership

- Other functions can and should share in the ownership of internal audits
- May also consider resources outside your own four walls: sister plants, tech centers, etc.



Auditor Shared Ownership

Who could be part of your auditor pool

- In addition to QA/FS
  - Health & Safety, Operations, Sanitation, Maintenance, Purchasing, Logistics, Line operators, etc.
  - Personnel from sister plants or tech centers
  - Other external resources (consultants, universities, etc.)
- It's the person, not the function that makes for a good auditor
- Importance of training/calibration
- Shadow audits – auditing with someone who is experienced

Auditor Qualities

- Good communication skills
- Meticulous attention to detail
- Excellent problem-solving skills
- A keen sense of awareness
- Professionalism
- Ability to work within deadlines
- Ability to work on your own initiative and as part of a team
- Independent, fair, impartial

Auditee Shared Ownership

Who could take ownership of each program/element

- Sanitation – e.g., individual SSOP or MSS completion
  - Maintenance supervisor
- Maintenance – e.g., work practices or PM completion
  - Sanitation supervisor
- CCP monitoring audits
  - Production scheduler

Auditee Shared Ownership

Who could take ownership of each program/element

- Record reviews, net weight program
  - Warehouse manager
- Metal detection process
  - Mixer operator
- Importance of training/calibration

Benefits of Shared Ownership

For the auditor

- Multidisciplinary audit teams – different background and skill set, bring additional knowledge to the audit
- Knowledge sharing training/education
- Professional development
- Exposure to other functions and networking
- Chance to learn about and explore future career paths

Benefits of Shared Ownership

For the auditee

- Unbiased
- Fresh set of eyes
- Helps avoid complacency
- May have become blind to issues over time
- Knowledge sharing training/education
- Professional development
- Exposure to other functions and networking
- Chance to learn about and explore future career paths

Benefits of Shared Ownership

For the Company

- Spread out the workload
- Increased transparency and accountability
- Creates opportunities for coaching
- Increased engagement and builds company culture
- Continued renewal of institutional knowledge
- Shared learnings between departments/facilities
- Better prepared for all audits and regulatory inspections

What’s wrong with this picture?

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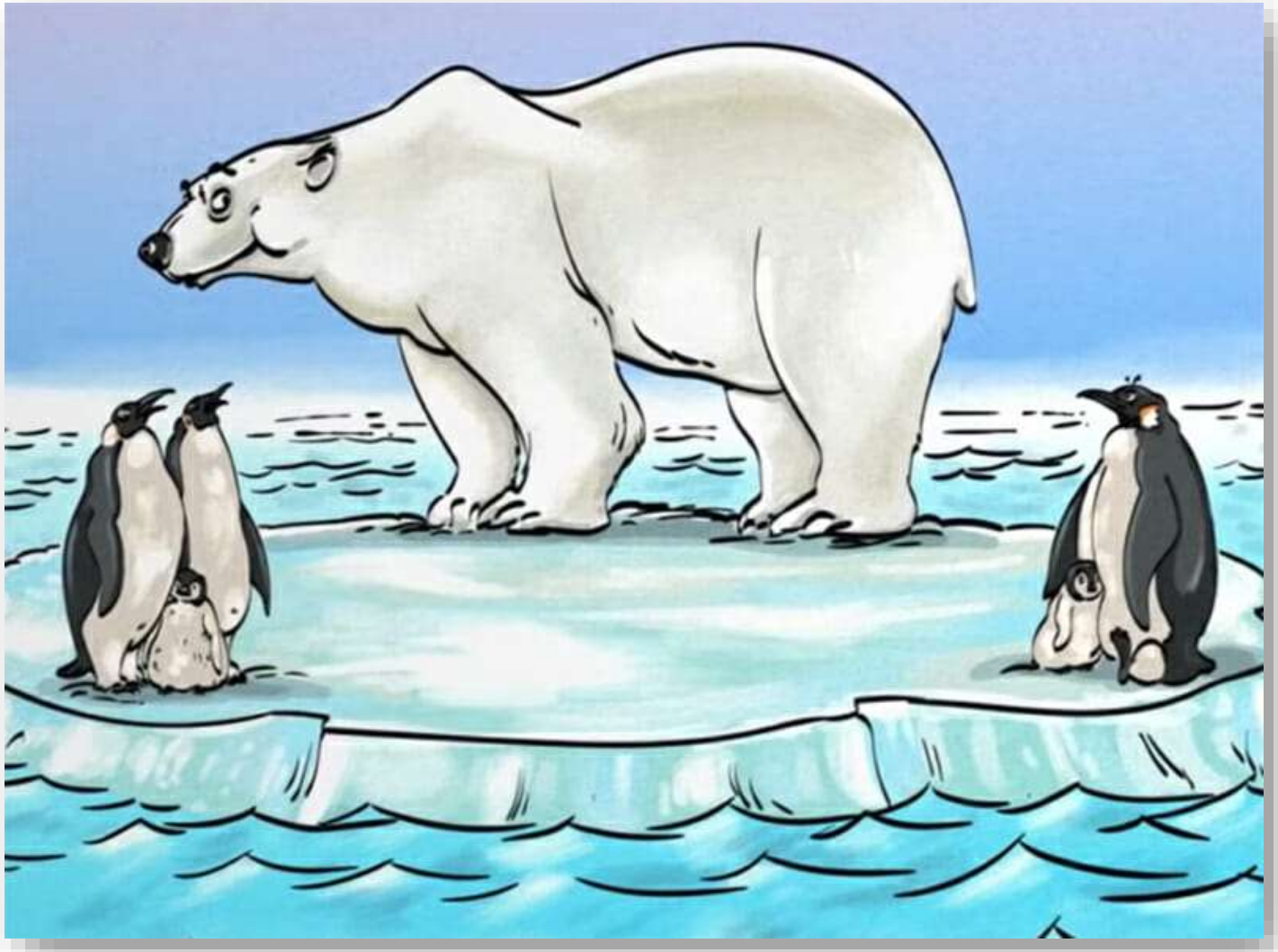

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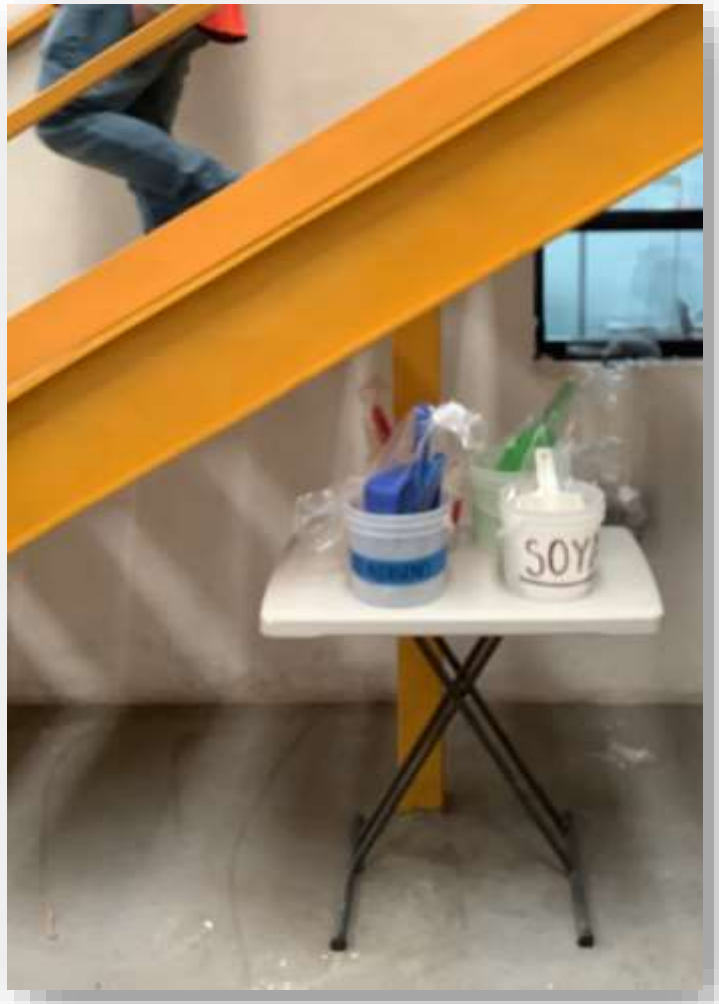

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What’s wrong with this picture?

All checks must be completed at the start of each shift and/or run, every 60 minutes(+/- 15 mins), the end of each shift and/or run, and when there is a stop in production greater than 2 hours.
If a check is not completed, a reason must be documented for that check (i.e., 2:00 NO PRODUCT)

Product ID Number	Time am/pm	MD On/Product Passing Thru? Yes/No	2.0mm Ferrous (Fe) Pass(P)/Fail(F)			2.0mm Non Ferrous NFe) Pass(P)/Fail(F)			2.5mm Stainless Steel (SS) Pass(P)/Fail(F)			Initials
123456	6:00	Y	✓	✓	✓	✓	✓	✓	✓	✓	✓	
"	7:00	Y	✓	✓	✓	✓	✓	✓	✓	✓	✓	
"	8:00	Y	✓	✓	✓	✓	✓	✓	✓	✓	✓	
"	9:00	Y	✓	✓	✓	✓	✓	✓	✓	✓	✓	
"	10:00	Y	✓	✓	✓	✓	✓	✓	✓	✓	✓	
"	11:00	Y	✓	✓	✓	✓	✓	✓	✓	✓	✓	
789012	12:00	Y	✓	✓	✓	✓	✓	✓	✓	✓	✓	
"	1:00	Y	✓	✓	✓	✓	✓	✓	✓	✓	✓	
"	2:00	Y	✓	✓	✓	✓	✓	✓	✓	✓	✓	

Lead Verified Correct Test Wands area used: Time 6:00 FE ✓ NFE ✓ SS ✓ Initials [illegible]

QA Verified Correct Test Wands area used: Time 6:15 FE 2.0 NFE 1.0 SS 2.5 Initials [illegible]

QA Verified Correct Procedure is Followed: Time 7:05 (Yes)/No Signature _____

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Internal Audits, Beyond Checking the Box

"Closing Findings" Kara Mikkelson – Hydrite

Closing the Findings

- Procedures to be followed when a out of specification or non-conformity is found
- Some corrective actions should be developed in advance, but some cannot be anticipated
  - Should be recorded properly

Closing the Findings

- Understand the root cause
- Document the corrective action plan
- Establish timeline
- Closure and effectiveness checks

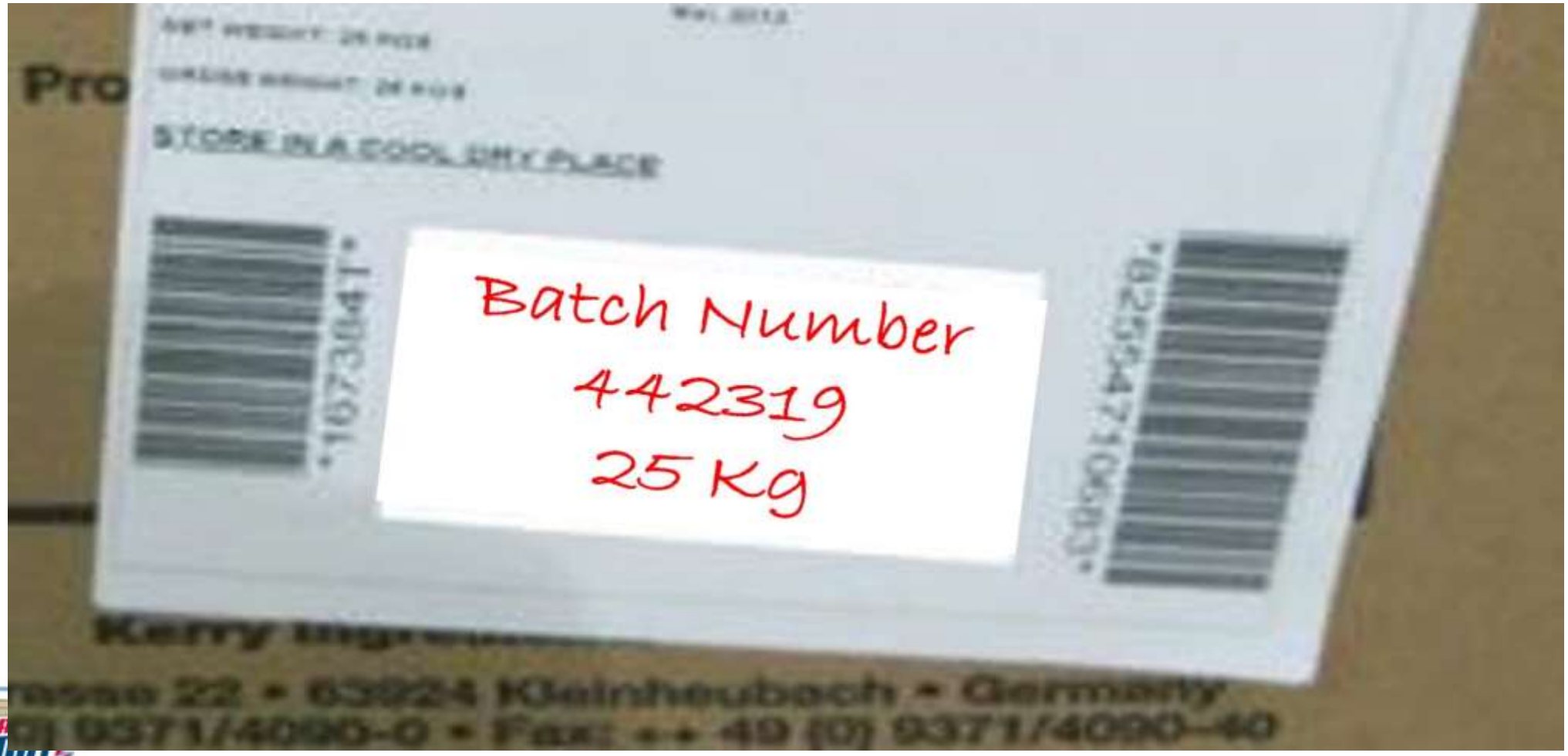
Closing the Findings

- Often, true root cause of the problem is not identified through corrective action
- Several different methods for root cause analysis
  - 5 whys

Examples of 5 Whys

- Method for pushing people to think about root cause
- Prevents settling on superficial solution
- Ask “why does this outcome occur?”
- Select one of the reasons and ask why again
- Continue this way until reaching potential cause
- Stop when reaching potential cause that is actionable

Examples of 5 Whys

- 

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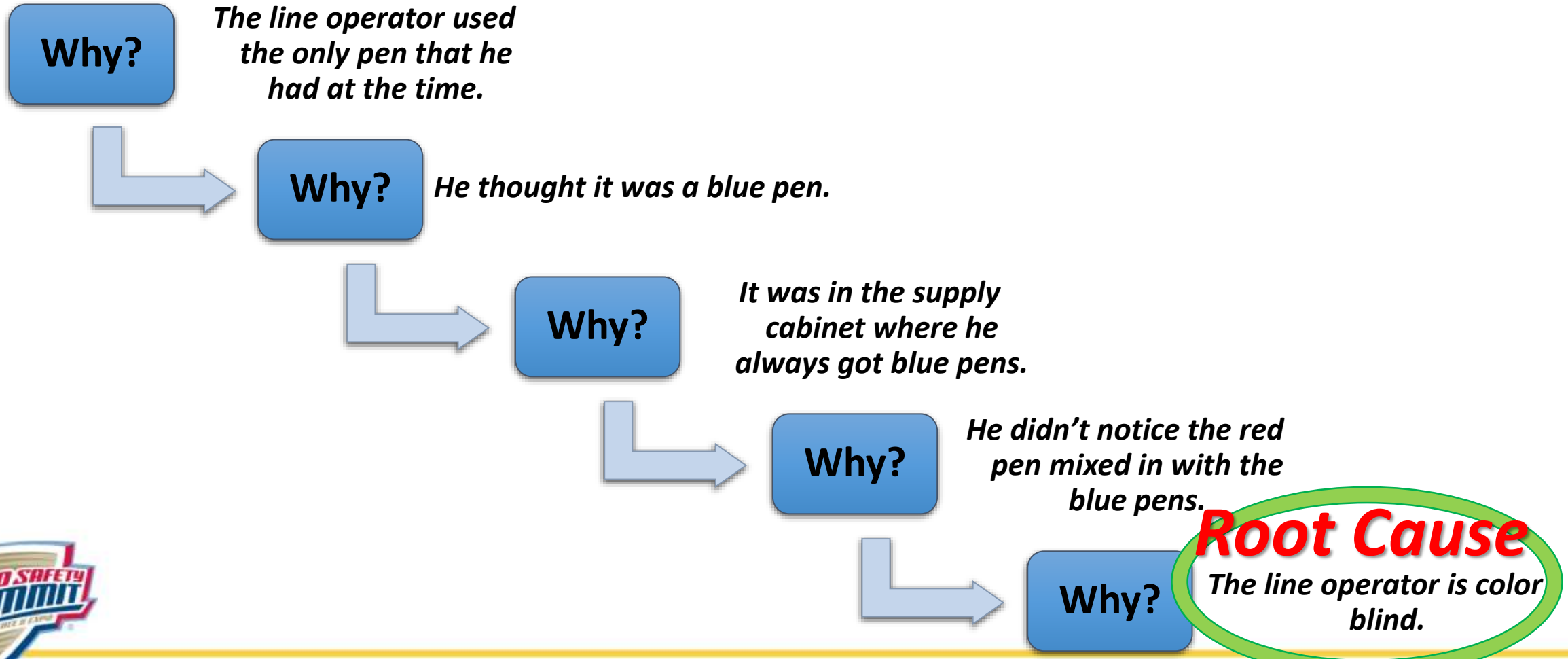
Problem Statement:

Line operator wrote batch information with a red pen instead of a blue pen as required by the customer.



Document the Corrective Action Plan

- Timeline
- Person(s) Responsible
- Prioritized by risk
- Necessary actions documented
- Preventive measures documented
- Effectiveness checks

Document the Corrective Action Plan

- Prioritize by risk
  - Riskier activities should receive expedited timeline and attention
    - Metal detector malfunction vs ceiling
    - Depends on risk to product and/ or environment

Document the Corrective Action Plan Short vs. Long Term

- Short term
  - Short term may be suitable fix on a temporary basis
    - Floor cleaned on a more frequent basis
    - Not big spend

- Long Term
  - Long term fix will remain in place for years
    - Replace floor
    - More expensive fix

Closing the Findings: Effectiveness Checks

- Corrective actions should be verified at later date
  - Physically checked by auditor
- Trends and repeated non-conformities should be observed
  - Root cause not identified
  - Repeated non-conformities indicates system failure

Closing the Findings

- Findings and corrective actions should be reported to senior management once audit is complete
  - Example: presenting at monthly management meeting
  - Communicate correct action effectiveness once complete

Closing the Findings

- Communication to employees is also important while discussing changes to process or procedures
- Review program if changes in
  - Regulatory requirements
  - Product lines
  - GFSI and/or other industry standards
  - Recalls and outbreaks