

Lean Six Sigma Tools: Digital QMS Live Webinar

Presented by Isolocity & Lean Six Sigma Specialists



Who We Are

ISOLOCITY



Today's Agenda

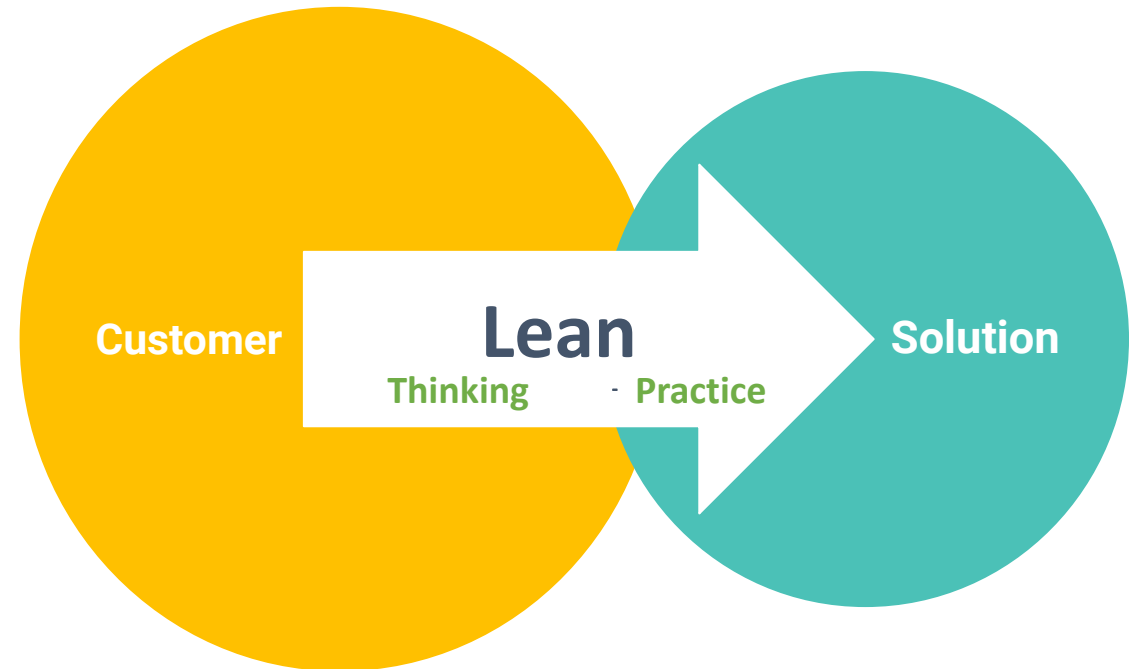
- What are Lean Principles?
- Setting the Standard with Lean Principles
 - Motion
 - Transportation
 - Waiting
 - Inventory
 - Overproduction
 - Over-processing
 - Defects
- Key Takeaways
- Thank-you + Q&A



What are Lean Principles?

Lean is a way of thinking about creating **VALUE-ADDED** with fewer resources and less waste.

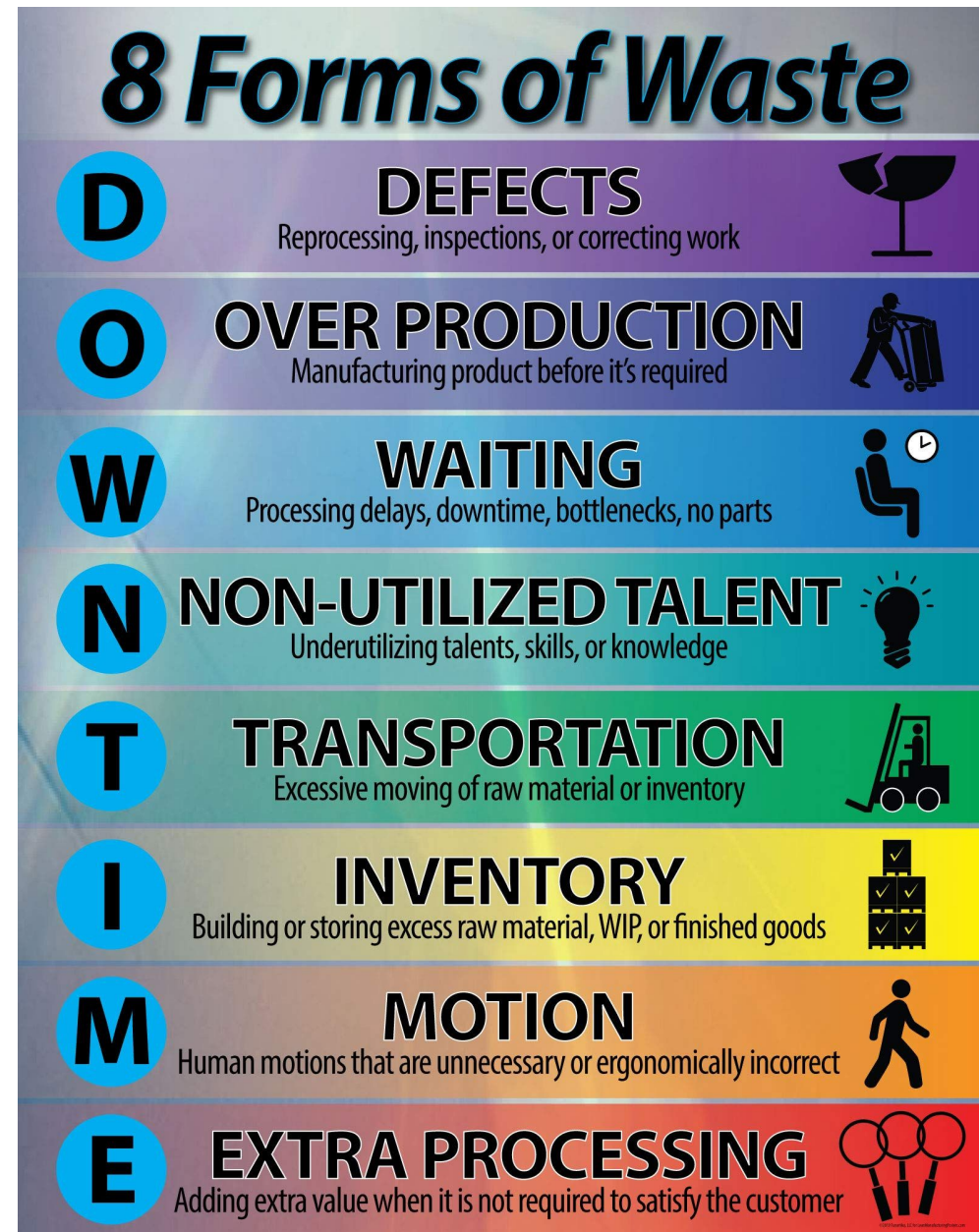
Lean thinking always starts with the customer. What does the customer value? In other words, **what problem does the customer need to solve?**



Setting the Standard

We all know the 8 “Classic” Forms of Waste

- Highlight opportunities in process which will either save time or reduce costs organization wide.



PROCESS MUDA, MURA, MURI CONTRADICT "ADDING-VALUE"

INFORMATION WASTE

1. REDUNDANT INPUT AND OUTPUT OF DATA
2. INCOMPLETE INFORMATION SYSTEMS
3. MANUAL CHECKING OF DATA THAT HAS BEEN ENTERED ELECTRONICALLY
4. DATA DEAD-ENDS (IE: DATA THAT IS INPUT BUT NEVER USED)
5. RE-ENTERING DATA
6. CONVERTING FORMATS
7. UNNECESSARY DATA
8. UNAVAILABLE, UNKNOWN, OR MISSING DATA
9. INCORRECT DATA
10. DATA SAFETY ISSUES (LOST OR INCORRECT DATA)
11. UNCLEAR OR INCORRECT DATA DEFINITIONS
12. DATA DISCREPANCIES
13. NON-SPECIFIC DATA, DESCRIBED IN GENERAL TERMS, RATHER THAN AT GRANULAR LEVEL, EXAMPLE: "OTHER"

PROCESS WASTE

1. DEFECTS
2. SCRAP
3. REWORK
4. WORK-AROUNDS
5. INSPECTING, CHECKING, AND DOUBLE-CHECKING
6. NEED FOR APPROVALS
7. VARIABLE FLOW IN A PROCESS
8. TOO MUCH INVENTORY
9. INCOMPLETE WORK
10. OVERPRODUCTION
11. WAITING & DELAYS
12. OVER-PROCESSING

PEOPLE WASTE

1. UNCLEAR ROLE, RESPONSIBILITY, AUTHORITY AND ACCOUNTABILITY
2. LACK OF TRAINING
3. WORK OR TASK INTERRUPTIONS
4. MULTI-TASKING
5. UNDERUTILIZATION OF TALENT
6. RECRUITING ERRORS
7. LACK OF STRATEGIC FOCUS



Presented by: Carlos Conejo,
Lean Six Sigma Master Black Belt



PHYSICAL ENVIRONMENT WASTE

1. CLUTTER
2. SAFETY
3. MOVEMENT

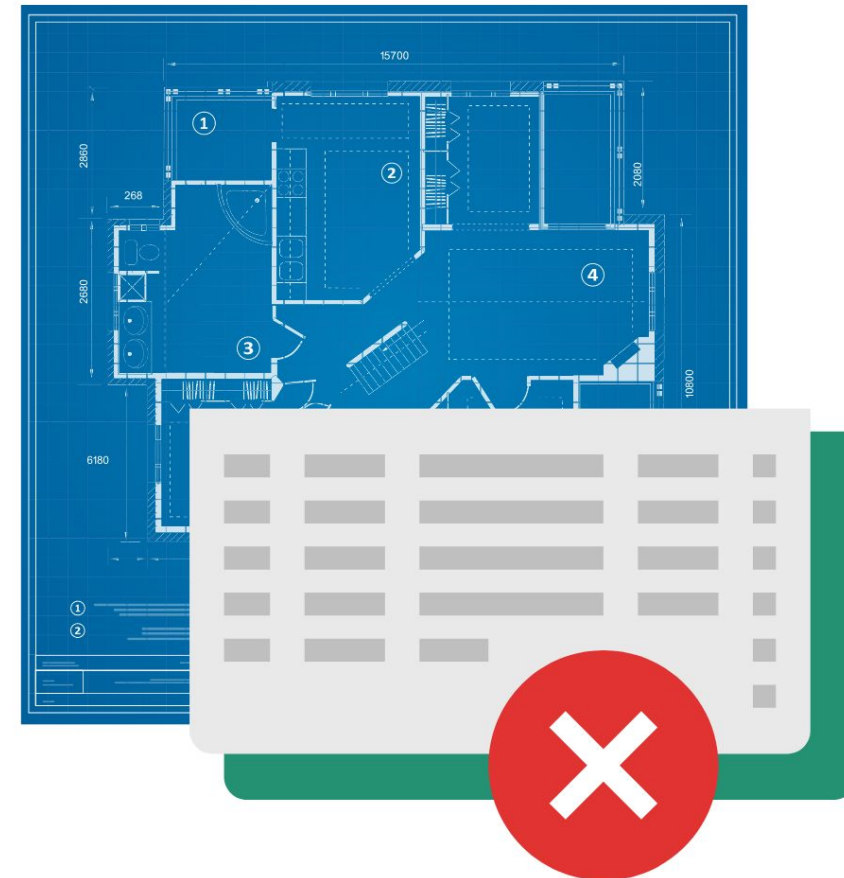
Muda is WASTE - Mura is UNEVENNESS or UNBALANCED - Muri is OVERBURDEN or EXCESSIVE
Check out the different kinds of waste above that can cause the feast or famine cycle

Driving Lean Principles Through QMS

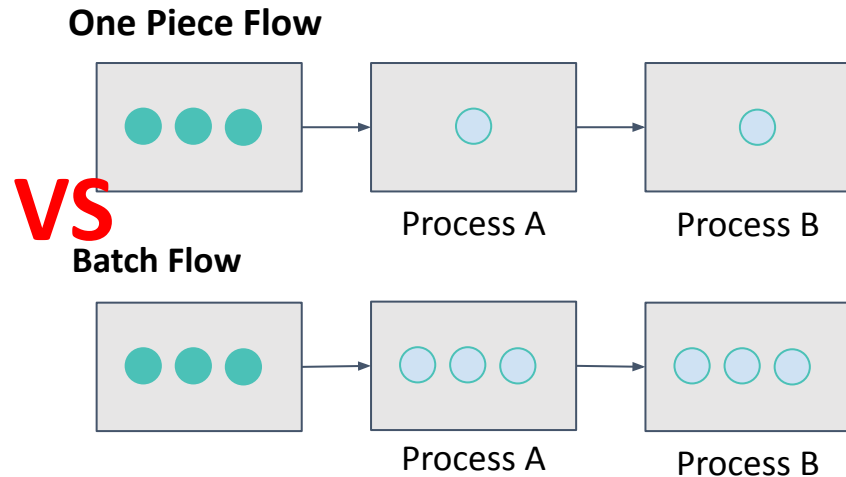


Motion Waste: Examples

- Poor layout of facilities.
- Machine terminals only located in office. Which leads to batching of data input.
- Binders full of paperwork.
- Making manual calculations of inventory or percentages consumed in recipes. These numbers can be automatically updated in real-time through IoT devices and other smart applications.



Motion Waste: Solutions



- **One piece flow.** Envelope exercise.
- Increasing locations of data entry.
- Utilizing **5S methodology** for document and tool location.
 - reference link provided end of presentation.
- Utilizing integrations to reduce double handling of data.
- Reduce the amount of systems used.



What is Waiting Waste?



Waiting refers to wasted time because of slowed or halted production in one step of the production chain while a previous step is completed.

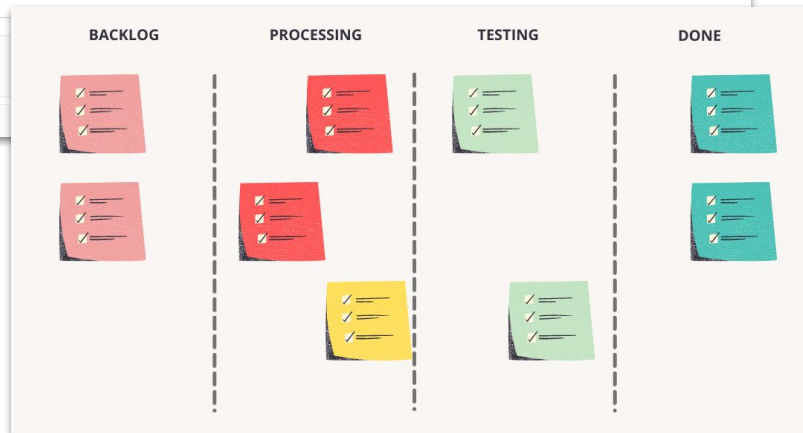
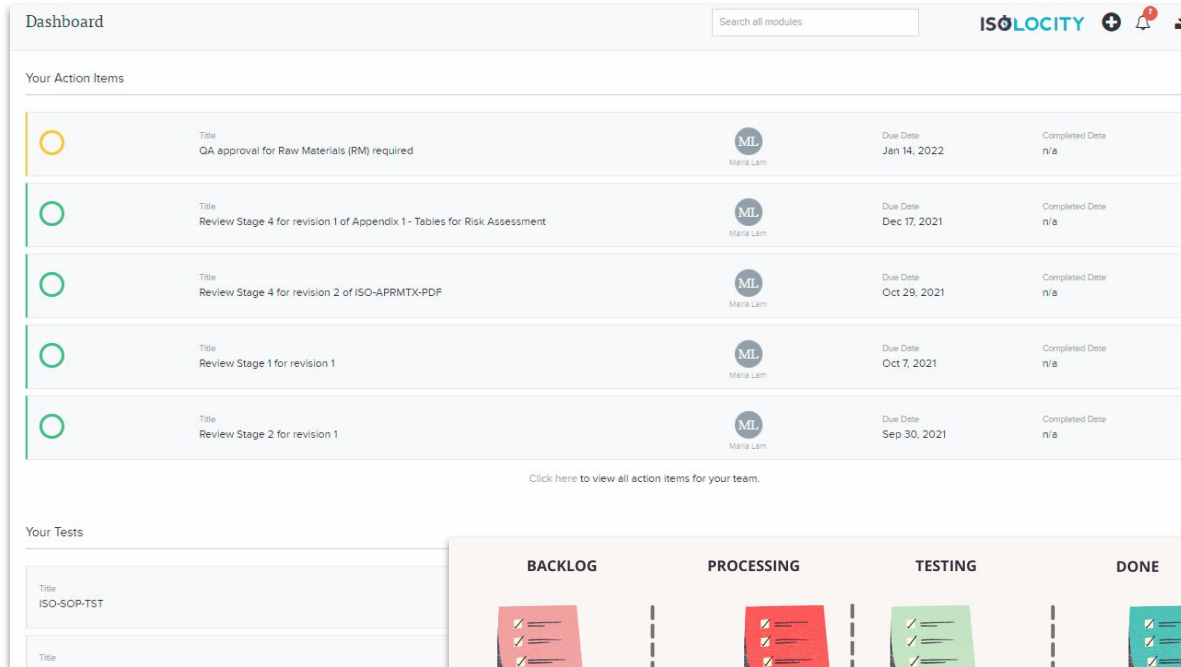


Waiting Waste: Examples

- Poor operational design leads to product release and record keeping to take longer than it should.
- Poor system management that create the double handling of data when information can be readily available automatically.
- Waiting on batch record completion prior to product release.






Waiting Waste: Solutions








- **Cross Training** – ensures processes are not dependent on one person for input.
- **Visual management** – KPIs, tick charts, WI, and SOPs. These ensure there is no confusion with instructions and allows teams to process data more efficiently. This will increase input quality while decreasing waiting time between stages and escalations of tasks.



Waiting Waste: Solutions


Dashboard Search all modules ISOLOCITY   

Your Action Items

	Title	ML Maria Lam	Due Date	Completed Date
	QA approval for Raw Materials (RM) required		Jan 14, 2022	n/a
	Review Stage 4 for revision 1 of Appendix 1 - Tables for Risk Assessment		Dec 17, 2021	n/a
	Review Stage 4 for revision 2 of ISO-APRMTX-PDF		Oct 29, 2021	n/a
	Review Stage 1 for revision 1		Oct 7, 2021	n/a
	Review Stage 2 for revision 1		Sep 30, 2021	n/a

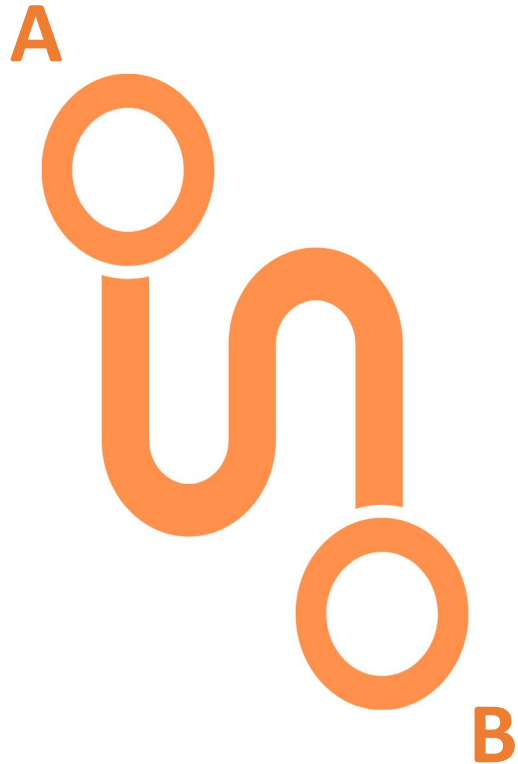
[Click here to view all action items for your team.](#)

Your Tests

Title	Status	Start Date	Due Date
ISO-SOP-TST	 Incomplete	Jun 8, 2021	



What is Transportation Waste?

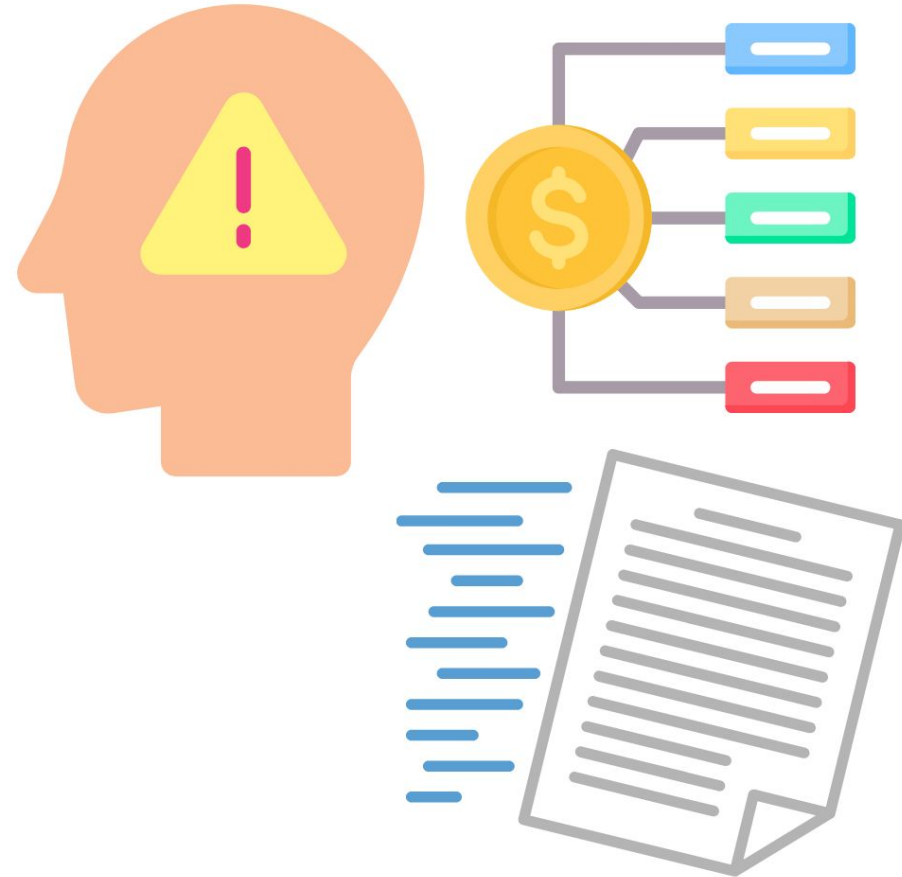


Transport refers to the movement of materials and records from one position to another.



Transportation Waste: Examples

- Adding to carbon-footprint by commuting to work location.
- Travelling paper documents such as lab results or batch records.
- Time cost of collecting quantitative and qualitative plant/product data that is unnecessary and prone to human errors.



Transportation Waste: Solutions

← Go Back Edit Corrective Action Report Create Change Control

Root Cause Analysis

Date Root Cause Occurred
Dec 9, 2020

Root Cause Description
From release of SOP-0009, Rev C Complaint Handling procedure on May 19, 2019 through December 1, 2020, 10 customer complaints have exceeded "3 business days to make a reportability determination from becoming aware date".
MDR Determination Form FRM-0082, and Vigilance Determination Form FRM-0081 were completed by external, off-site Quality Assurance Consultants that supported multiple customers. Consequently, they were not able to provide consistent support to complete the reviews within 3 business days.

5-Why Analysis
Perform a Fishbone Analysis

Why 1
1. Write down the specific problem. Writing the issue helps you formalize the problem and describe it completely. It also helps a team focus on the same problem.
2. Ask Why the problem happens and write the answer down here.

Conclusion
Investigation was performed by quantifying the number of days it has taken to make a reportability determination from the becoming aware date.

Authorized By
Pamela Razzani
303221

Timestamp
Authorized
on Jun 4, 2021 12:03 PM

Preventative
Remove Rep

Search activities From Date To Date

Corrective Action Report #Quality System-226 has been downloaded # 19732
Sep 3, 2021 at 2:16 PM

Corrective Action Report Quality System-226 has been re-opened # 19710
Data verification
View Diff
Sep 3, 2021 at 11:16 AM

Save Save & Close

- Automated data inputs with sensors, integrations and IoT devices.
- Use secure electronic system that allows employees to work remotely.
- Implement e-signatures to manage documentation approvals instead of paper.



Transportation Waste: Solutions

← Go Back

Edit Corrective Action Report

Create Change Control

Root Cause Analysis

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Preventative Actions

Remove Report

Save Save & Close

Search activities

From Date To Date

Angel LI 247221

Corrective Action Report #Quality System-226 has been downloaded # 19732

Sep 3, 2021 at 2:16 PM

Angel LI 247221

Corrective Action Report Quality System-226 has been re-opened # 19710

“ Data verification ”

View Diff

Sep 3, 2021 at 11:16 AM

Perform a Fishb...

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Permisa Razavi 303221

Timestamp

Authorized

on Jun 4, 2021 12:03 PM



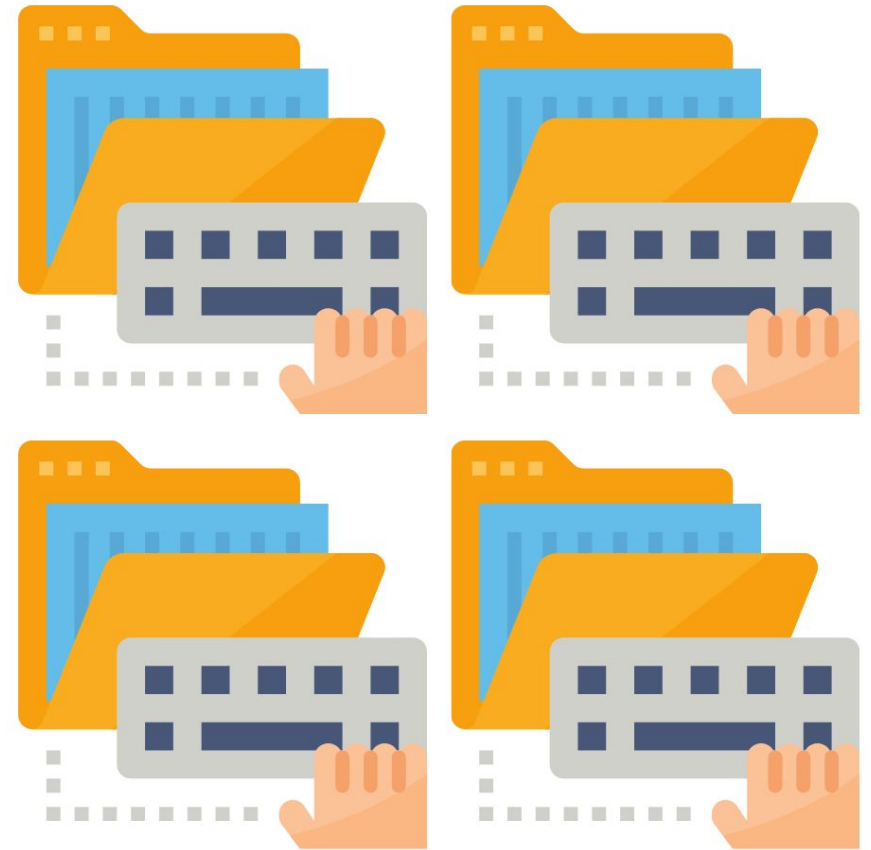
What is Inventory Waste?

Inventory waste refers to the waste produced by unprocessed inventory.

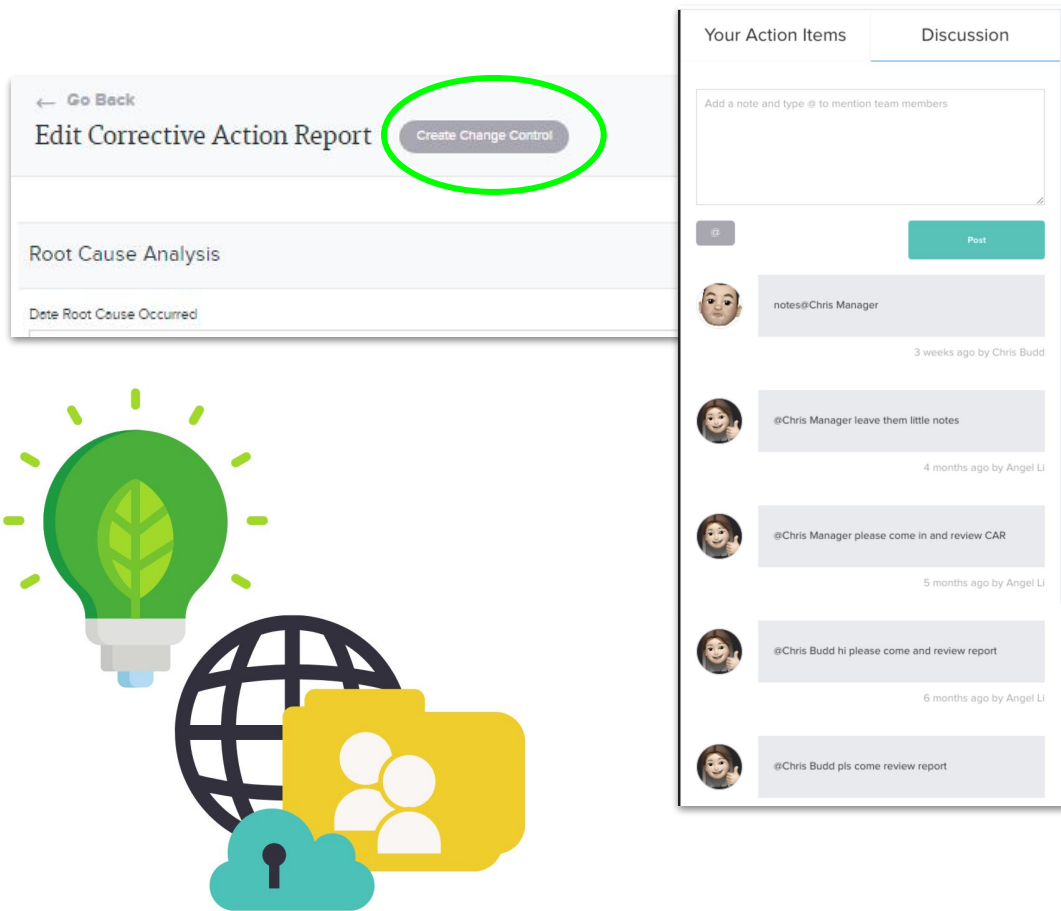


Inventory Waste: Examples

- Duplication of records leading to unnecessary errors and a finding exercise to locate information.
- Manual inputs of data or other information which take time to process for digital warehousing. Take up space and time while amplifying security risks.
- Unnecessary emails.



Inventory Waste: Solutions



- Prioritize sustainability by using less paper and less materials which reduces costs of data warehousing and reduces the risk of lost data in the long run.
- Standardizing and reducing points of inputs to create a system for one input that feed multiple endpoints. Thus improving automation with record keeping.
- Adopt streamlined communication tools that line up with your record keeping.



Inventory Waste: Solutions

← Go Back

Edit Corrective Action Report

Create Change Control

Root Cause Analysis

Date Root Cause Occurred

Your Action Items

Discussion

Add a note and type @ to mention team members

@

Post



notes@Chris Manager

3 weeks ago by Chris Budd



@Chris Manager leave them little notes

4 months ago by Angel Li



@Chris Manager please come in and review CAR

5 months ago by Angel Li



@Chris Budd hi please come and review report

6 months ago by Angel Li



@Chris Budd pls come review report



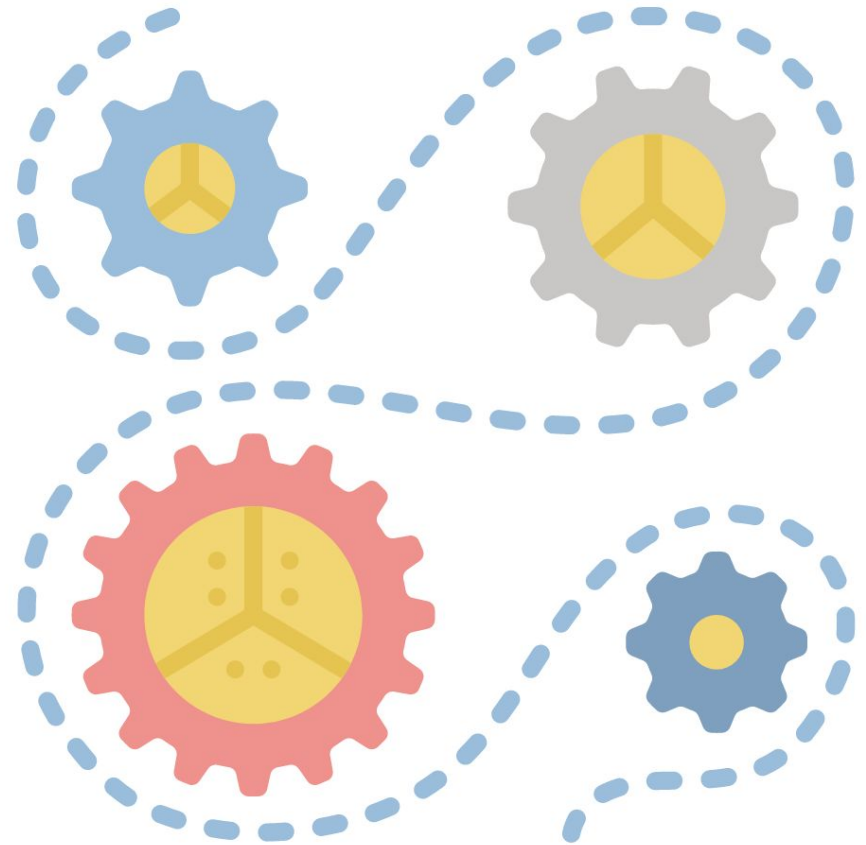
What is Overproduction Waste?

The most serious of the wastes, overproduction can cause all other types of wastes and results in excess inventory and record keeping.



Overproduction Waste: Example

- Mistakes in processing raw materials and data due to human error cause an excess of resources to be used up. This limits the production output while driving up costs.
- Producing too much paperwork for one process.



Overproduction Waste: Solutions

Inspection #1269

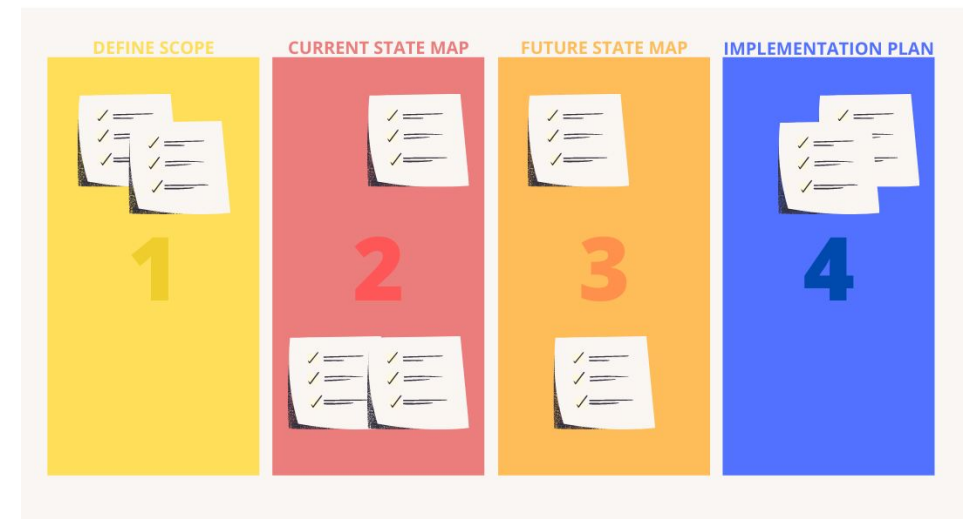
Sample 1
Batch rose
Jan 14, 2022 4:32 PM

Sample 1 - Batch rose

Inspection Date: Jan 14, 2022 4:32 PM

Steps to produce	Operations	Test Criteria	Signature Required	Inspection Method / Equipment
Line Clearance	Sanitation	Acceptable / Unacceptable Pass		Floor Cleaner 1 Table 1

- Standardization data handling and input requirements.
- Good document practices.
- **Value stream mapping** your data flow. Cut the waste.

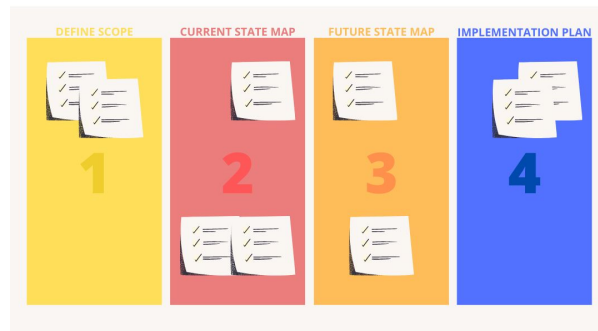


Overproduction Waste: Solutions

- Standardization data handling and input requirements.
- Good document practices.
- **Value stream mapping** your data flow. Cut the waste.

The screenshot shows a digital inspection form for 'Inspection #1269'. At the top, there is a 'Go Back' button and a 'Switch to Batch View' link. A 'Sample 1' card indicates 'Batch rose' with a timestamp of 'Jan 14, 2022 4:32 PM'. Below this, there is a section for 'Sample 1 - Batch rose' with an 'Add Photo of Sample' button. The form includes input fields for 'Inspection Date' (filled with 'Jan 14, 2022 4:32 PM') and 'Batch', along with a 'Signature' field and a 'Sign and Finalize Sample' button. A table below these fields is highlighted with a green border. The table has five columns: 'Steps to produce', 'Operations', 'Test Criteria', 'Signature Required', and 'Inspection Method / Equipment'. The 'Test Criteria' column contains a radio button for 'Acceptable' (which is selected) and 'Unacceptable', and a 'Pass' button at the bottom. The 'Inspection Method / Equipment' column contains the text 'Floor Cleaner 1 Table 1'.

Steps to produce	Operations	Test Criteria	Signature Required	Inspection Method / Equipment
Line Clearance	Sanitation	<input checked="" type="radio"/> Acceptable / <input type="radio"/> Unacceptable <input type="button" value="Pass"/>		Floor Cleaner 1 Table 1



Overproduction Waste: Solutions

← Go Back
Inspection #1269

Switch to Batch View

Sample 1
Batch rose
Jan 14, 2022 4:32 PM

Sample 1 - Batch rose [+ Add Photo of Sample](#)

Inspection Date: Jan 14, 2022 4:32 PM
Batch:
Signature: Sign and Finalize Sample

Steps to produce	Operations	Test Criteria	Signature Required	Inspection Method / Equipment
Line Clearance	Sanitation	<input checked="" type="radio"/> Acceptable / <input type="radio"/> Unacceptable <input type="text"/>		Floor Cleaner 1 Table 1
		<input checked="" type="radio"/> Pass		



What is Overprocessing Waste?

Over-processing refers to any component of the process of manufacture that is unnecessary.



Overprocessing Waste: Example

- Multiple prints of the same document in circulation due to fragmented training or onboarding systems.
- Excess paper as a result of duplication in testing, approvals, training and more.
- Increased data handling efforts due to excess raw material, parts and other records being processed.
- Too many steps to complete simple tasks - Employee Training and SOP revisions.



Overprocessing Waste: Solutions

- Reducing waste involved with document revisions by standardizing training procedures for employees and onboarding processes.
- Introducing employee training portals or cloud based systems to ensure a single source of truth as new revisions are added and approved for circulation.
- Automating through electronic systems to allow for pre-programmed and systemic responses for each step of document processing.

← Go Back
Edit SOP 0004 - Risk Management Revision 4

This document is currently under revision. It is only viewable by document owners and organization admins.

1 Initial Draft
2 Final Draft
3 Approved - Not Effective
4 Approved - Effective
Incomplete change control



Document Information

ID: DOC-304
Is the document being edited? No / yes
Approval Matrix: [Dropdown]
Parent Document: [Dropdown]
Document Name: SOP 0004 - Risk Management
Document Type: Procedure
Department: [Dropdown]
Last Review Date: Choose Date
Frequency: 12
Duration: Months
Next Review Date: May 24, 2021

Create Training Activity





Overprocessing Waste: Solutions



← Go Back Edit SOP 0004 - Risk Management Revision 4  

This document is currently under revision, it is only viewable by document owners and organization admins.



1
Initial Draft

 2/2 


2
Final Draft



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3
Approved - Not Effective



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4
Approved - Effective


Incomplete change control

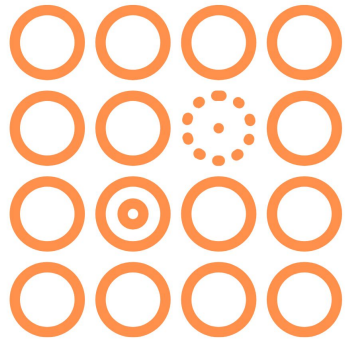
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Document Information 

ID	Is the document being edited?	Approval Matrix	
DOC-304	 No / yes	<input type="text"/>	
Parent Document	Document Name	Document Type	Department
<input type="text"/>	SOP 0004 - Risk Management	Procedure	<input type="text"/>
Last Review Date	Frequency	Duration	Next Review Date
Choose Date	12	Months	May 24, 2021



What is Defect Waste?

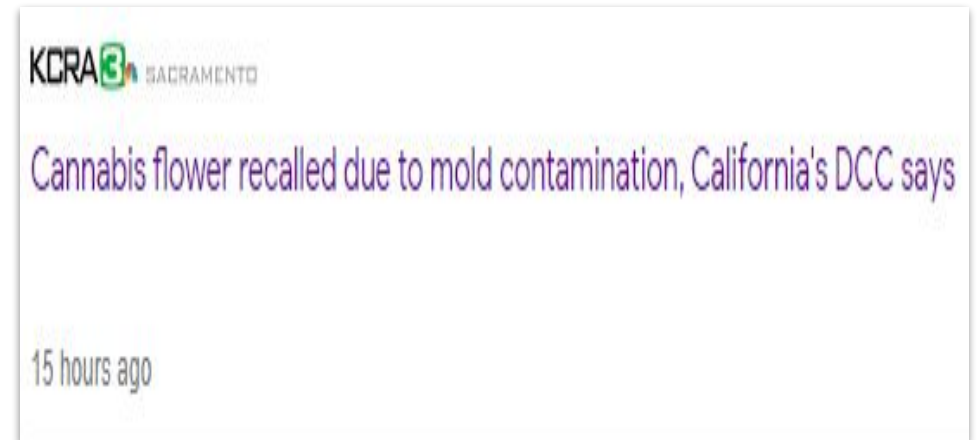


Defects refer to a product or record deviating from the standards of its design or from the customer's expectation.



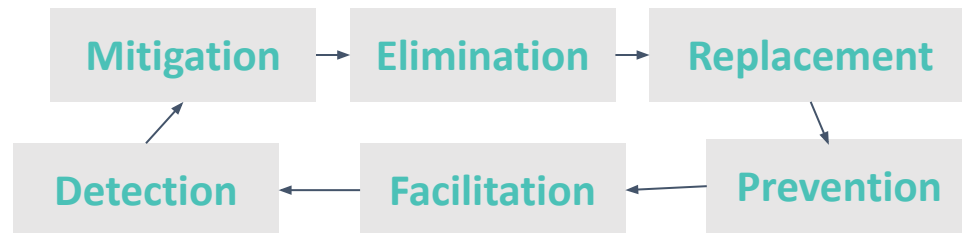
Defects Waste: Example

- When certain steps of inspection are missed leading to contaminants entering the supply chain ultimately leading to product waste.
- Poor documentation practices or form design.



Defects Waste: Solutions

Poke Yoke (Error Proof Design)



- Standardizing data input requirements. Good document practices.
- Layout for data inputs in relation to where work is being completed.
- Error proof input requirements through form design.
- Automated inputs – sensors, equipment, and integrations.
- **Poke Yoke** release requirements to ensure no steps have been missed.
- Manage risk through the use of analytics and reporting to drive preventative actions.



Key Takeaways

- One Piece flow data input
- Implement 5S/6S
- Integrations with Technology
- Increase Data input centers
- SaaS or cloud based solutions allowing for remote work
- Excellent documentation practices
- Poke Yoke your process
- Visual Management
- Data integrity
- **MORE AUTOMATION!!!**



ISO  **LOCITY**



Thanks + Q&A

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Master Black Belt

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Resources

DQMS White Paper - Subscribe on LinkedIn

<https://www.linkedin.com/build-relation/newsletter-follow?entityUrn=7053773645059428352>

[5S in the Workplace](#)

[Improve Productivity With TPM Implementation and OEE](#)

Use Promo Code: LI22 when calling to inquire about our Digital QMS Solution

Upcoming Events



March 11-14, 2024
Hyatt Regency | New Orleans

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SQF New Orleans. March 11-13

