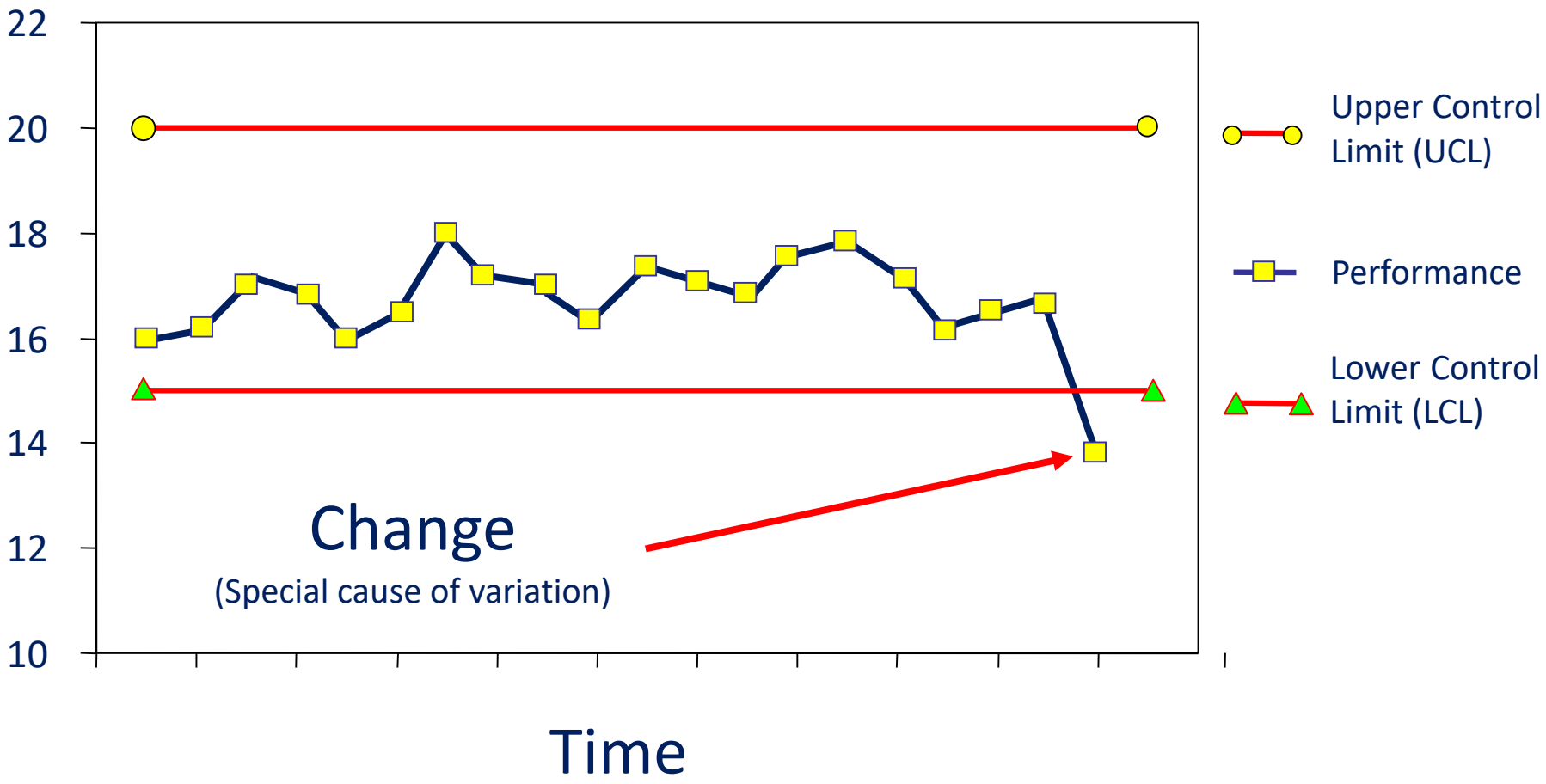
Root Cause Investigation for CAPA

Rob Weaver, President, Weaver Consulting

Introduction

Realistic Investigation Scenario



Common Investigation Mistakes

- Inconsistent approach to investigations
- Focus on possible causes from beginning of investigation
- Unnecessary experiments & studies
- Neglect to identify and address systemic root causes
- Weeks or months without resolution

Correction

- Action taken to eliminate a detected nonconformity
- Containment to stabilize problem
- Examples
  - Scrap
  - Repairs or modifications
  - Recalls
- Investigation has not been conducted
- Nonconformities continue
- Additional work + expense

Corrective Action……..vs Preventive Action

- Action taken to eliminate the cause of a detected nonconformity
- Requires investigation and identification of root cause
- Action taken to stop or minimize recurrence

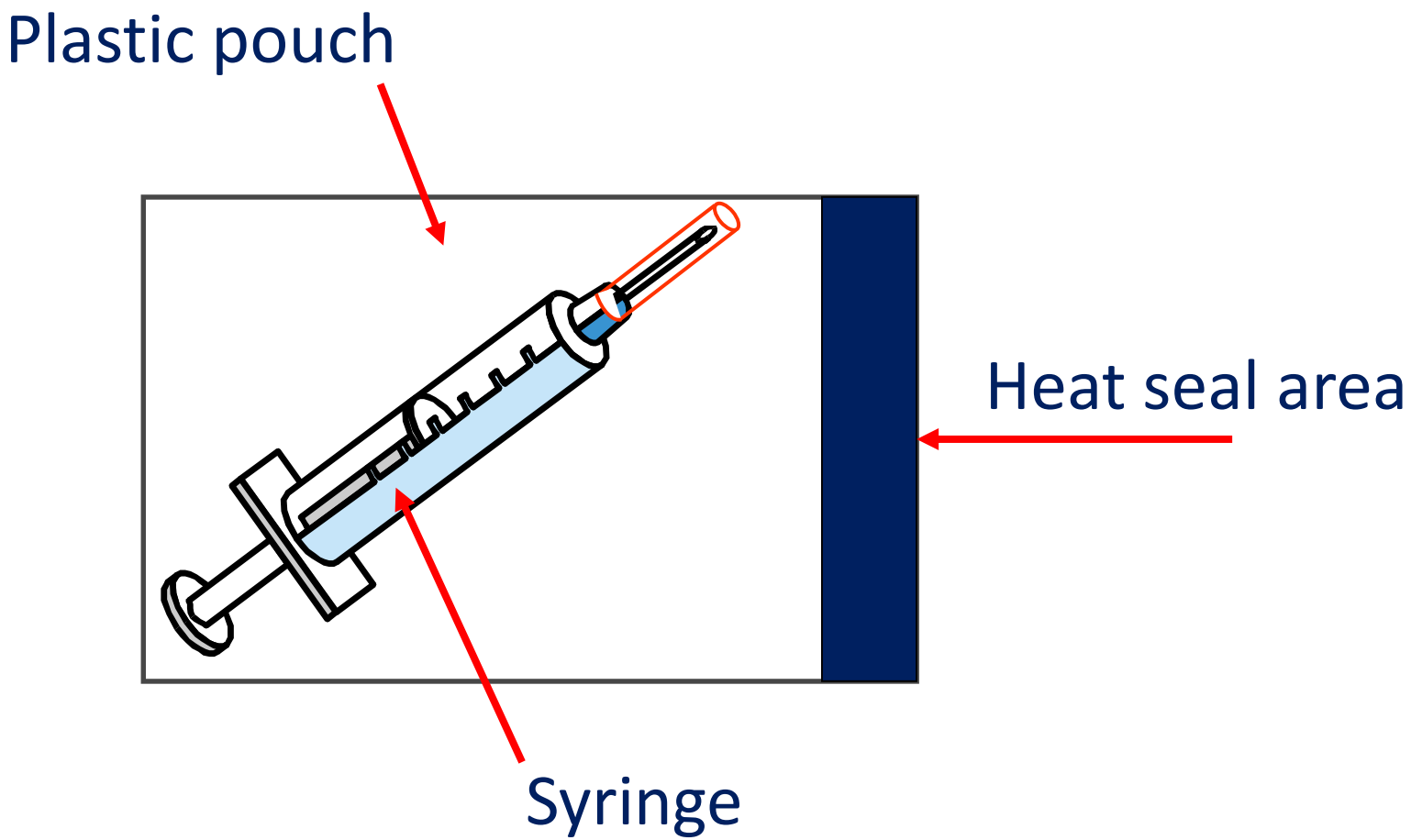
- Action taken to eliminate the cause of a potential nonconformity
- Often impractical to prevent all possible nonconformities
- Some, perhaps most can be prevented

Step 1: Define the Performance Problem

Define the Performance Problem

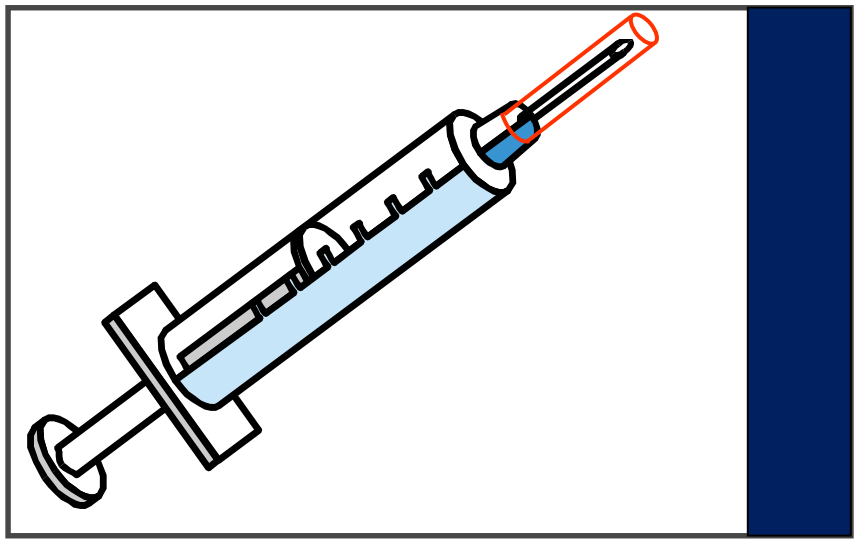
Input	Process	Output
Performance gap	State the problem	Problem statement
	Describe the problem	Is/Is Not diagram
	Describe the process	Process flow diagrams
	Identify the inputs	Input/output diagrams
	Timeline of events	Timeline of events
	Team charter	Team charter

Case of the Unsealed Pouch



Case of the Unsealed Pouch

- Seal requirements
  - Withstand a 10 lb (44 n) pull test
  - Open with a 20 lb (88 n) pull test



Case of the Unsealed Pouch

Customers are reporting some seals are open upon receipt…

…sterility has been compromised

State the Problem

What specific object has the defect?

Syringe pouch seals…

What is the specific defect?

…are open

…or failing the 10 lb pull test

Describe the Problem

Change	Is Not	Change
Is Not	What / How much / Is / Where / When	Is Not
Change	Is Not	Change

Is/Is Not Diagram

	Is	Is Not
What	What specific object has the defect?	What similar objects could have the defect but don't?
	What is the specific defect?	What other defects could be seen but aren't?
	What are the defect characteristics?	*What could the characteristics be but aren't?*
	What product lots have the defect?	What product lots could have the defect but don't?
	Are any part lots associated with the defect?	What part lots could be associated with the defect but aren't?
	What patterns are in the "What" answers?	What patterns aren't seen in the "What" answers?
Where	Where is the defective object observed geographically?	Where could the defective object be observed geographically but isn't?
	Where is the defect on the object?	Where could the defect be on the object but isn't?
	Where is the defect 1st seen in the process?	*Where could the defect 1st be seen in the process but isn't?*
	Where else is the defect?	Where else could the defect be but isn't?
	What patterns are in the "Where" answers?	What patterns aren't seen in the "Where" answers?
When	*When was the defective object 1st seen (date/time)?*	*When could the defective object 1st been seen but wasn't?*
	When since the 1st time has the defective object been seen (date/time)?	When since the 1st time could the defective objective have been seen but wasn't?
	What is the trend (stable, better, worse)?	What could the trend be but isn't?
	What patterns are in the "When" answers?	What patterns aren't seen in the "When" answers?
How Much	How many objects have the defect?	How many objects could have the defect but don't?
	How big or small is the defect?	How big or small could the defect be but isn't?
	How many defects are on the object?	How many defects could be on the object but aren't?
	What patterns are in the "How Much" answers?	What patterns aren't seen in the "How Much" answers?

Is/Is Not Diagram: What Questions

Problem Statement: Syringe pouch seals are either open or failing the 10 lb pull test

Is	Verified	Is Not	Verified
What specific object has the defect?		What similar objects could have the defect but don't?	
Syringe pouch seals		**Surgeon glove pouch seals**	
What is the specific defect?		What other defects could be seen but aren't?	
Seals are open or failing the pull test		**Tears, holes, product in seal, etc**	
What are the defect characteristics?		*What could the defect characteristics be but aren't?*	
Failing 10 lb requirement		**Failing 20 lb requirement**	
What product lots have the defect?		What product lots could have the defect but don't?	
SY217, SY218…SY235		**SY216 and earlier**	
Are any part lots associated with the defect?		What part lots could be associated with the defect but aren't?	
None		**None**	
What patterns are in the "What" answers?		What patterns aren't seen in the "What" answers?	
See above		**See above**	

Is/Is Not Diagram: Where Questions

Problem Statement: Syringe pouch seals are either open or failing the 10 lb pull test

Is	Verified	Is Not	Verified
Where is the defective object observed geographically?		Where could the defective object be observed geographically but isn't?	
All 30 North American sales regions (CA, US, MX)		**Single country, some sales regions**	
Johnsville facility		**Janesville facility**	
Where is the defect on the object?		Where could the defect be on the object but isn't?	
Final seal (1)		**Supplier's seals (3)**	
Where is the defect 1st seen in the process?		*Where could the defect 1st seen in the process but isn't?*	
Final inspection & release (100% pull test)?		**Before final inspection & release?**	
Where else is the defect?		Where else could the defect be but isn't?	
Production 3 in Johnsville		**Production lines 1, 2, and 4 in Johnsville**	
What patterns are in the "Where" answers?		What patterns aren't seen in the "Where" answers?	
See above		**See above**	

Is/Is Not Diagram: When Questions

Problem Statement: Syringe pouch seals are either open or failing the 10 lb pull test

Is	Verified	Is Not	Verified
When was the defective object 1st seen (date/time)?		*When could the defective object 1st been seen but wasn't?*	
Approximately two weeks ago (June 1st)?		**Before June 1st?**	
When since the 1st time has the defective object been seen (date/time)?		When since the 1st time could the defective object been seen but wasn't?	
Continuously ever day since approximately June 1st		**Every other day, sporadic, some other pattern**	
What is the trend (stable, worse better)?		What could the trend be but isn't?	
Stable		**Worse, better**	
What patterns are in the "When" answers?		What patterns aren't seen in the "When" answers?	
See above		**See above**	

Is/Is Not Diagram: How Much Questions

Problem Statement: Syringe pouch seals are either open or failing the 10 lb pull test

Is	Verified	Is Not	Verified
How many objects have the defect?		How many objects could have the defect but don't?	
Avg 5% daily production		**Historical defect avg .01%**	
How big or small is the defect?		How big or small could the defect be but isn't?	
Avg defective seal 9.3 lbs		**More or less**	
How many defects are on the object?		How many defects could be on the object but aren't?	
1 defect (final seal)		**2, 3, 4 defects (supplier seals)**	
What patterns are in the "How Much" answers?		What patterns aren't seen in the "How Much" answers?	
See above		**See above**	

Is/Is Not Diagram: Key Points

- Ask every question, understanding not all will be applicable
- If an Is answer is recorded; always record an Is Not as well
- Ask each Is and corresponding Is Not question together
- Record multiple answers to the same question separately
- Record disagreements to questions
- Answers at this step are opinions…nothing more

Is/Is Not Diagram: Key Points

- The defective object can be anything: widgets, people, software, physical/virtual processes, systems, etc
- The Where questions are attempting to identify location related patterns: geographically, on the object, in a process, etc
- The When questions are attempting to identify time related patterns: time of day/week/month/year, shift, season, etc
- The How Much questions are attempting to identify numerically related patterns, specific or general

Is/Is Not Diagram: Key Points

- The most critical question: What are the defect characteristics?

- May need to conduct a technical analysis to better characterize the defect

- A sensory description may be beneficial…how does the defect…
  - Feel: rough surface
  - Smell: burnt
  - Sound: hiss
  - Look: blackened material
  - Taste: bitter

Is/Is Not Diagram: Key Points

- The 3 most important questions to describe the problem:
  - *What are the defect characteristics?*
  - *Where is the defect 1st seen in the process?*
  - *When was the defect 1st seen (date and time)?*
- More detail = tighter fence

Is/Is Not Diagram: Key Points

- This is the problem description
- The team must understand the problem in this level of detail
- Places limits on the investigation
- Helps identify critical patterns

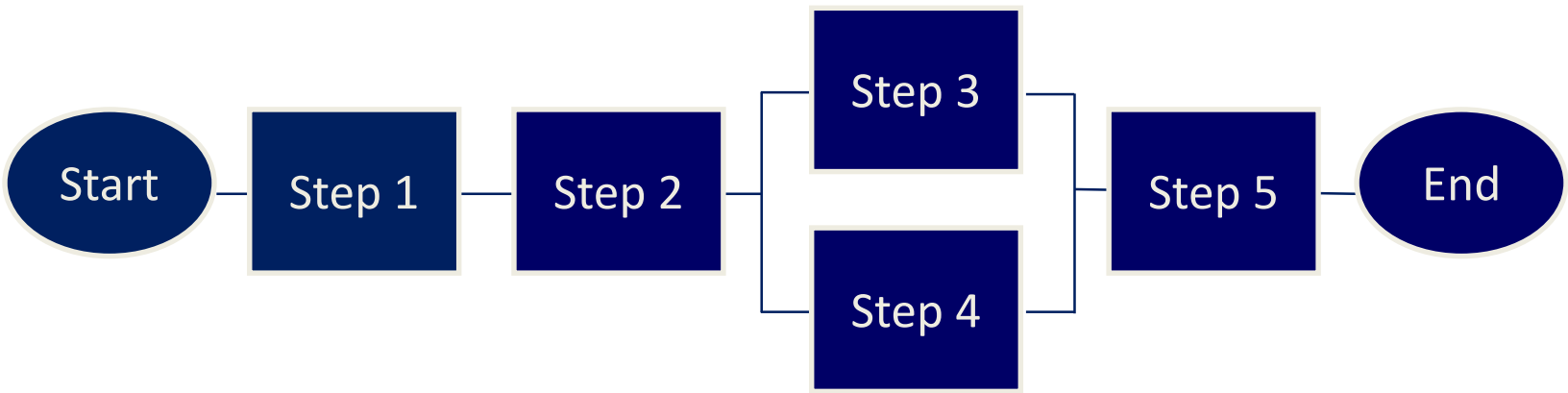
	Is	Is Not
What	What specific object has the defect?	What similar objects could have the defect but don't?
	What is the specific defect?	What other defects could be seen but aren't?
	What are the defect characteristics?	*What could the characteristics be but aren't?*
	What product lots have the defect?	What product lots could have the defect but don't?
	Are any part lots associated with the defect?	What part lots could be associated with the defect but aren't?
	What patterns are in the "What" answers?	What patterns aren't seen in the "What" answers?
Where	Where is the defective object observed geographically?	Where could the defective object be observed geographically but isn't?
	Where is the defect on the object?	Where could the defect be on the object but isn't?
	Where is the defect 1st seen in the process?	*Where could the defect 1st be seen in the process but isn't?*
	Where else is the defect?	Where else could the defect be but isn't?
	What patterns are in the "Where" answers?	What patterns aren't seen in the "Where" answers?
When	*When was the defective object 1st seen (date/time)?*	*When could the defective object 1st been seen but wasn't?*
	When since the 1st time has the defective object been seen (date/time)?	When since the 1st time could the defective objective have been seen but wasn't?
	What is the trend (stable, better, worse)?	What could the trend be but isn't?
	What patterns are in the "When" answers?	What patterns aren't seen in the "When" answers?
How Much	How many objects have the defect?	How many objects could have the defect but don't?
	How big or small is the defect?	How big or small could the defect be but isn't?
	How many defects are on the object?	How many defects could be on the object but aren't?
	What patterns are in the "How Much" answers?	What patterns aren't seen in the "How Much" answers?

Describe the Process(es)

Develop process flow diagram of work being conducted

Product development
Manufacturing
Sterilization
Release
Distribution

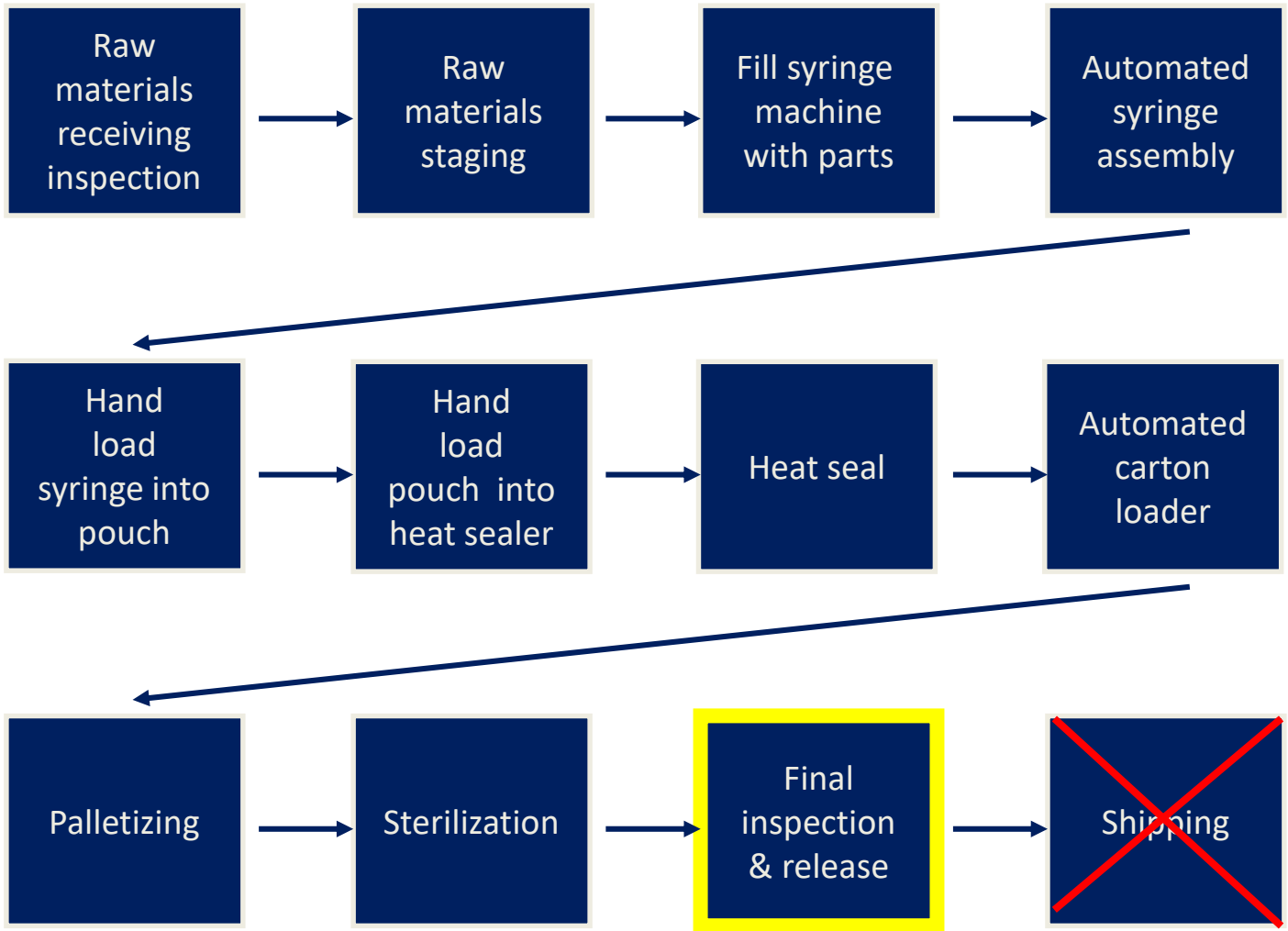
Laboratory
Customer usage
Disposal
Repair/service



Technical root causes often result from a process change

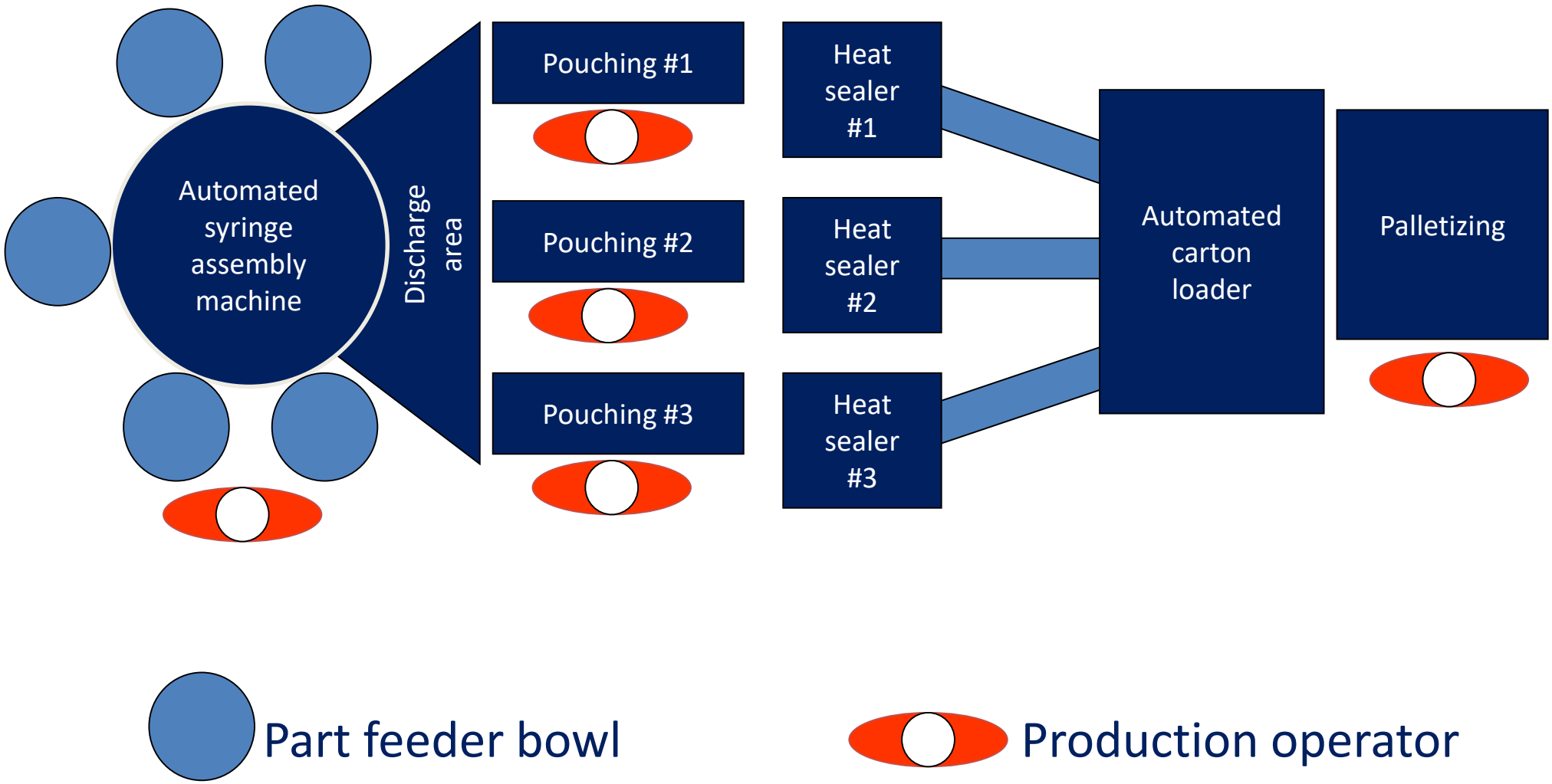
Describe the Process(es)

Syringe production process flow diagram



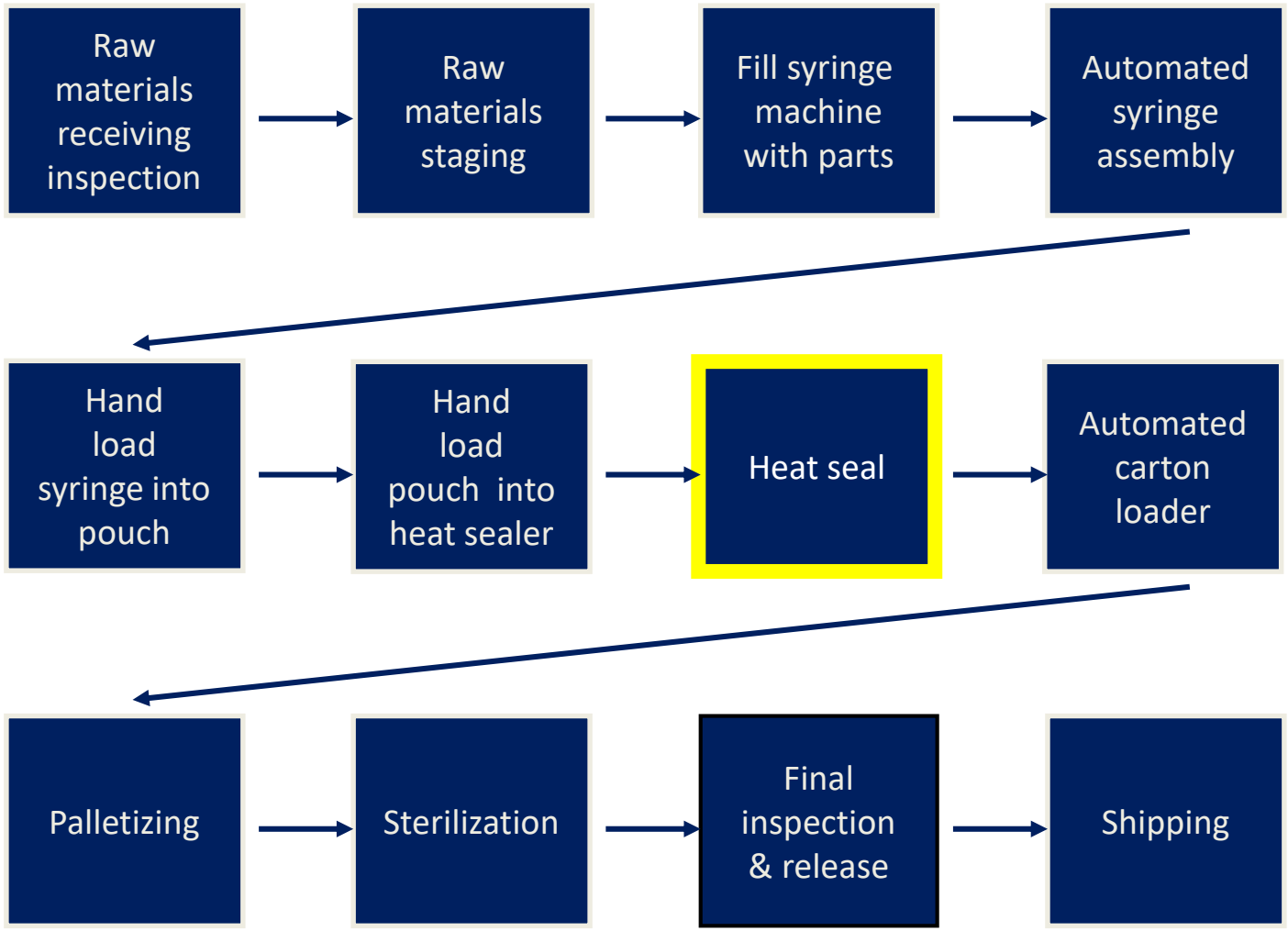
Describe the Process(es)

Other techniques such as a schematic diagram can be leveraged to supplement the process flow diagram



Identify the Inputs

Syringe production process flow diagram



Identify the Inputs

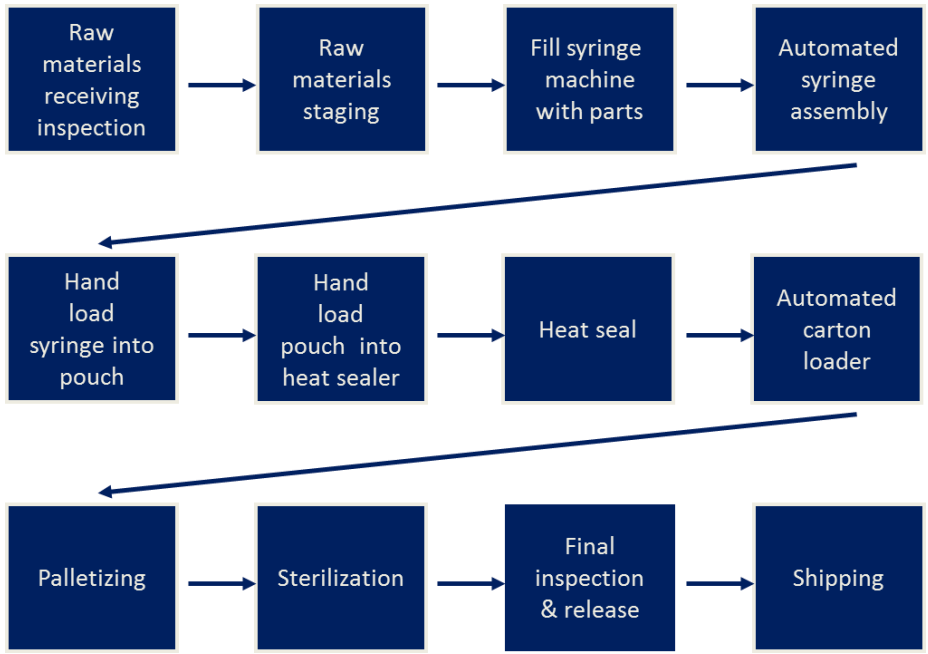
Key

Input | **Process** | **Output**

Technical root causes often result from an input change

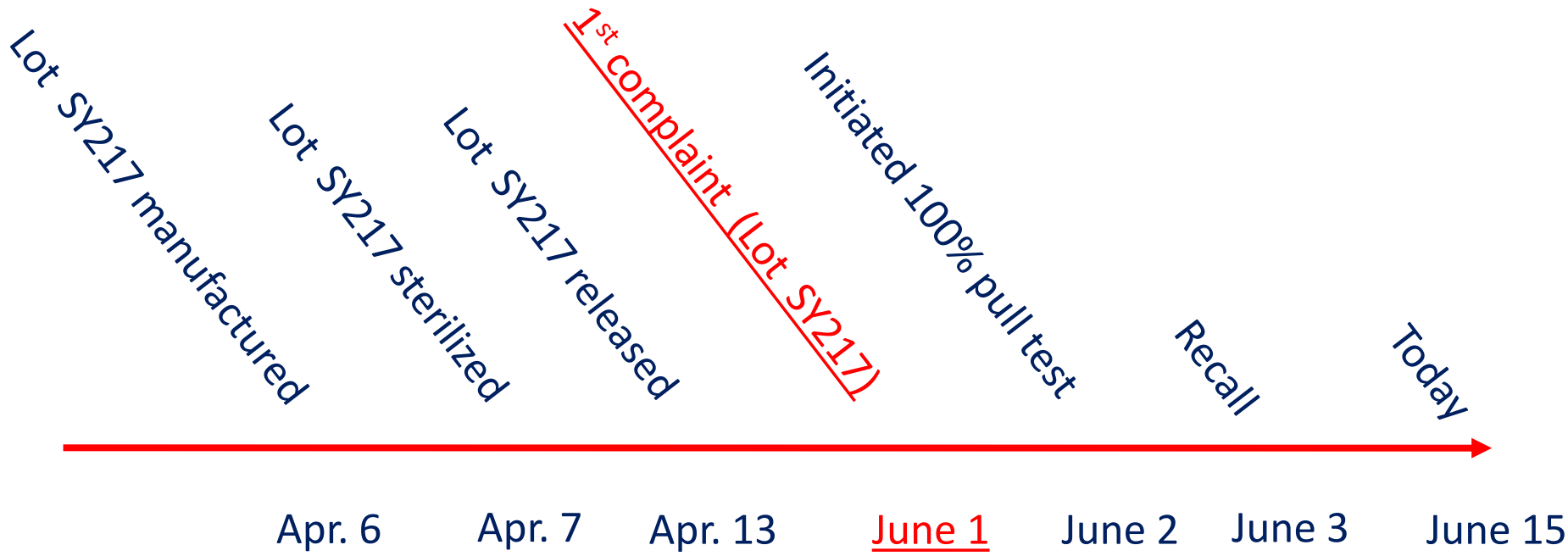
Flow Diagram with Inputs: Key Points

- Assures team understands the process being investigated
- Develop with the experts: individuals executing process regularly
- Will be leveraged throughout the investigation



Timeline of Events

List known relevant events in chronological order



Provides clarification when many events have occurred

Team Charter

- High level statement describing the who, what and why of the investigation

- Used selectively to capture senior management's attention to convey importance of the investigation

Team Charter

- Purpose of the investigation
  - Problem statement
  - Acceptance Criteria: restore performance to requirement
  - Cost savings goal: monetary estimate of expenses
- Identify the investigation team & leader
- Identify the member(s) of management sponsoring the investigation
- Everyone signs the charter to:
  - Verify what the team is working toward
  - Identify any concerns of the team, management, or sponsors
  - Identify key issues where the team will need help

Documentation

- Problem statement
- Is/Is Not diagram
- Process flow diagrams
- Input/output diagrams

Strongly recommended

- Timeline of events
- Team charter

As needed

Step 2: Collect Data

Collect Data

Input	Process	Output
Opinions		Facts
Is/Is Not diagram	Data collection plan	Is/Is Not diagram
Flow diagrams with inputs		Flow diagrams with inputs

Objectives: Determine Data Needed

- Verify initial opinion based Is/Is Not answers

	Is	Verified	Is Not	Verified
What	What object has the defect?		What similar objects could have the defect but don't?	
	Syringe pouches		**Surgeon glove pouches**	
	What is the specific defect?		What other defects could be seen but aren't?	
	Seals open or failing pull test		**Tears, holes, product in seal, etc.**	
	What are the defect characteristics?		What could the characteristics be but aren't?	
	Failing 10 lb requirement		**Failing 20 lb requirement**	

- Determine additional data needed

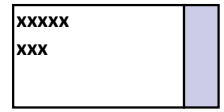
Objectives: Determine Data Location

- Some already exists
  - Batch records
  - Lab notebooks
  - Previous experiments/studies

- Some can be captured on a go forward basis as it is generated during the investigation
  - Limited experiments to better characterize the problem
  - Not to test a possible cause

Objectives: Determine Data Analysis

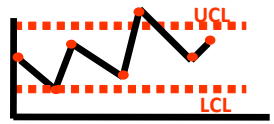
- Format data so it can be interpreted:
  - Check sheets/spreadsheets
  - Pivot tables
  - Pareto analysis
  - Concentration diagrams
  - Control charts
  - ANOM (analysis of mean)
  - Multi-variable charts
  - Capability studies
  - Histograms
  - Summary reports
  - Pie charts
  - Scatter diagrams



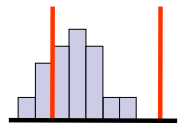
Concentration Diagram

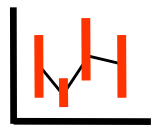
	M	T	W	T	F
1	X	X			X
2		X		X	X
3	X		X	X	

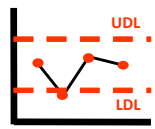
Checksheet



Control Chart


Capability Study


Multi-Vari Chart



Analysis of Mean

Collect Data: Verify Initial Answers

Problem Statement: Syringe pouch seals are either open or failing the 10 lb pull test

	Is	Verified	Is Not	Verified	Data Needed	Data Location	Analysis Tool
What	What specific object has the defect?		What similar objects could have the defect but don't?				
	Syringe pouch seals	✓	**Surgeon glove pouch seals**	✓	**Surgeon glove defect history**	**Production records**	**Check sheet**
	What is the specific defect?		What other defects could be seen but aren't?				
	Seals are open or failing the pull test	✓	**Tears, holes, product in seal, etc.**	✓	**Verify actual defects: are these the only defects being experienced?**	**Non conformance reports (NCRs)**	**Pareto analysis**
	What are the defect characteristics?		What could the characteristics be but aren't?				
	Failing 10 lb requirement	✓	**Failing 20 lb requirement**	✓	**Potential additional characteristics**	**Analysis of scrap product; NCR review**	**Pareto analysis, summary report**
	What product lots have the defect?		What product lots could have the defect but don't?				
	SY217, SY218…SY235	✓	**SY216 and earlier**	✓	**Confirm affected product lots**	**Production records**	**Check sheet**
	Are any part lots associated with the defect?		What part lots could be associated with the defect but aren't?				
	None	✓	**None**	✓	**Compare part lots to product lots**	**Production records**	**Pivot table**
Where	Where is the defective object observed geographically?		Where could the defective object be observed geographically but isn't?				
	All 30 NA regions (CA, US, MX) Johnsville facility	✓	**Single country, some sales regions Janesville facility**	✓	**Affected sales regions Confirm only Johnsville**	**Customer compliant records Janesville NCRs**	**Pareto Y/N check sheet**
	Where is the defect on the object?		Where could the defect be on the object but isn't?				
	Final seal (1)	✓	**Supplier's seals (3)**	✓	**Confirm only final seal is affected**	**NCRs**	**Concentration diagram**
	Where is the defect 1st seen in the process?		*Where could the defect 1st be seen in the process but isn't?*				
	Final inspection & release (100% pull test)	✓	**Before final inspection & release**	✓	**Confirm when defect is 1st being identified**	**Production records**	**Process flow diagram**
	Where else is the defect?		Where else could the defect be but isn't?				
	Production line 3 Johnsville	✓	**Production lines 1, 2, and 4 in Johnsville**	✓	**Confirm only line 3**	**NCR and production records from 1,2,4**	**Check sheet**
	When was the defective object 1st seen (date/time)?		*When could the defective object 1st been*				

Collect Data: Determine Additional Data

Determine data needed to better characterize the answers to:

- 3 most important questions from Is/Is Not Diagram (red)

Collect Data

Problem Statement: Syringe pouch seals are either open or failing the 10 lb pull test

Is	Verified	Is Not	Verified	Data Needed	Data Location	Analysis Tool
What are the defect characteristics?		*What could the characteristics be but aren't?*				
Failing 10 lb requirement	✓	**Failing 20 lb requirement**	✓	**Additional Data:** Are there any other characteristics (sight, sound, smell, feel, etc)?	NCRs, scrap product	Summary report

No additional characteristics identified

Collect Data

Problem Statement: Syringe pouch seals are either open or failing the 10 lb pull test

Is	Verified	Is Not	Verified	Data Needed	Data Location	Analysis Tool
Where is the defect 1st seen in the process		*Where could the defect 1st be seen in the process but isn't?*				
Final inspection & release (100% pull test)?	✓	**Before 100% pull test?**	✓	**Additional Data:** Pull samples after heating sealing step	Real time data collection	None needed

Defective seals were identified after heat sealing

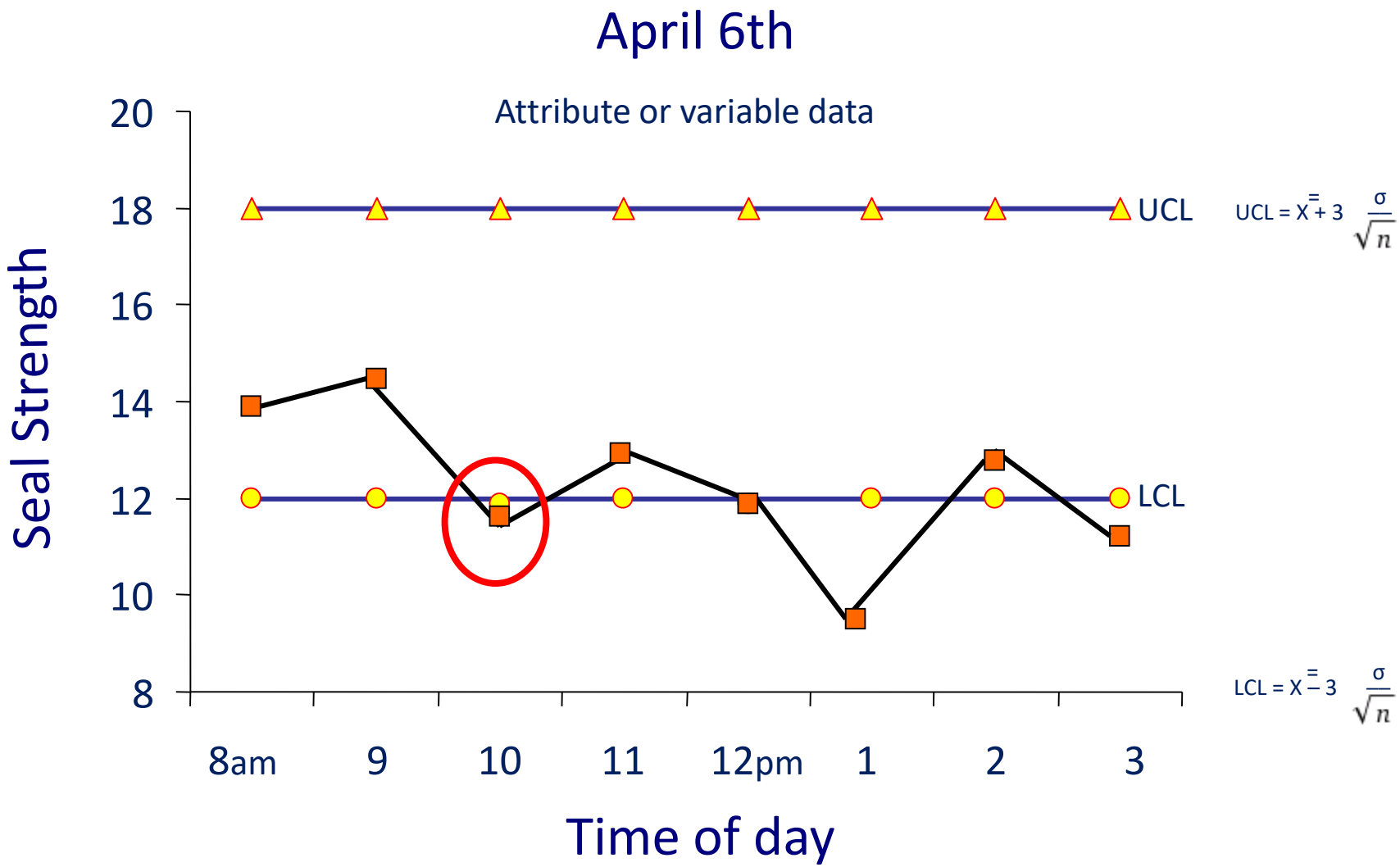
Collect Data

Problem Statement: Syringe pouch seals are either open or failing the 10 lb pull test

Is	Verified	Is Not	Verified	Data Needed	Data Location	Analysis Tool
When was the defective object 1st seen (date/time)?		*When could the defective 1st been seen but wasn't?*				
June 1st	✓	**Before June 1st**	✓	**Additional Data** Can this issue be identified before June 1st?	QC records for production line 3	Control chart measuring seal strength

Control Charts

Used to collect When data



Collect Data: Determine Additional Data

Determine data needed to better characterize the answers to:

- 3 most important questions from Is/Is Not Diagram (red)
- Patterns
- Anything else deemed important

Collect Data

Problem Statement: Syringe pouch seals are either open or failing the 10 lb pull test

Is	Verified	Is Not	Verified	Data Needed	Data Location	Analysis Tool
How many objects have the defect?		How many objects could have the defect but don't?				
Avg 5% daily production	✓	**Historical defect avg .01%**	✓	**Additional Data** Is the defect rate consistently 5% throughout a production shift?	Begin collecting	✓ sheet

Checksheet

Used to collect What, Where, When, & How Much data

Hour	1	2	3	4	5	6	7	8
Defect count	𝍸𝍸𝍸𝍸	𝍸𝍸𝍸 I	𝍸𝍸𝍸 III	𝍸𝍸𝍸 IIII	𝍸𝍸𝍸𝍸	𝍸𝍸𝍸𝍸	𝍸𝍸𝍸 III	𝍸𝍸𝍸 II
Total defects	72	61	73	69	79	75	68	77
Product produced	1412	1298	1431	1380	1519	1470	1388	1481
Hourly defect %	5.1%	4.7%	5.1%	5.0%	5.2%	5.1%	4.9%	5.2%

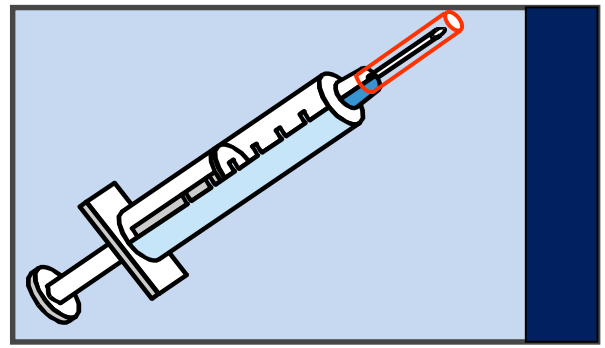
Collect Data

Problem Statement: Syringe pouch seals are either open or failing the 10 lb pull test

Is	Verified	Is Not	Verified	Data Needed	Data Location	Analysis Tool
Where is the defect on the object?		Where could the defect be on the object but isn't?				
Final seal (1)	✓	**Supplier's seals (3)**	✓	**Additional Data** Can the issue be narrowed down to a particular section of the final seal?	Begin collecting	Concentration diagram of a syringe pouch

Concentration Diagram

Used to collect Where and How Much data

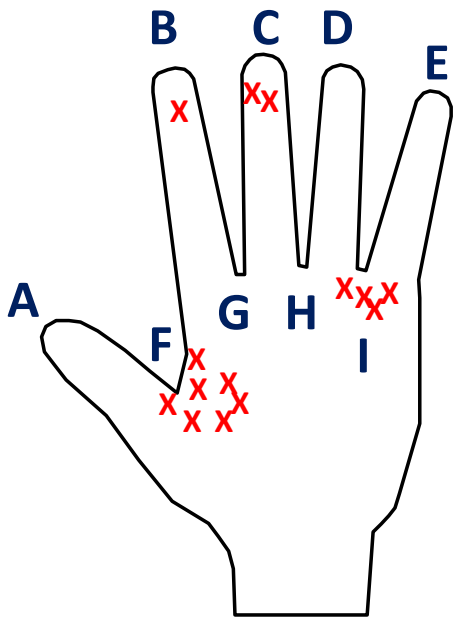


Section 1	xxxxxx xxxxxx x
Section 2	xxxxxx xxxxxx xxxxxx
Section 3	xxxxxx xxxxxx xx
Section 4	xxxxxx xxxxxx xxxx
Section 5	xxxxxx xxxxxx xxx

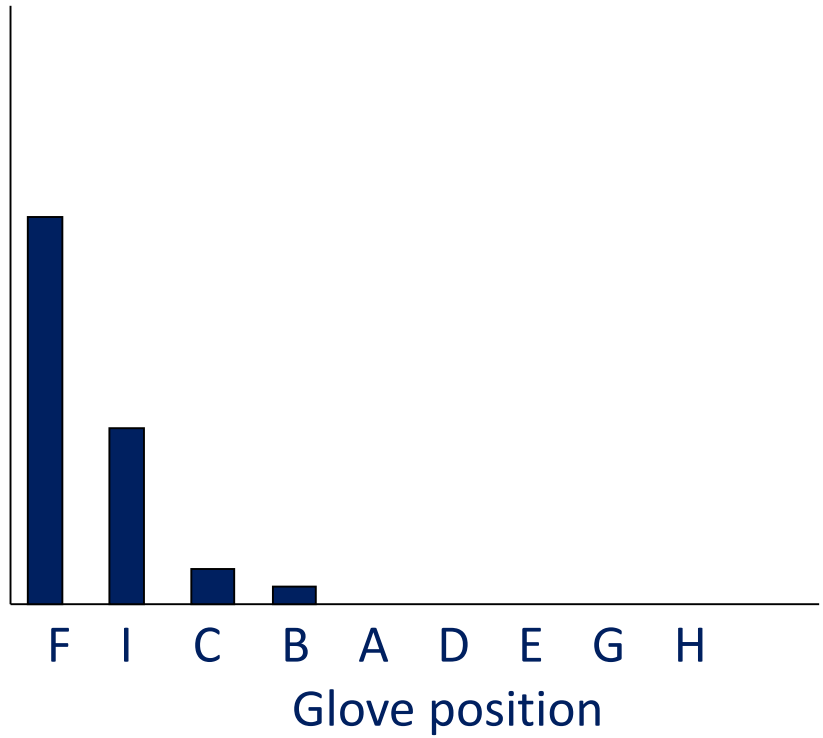
Defective area of seal

Concentration Diagram

Concentration diagram



Pareto analysis



Collect Data

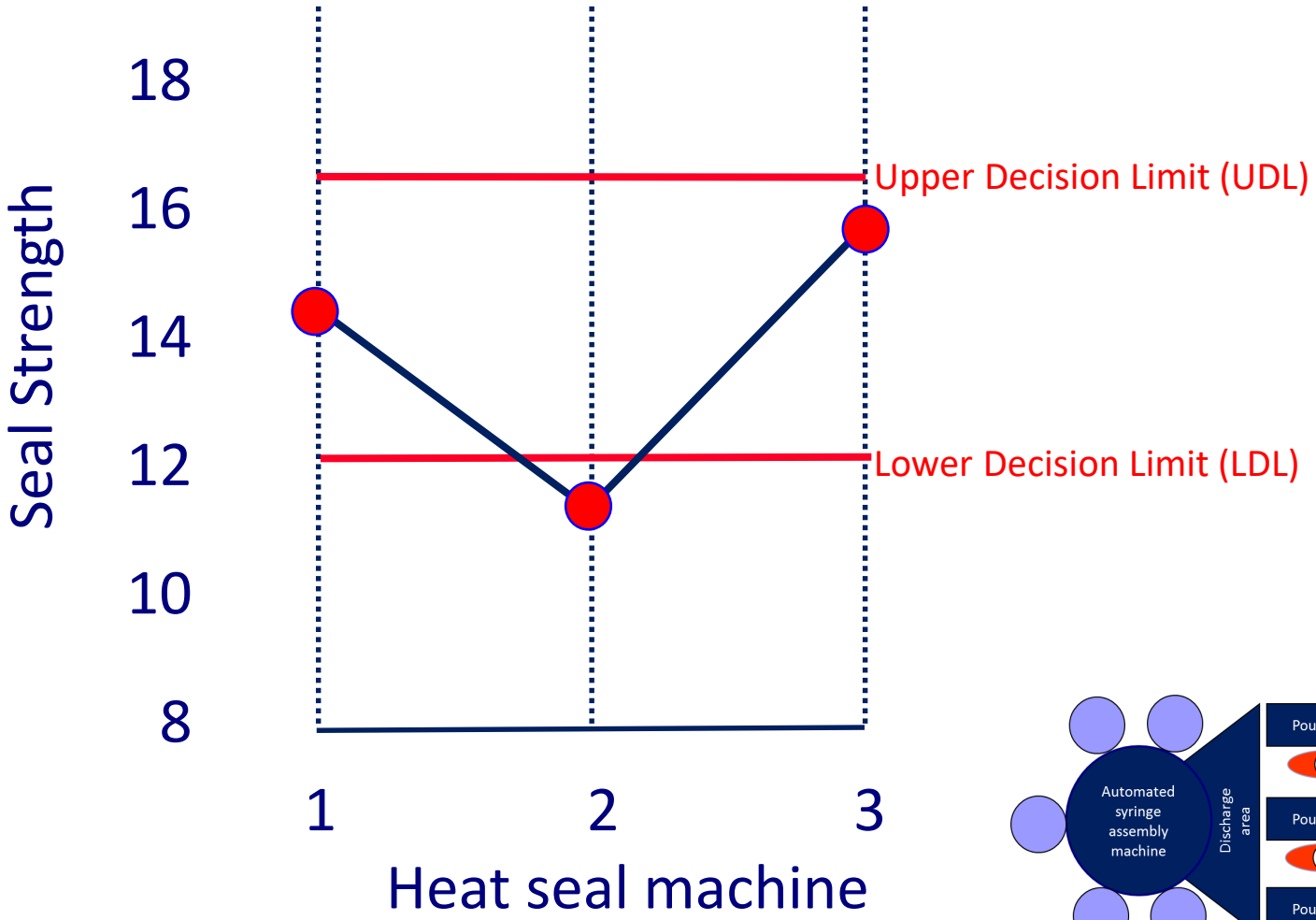
Problem Statement: Syringe pouch seals are either open or failing the 10 lb pull test

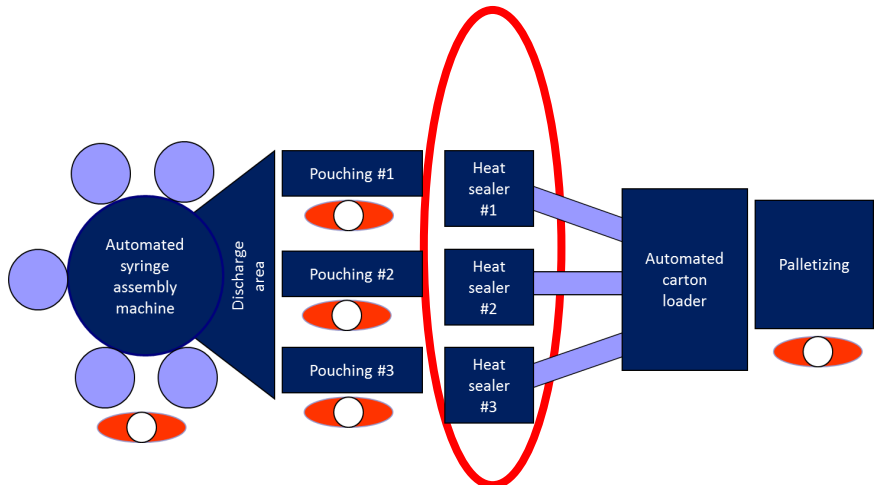
Is	Verified	Is Not	Verified	Data Needed	Data Location	Analysis Tool
Where else is the defect?		Where else could the defect be but isn't?				
Production line 3 in Johnsville	✓	**Production lines 1, 2, and 4 in Johnsville**	✓	**Additional Data** Can the issue be narrowed down to a particular heat seal machine on production line 3?	Begin collecting samples from each heat seal machine	ANOM Multi-vari chart Histogram/Capability study

Analysis of Mean (ANOM)

Detecting differences between similar entities

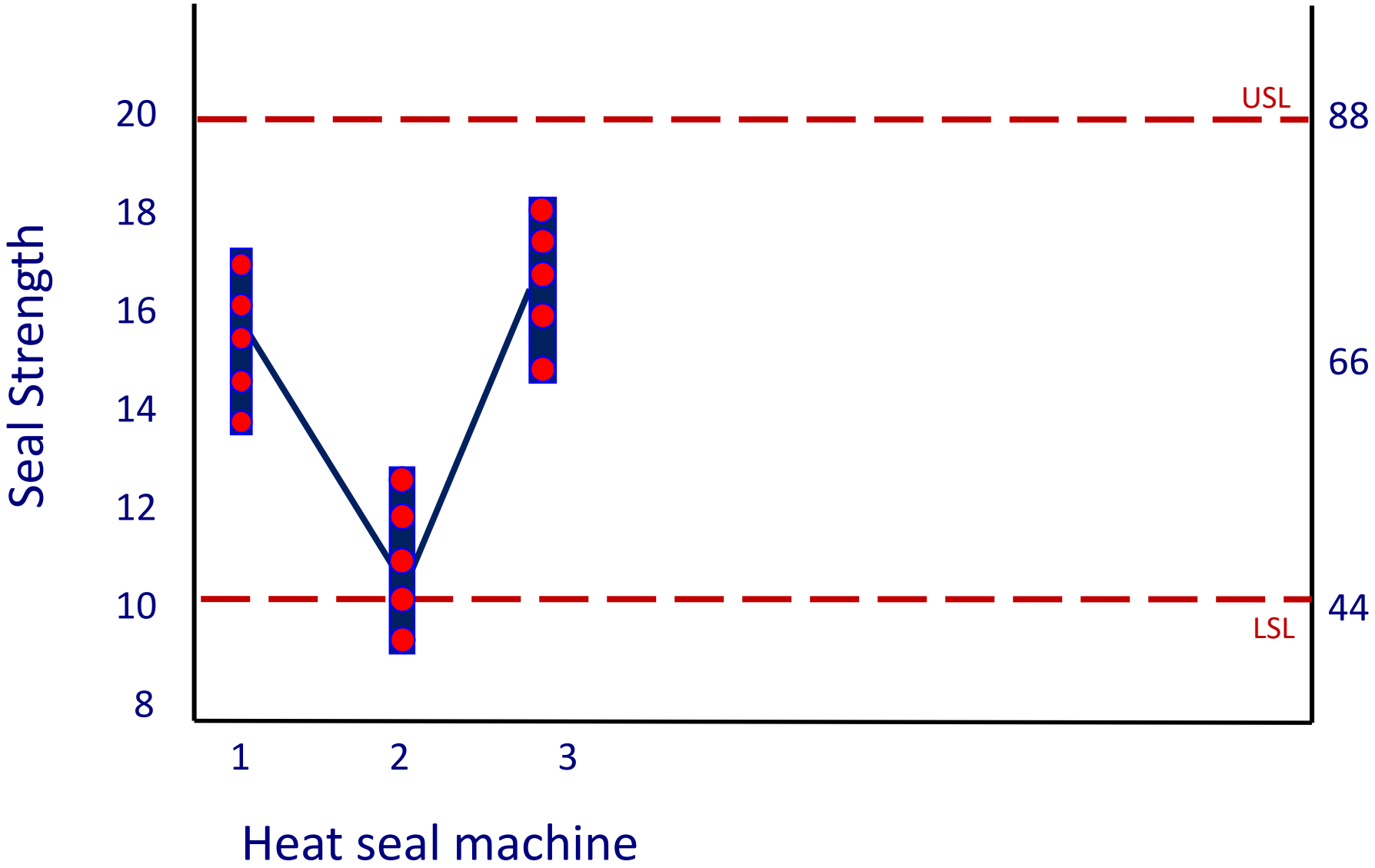
(people, work streams, machines, products, etc)





Multi-Variable Chart

Detecting variation within and between similar entities

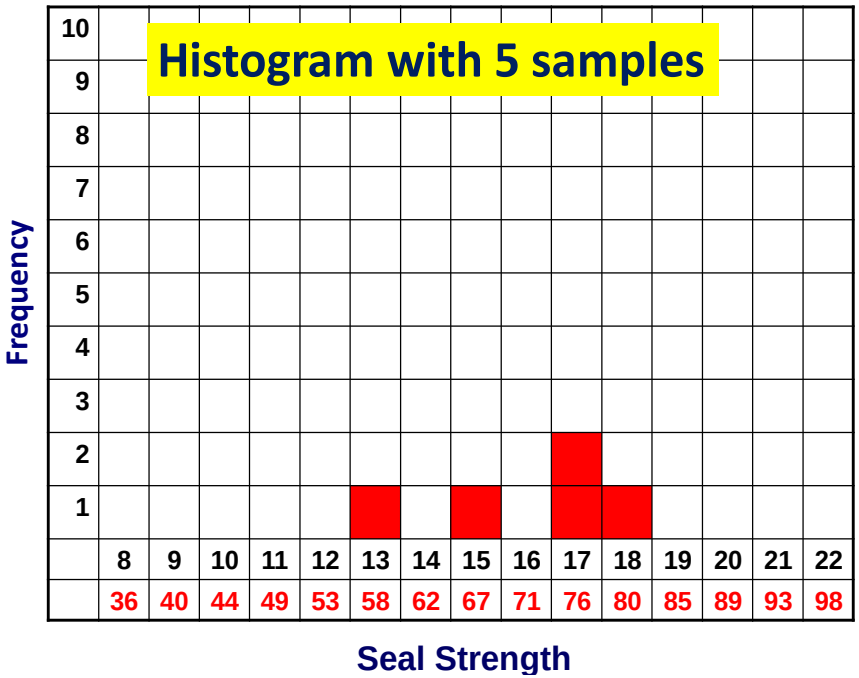


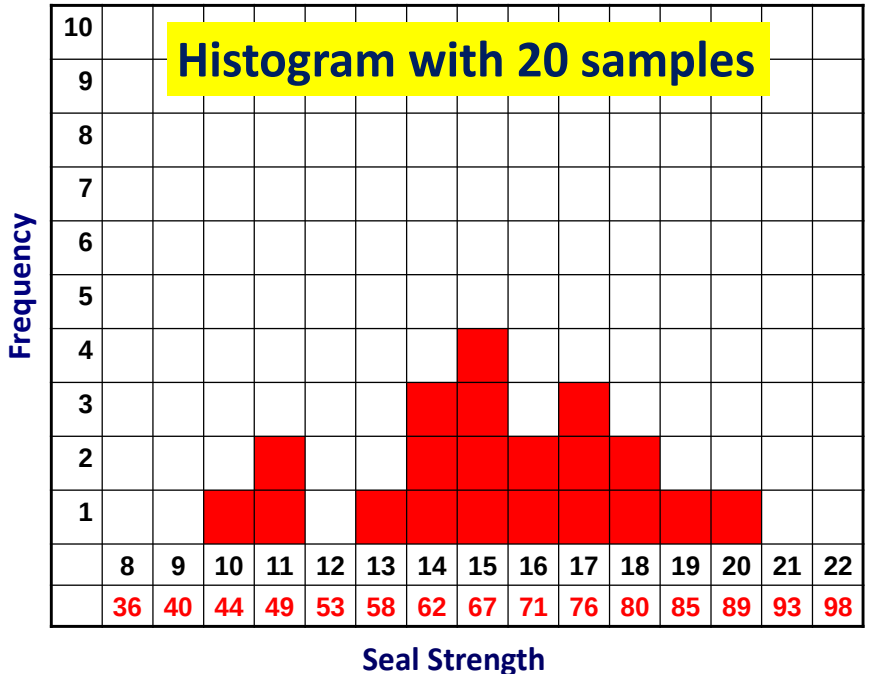
Capability Study

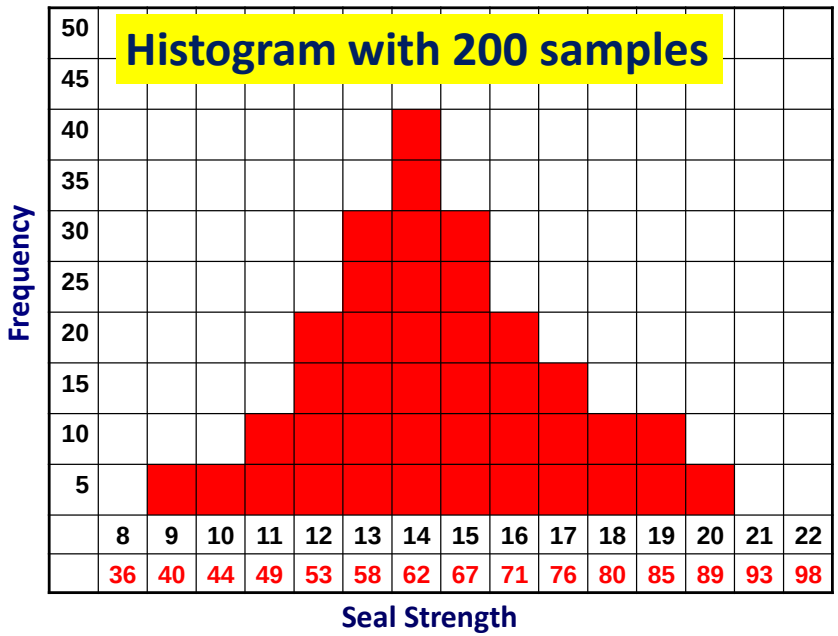
- Describes the performance of the product, process, machine, system, etc
  - Is there too much variation?
  - Is the variation properly targeted?

- How capable is the entity of meeting requirements?

Capability Study

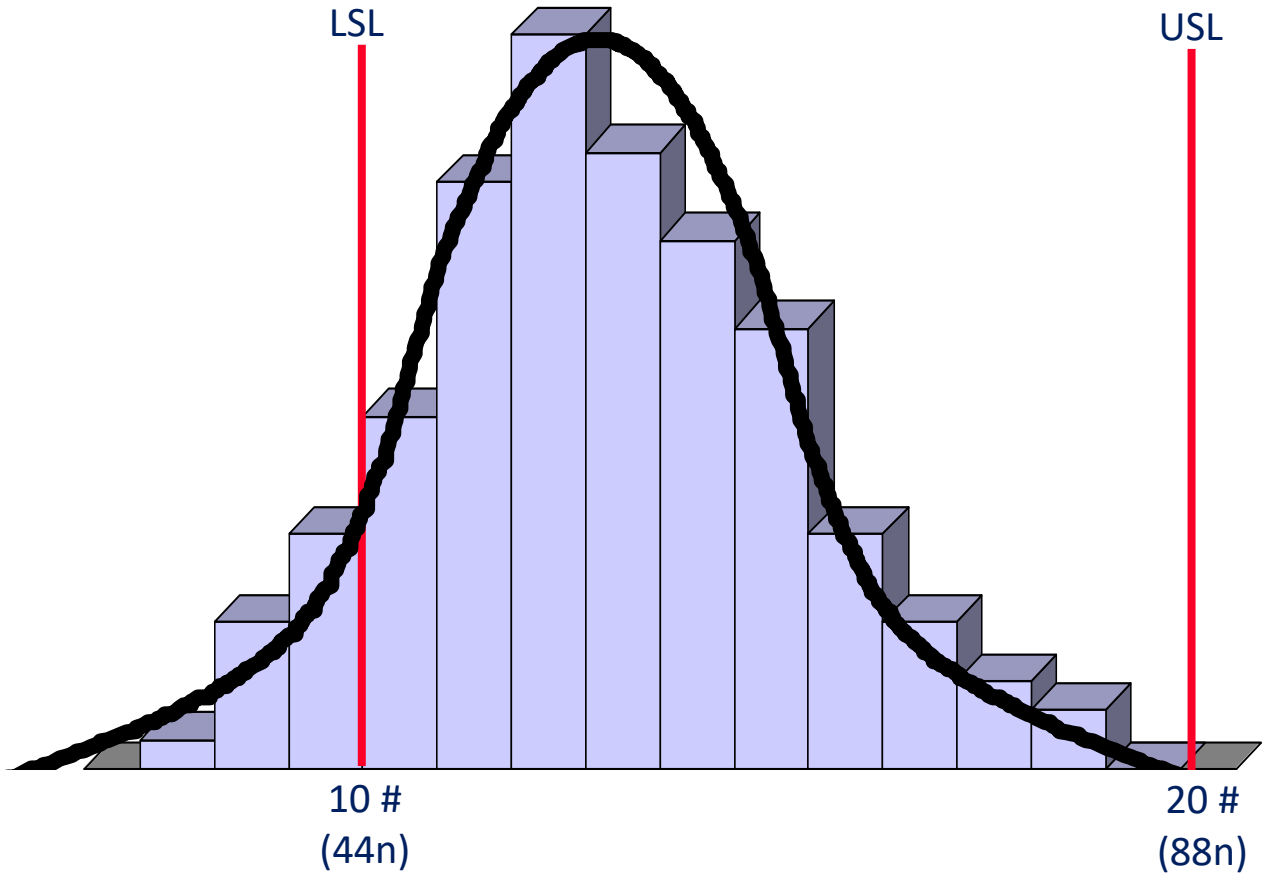






Capability Study

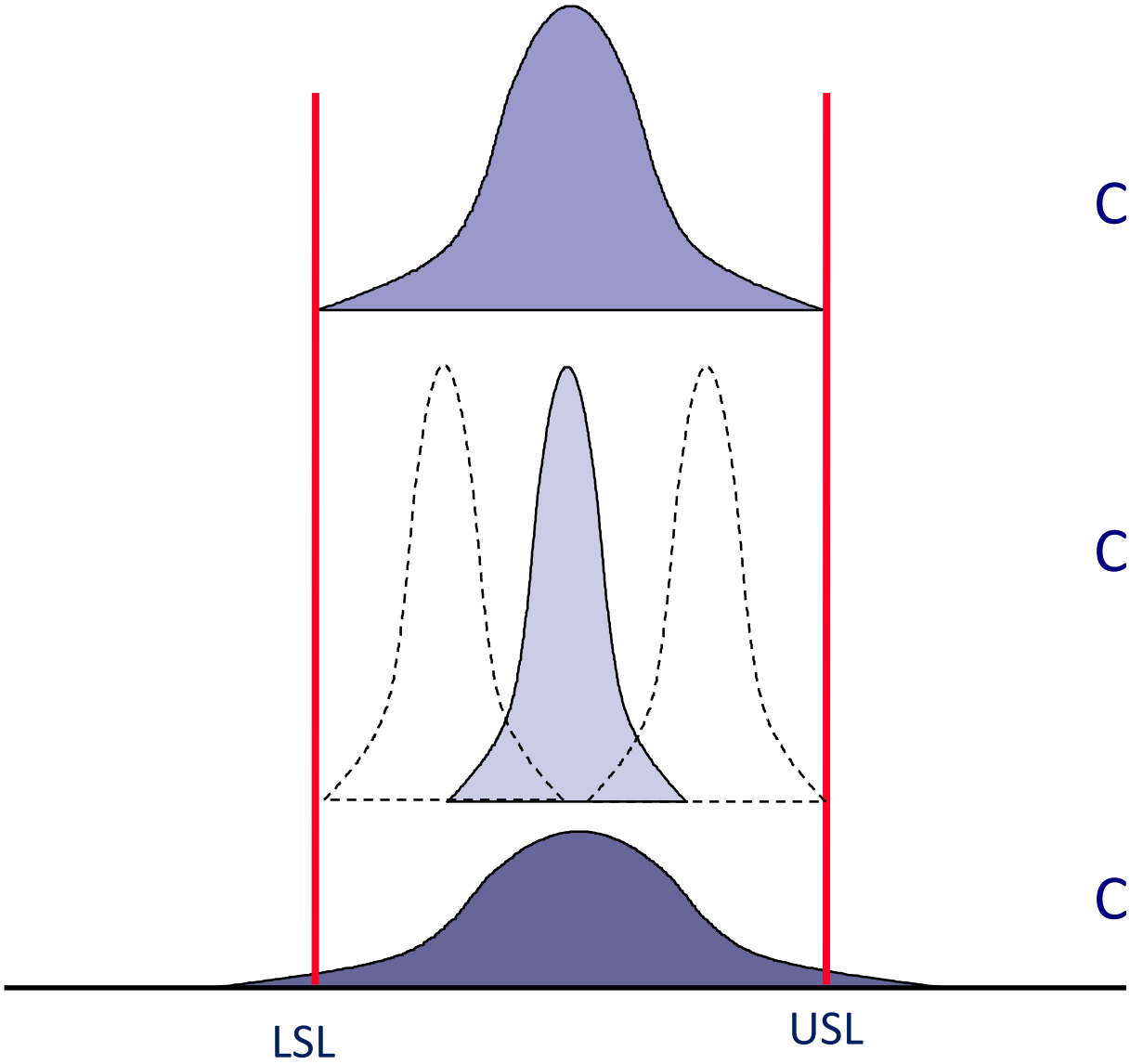
Heat seal machine #2 actual results



Is the problem one of:

- Too much variation?
- Incorrect targeting?
- Both? ✓

Capability Study



Cpk = 1

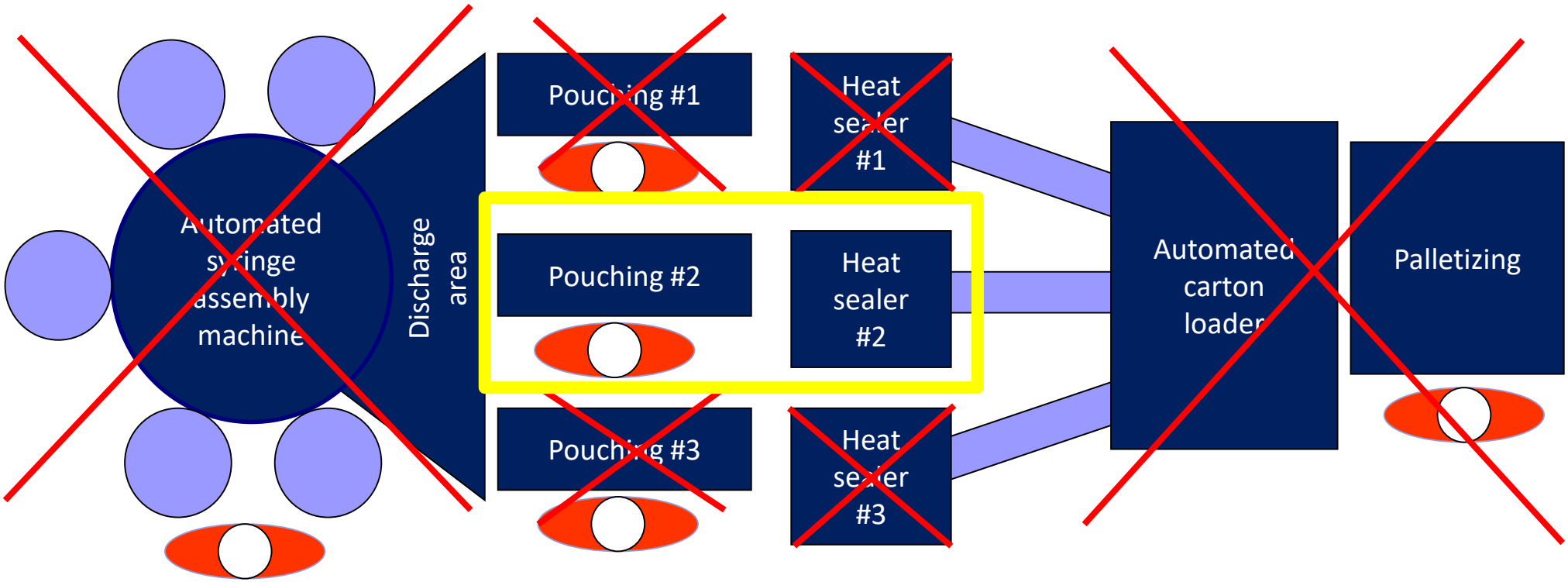
Cpk = 2

Cpk = .8

Recommended minimum Cpk $\geq$ 1.33

Leverage Data to “Tighten Fence”

Defects are in or around heat seal machine #2…



Part feeder bowl

Production operator

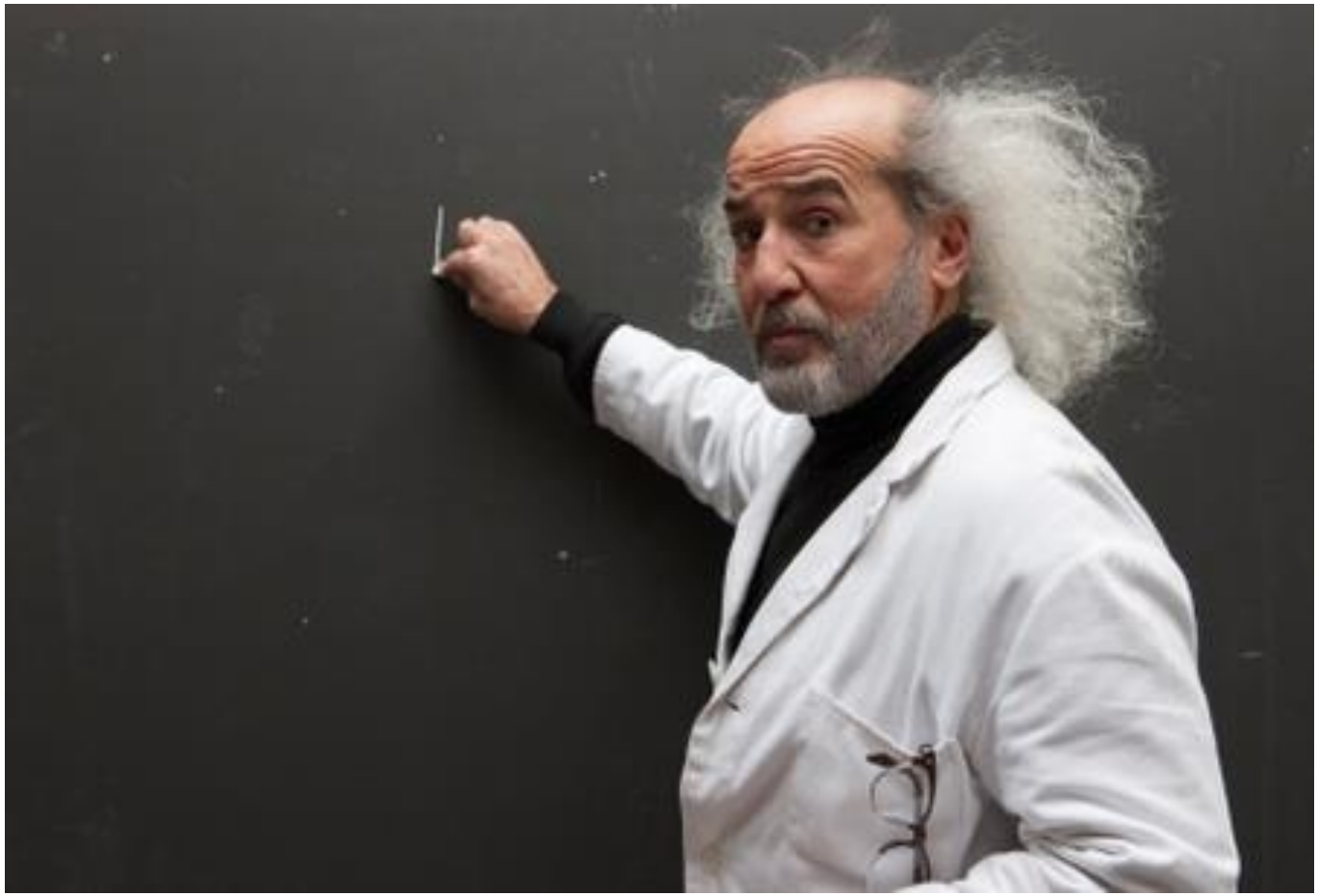
Output: Factual Is/Is Not Diagram

Problem Statement: Syringe pouch seals are either open or failing the 10 lb pull test

	Is	Verified	Is Not	Verified
What	What specific object has the defect?		What similar objects could have the defect but don't?	
	Syringe pouch seals	✓	**Surgeon glove pouch seals**	✓
	What is the specific defect?		What other defects could be seen but aren't?	
	Seals are open or failing the pull test	✓	**Tears, holes, product in seal, etc.**	✓
	What are the defect characteristics?		What could the characteristics be but aren't?	
	Failing 10 lb requirement, excessive variation	✓	**Failing 20 lb requirement, acceptable variation**	✓
	What product lots have the defect?		What product lots could have the defect but don't?	
	SY217, SY218…SY235	✓	**SY216 and earlier**	✓
	Are any part lots associated with the defect?		What part lots could be associated with the defect but aren't?	
	None	✓	**None**	✓
Where	Where is the defective object observed geographically?		Where could the defective object be observed geographically but isn't?	
	All 30 NA regions (CA, US, MX) Johnsville facility	✓	**Single country, some sales regions Janesville facility**	✓
	Where is the defect on the object?		Where could the defect be on the object but isn't?	
	Final seal (1), entire seal	✓	**Supplier's seals (3), part of the seal**	✓
	Where is the defect 1st seen in the process?		*Where could the defect 1st be seen in the process but isn't?*	
	After heat sealing	✓	**Before heat sealing**	✓
	Where else is the defect?		Where else could the defect be but isn't?	
	Production line 3 Johnsville	✓	**Production lines 1, 2, and 4 in Johnsville**	✓
	Heat seal machine #2		**Heat seal machine's 1 and 3**	
When	*When was the defective object 1st seen (date/time)?*		*When could the defective object 1st been seen but wasn't?*	
	April 6th at 10:00 a.m.	✓	**Before April 6th at 10:00 a.m.**	✓
	When since the 1st time has the defective object been seen?		When since the 1st time could the defective object been seen but wasn't?	
	Continuously every day	✓	**Every other day, sporadic, some other pattern**	✓

Collect Data: Key Points

Leverage subject matter experts from outside the investigation team to help determine information needed, analyze data, identify patterns, etc



Collect Data: Key Points

- Whenever possible, collect data from:
  - Actual place where the work is being conducted
  - Actual people executing the work
  - Real time as the problem is occurring

- Critical thinking to determine additional data needed

Documentation

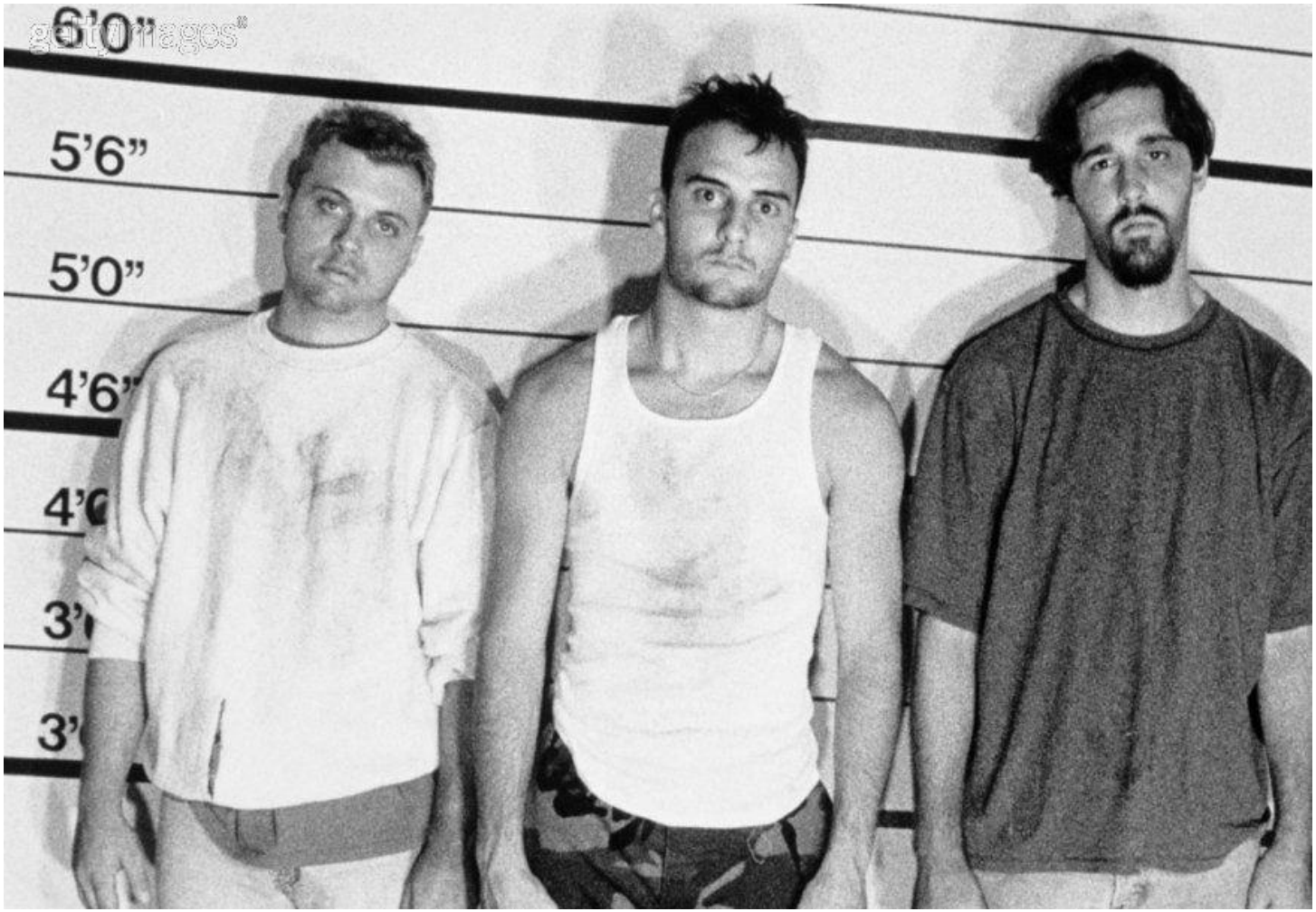
- Data collection plan
- Factual Is/Is Not diagram

Strongly recommended

- Data analysis tools

Leverage whatever is appropriate

Step 3: Identify Possible Causes



Identify Possible Causes

Input	Process	Output
Factual Is/Is Not diagram	Timeline of changes	Possible causes
Flow diagram with inputs	Differences & changes	
	Review risk analysis	
	Cause & effect diagram	
	Brainstorming techniques	

Identify Possible Causes: Key Points

- The investigation will fail if the real root cause isn't identified
- Develop a robust list of possible causes to ensure success

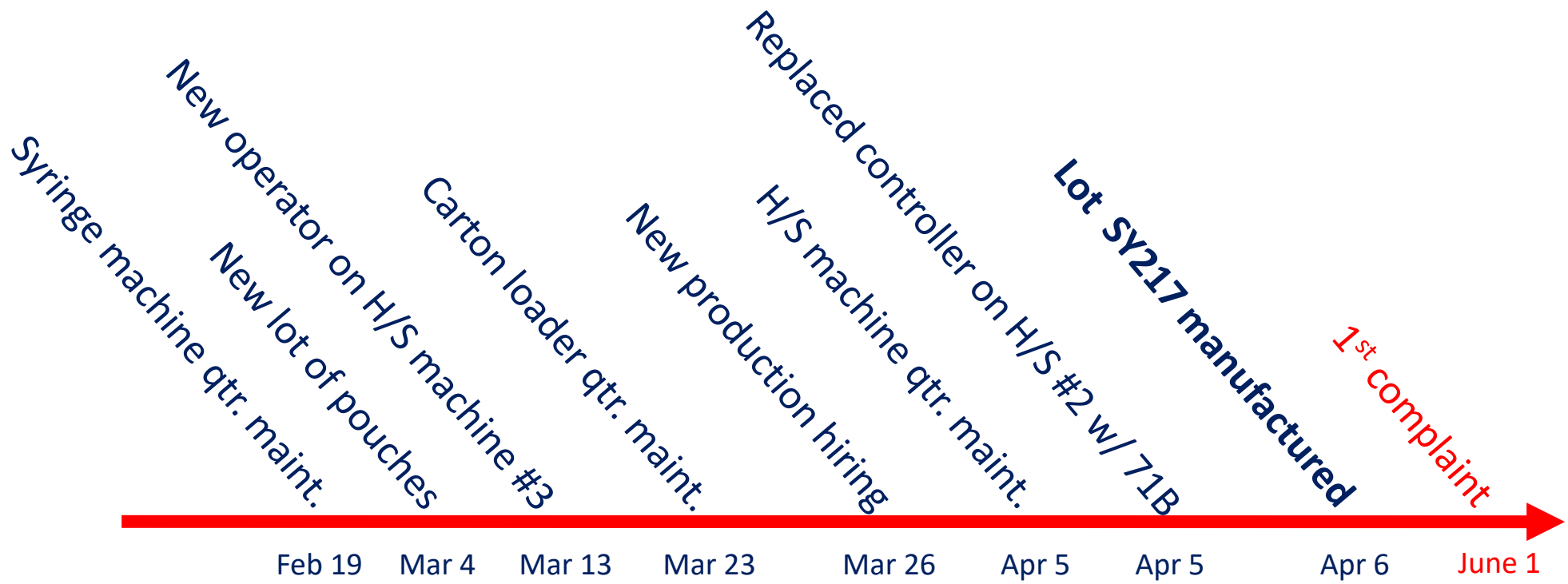
Identify Possible Causes: Key Points

- Knowledge gained from Steps 1 and 2 will generate possible cause ideas
- Past experiences of investigation team members will generate possible cause ideas
- More strategies should be leveraged to ensure success

Timeline of Changes

- The problem was caused by 1 or more changes….

- List all known relevant changes in chronological order: each change identified becomes a possible cause

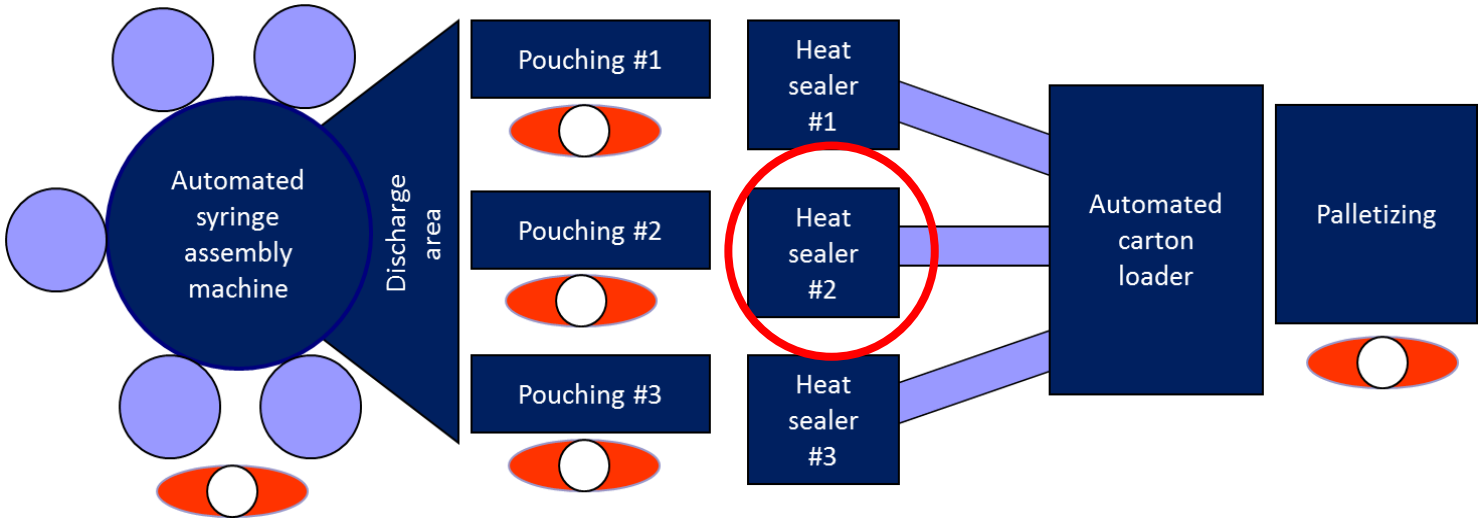


Differences Between Is and Is Not Facts

Problem Statement: Syringe pouch seals are either open or failing the 10 lb pull test

	Is	Verified	Is Not	Verified	Differences
What	What specific object has the defect?		What similar objects could have the defect but don't?		
	Syringe pouch seals	✓	**Surgeon glove pouch seals**	✓	Material composition
	What is the specific defect?		What other defects could be seen but aren't?		
	Seals are open or failing the pull test	✓	**Tears, holes, product in seal, etc.**	✓	
	What are the defect characteristics?		What could the characteristics be but aren't?		
	Failing 10 lb requirement, excessive variation	✓	**Failing 20 lb requirement, acceptable variation**	✓	
	What product lots have the defect?		What product lots could have the defect but don't?		
	SY217, SY218…SY235	✓	**SY216 and earlier**	✓	
	Are any part lots associated with the defect?		What part lots could be associated with the defect but aren't?		
	None	✓	**None**	✓	
Where	Where is the defective object observed geographically?		Where could the defective object be observed geographically but isn't?		
	All 30 NA regions (CA, US, MX) Johnsville facility	✓	**Single country, some sales regions Janesville facility**	✓	Highly automated
	Where is the defect on the object?		Where could the defect be on the object but isn't?		
	Final seal (1), entire seal	✓	**Supplier's seals (3), part of the seal**	✓	
	Where is the defect 1st seen in the process?		*Where could the defect 1st be seen in the process but isn't?*		
	After heat sealing	✓	**Before heat sealing**	✓	
	Where else is the defect?		Where else could the defect be but isn't?		
	Production line 3 Johnsville	✓	**Production lines 1, 2, and 4 in Johnsville**	✓	Training line
	Heat seal machine #2		**Heat seal machine's 1 and 3**		Operator, location, 71B controller

Changes Made to Identified Differences



Assy machine qtr. maint.

New lot of pouches

New operator on H/S machine #3

Carton loader qtr. maint.

New production hiring

H/S machine qtr. maint.

Replaced controller on H/S #2 w/ 71B

Lot SY217 manufactured

1st complaint

Changes Made to Identified Differences

Problem Statement: Syringe pouch seals are either open or failing the 10 lb pull test

	Is	Verified	Is Not	Verified	Differences	Changes
What	What specific object has the defect?		What similar objects could have the defect but don't?			
	Syringe pouch seals	✓	**Surgeon glove pouch seals**	✓	Material composition	Changed material Feb 25
	What is the specific defect?		What other defects could be seen but aren't?			
	Seals are open or failing the pull test	✓	**Tears, holes, product in seal, etc.**	✓		
	What are the defect characteristics?		What could the characteristics be but aren't?			
	Failing 10 lb requirement, excessive variation	✓	**Failing 20 lb requirement, acceptable variation**	✓		
	What product lots have the defect?		What product lots could have the defect but don't?			
	SY217, SY218…SY235	✓	**SY216 and earlier**	✓		
	Are any part lots associated with the defect?		What part lots could be associated with the defect but aren't?			
	None	✓	**None**	✓		
Where	Where is the defective object observed geographically?		Where could the defective object be observed geographically but isn't?			
	All 30 NA regions (CA, US, MX) Johnsville facility	✓	**Single country, some sales regions Janesville facility**	✓	Highly automated	None
	Where is the defect on the object?		Where could the defect be on the object but isn't?			
	Final seal (1), entire seal	✓	**Supplier's seals (3), part of the seal**	✓		
	Where is the defect 1st seen in the process?		*Where could the defect 1st be seen in the process but isn't?*			
	After heat sealing	✓	**Before heat sealing**	✓		
	Where else is the defect?		Where else could the defect be but isn't?			
	Production line 3 Johnsville	✓	**Production lines 1, 2, and 4 in Johnsville**	✓	Training line	New hires March 26
	Heat seal machine #2		**Heat seal machine's 1 and 3**		Operator, location, 71B controller	Assigned March 28

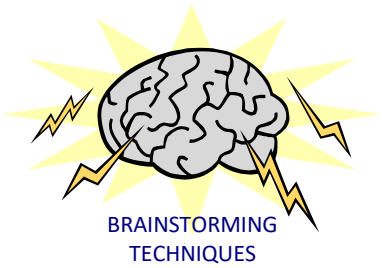
Review Risk Analysis

- Risk analysis may reveal a problem similar to the one being investigated, in which case potential failure modes and/or causes would have been identified

Example: Failure Mode and Effects Analysis (FMEA)

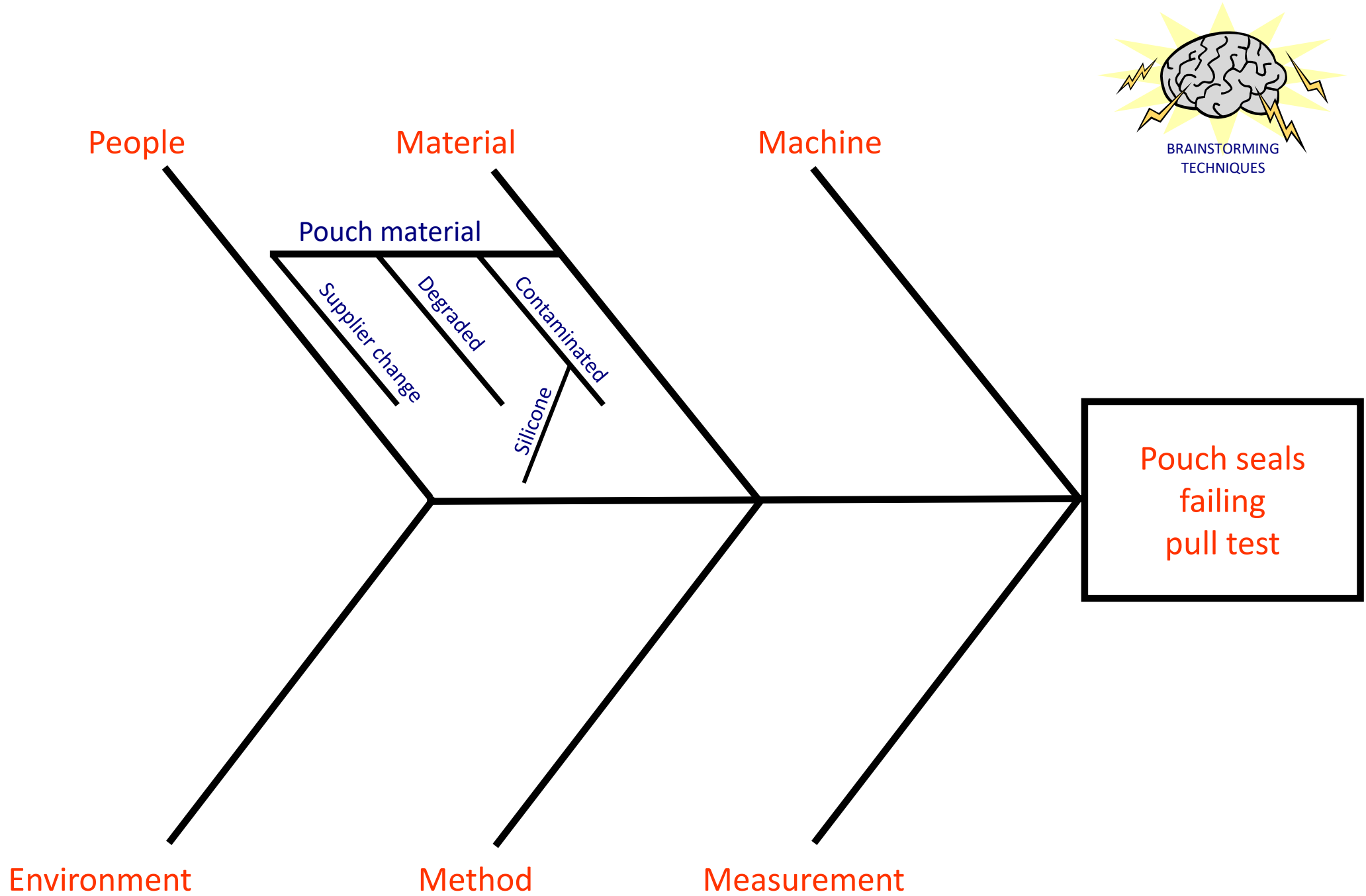
Item or Process Step	Item or Step Function	Potential Failure Mode	Potential effect	Potential Cause of Failure
- Load pouch into heat seal machine	- Proper orientation of pouch into heat seal machine	- Incorrect pouch orientation	- Seal incorrect area - Product damage - **Incomplete seal across pouch**	- Improper training - Improper guide setup

Brainstorming: Cause & Effect Diagram

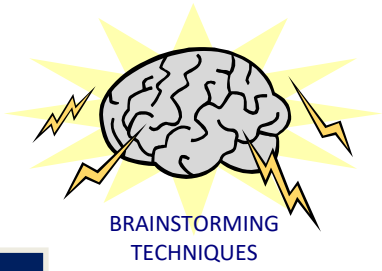


People
Material
Machine
Pouch material
New controller
Improper training
Lubrication
Improper setup
SOPs not detailed
Pouch seals failing pull test
Humidity
Guide setup
Calibration of test equipment
Environment
Method
Measurement

Brainstorming: Cause & Effect Diagram



Brainstorm: Process Flow Diagram(s)



Wrong pouch material from supplier

Pouch contaminated

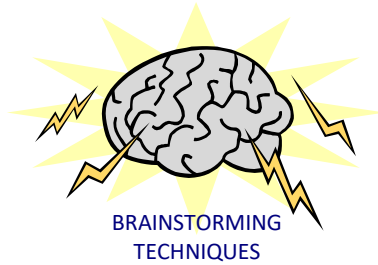
Incorrect machine parameters

Raw materials receiving inspection → Raw materials staging → Fill syringe machine with parts → Automated syringe assembly

Hand load syringe into pouch → Hand load pouch into heat sealer → Heat seal → Automated carton loader

Palletizing → Sterilization → Final inspection & release → Shipping

Brainstorming: Other Techniques



Technique

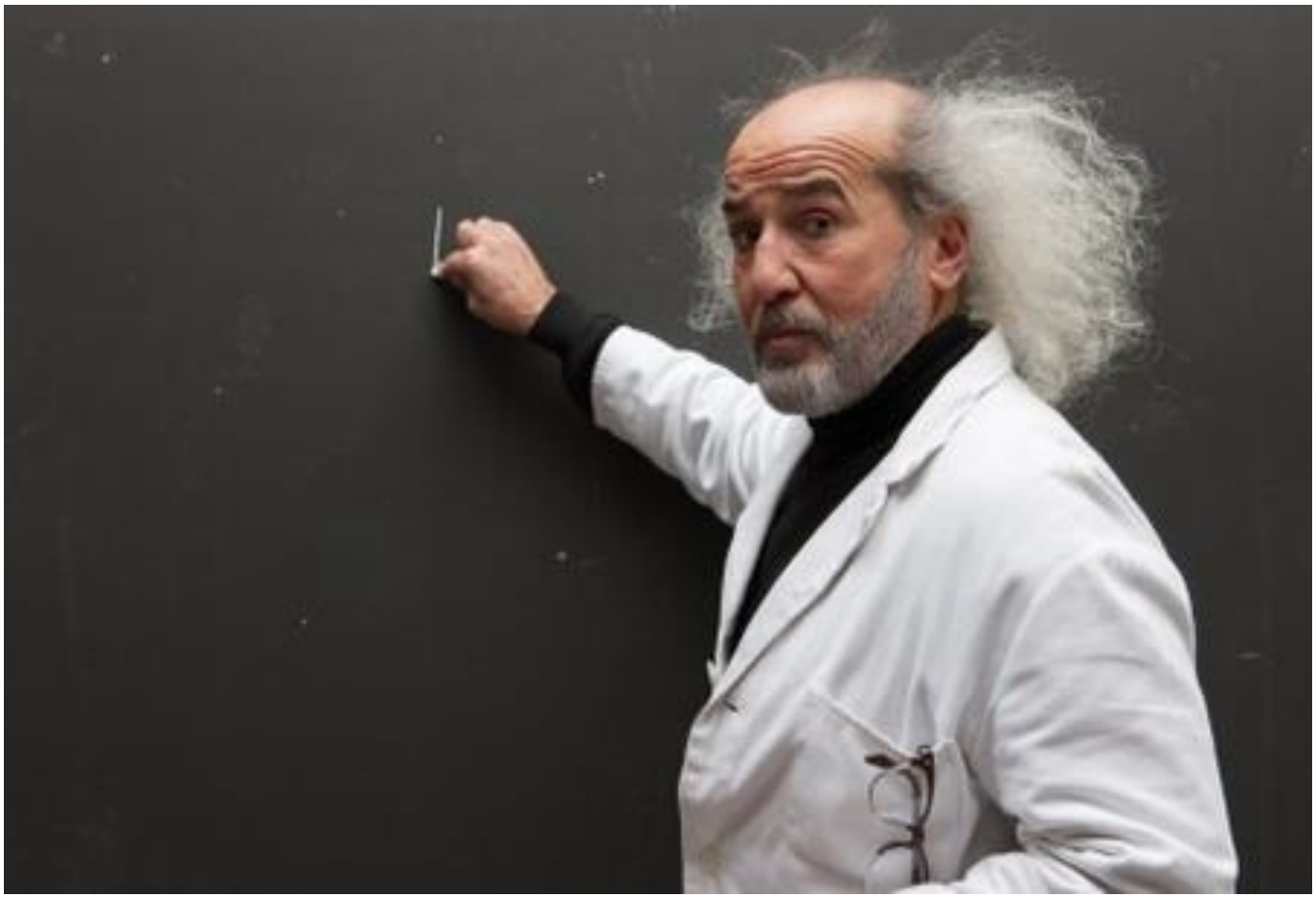
- Share ideas out loud with group
- Share ideas anonymously with group

Brainstorming rules, regardless of technique:

- Determine which method of brainstorming is most appropriate
- Record all ideas
- Do not debate ideas

Identify Possible Causes: Key Points

Leverage subject matter experts from outside the investigation team to help identify possible causes



Documentation

- Timeline of changes
- Differences and changes
- Risk analysis review
- Master list of possible causes

Strongly recommended

- Brainstorming techniques

Leverage whatever is appropriate

Step 4: Test Possible Causes

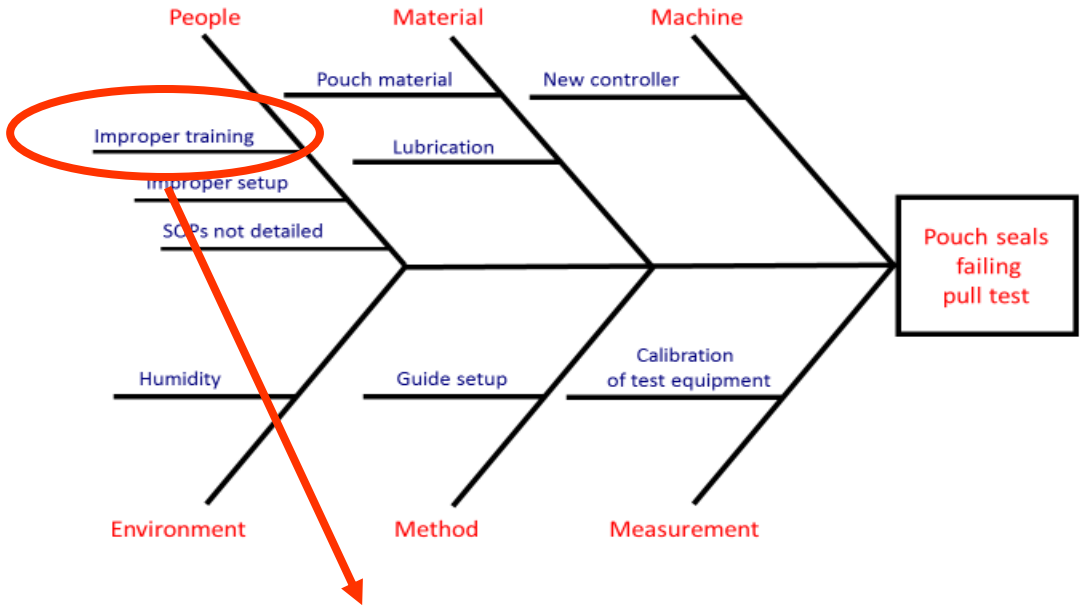
Test Possible Causes

Input	Process	Output
Factual Is/Is Not diagram Robust list of possible causes	Test possible causes against facts	Reduced list of probable causes

Test Possible Causes

Test each possible cause…

…against each set of facts in the Is/Is Not diagram



	Is	Verified	Is Not	Verified
What	What specific object has the defect?		What similar objects could have the defect but don't?	
	Syringe pouch seals	✓	Surgeon glove pouch seals	✓
	What is the specific defect?		What other defects could be seen but aren't?	
	Seals are open or failing the pull test	✓	Tears, holes, product in seal, etc.	✓
	What are the defect characteristics?		What could the characteristics be but aren't?	
	Failing 10 lb requirement, excessive variation	✓	Failing 20 lb requirement, acceptable variation	✓
	What product lots have the defect?		What product lots could have the defect but don't?	
	SY217, SY218…SY235	✓	SY216 and earlier	✓
	Are any part lots associated with the defect?		What part lots could be associated with the defect but aren't?	
	None	✓	None	✓
Where	Where is the defective object observed geographically?		Where could the defective object be observed geographically but isn't?	
	All 30 NA regions (CA, US, MX) Johnsville facility	✓	Single country, some sales regions Janesville facility	✓
	Where is the defect on the object?		Where could the defect be on the object but isn't?	
	Final seal (1), entire seal	✓	Supplier's seals (3), part of the seal	✓
	Where is the defect 1st seen in the process?		*Where could the defect 1st be seen in the process but isn't?*	
	After heat sealing	✓	Before heat sealing	✓
	Where else is the defect?		Where else could the defect be but isn't?	
	Production line 3 Johnsville	✓	Production lines 1, 2, and 4 in Johnsville	✓
	Heat seal machine #2		Heat seal machine's 1 and 3	
When	*When was the defective object 1st seen (date/time)?*		*When could the defective object 1st been seen but wasn't?*	
	April 6th at 10:00 a.m.	✓	Before April 6th at 10:00 a.m.	✓
	When since the 1st time has the defective object been seen?		When since the 1st time could the defective object been seen but wasn't?	
	Continuously every day	✓	Every other day, sporadic, some other pattern	✓

Test Possible Causes

Testing formula:

If x is the cause, how does it explain each set of Is and Is Not facts?

Example:

If the new 71B controller installed on heat seal machine #2 the evening of April 5 is causing the pouch seal failures, how does it explain…

Test Sheet

	Is	Verified	Is Not	Verified	Fact(s) Support Cause Y/N	Fact(s) Not Explained	Assumptions
What	What specific object has the defect?		What similar objects could have the defect but don't?				
	Syringe pouch seals	✓	**Surgeon glove pouch seals**	✓	**Y**	----------	----------

Test Possible Causes

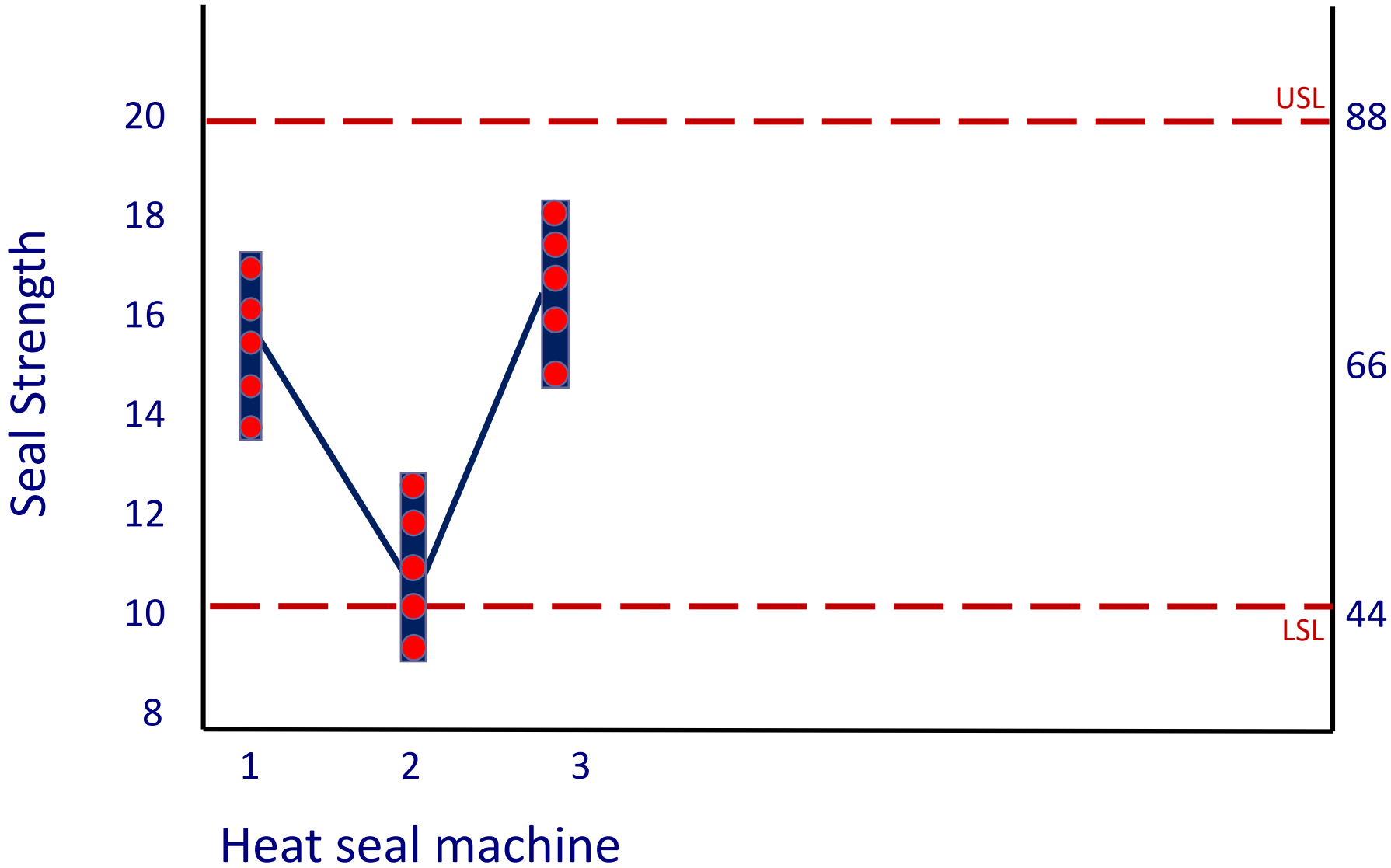
If the new 71B controller installed on heat seal machine #2 the evening of April 5 is causing the pouch seal failures, how does it explain…

Test Sheet

	Is	Verified	Is Not	Verified	Fact(s) Support Cause Y/N	Fact(s) Not Explained	Assumptions
When	*When was the defective object 1st seen (date/time)?*		*When could the defective object 1st been seen but wasn't?*				
	April 6th at 10:00 a.m.	✓	**Before April 6th at 10:00 a.m.**	✓	**N**	**Seal strength 1st changed at 10:00 a.m. on April 6th**	**Historical sampling plan wasn't robust enough**

Multi-Vari Chart

Heat seal machine #2 actual results



Test Possible Causes

If a ~~change in sterilization~~ is causing the pouch seal failures, how does it explain…

Test Sheet

	Is	Verified	Is Not	Verified	Fact(s) Support Cause Y/N	Fact(s) Not Explained	Assumptions
Where	*Where is the defect 1st seen in the process?*		*Where could the defect 1st be seen in the process but isn't?*				
	After heat sealing	✓	**Before heat sealing**	✓	**N**	**Defective seals 1st identified after heat sealing**	**None**

Test Possible Causes

If a inadequate operator training is causing the pouch seal failures, how does it explain…

Test Sheet

	Is	Verified	Is Not	Verified	Fact(s) Support Cause Y/N	Fact(s) Not Explained	Assumptions
Where	Where else is the defect?		Where else could the defect be but isn't?				
	Heat seal machine #2	✓	**Heat seal machine's 1 and 3**	✓	**N**	**Issue only occurs at heat seal machine #2…all 3 operators had exact same training at same time** **No problems from March 28th – April 5th**	**Operator working machine #2 has different learning needs** **Less supervision starting April 6th**

Contradiction Matrix

Problem Statement: Syringe pouch seals are either open or failing the 10 lb pull test

Facts / Possible Causes	Syringe vs. surgeon glove pouches	Open or failing seals vs. tears, holes, etc	Failing 10 lb vs. 20 lb spec	SYS17 – present vs earlier lots	All sales regions vs. select regions	Johnsville vs. Janesville	Final seal vs. supplier's seals	After heat sealing vs. before	Line 3 vs lines 1, 2, 4
71B Controller	O	A	A	O	O	O	O	O	O
Sterilization	X								
Inadequate operator training	O	A	A	A	O	O	O	O	O
Humidity	A	O	O	A	O	O	A	O	X
Test calibration equipment	A	O	O	X					

O: Facts support cause | **X: Facts contradict cause** | **A: Assumption**

Test Possible Causes: Key Points

- Possible causes must only be ruled out using facts
- Assumptions must be based on real life experiences

Documentation

- Test sheet for each possible cause — Strongly recommended
- Contradiction matrix — Optional

Step 5: Identify Technical & Systemic Root Causes

Identify Technical & Systemic Root Causes

Input	Process	Output
Probable causes	Verify assumptions Conduct experiments	Technical root cause(s)
	3 Legged 5 Why	Systemic root cause(s)

Identify Technical Root Cause(s)

Assumptions

Collect data to verify assumptions made to help a probable cause explain the Is/Is Not facts

Verify Assumptions

If the new 71B controller installed on heat seal machine #2 the evening of April 5 is causing the pouch seal failures, how does it explain…

Test Sheet

	Is	Verified	Is Not	Verified	Fact (s) Support Cause Y/N	Fact(s) Not Explained	Assumptions	Verification of Assumptions
When	*When was the defective object 1st seen (date/time)?*		*When could the defective object 1st been seen but wasn't?*					
When	**April 6th at 10:00 a.m.**	✓	**Before April 6th at 10:00 a.m.**	✓	**N**	**Seal strength 1st changed at 10:00 a.m. on April 6th**	**Historical sampling plan wasn't robust enough**	**Verified**

Verify Assumptions

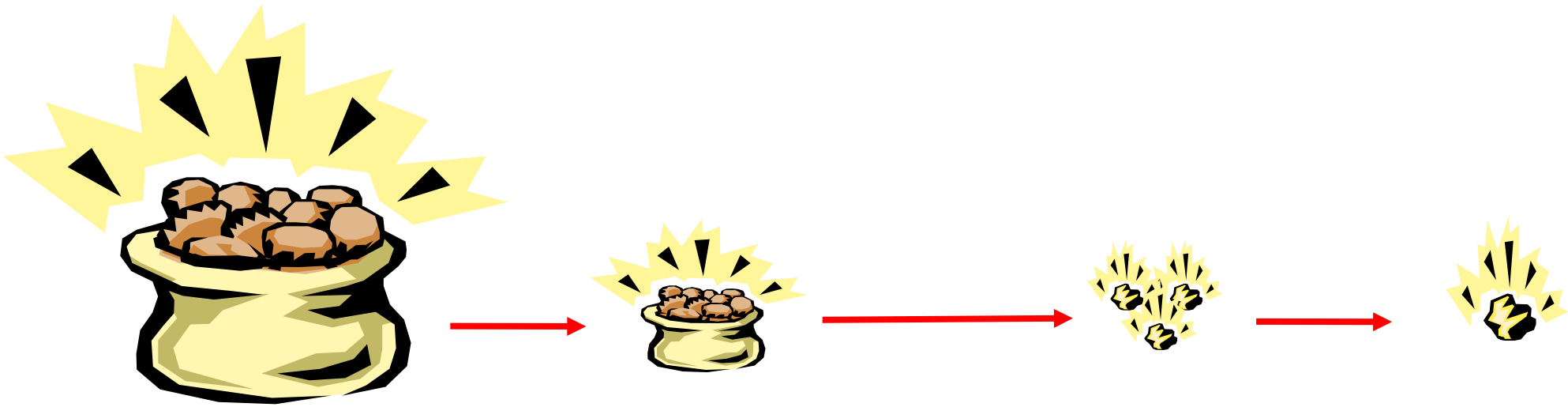
If a inadequate operator training is causing the pouch seal failures, how does it explain…

Test Sheet

	Is	Verified	Is Not	Verified	Fact(s) Support Cause Y/N	Fact(s) Not Explained	Assumptions	Verification of Assumptions
Where	Where else is the defect?		Where else could the defect be but isn't?					
	Heat seal machine #2	✓	**Heat seal machine's 1 and 3**	✓	**N**	**Issue only occurs at heat seal machine #2…all 3 operators had exact same training at same time** **No problems from March 28th – April 5th**	**Operator working machine #2 has different learning needs** **Less supervision starting April 6th**	**Assumption false; the problem always happens at machine #2 regardless of whose working there**

Identify Technical Root Cause(s)

- A large list of possible causes has been reduced to a smaller list of probable causes
- Verifying assumptions may further reduce the list of probable causes
- Leverage experiments to find the technical root cause(s)

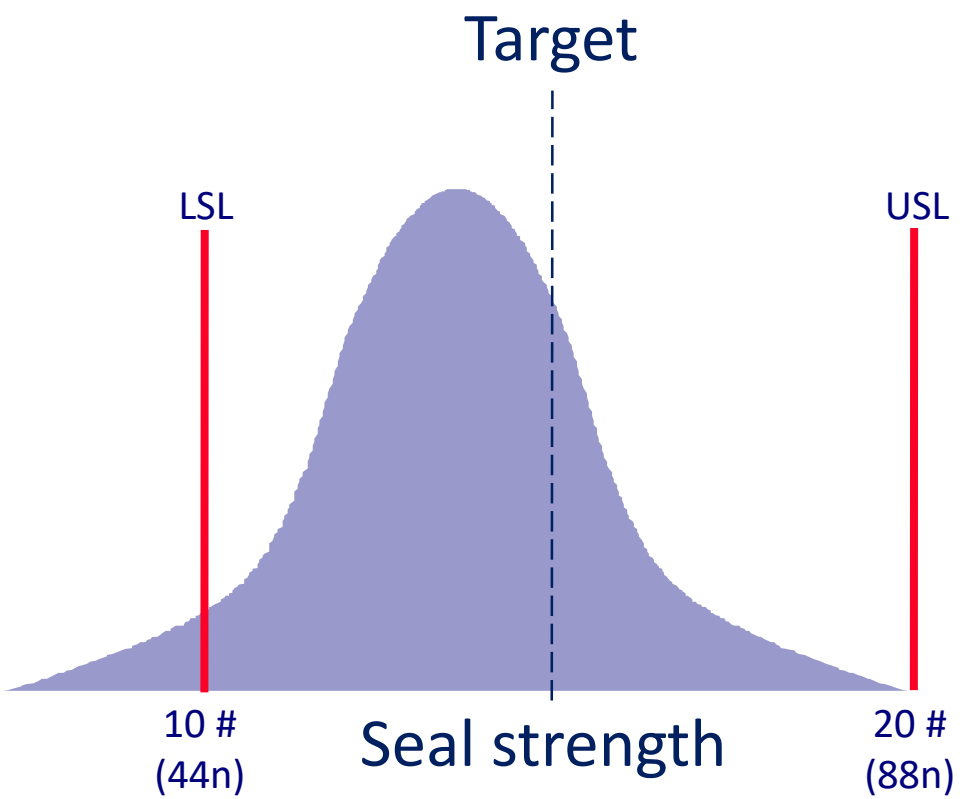


Identify Technical Root Cause(s)

Examples of experiments

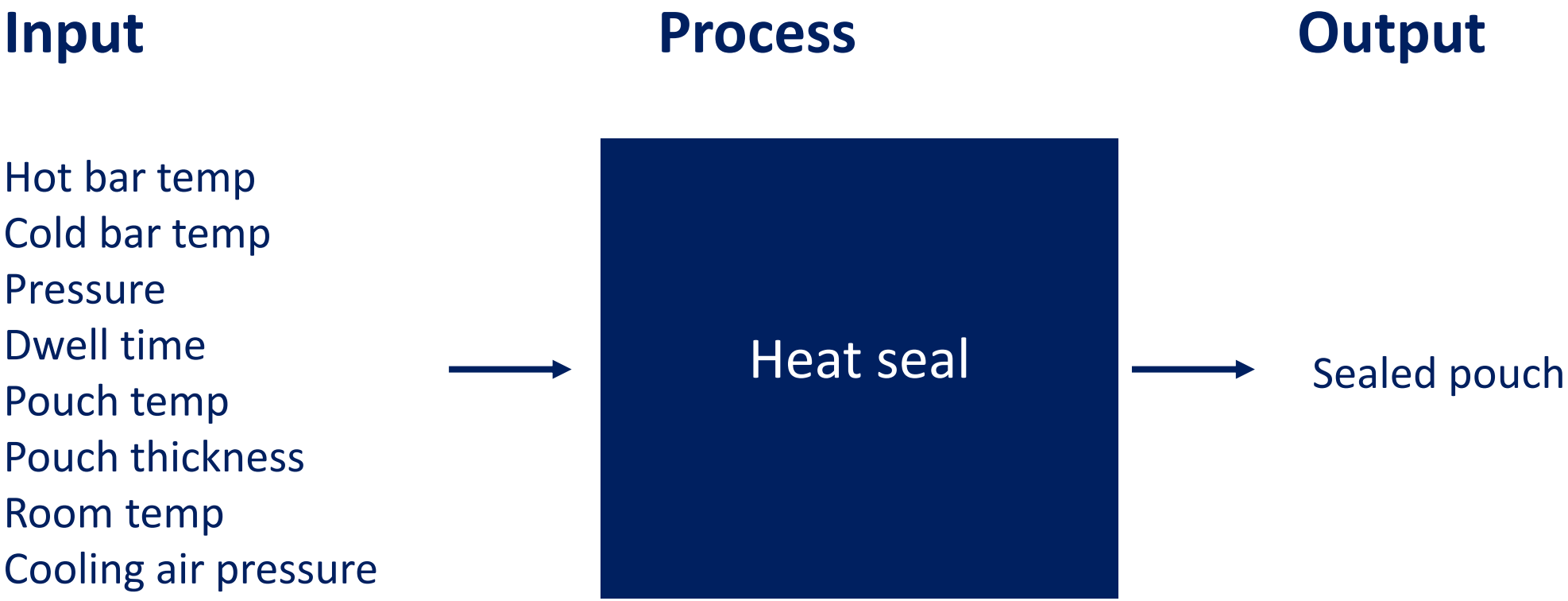
Input	Process	Output
Probable causes	Component swapping study Screening experiment Response surface studies Robust tolerance analysis	Technical root cause(s)

Causes for Excessive Variation



- Excessive variation
- Improper targeting

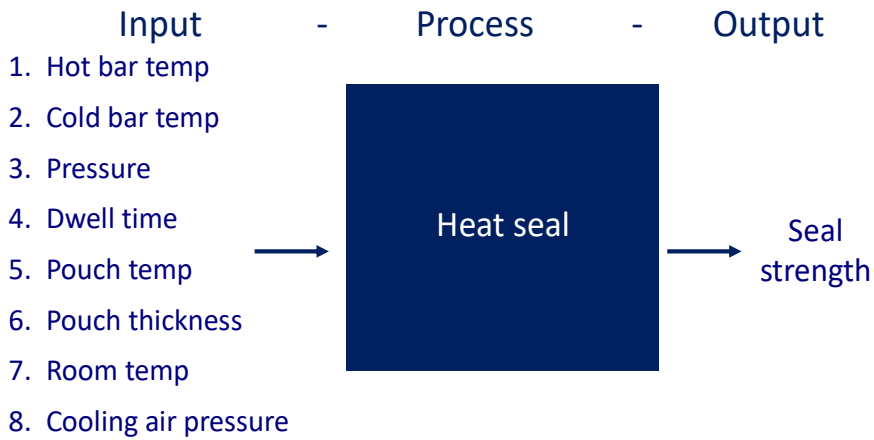
Causes for Excessive Variation



Excessive variation and/or improper targeting of 1 or more inputs may cause excessive variation and/or improper targeting of the output

Screening Experiment

- Identifies the key inputs that affect the output
- Used when there are numerous inputs (≥ 6) to dramatically reduce the amount of effort needed with a follow up response surface study



This type of experiment involves changing one or more inputs and measuring the resulting effect on one or more outputs

Screening Experiment

Results

Some input variables have little or no effect on pouch seal strength

1. Cold bar temperature
2. Cooling air pressure
3. Pouch thickness
4. Room temperature

Other input variables do have an effect on pouch seal strength

1. Hot bar temperature
2. Pressure
3. Dwell time
4. Pouch temperature

Response Surface Studies

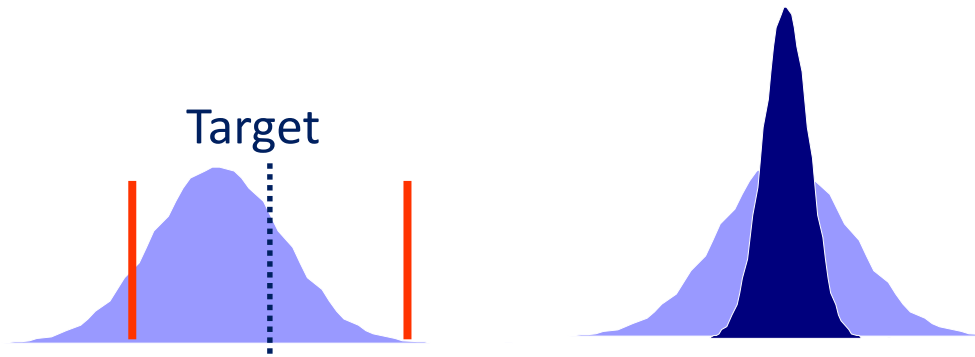
- Builds on the data from a screening experiment
- Determines the equation relating the inputs to the outputs
- Identifies the best set points of the inputs

Response Surface Studies

Results

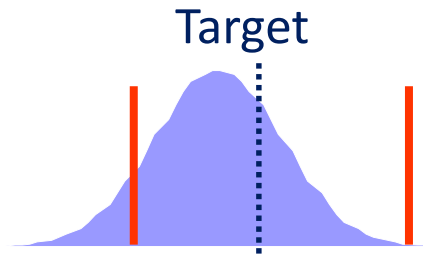
2 input variables affect both the seal strength average and the amount of variation

- Hot bar temperature
- Dwell time



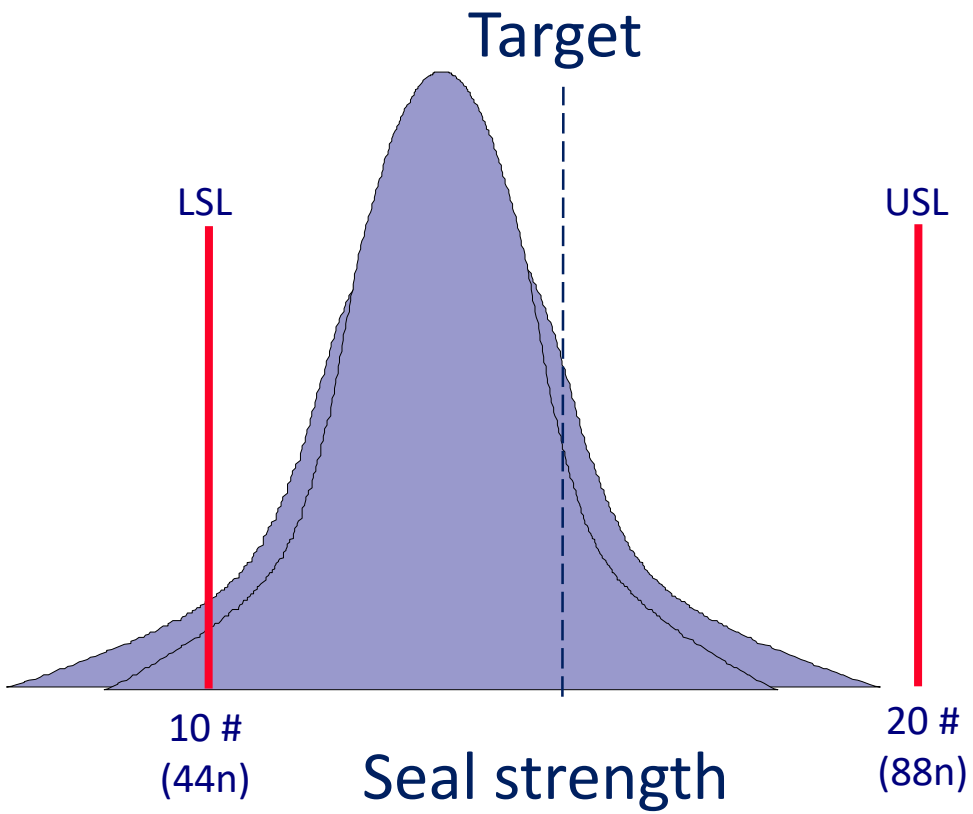
2 other input variables affect only the seal strength average

- Pressure
- Pouch temperature



Response Surface Studies

First, reduce variation…

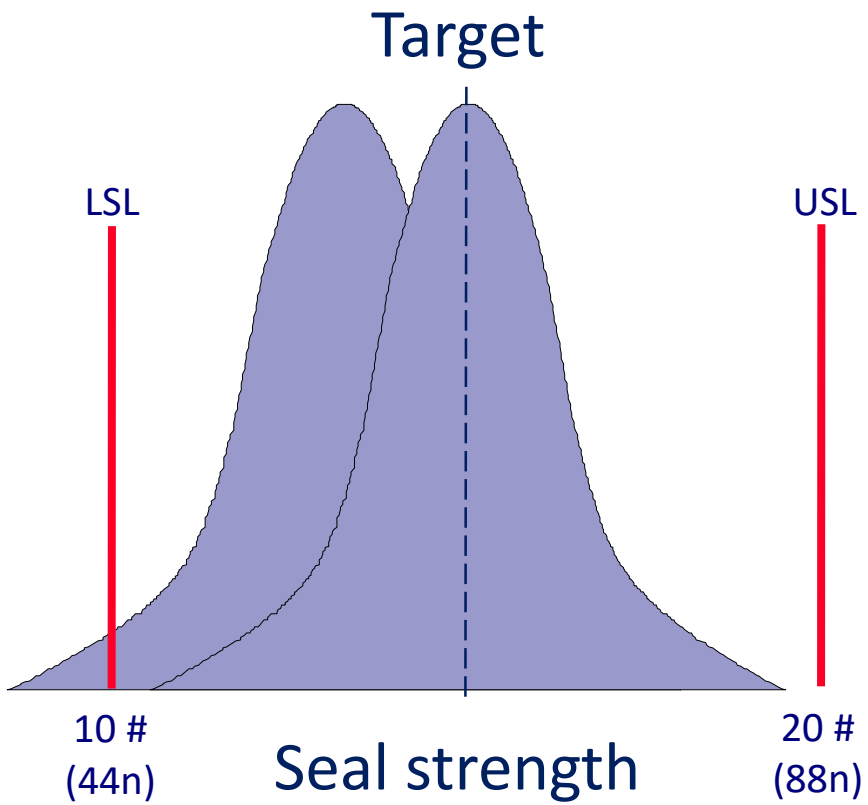


1. Set hot bar temperature to 200°F (93°C)

2. Set dwell time to .75 seconds

Response Surface Studies

Second, optimize variation…



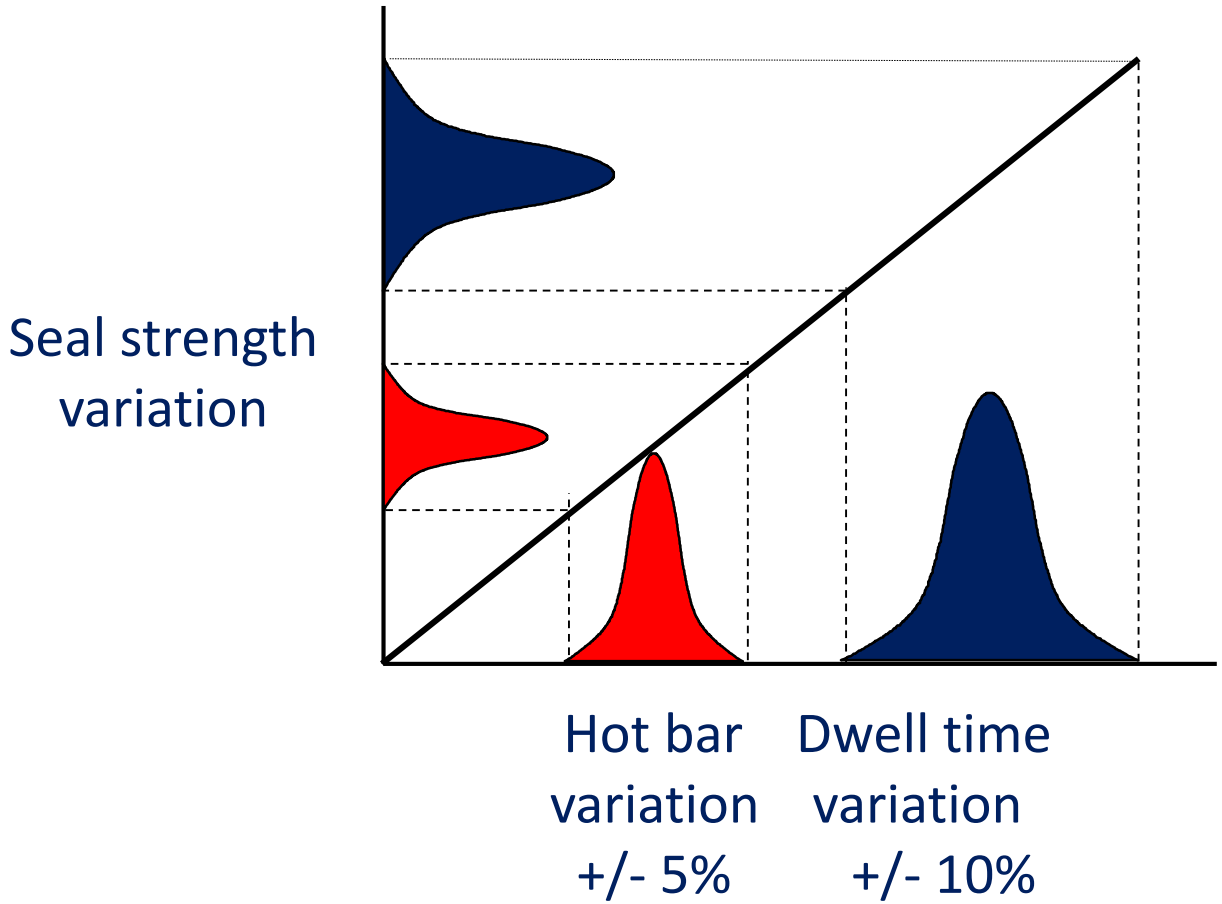
Options

- Adjust the pressure setting to 80 psi (550 kPa)

or

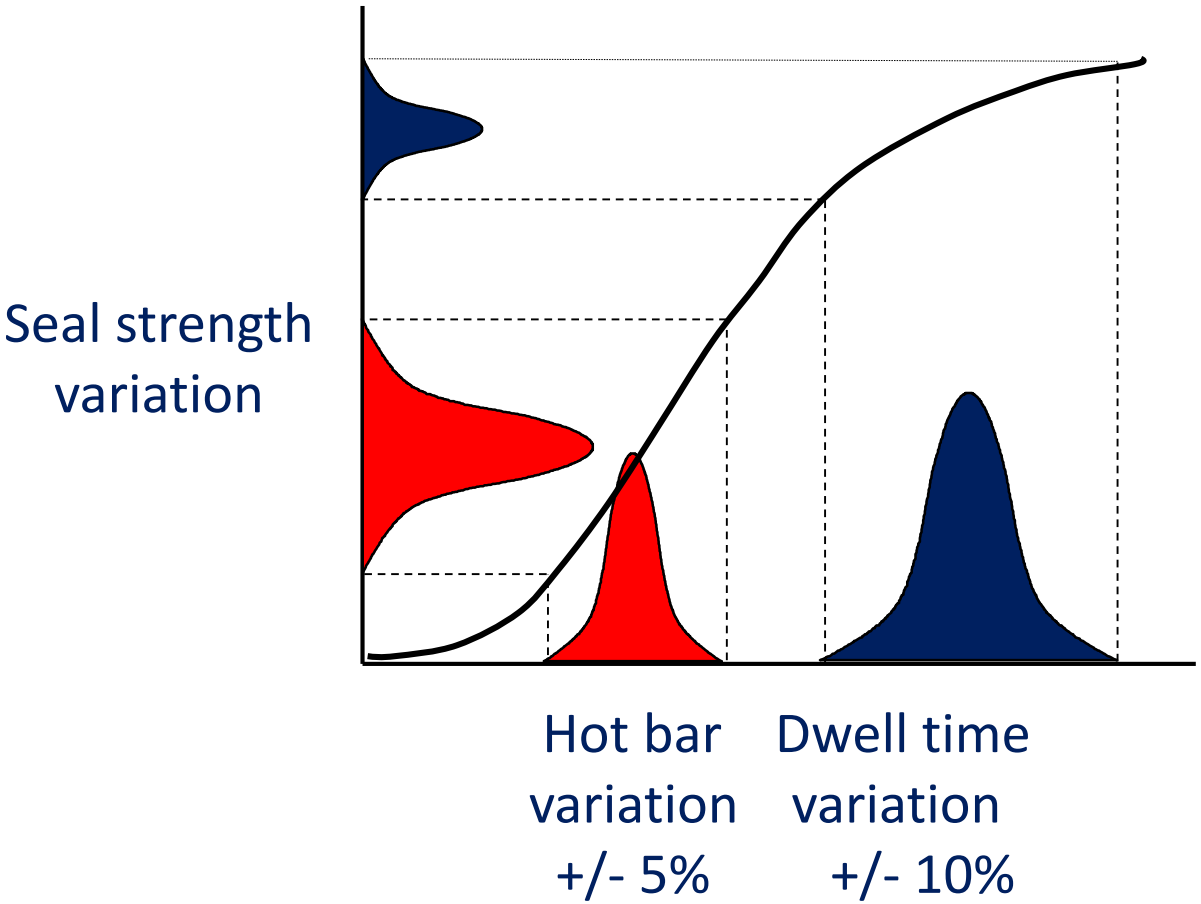
- Maintain the pouch temperature at 95º F (35ºC) to center the process on the target

Robust Tolerance Analysis



Effects of input variation on output variation

Robust Tolerance Analysis

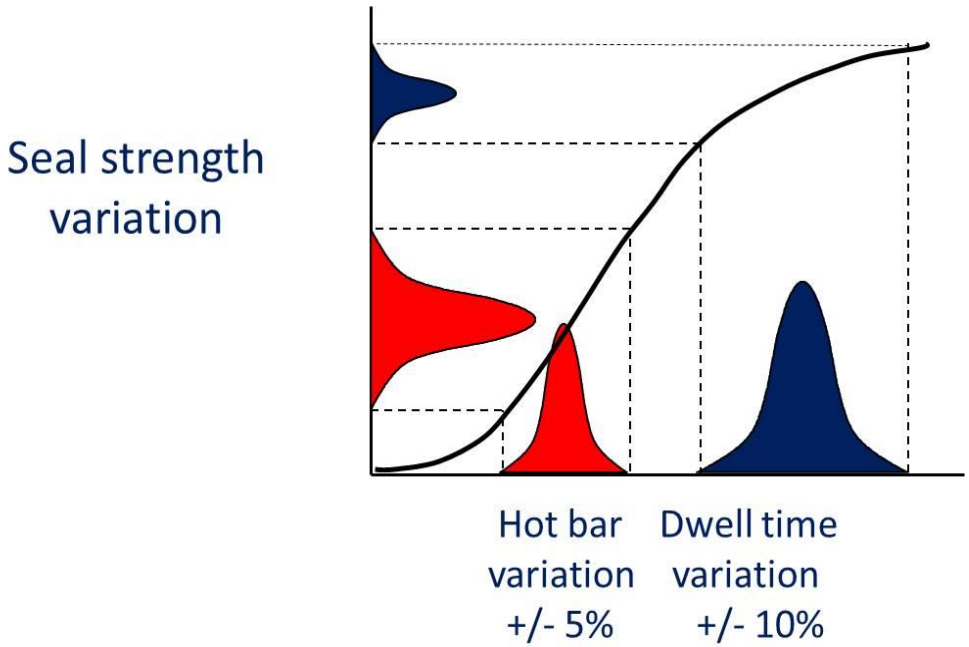


Effects of input variation on output variation

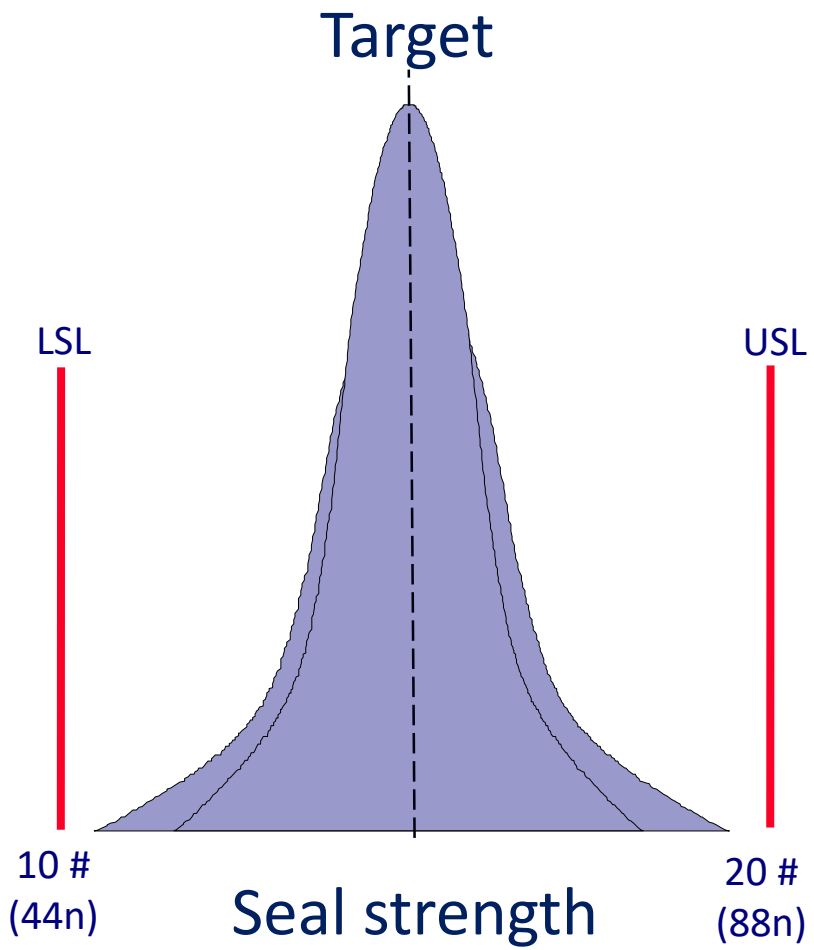
Robust Tolerance Analysis

- The hot bar setting contributed more variation to seal strength than dwell time

- Reduce hot bar variation further by investing in a more capable controller



Robust Tolerance Analysis



Purchase a controller capable of holding temperature at 200°F ± 2% (93°C ± 2%)

Identify Technical Root Cause(s): Key Points

Experiment: component swapping study

When, through experiments, the problem can be controlled, moved, manipulated, etc…the technical root cause has been identified

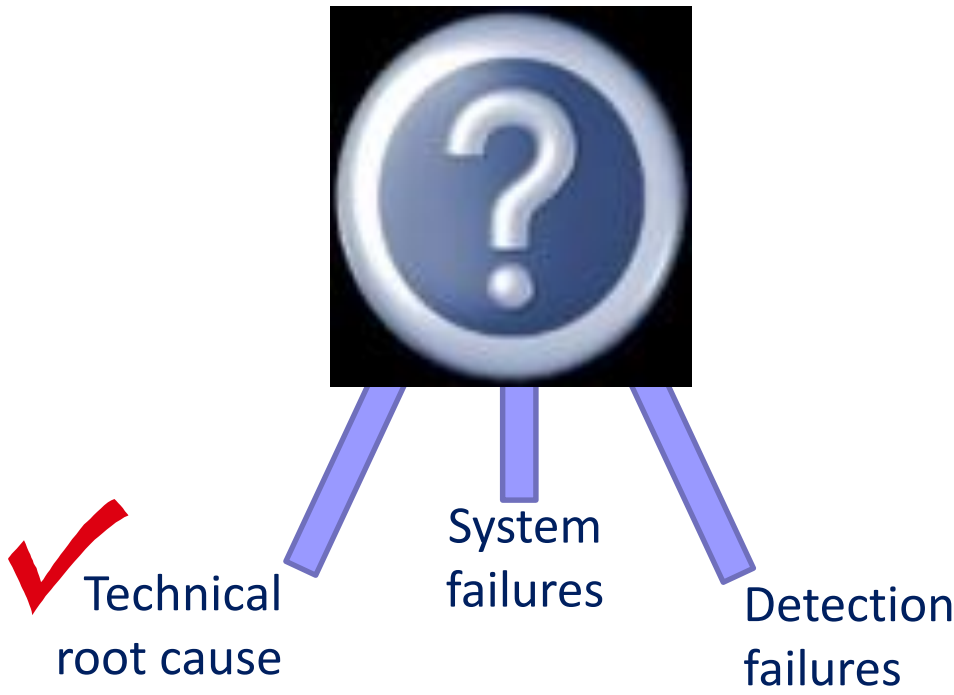
Identify Technical & Systemic Root Causes

Input	Process	Output
Probable causes	Verify assumptions Conduct experiments	Technical root cause(s)
	3 Legged 5 Why	Systemic root cause(s)

Identify Systemic Root Cause(s)

Asking “why” may uncover systemic root causes that:

- Allowed the change to occur
- Failed to detect the change



3L5WHY
(3 Legged 5 Why’s)

Identify Systemic Root Cause(s)

Technical root cause

System failures

Detection failures

Why did this change occur?

The 71B controller was not capable of meeting process requirements

Why was a controller selected that wasn't capable?

Process needs weren't reviewed before a replacement was selected

Why weren't process needs reviewed?

Focus was on cost, 71B was less expensive

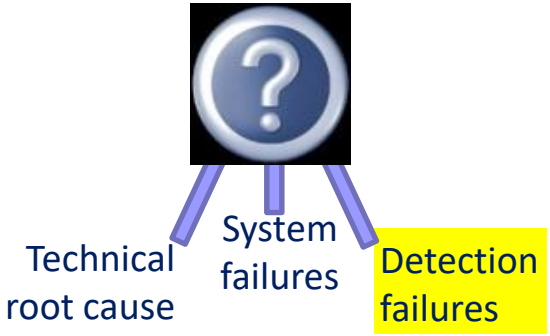
Why was focus on cost?

Bonus structure allowed people to prioritize cost over quality

Why did the system allow this to happen?

???

Identify Systemic Root Cause(s)



Why didn't we detect the controller wasn't capable?

Process validation wasn't conducted

Why wasn't process validation conducted?

Validation department was unaware the control had been changed

Why was the Validation Department unaware?

Systems allowed the Mechanic to forgot to communicate

Why did the systems allow this to happen?

???

Documentation

- Test sheet with verification of assumptions
- Experiments & results
- 3L5Why detailing technical & systemic root cause(s)

Strongly recommended

Step 6: Determine Corrective & Preventive Actions

Determine Corrective & Preventive Actions

Input	Process	Output
Technical & systemic root causes	Mistake proofing vs. optimization & variation reduction (OVR)	Corrective/preventive action(s)
	FMEA Design verification Process validation	Risk mitigation
	Future monitoring	Control plan

Documentation

21 CFR 820.100(a)(3) Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems

Determine Corrective & Preventive Actions

All root causes will result from:

Human error

Mistake proofing

Too much variation

Optimization & variation reduction (OVR)

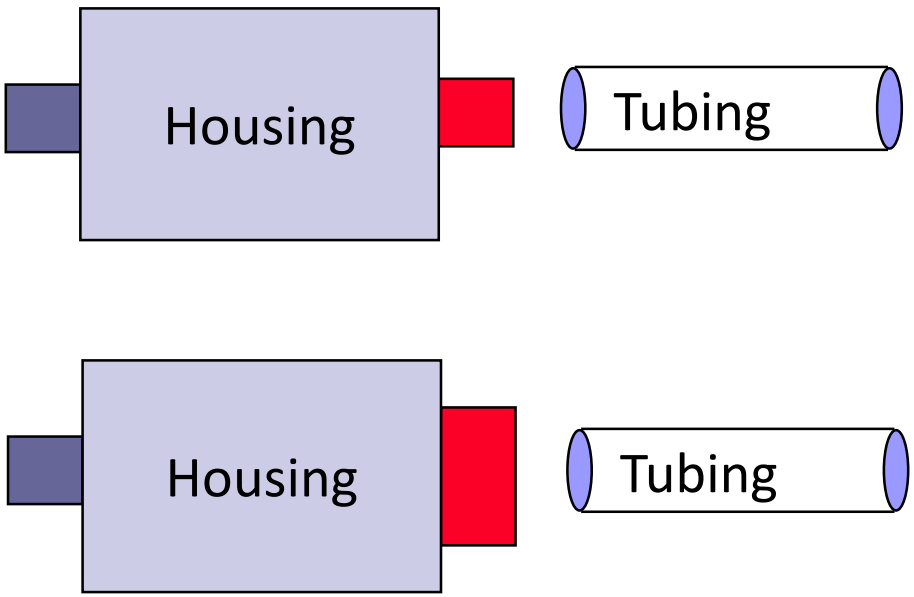
Mistake Proofing

Ensuring the problem…

- cannot occur again
- cannot get through our systems undetected

Mistake Proofing

Eliminate: Make it impossible for the defect to occur



Example: Designing components so they can only be assembled the correct way

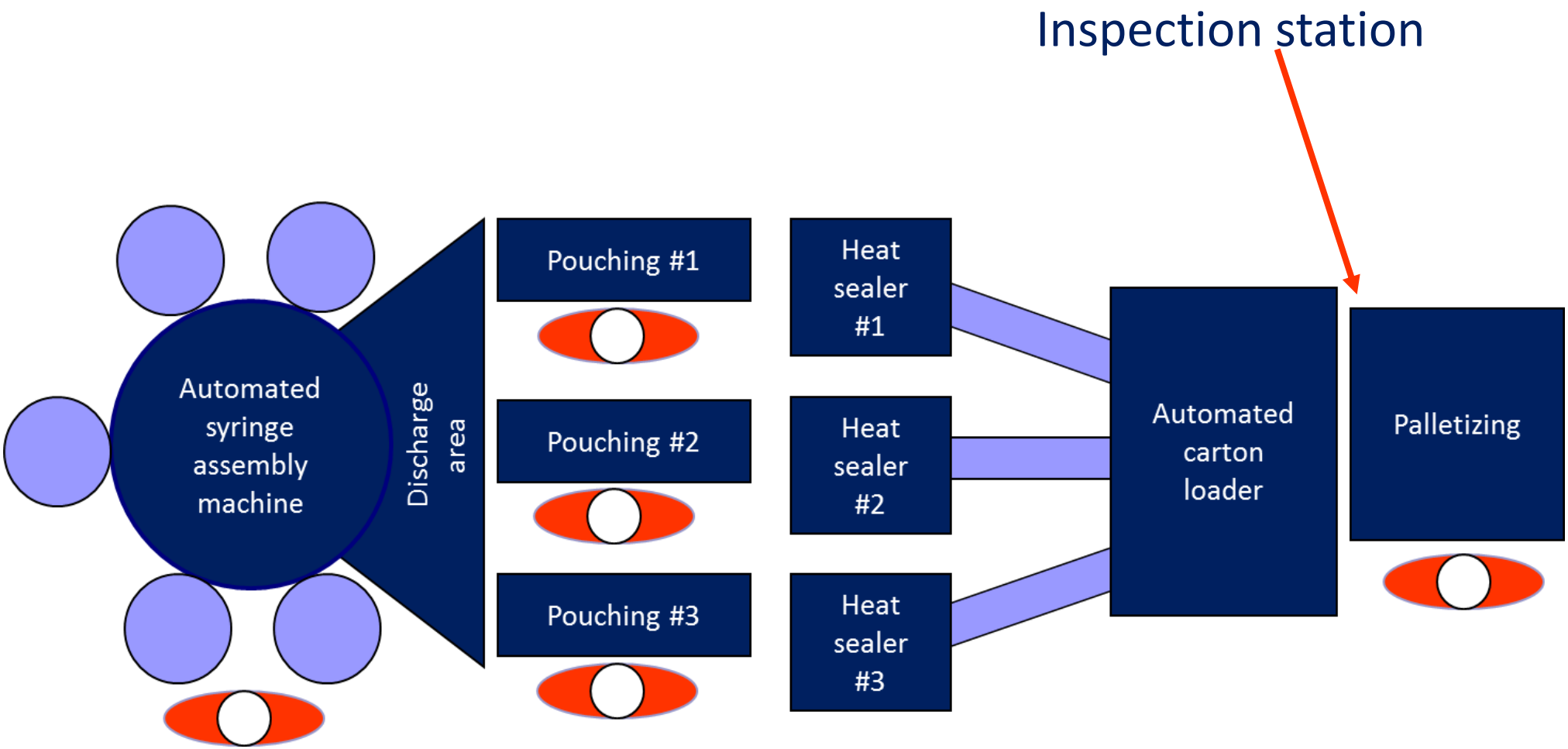
Mistake Proofing

Facilitate: Reduce the probability of the defect occurring

Example: Double entries when establishing a new password to reduce the probability of a typing error

Mistake Proofing

Flag: Implementing an inspection

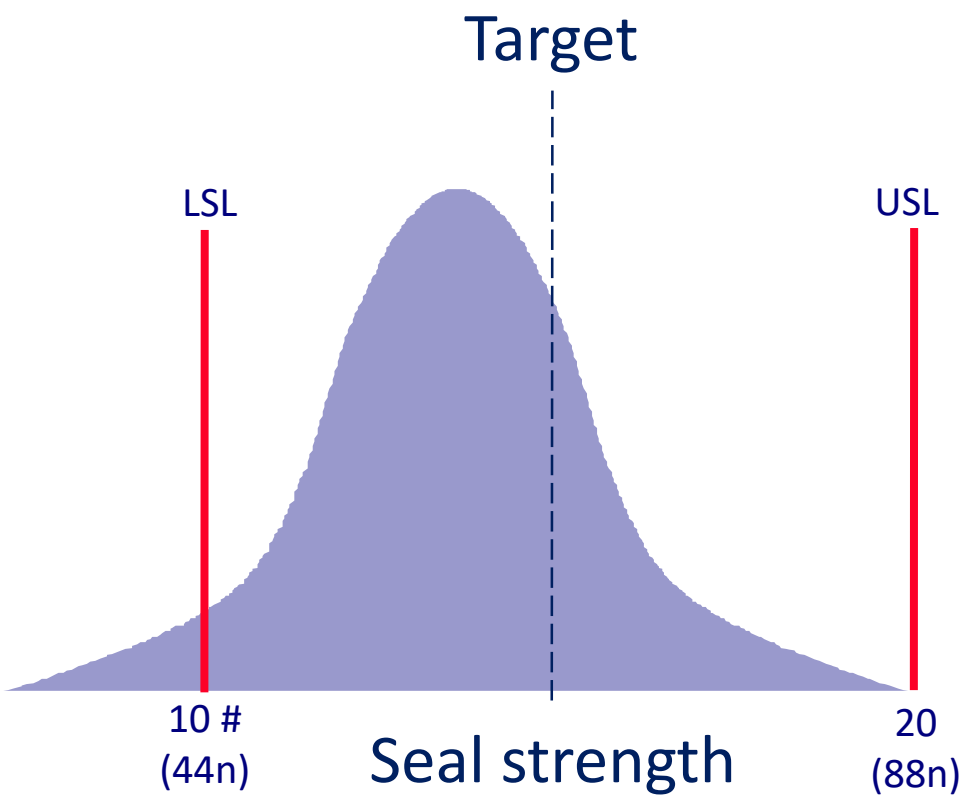


Mistake Proofing

Mitigation: Reduce the consequences of defect as it's occurring

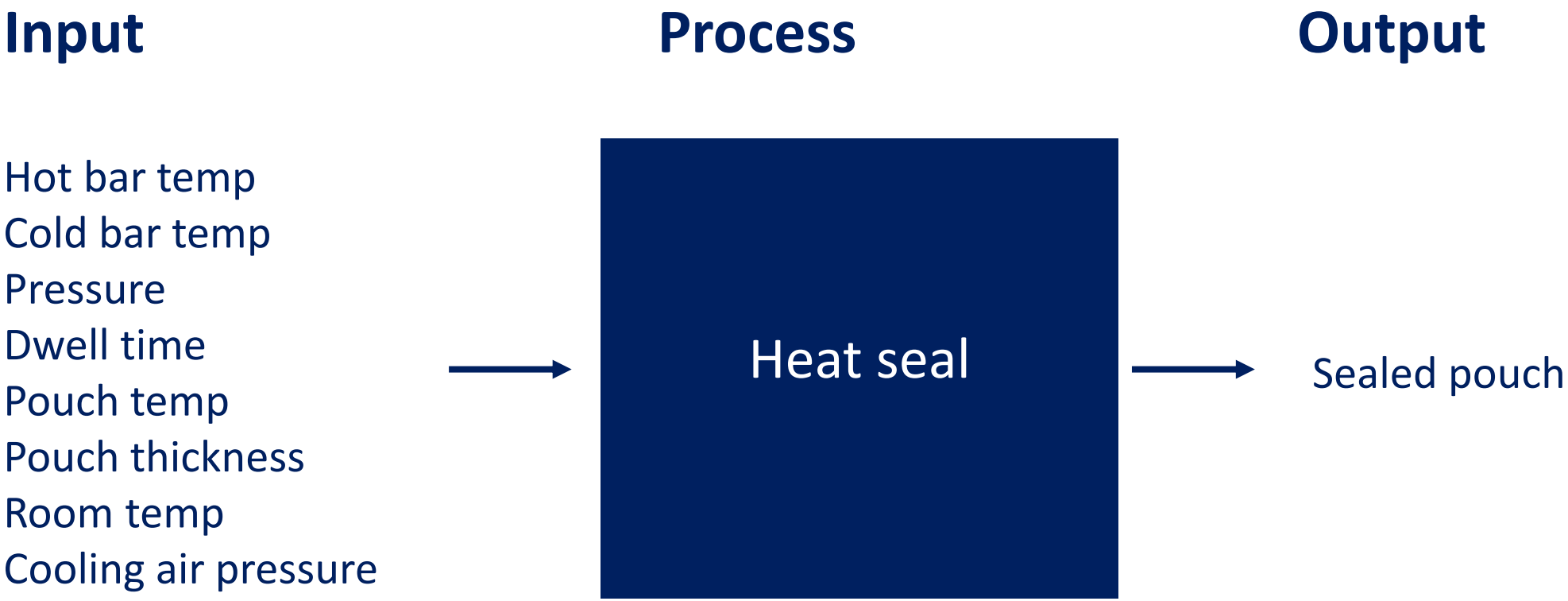
Used when the defect cannot be controlled

Optimization & Variation Reduction (OVR)



- Excessive variation
- Improper targeting

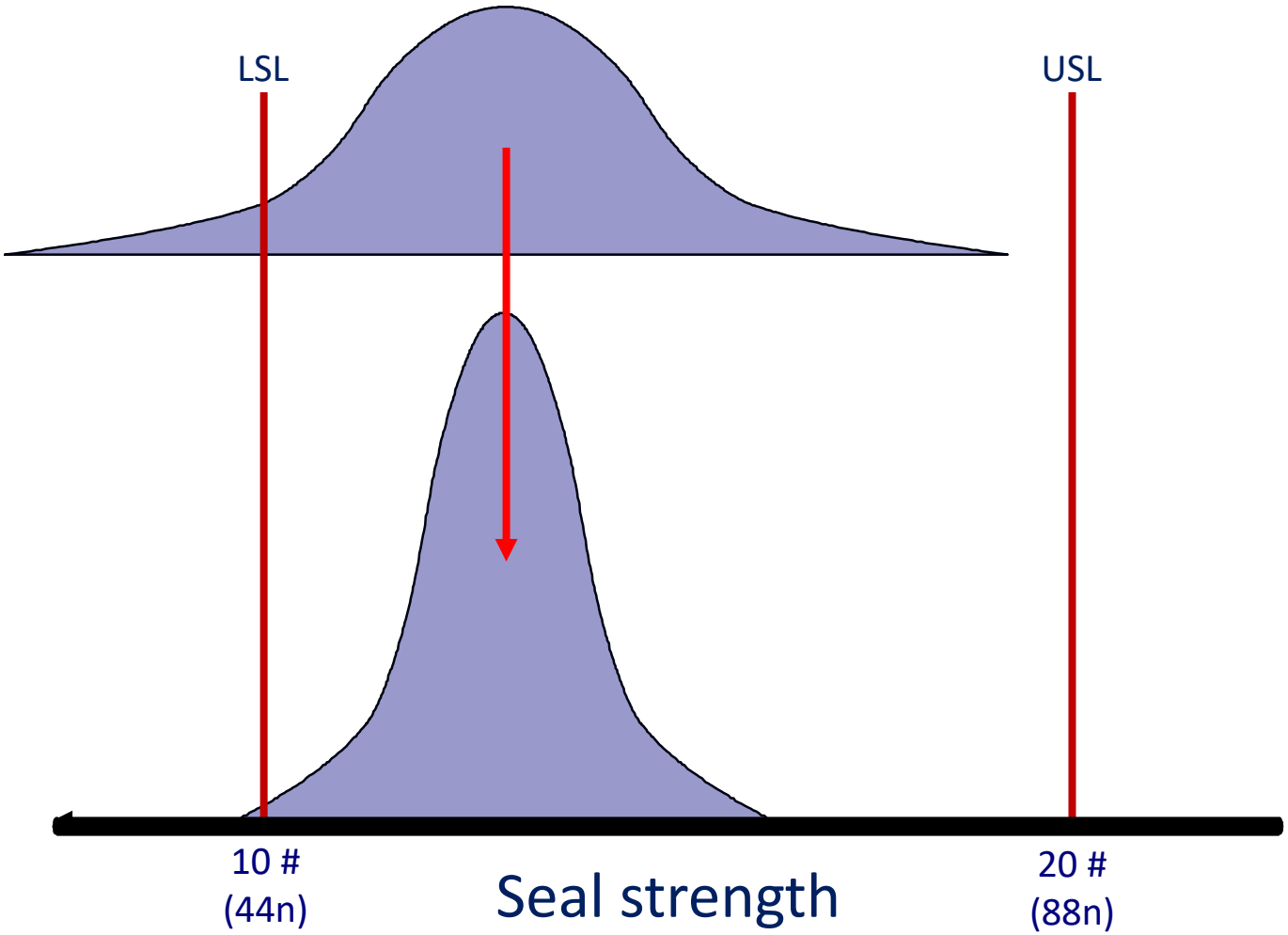
Optimization & Variation Reduction (OVR)



Excessive variation and/or improper targeting of 1 or more inputs may cause excessive variation and/or improper targeting of the output

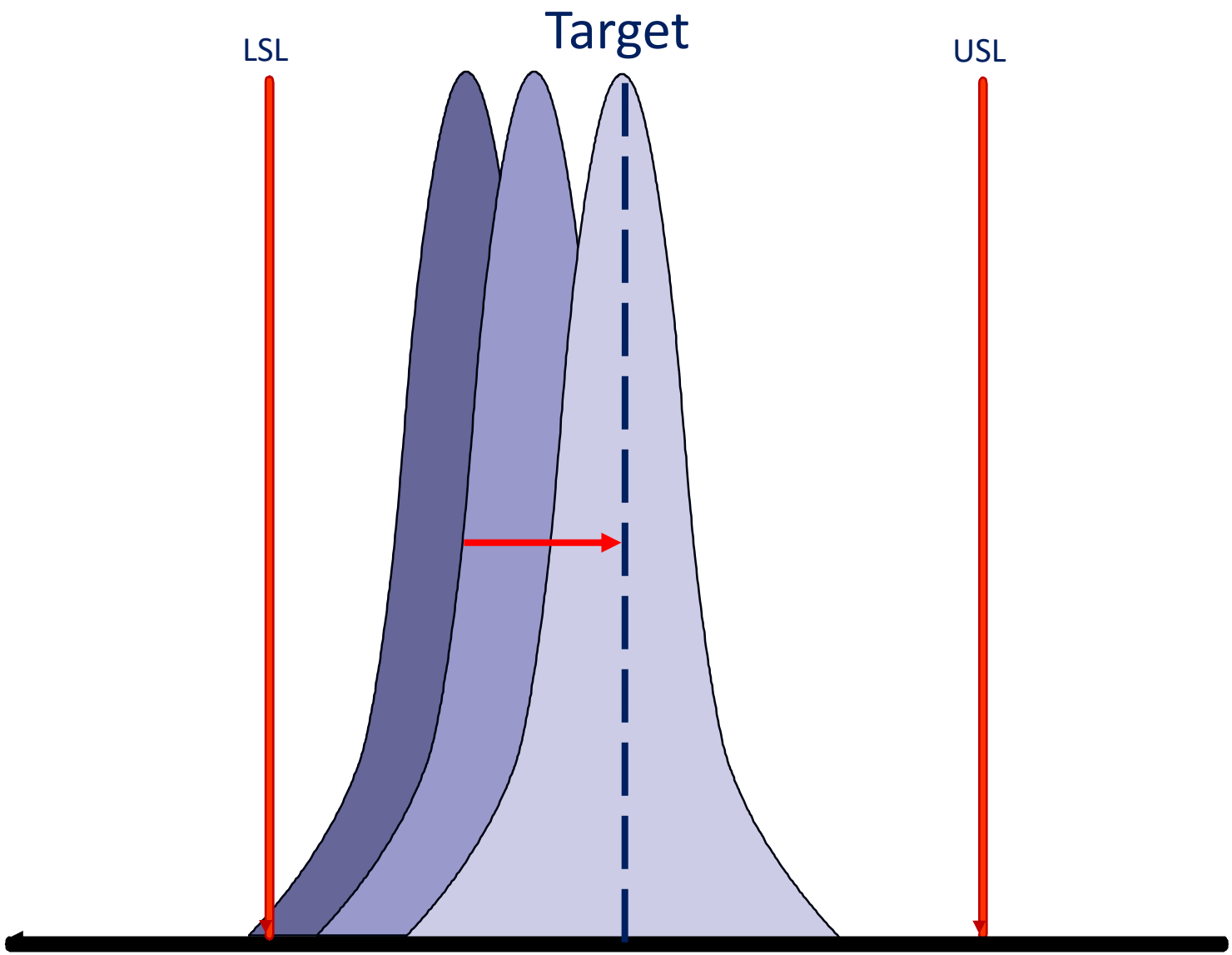
Optimization & Variation Reduction (OVR)

1st reduce performance variation…



Optimization & Variation Reduction (OVR)

2nd move performance as close to target as possible



Corrective & Preventive Action Plan (3L5Why)

Root Cause	Corrective Action	Risk Mitigation	Control Plan	Acceptance Criteria
Technical: Change to 71B controller	Replace with standard model controller historically leveraged			Defect rate returns to .01% for 3 consecutive, full production days
System: People overreacting to management stressing cost control	Mgmt to address balancing cost and quality at next all employee meeting			Conduct by 8/31
Detection: Mechanic forgot to communicate to Validation Dept	Revise maintenance electronic system to not allow mechanic to close out WO without sending change notice to Validation Dept			No communication failure in next 6 months

Risk Mitigation

Consider unintended consequences of the correction/preventive actions…

- Review risk analysis
  - FMEA, fault tree analysis, etc
- Repeat design verification studies
- Repeat process validation studies

Corrective & Preventive Action Plan (3L5Why)

Root Cause	Corrective Action	Risk Mitigation	Control Plan	Acceptance Criteria
Technical: Change to 71B controller	Replace with standard model controller historically leveraged	Validate heat seal process		Defect rate returns to .01% for 3 consecutive, full production days
System: People overreacting to management stressing cost control	Mgmt to address balancing cost and quality at next all employee meeting	Front line mgrs stress importance at next team meeting		Conduct by 8/31
Detection: Mechanic forgot to communicate to Validation Dept	Revise maintenance electronic system to not allow mechanic to close out WO without sending change notice to Validation Dept	Validate electronic system		No communication failure in next 6 months

Control Plan

Ensure the problem remains fixed…

- Before & after measurements
- Monitoring performance
- Quality process checks
- Standardization

CONTROL PLAN

Company Name: _____ **Prepared by:** _____ **Date:** _____ **Document No:** _____

Process Name: _____ **Approved by:** _____ **Date:** _____ **Initiation Date:** _____

Project ID: _____ **Process Owner:** _____ **Revision No.:** _____

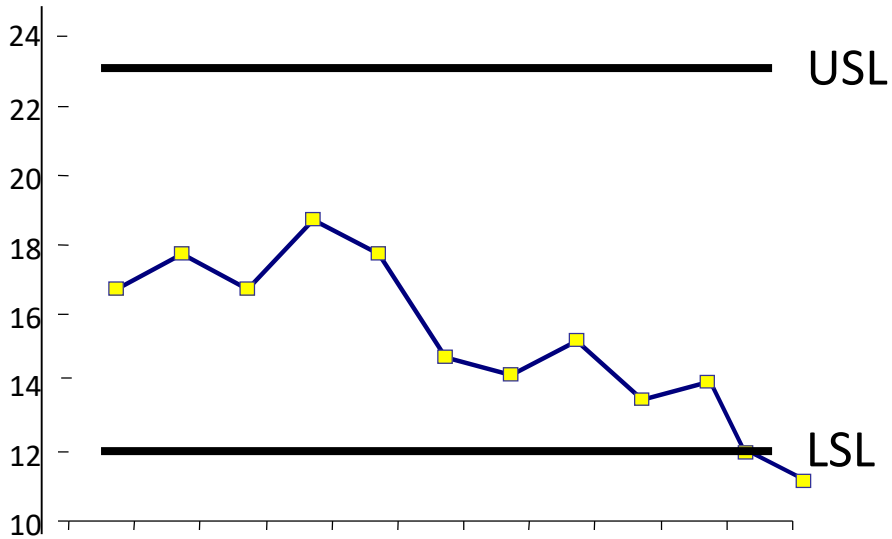
Project Scope: **START:** _____ **END:** _____ **Page:** ___ **of** ___ **Revision Date:** _____

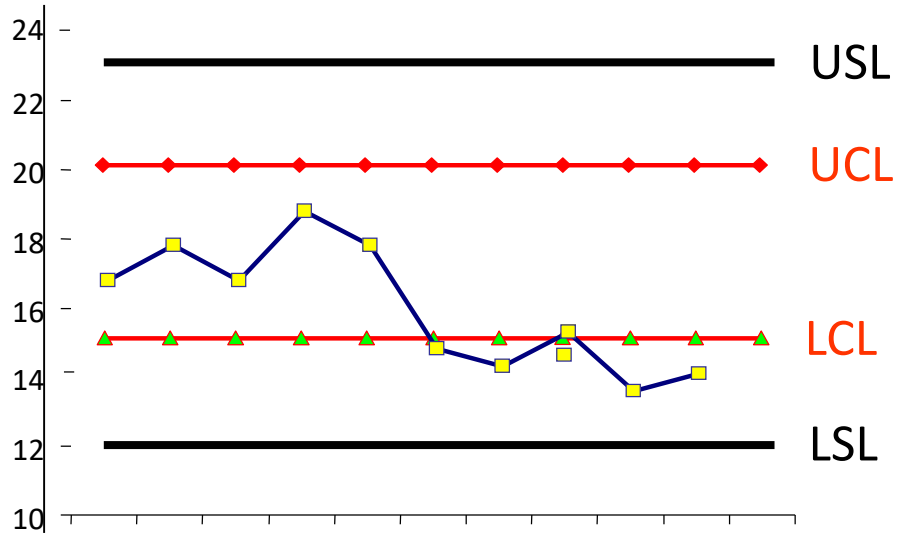
Process Step	CTQ		Specification Characteristic	Specifications		Unit of Measurement	Data Description	Measurement Method	Sample Size	Frequency of Measurement	Who Measures	Where Recorded	Corrective Action	Applicable Standard Operating Prodedure
	KPIV	KPOV		LSL	USL									
Polishing	X		Outer Diameter	0.0004	0.0006	mm	variables	Optical Comparator	10 parts / lot	Hourly	Operator	X-bar & R subgroup size = 10	Replace paper, retrain, check machine	PM-005
Delivery		X	Customer specified due date	98%	100%	The time delivery enters truck	attributes (not late / late)	Late = 1 Defect = 1 Defective	Each Delivery	Each Delivery	Prod. Control	P Chart	Conduct 5-WHY	PC-001 & PC-002

Control Plan

Monitor performance

- Early warning to minimize recurrence

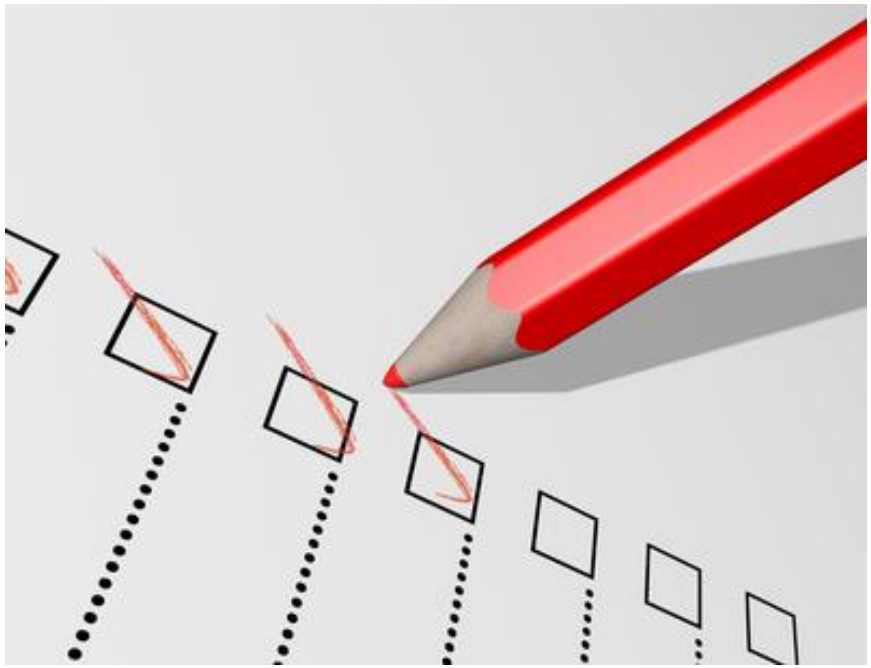




Control Plan

Quality process checks (audits)…

- Checking process inputs to minimize non conformances

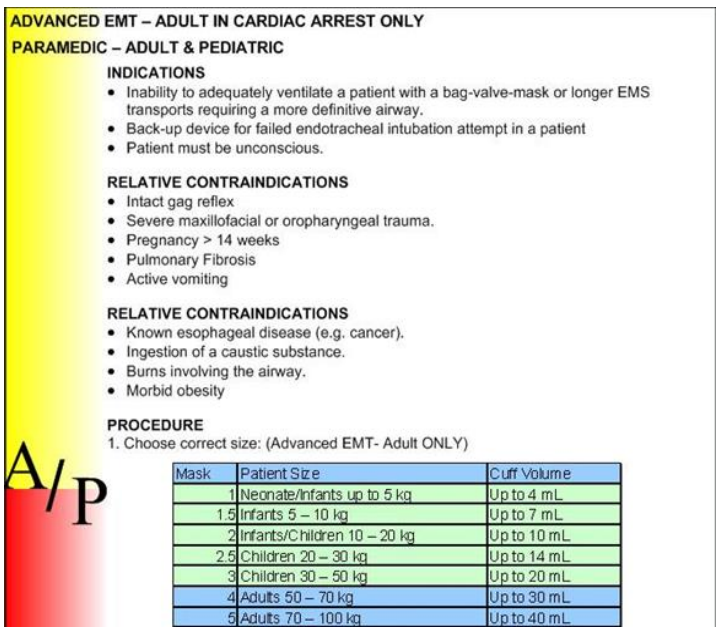


Control Plan

Standardization

- Ensuring important elements of a process are performed consistently

- Developing procedures:
  - Specify tasks and how they need to be executed
  - Provide direction when and how inputs are to be adjusted
  - Training



ADVANCED EMT – ADULT IN CARDIAC ARREST ONLY

PARAMEDIC – ADULT & PEDIATRIC

INDICATIONS

- Inability to adequately ventilate a patient with a bag-valve-mask or longer EMS transports requiring a more definitive airway.
- Back-up device for failed endotracheal intubation attempt in a patient
- Patient must be unconscious.

RELATIVE CONTRAINDICATIONS

- Intact gag reflex
- Severe maxillofacial or oropharyngeal trauma.
- Pregnancy > 14 weeks
- Pulmonary Fibrosis
- Active vomiting

RELATIVE CONTRAINDICATIONS

- Known esophageal disease (e.g. cancer).
- Ingestion of a caustic substance.
- Burns involving the airway.
- Morbid obesity

PROCEDURE

1. Choose correct size: (Advanced EMT- Adult ONLY)

A/P

Mask	Patient Size	Cuff Volume
1	Neonate/Infants up to 5 kg	Up to 4 mL
1.5	Infants 5 – 10 kg	Up to 7 mL
2	Infants/Children 10 – 20 kg	Up to 10 mL
2.5	Children 20 – 30 kg	Up to 14 mL
3	Children 30 – 50 kg	Up to 20 mL
4	Adults 50 – 70 kg	Up to 30 mL
5	Adults 70 – 100 kg	Up to 40 mL

Corrective & Preventive Action Plan (3L5Why)

Root Cause	Corrective Action	Risk Mitigation	Control Plan	Acceptance Criteria
Technical: Change to 71B controller	Replace with standard model controller historically leveraged	Validate heat seal process	- Control chart each machine - Same for all lines	Defect rate returns to .01% for 3 consecutive, full production days
System: People overreacting to management stressing cost control	Mgmt to address balancing cost and quality at next all employee meeting	Front line mgrs stress importance at next team meeting	Electronic tracking of front line mgrs	Conduct by 8/31
Detection: Mechanic forgot to communicate to Validation Dept	Revise maintenance electronic system to not allow mechanic to close out WO without sending change notice to Validation Dept	Validate electronic system	Verify during internal audits	No communication failure in next 6 months

Documentation

Leverage the 3L5Why to document:

- Corrective/preventive actions plans for technical, systemic, and detection failures
- Risk mitigation for unintended consequences (leveraging appropriate techniques)
- Control plan to monitor corrective/preventive action plan performance
- Acceptance criteria to determine success

Strongly recommended

Step 7: Verify Corrective & Preventive Actions

Verify Corrective & Preventive Actions

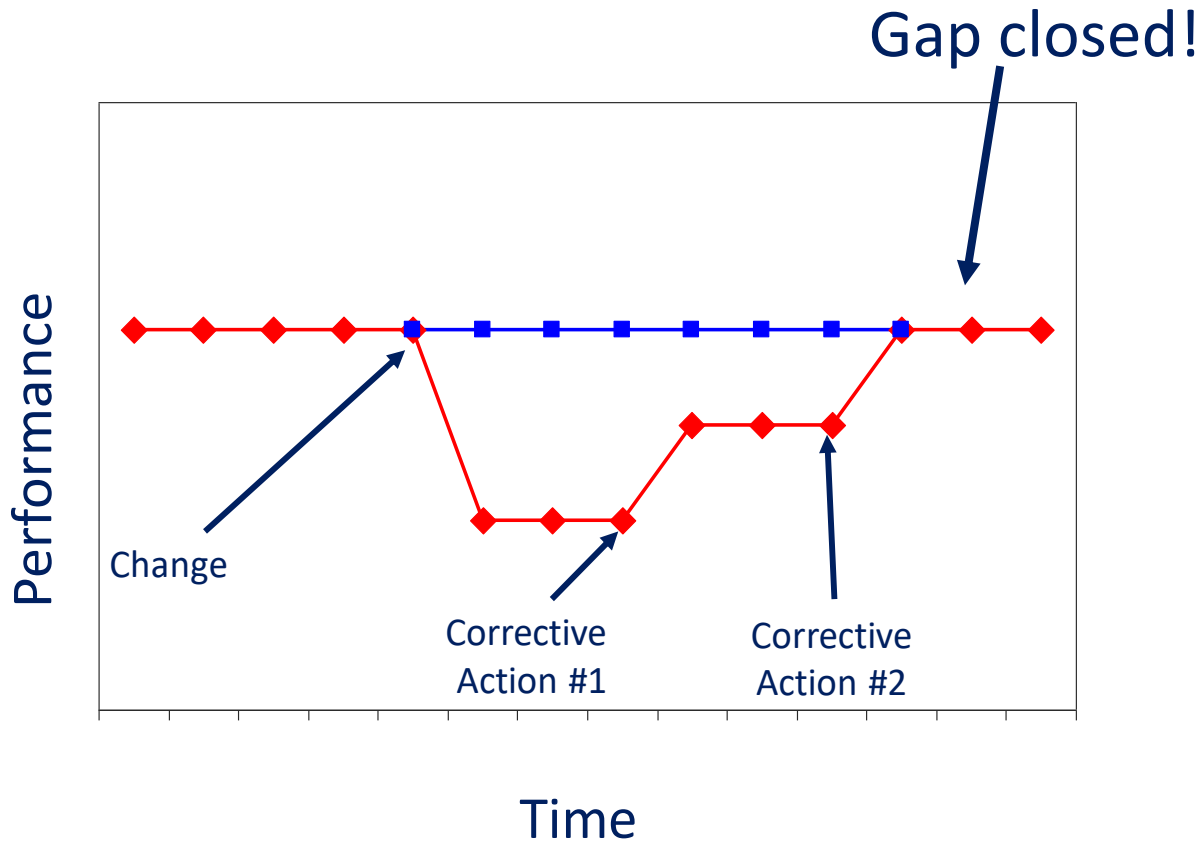
Input	Process	Output
Corrective/preventive actions	Implement Measure effectiveness Ensure control plan is working Share the knowledge	Technical problem disappears No new problems arise Problem stays corrected

Verifying Corrective & Preventive Actions

Documenting that the corrective/preventive actions have been implemented

Validating Corrective & Preventive Actions

Demonstrating with data that the previous level of performance has been restored or the requirement is now being met (effectiveness checks)



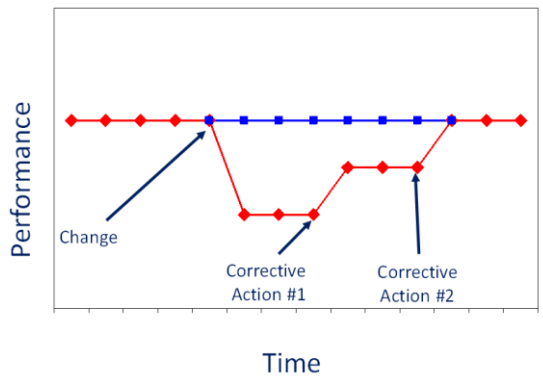
Validating Corrective & Preventive Actions

If the performance gap persists…

- The corrective action may not have been completely effective
  - How was corrective action implemented?
  - How were effectiveness measures taken?
  - Does more need to be done?

If the performance gap still persists…

- There must be more than 1 technical root cause
  - Assumptions may need to be reviewed to flush out a 2nd technical root cause
  - Go back to Step 3 to identify more possible causes and continue to follow the process



Root Cause	Corrective/Preventive Action	Risk Mitigation	Control Plan	Acceptance Criteria	Actual Measure
Technical: Change to 71B controller	Replace with standard model controller historically leveraged	Validate heat seal process	- Control chart at each machine - Same on all lines	Defect rate return to .01% for 3 consecutive days	Defect rate ≥ .01%
System: People overreacting to management stressing cost control	Mgt to address at next all employee meeting	Dept. managers stress at following dept meeting	Electronic tracking of front line mgrs	Conduct by 8/31	Conducted on 8/27
Detection: Mechanic forgot to communicate to Validation Dept	Revise maint. system to not allow mechanic to close out WO without sending change notice to Validation Dept	Validate system	Verify during internal audits	No communication failure in next 6 months	No Failures

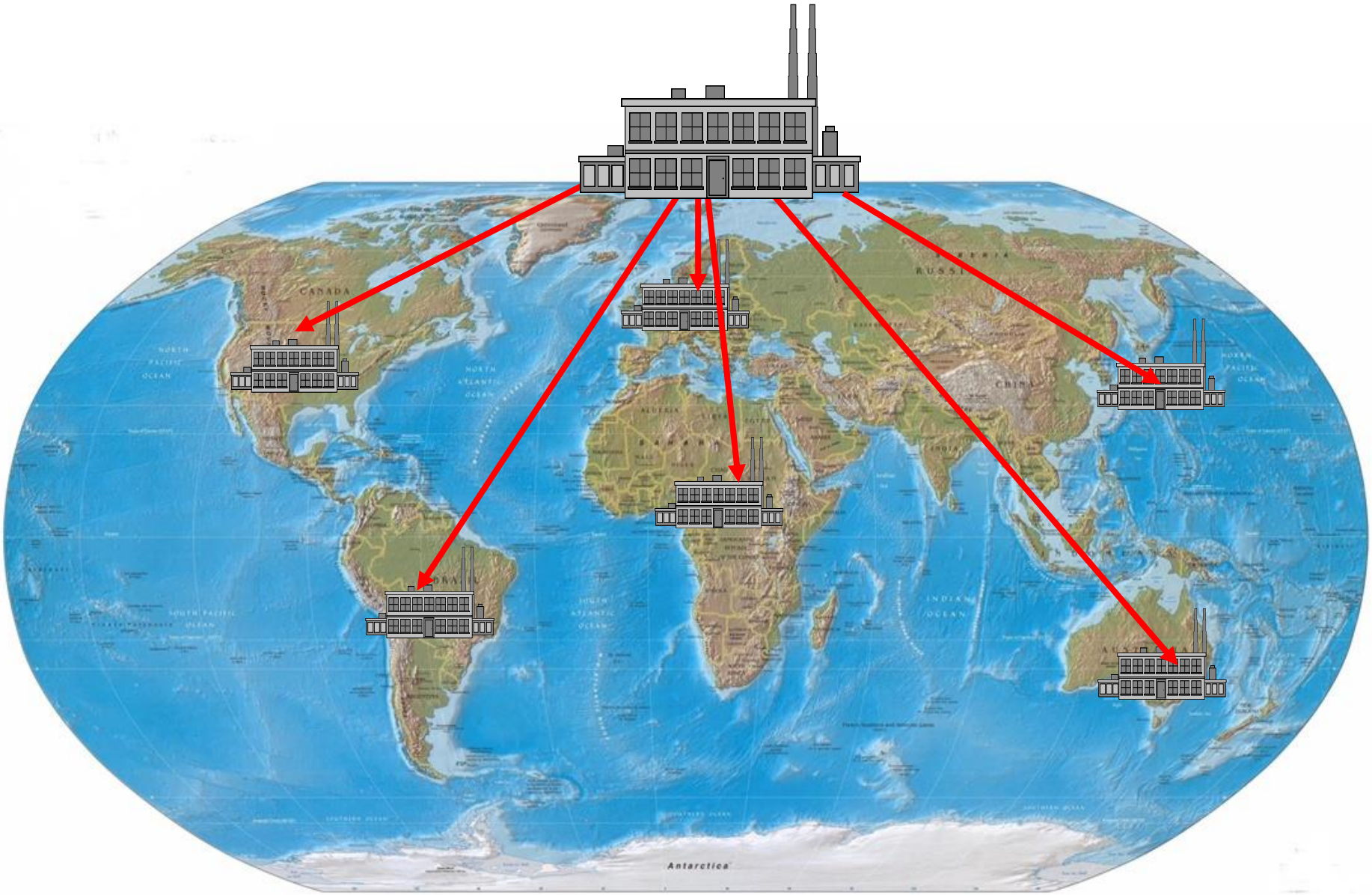
Capture the Knowledge

- Update risk analysis to reflect knowledge gained during the investigation
- If problem occurs again in the future, new investigation team should be able to resolve much more quickly

Failure Mode & Effects Analysis (FMEA)

Item or process step	Item/step function	Potential failure mode	Potential effect	Potential causes of failure
Stencil "For Demo Only" on flotation device	Identify flotation device to be used for demo	Incorrect paint	• Red sweat • Itching / burning sensation	• Improper training • Forgets

Preventive Actions



Communicate lessons learned to appropriate parties

Root Cause	Corr. / Prev. Action	Acceptance Criteria	Actual Measure	Additional Prev. Actions
Technical: Change to 71B controller	Replace with standard model controller historically leveraged	Defect rate .01% for 3 consecutive days	Defect rate ≥ .01%	- Control chart at all heat seal stations - Review with Janesville
System: People overreacting to management stressing cost control	Mgt to address at next all employee meeting	Conduct by 8/31	Conducted on 8/27	Review with Janesville facility
Detection: Mechanic forgot to transmit change notice to Validation Dept	Revise maint system so WO can't be closed out without sending change notice to Validation Dept	No communication failure in next 6 months	No Failures	Review with Janesville facility

Documentation

Leverage the 3L5Why to document:

- Verify the corrective/preventive actions have been implemented & documented
- Validate with data (effectiveness checks) that performance has been restored

Strongly recommended

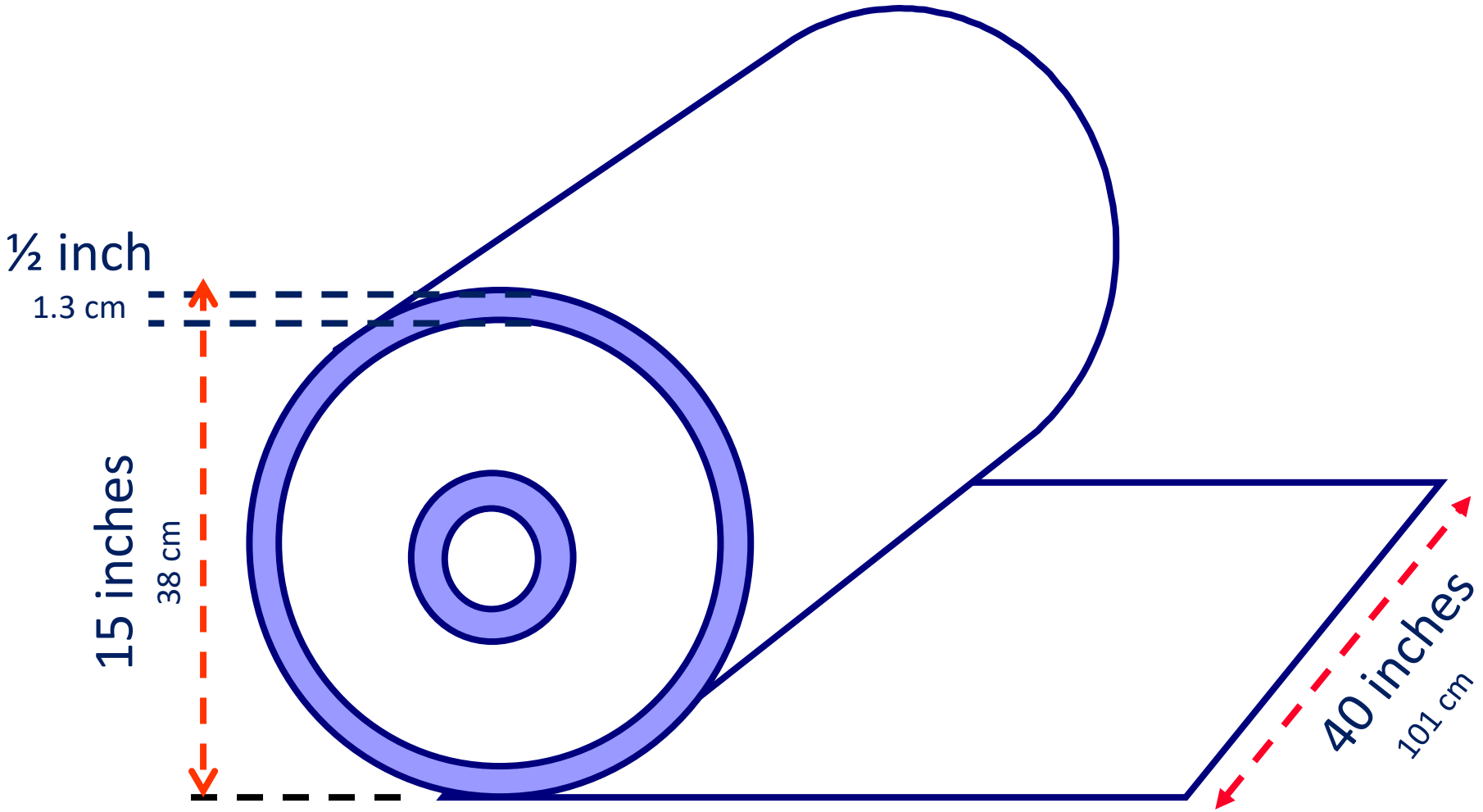
Verify Corrective & Preventive Actions

If the corrective/preventive actions were successful…

- The technical problem disappears
- No new problems arise
- Problem stays corrected

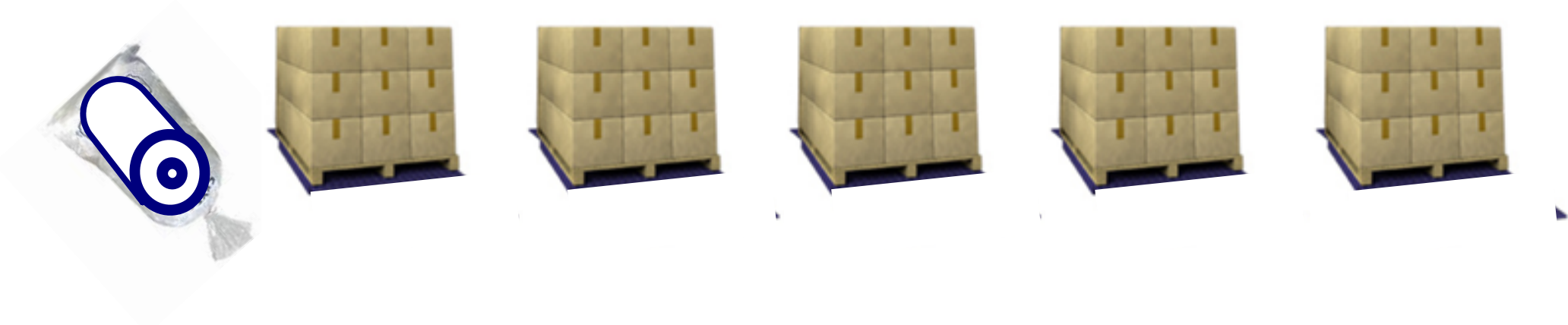
The Orange Company Case

Film Dimensions



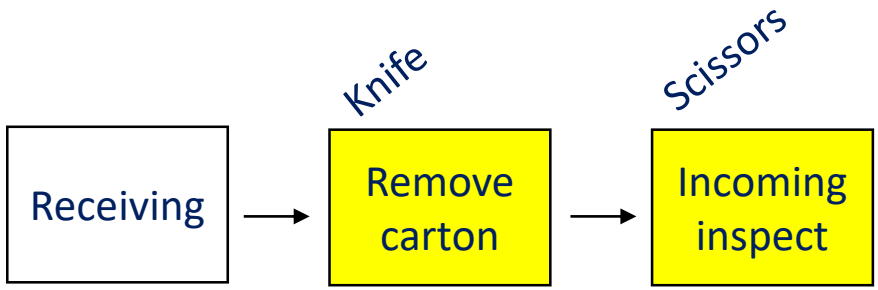
New Tech Process Flow

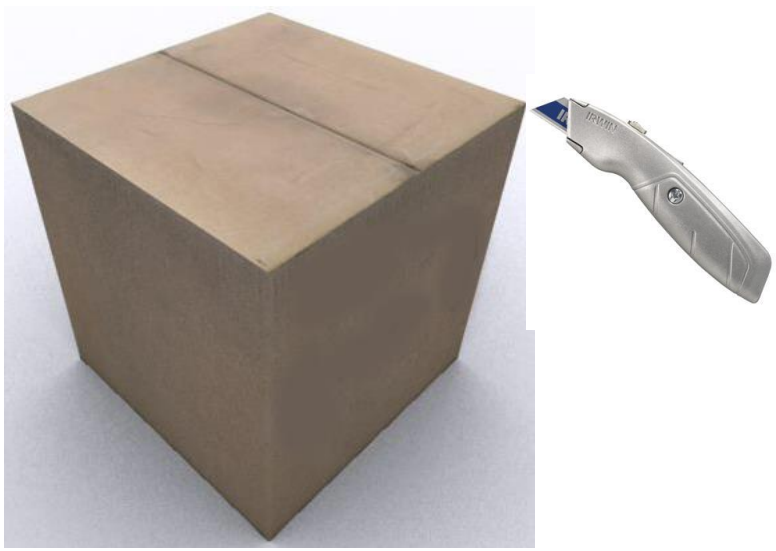
Receiving

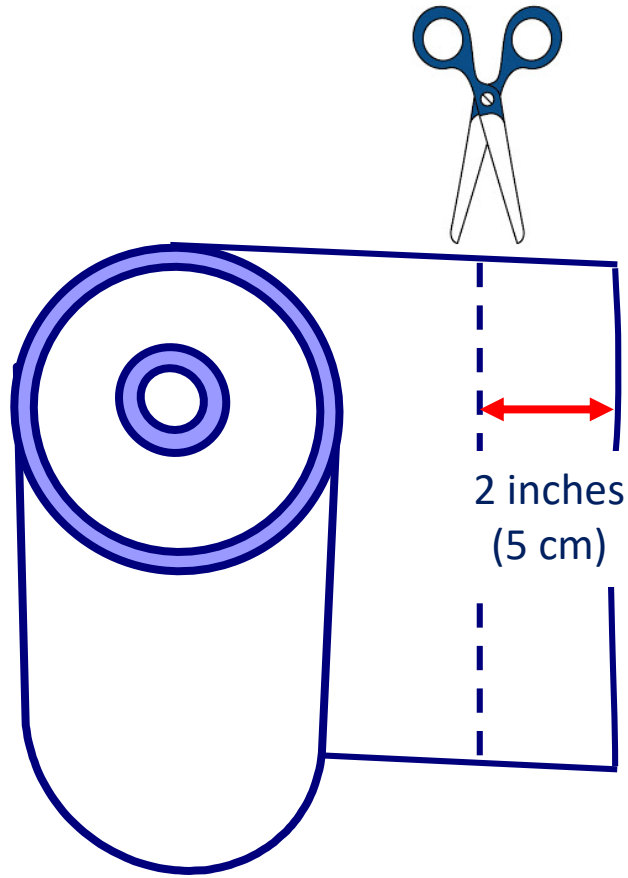


Each film shipment = 1 supplier/part lot = 5 pallets with 9 cartons/pallet

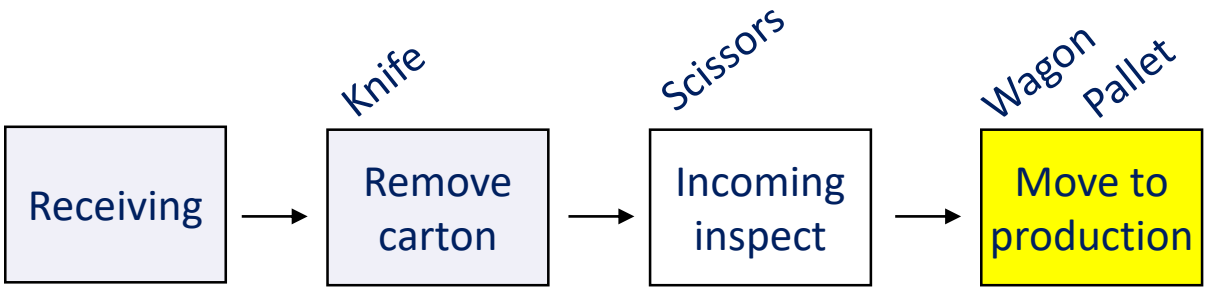
New Tech Process Flow



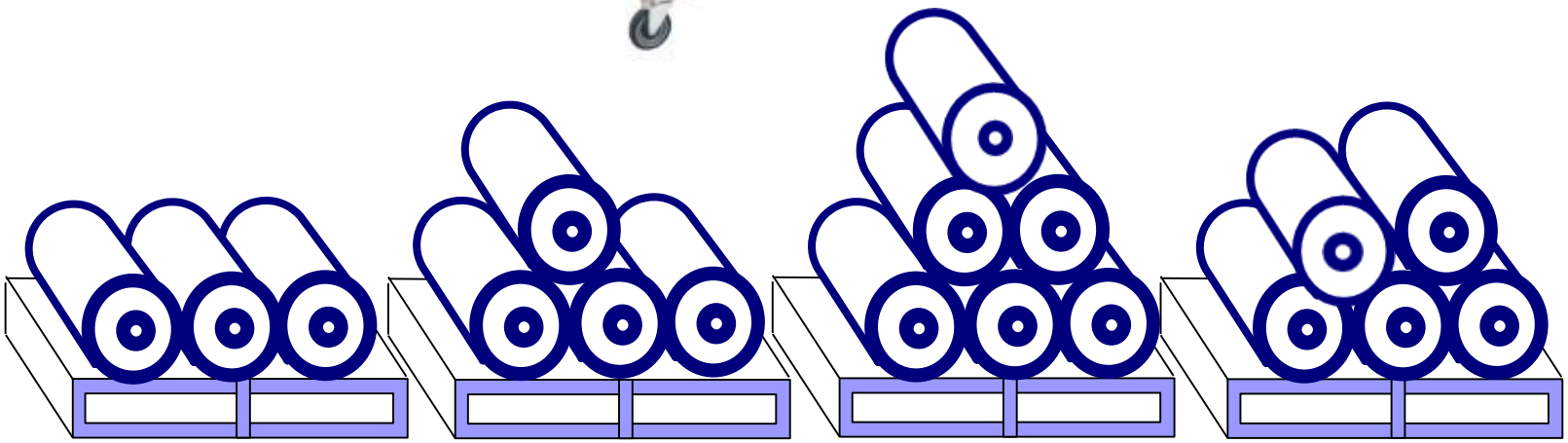




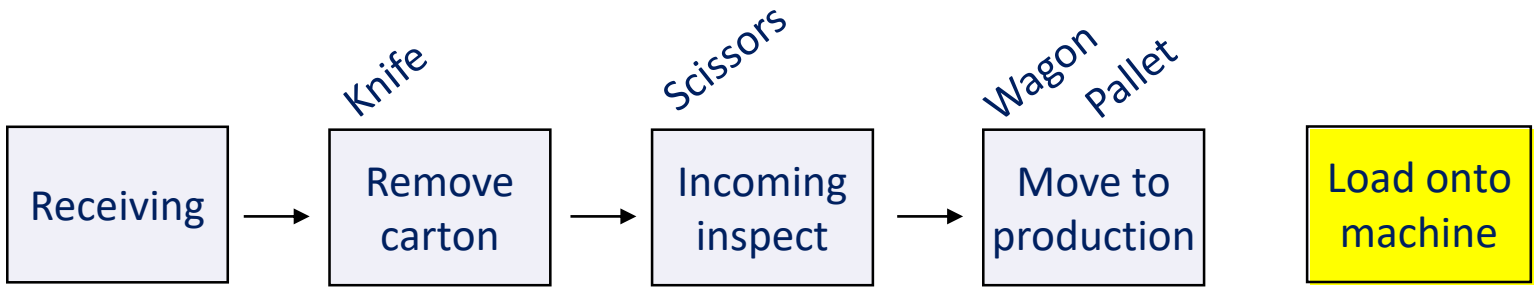
New Tech Process Flow



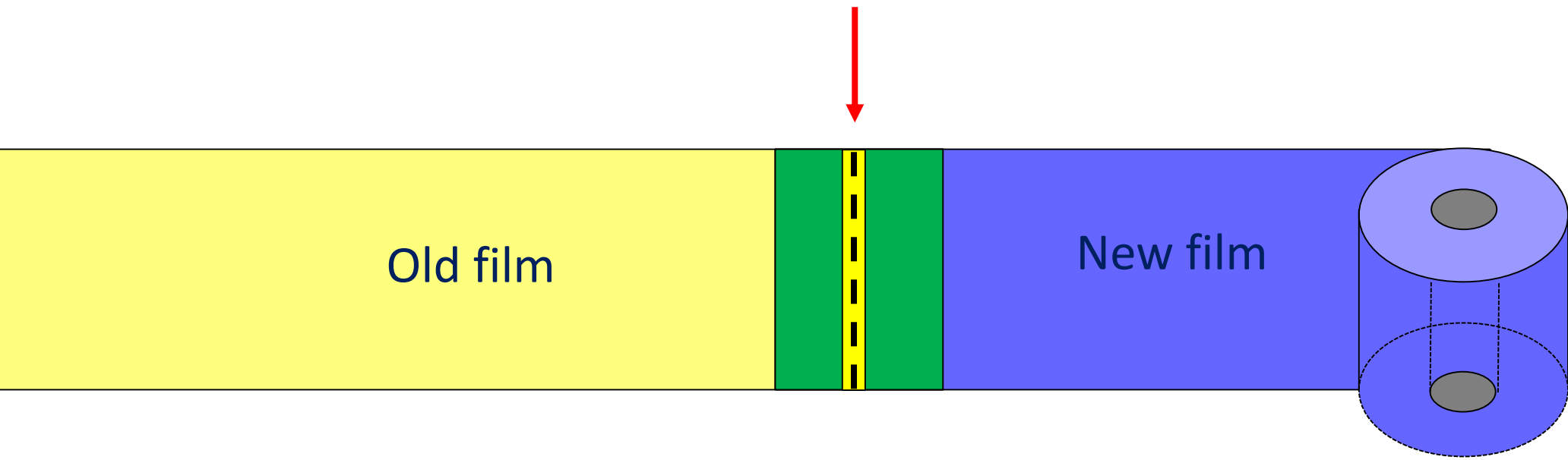
Film still in polybag



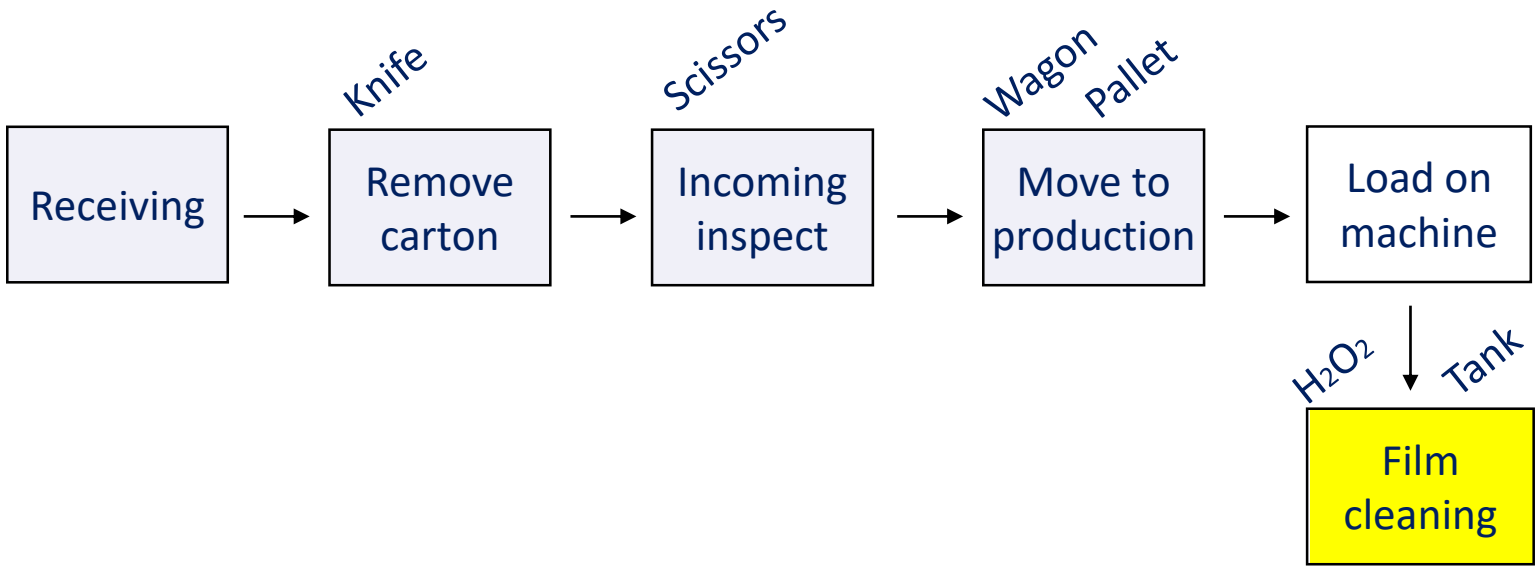
New Tech Process Flow

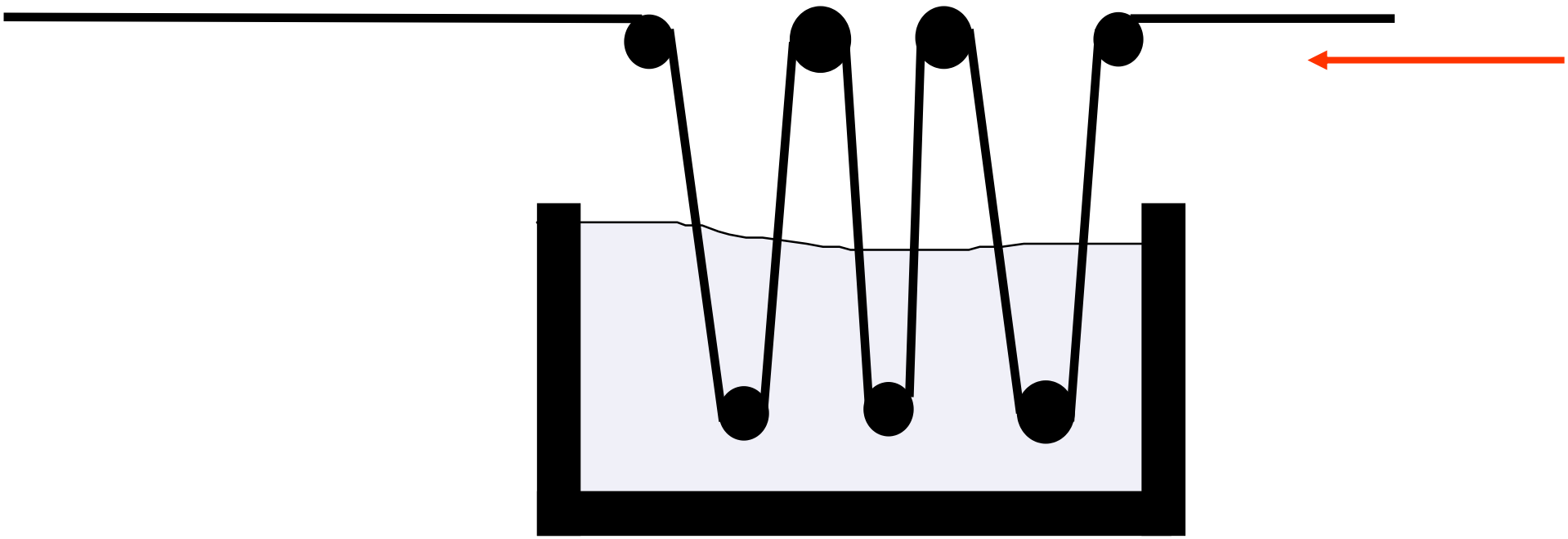


Heat seal the overlap to splice film together

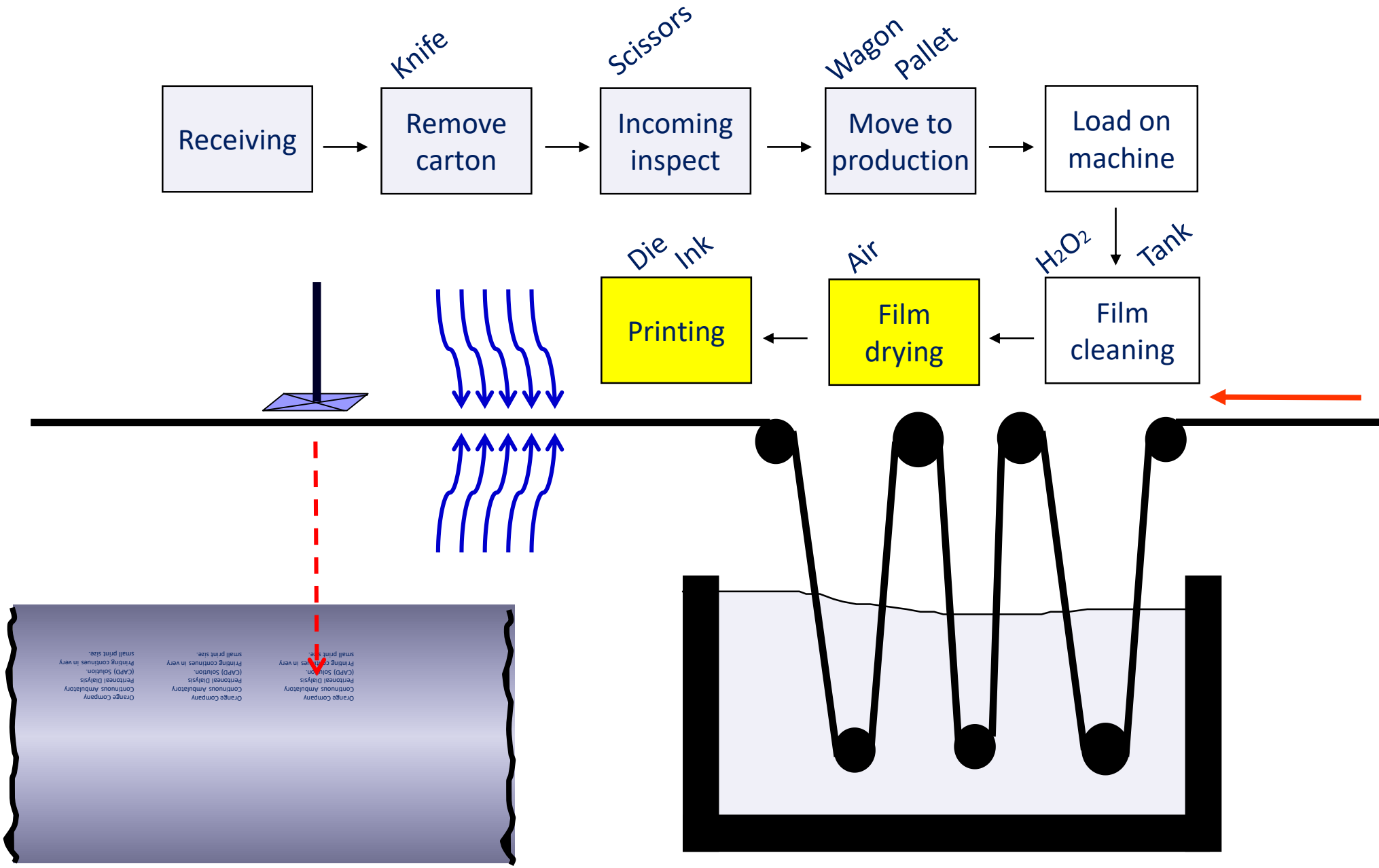


New Tech Process Flow

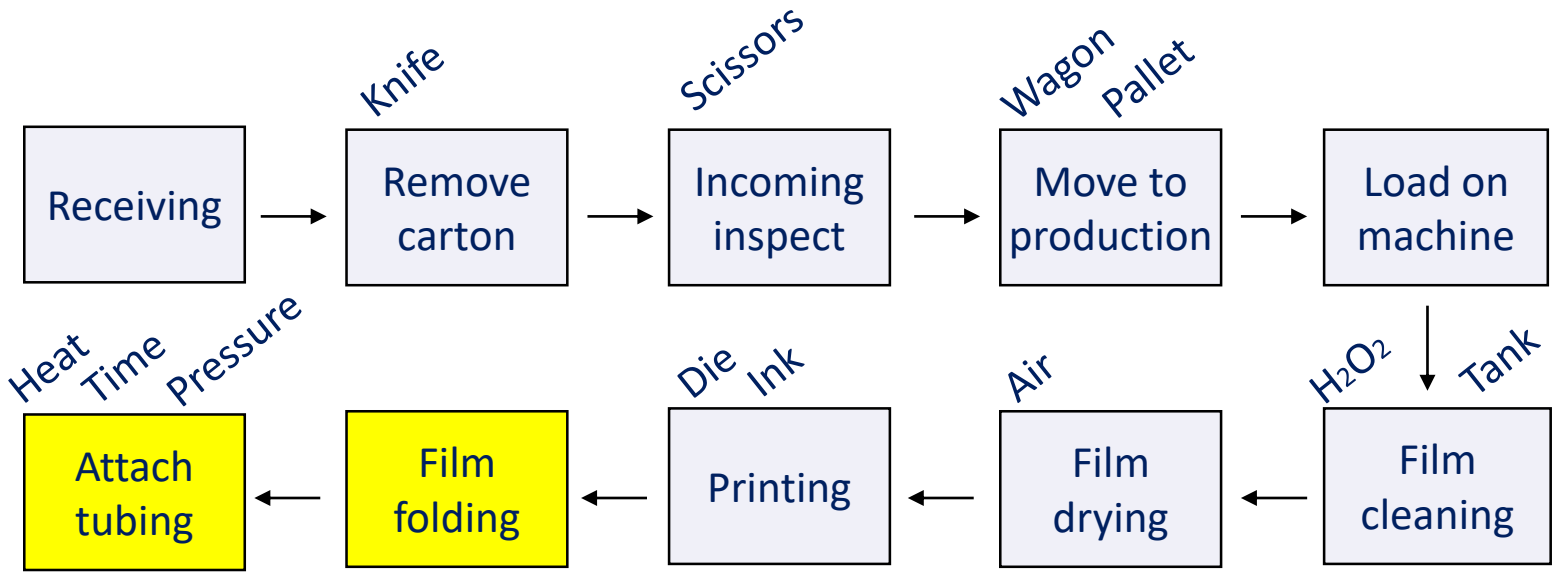


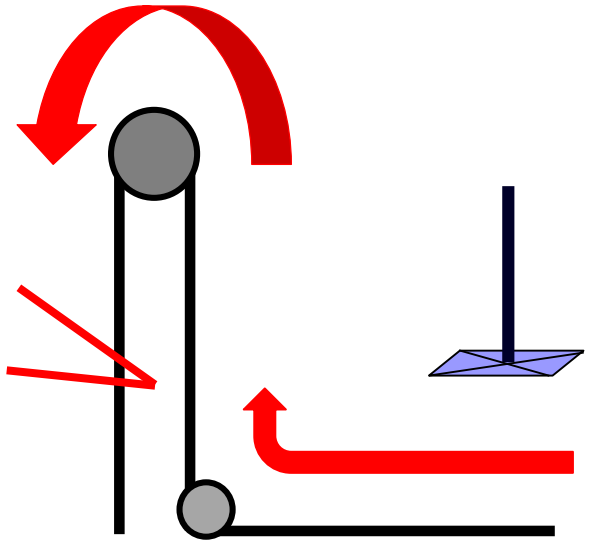


New Tech Process Flow



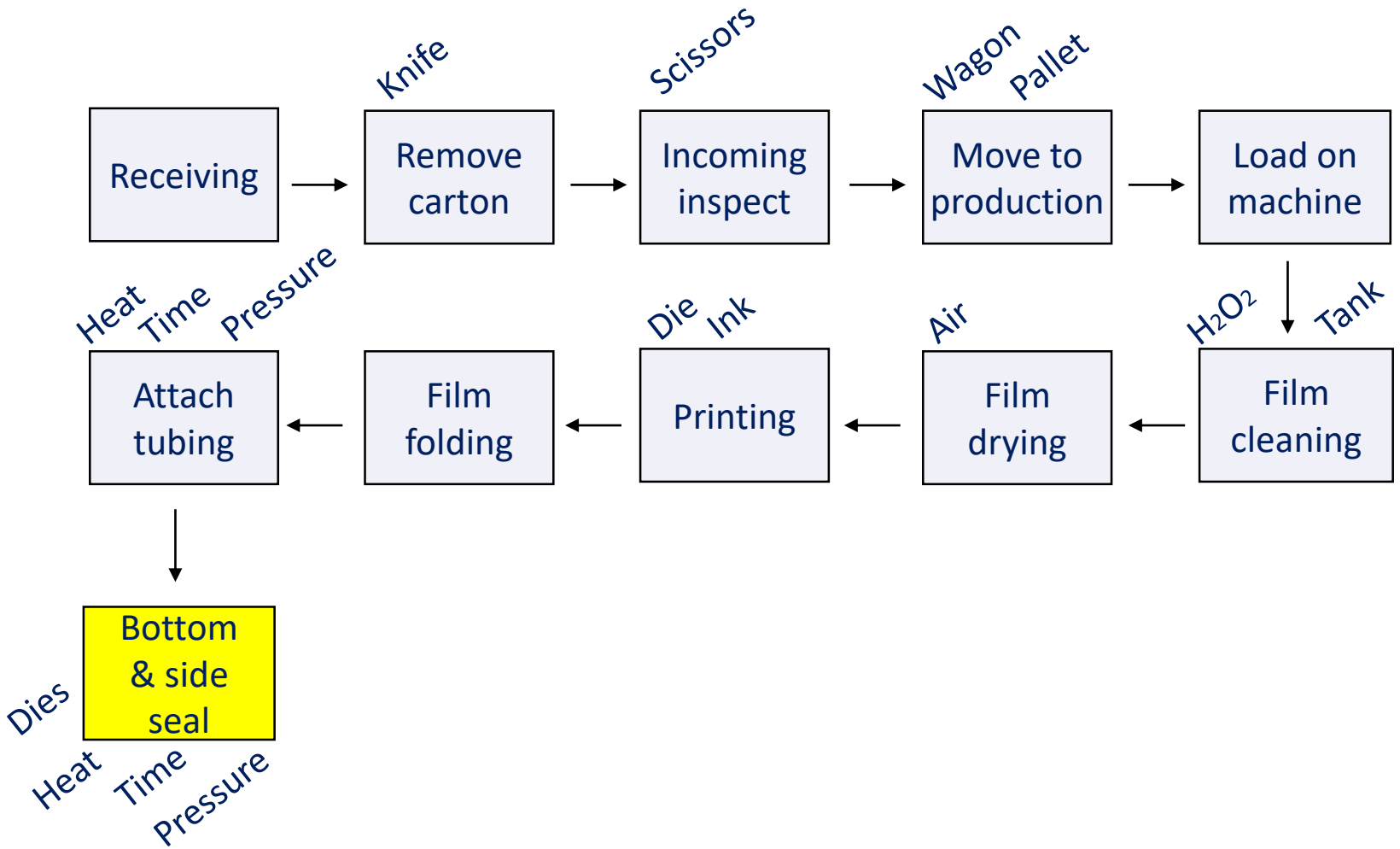
New Tech Process Flow



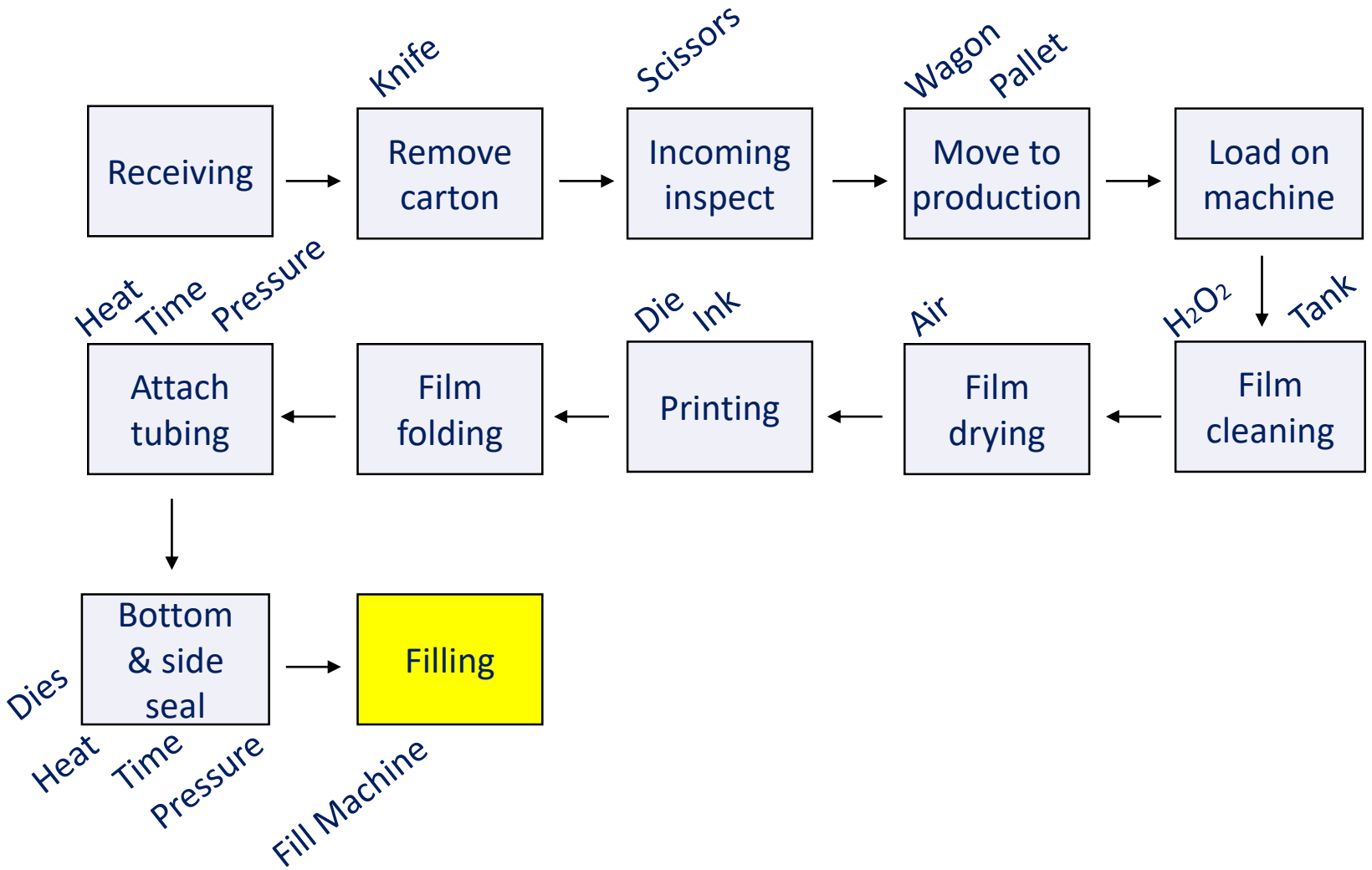


Folding film & attaching tube

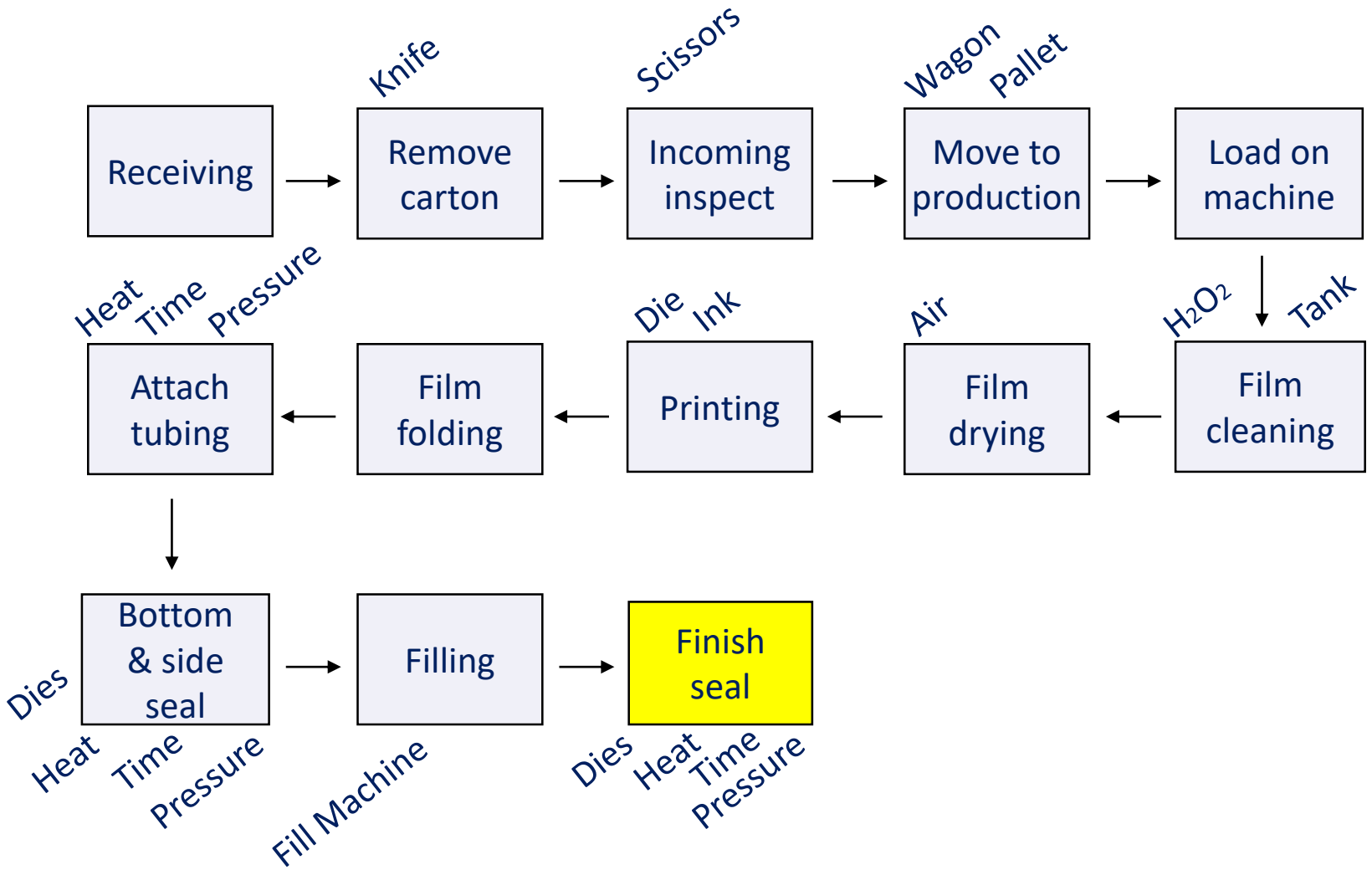
New Tech Process Flow



New Tech Process Flow

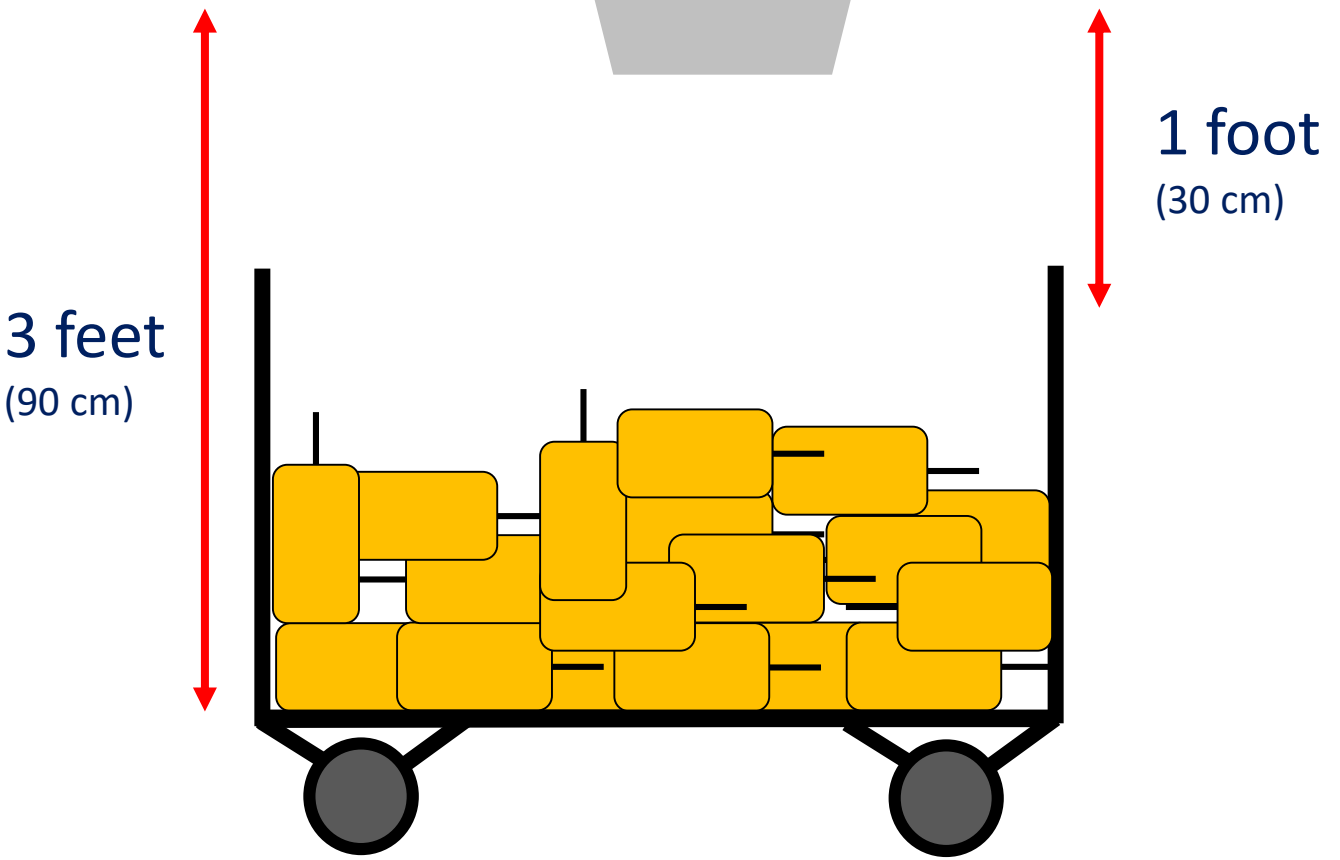


New Tech Process Flow

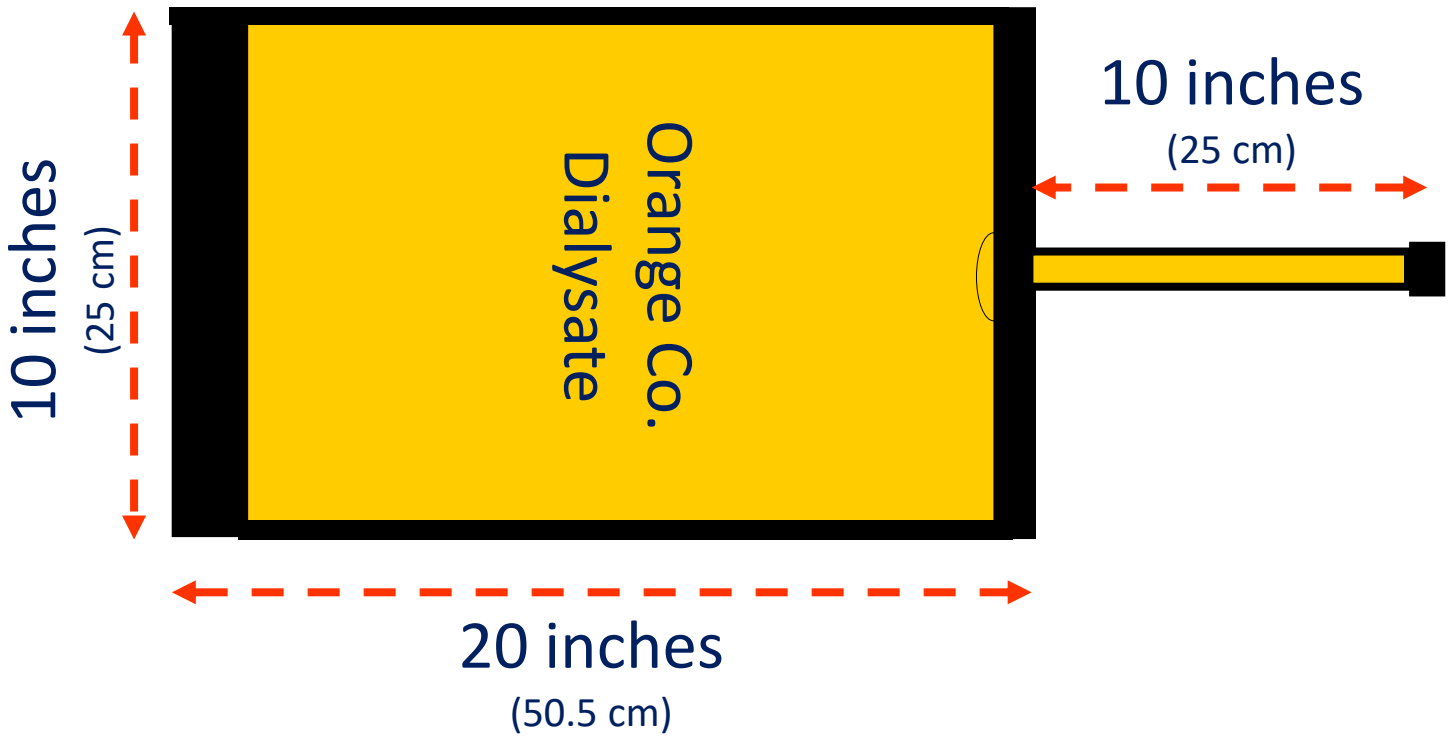


Material flow
Fill tube
Fold line
Orange Company Continuous Ambulatory Peritoneal Dialysis (CAPD) Solution. Printing continues in very small print size.
Orange Company Continuous Ambulatory Peritoneal Dialysis (CAPD) Solution. Printing continues in very small print size.
Orange Company Continuous Ambulatory Peritoneal Dialysis (CAPD) Solution. Printing continues in very small print size.

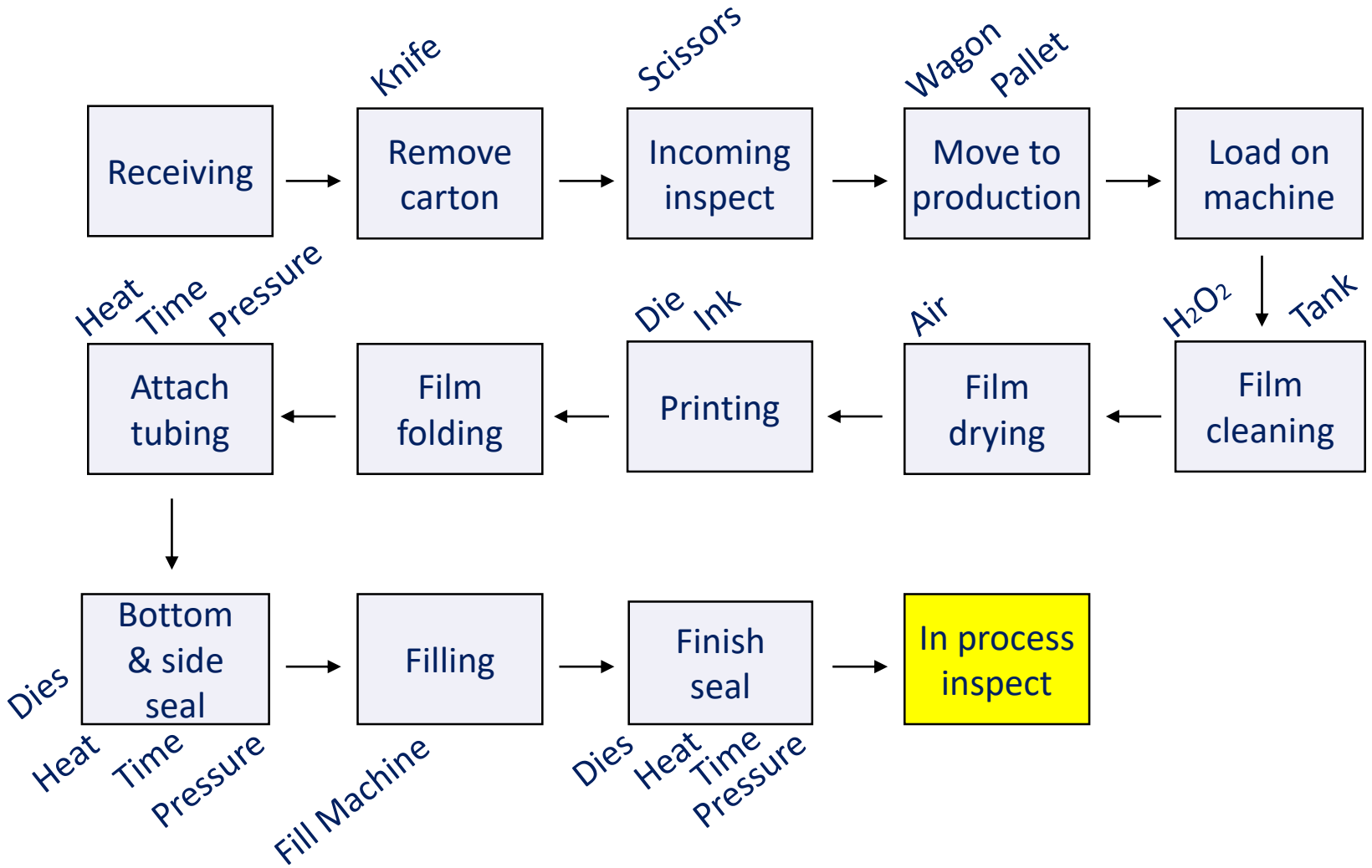
New Tech Machine



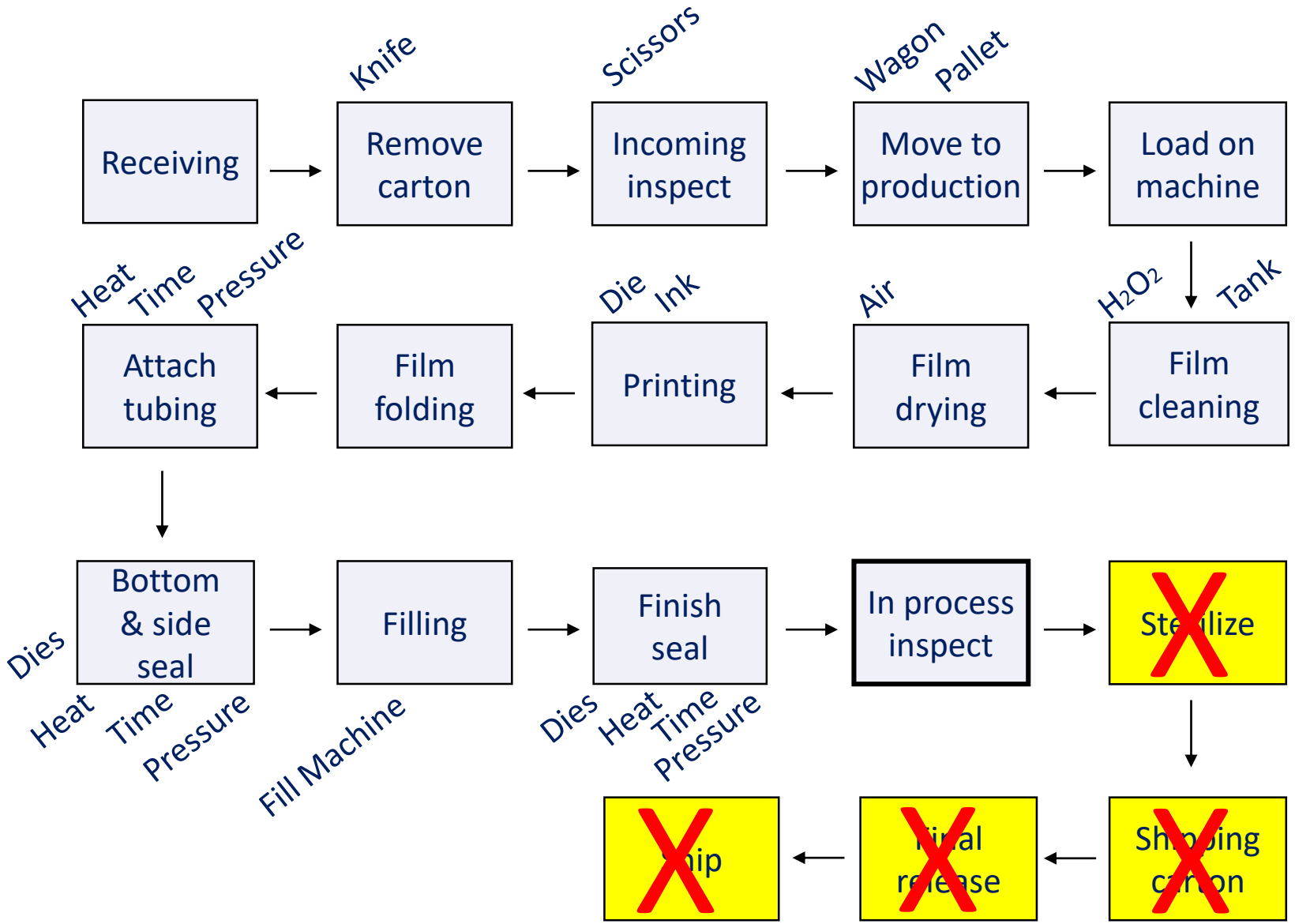
New Tech Product Dimensions



New Tech Process Flow



New Tech Process Flow



New Tech Vs. Old Tech

New Tech Production

- Australian film supplier
- 1st shift – bag fabrication & filling
- 2nd shift – cleaning & sanitizing
- 3rd shift – mixing pharmaceutical for use the next day
- 1 day's production = 1 product (finished goods) lot

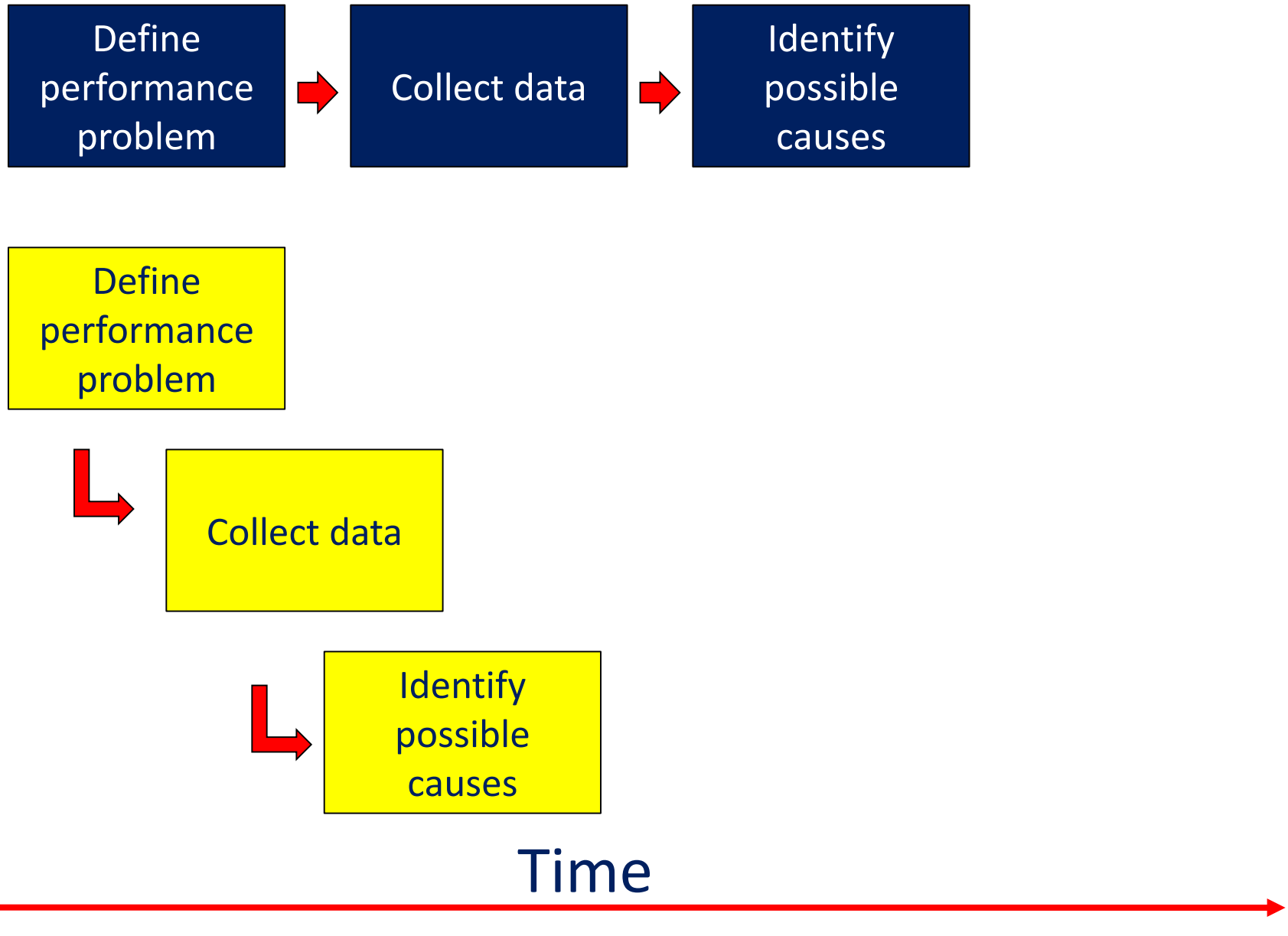
Old Tech Production

- Different film material
- U.S. film supplier
- Different fabrication method
  - Fabricate bag in one production room
  - Fill bag in a second production room

Finale

Shortcuts

Steps 1, 2, & 3 can overlap



Shortcuts

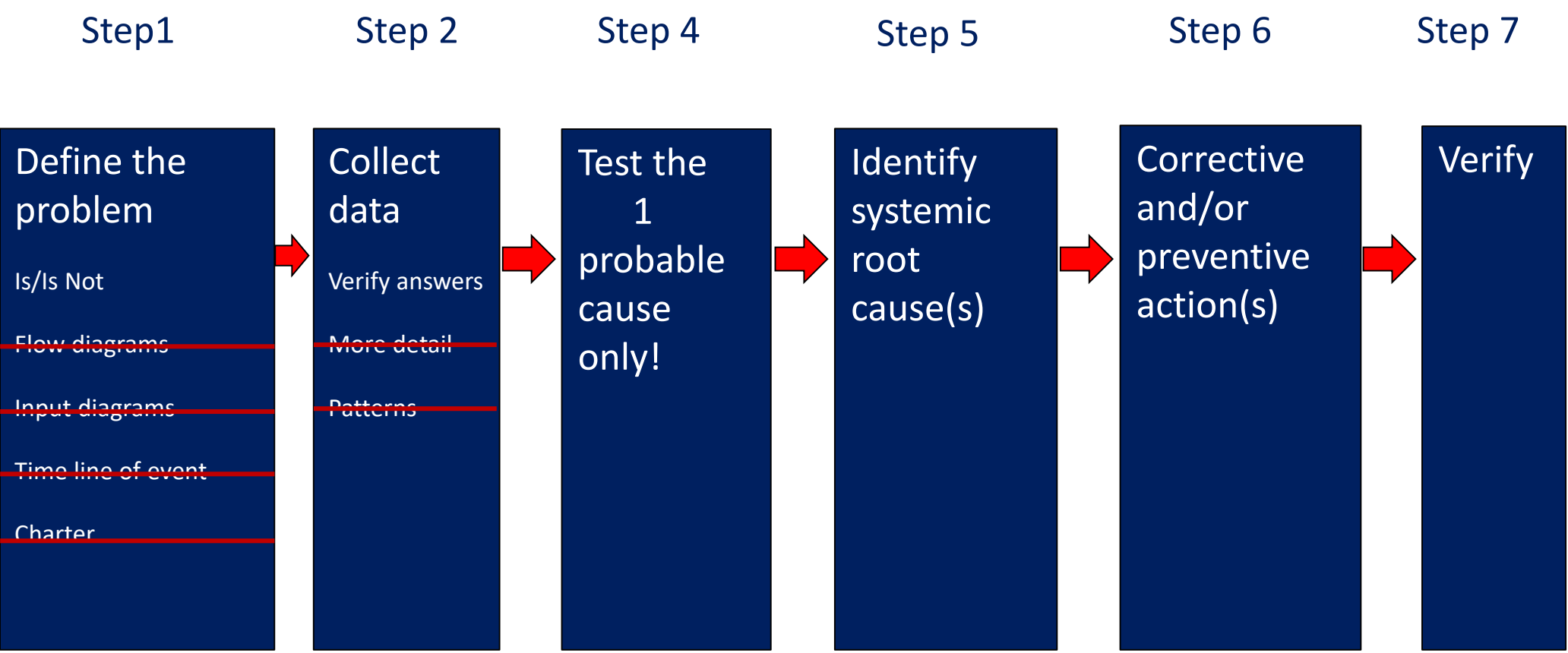
Develop “pretest” leveraging the strongest patterns

	Is	Verified	Is Not	Verified
What	*Attendants	✓	*Pilots, passengers, etc.	✓
	“Red sweat”	✓	Flu, common cold, allergies, etc.	✓
	*Red pigment in sweat/spots	✓	*Other color pigment in sweat/spots	✓
	Both genders, young & old	✓	1 gender, only young or old	✓
Where	*Flights b/w LGA-MIA, both ways	✓	*Flights b/w LGA-DFW, LGA-LAX	✓
	* Exposed skin on face, neck, arms, hands	✓	*Other exposed body parts or covered skin	✓
	* Symptoms 1st seen during trolley prep	✓	*Earlier	✓
	*All 5 A300s	✓	*< 5 A300s, other aircraft	✓
When	January 3 1980	✓	Earlier	✓
	*Increasing frequency each wk	✓	*Sporadic, decreasing	✓
How Much	69 attendants	✓	More or less	✓
	127 incidences	✓	More or less	✓
	*”pin prick” size spots	✓	*Larger than “pin prick” size spots	
	*Many spots	✓	*A few	✓

	Is	Verified	Is Not	Verified
What	*Attendants	✓	*Pilots, passengers, etc.	✓
Where	*Flights b/w LGA-MIA, both ways	✓	*Flights b/w LGA-DFW, LGA-LAX	✓
	*All 5 A300s	✓	*< 5 A300s, other aircraft	✓

Simple Investigations

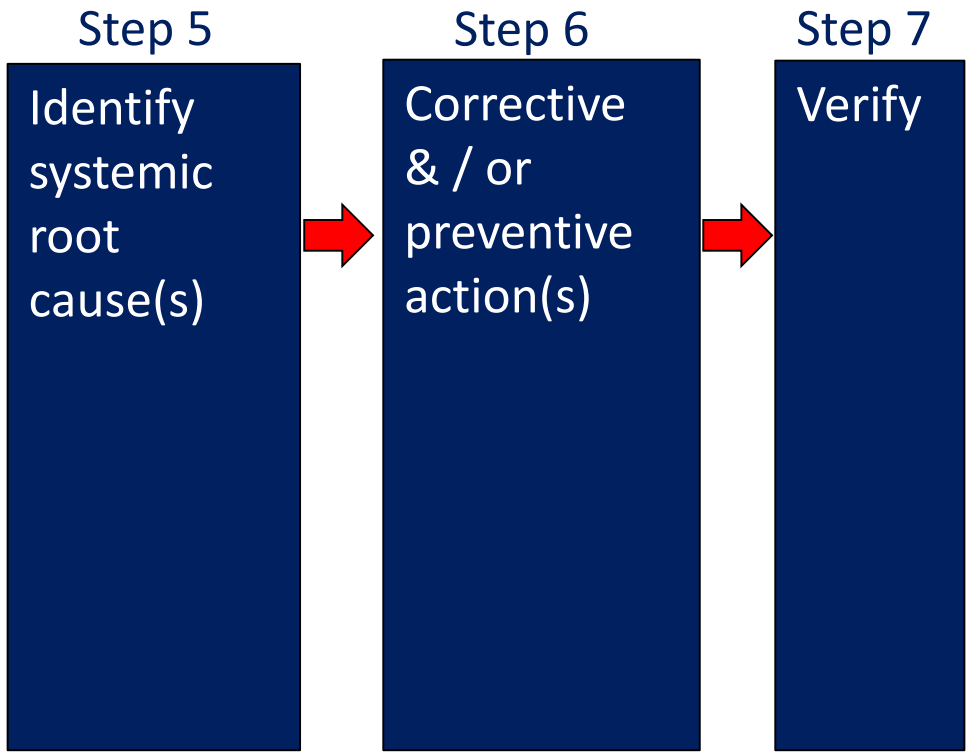
Sometimes the root cause is already known



Simple Investigations

Sometimes there hasn't been a change…

Example: An internal audit reveals a regulatory requirement is not being met



Difficult Investigations

Worse case scenarios…

- Can’t get data
- One time events
- Out of box failures

How to handle…

- Follow the methodology
- Carefully document what’s opinion & what’s fact
- Carefully document actions taken to obtain the facts
- May need to rely more on experiments
- May need to take corrective action on many more possible causes

Investigation Report

Investigation leveraged the 7 step methodology as per our internal procedure…

- Step 1
  - Defined the problem using an Is/Is Not Diagram (Attachment A)
  - Flow charted processes under investigation & identified inputs (Attachments B, C, & D)
  - Constructed timeline of events (Attachment E)
- Step 2
  - Developed data collection plan (Attachment F)
  - Restated problem in fact based Is/Is Not diagram (Attachment G)
- Etc

Return on Investment

- Training
  - Train a critical mass of investigators
  - Educate management
- Implementation
  - Ask investigators to use the methodology
  - Have investigators show you how they used methodology
  - Develop and issue a procedure
- Measure
  - Average investigation time
  - # of investigations over time
  - Audit investigations
- Celebrate
  - Recognize & publicize success