SPC & FMEA: Integrating Systems Thinking Into Your Quality Architecture to Drive Improvement

Nicole M. Radziwill, PhD, MBA

ASQ Fellow & Editor, *Software Quality Professional*

Quality Practice Leader

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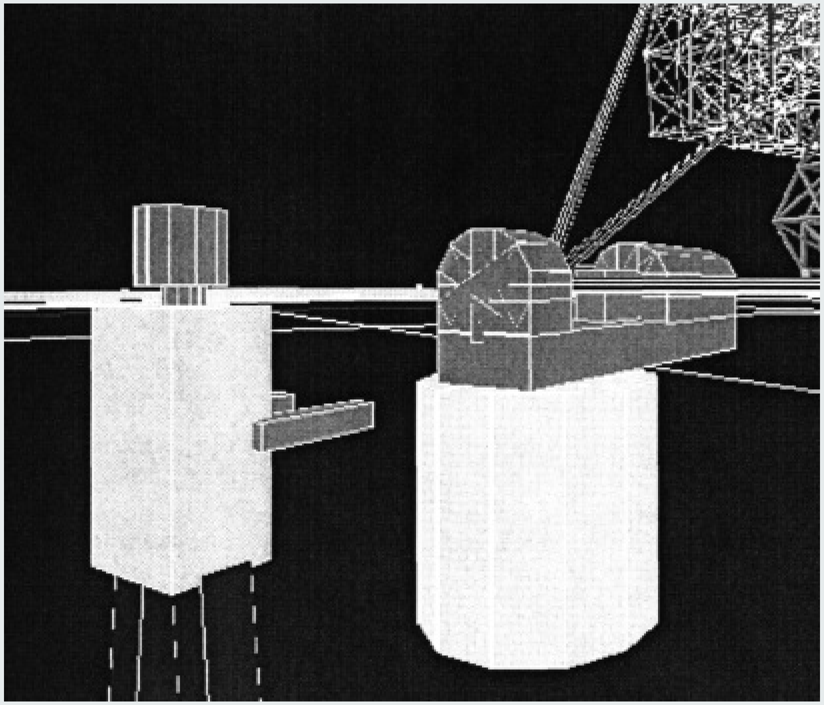

Image Credit: D. Wells (1998)

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From Beck, M. (2015). Do more roads really mean less congestion for commuters? World Economic Forum, April 14. https://www.weforum.org/agenda/2015/04/do-more-roads-really-mean-less-congestion-for-commuters/

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“In isolation, building more roads can certainly improve traffic conditions but these effects may only be local and only in the short run. **Congestion may become worse in other parts of the network** and experience shows that spare road capacity is quickly filled up with new cars.

Even without the extra road users that new roads create, *if the new roads are built in the wrong locations congestion may actually become worse simply because of the way people behave*. Roads alone do not solve congestion in the long term; they are only one (problematic) tool in a transport management toolkit.”

From Beck, M. (2015). Do more roads really mean less congestion for commuters? World Economic Forum, April 14.
https://www.weforum.org/agenda/2015/04/do-more-roads-really-mean-less-congestion-for-commuters/

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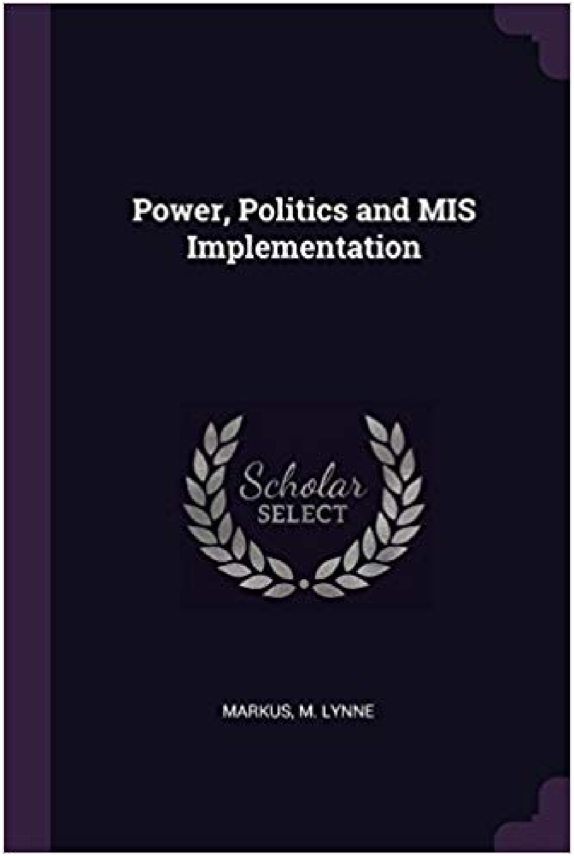
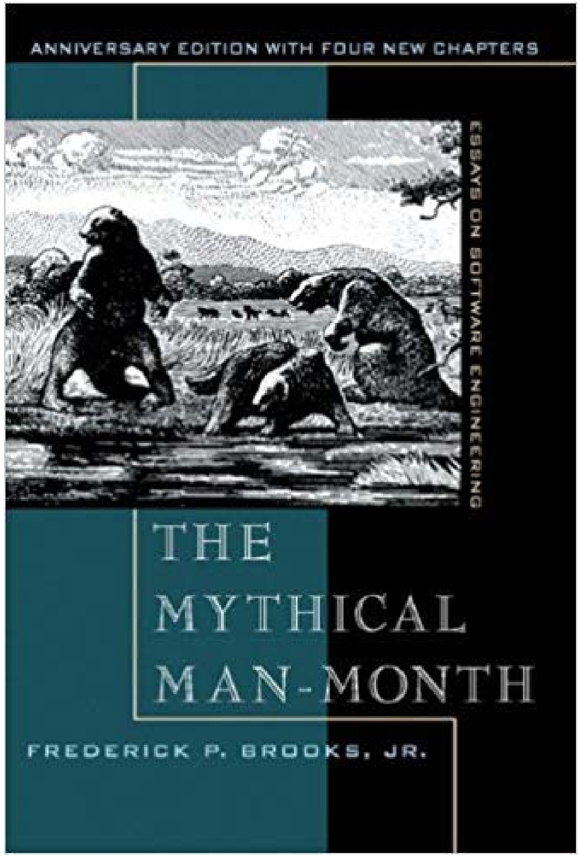


Markus, M. L. (1983). Power, politics, and MIS implementation. Communications of the ACM, 26(6), 430-444.



Brooks Jr, F. P. (1995). The Mythical Man-Month: Essays on Software Engineering, Anniversary Edition, 2/E. Pearson Education India.

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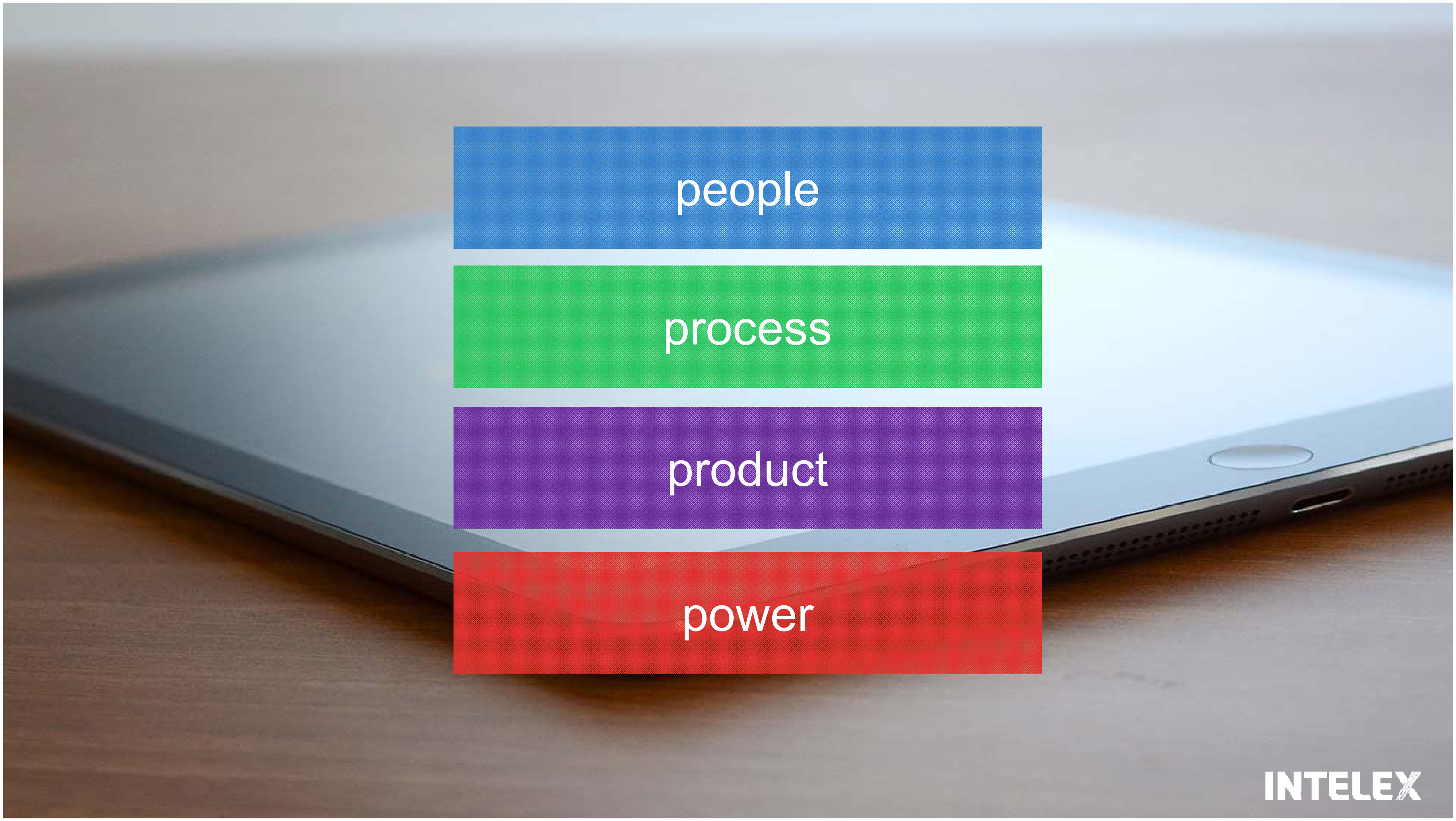
people
process
product
power
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Objectives

1. Describe how **FMEA** can be used to identify corrective and preventive actions, launch improvement plans, and address risk
2. Explain **SPC** terminology, basic concepts, and how to apply it -- particularly beyond manufacturing
3. Explain how **QMS components** work together, including NCR, CAPA, FMEA, SPC, DMAIC, APQP/PPAP, document management, training management, audit management, design controls, material controls, equipment and facility controls, and change control.

To help your organization:

1. Avoid disconnected (and inefficient) management of quality events
2. Identify quality issues faster/more effectively
3. Capture opportunities for improvement

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Motivation

Intelex released a **Process FMEA** module designed for collaboration between business and engineering

New partnership with **InfinityQS** for **Statistical Process Control (SPC)**

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Nicole Radziwill

Quality Practice Lead, Intelex
Fellow, American Society for Quality (ASQ)
CSSBB #11962 & CMQ/OE #9583
Ph.D. Quality Systems, Indiana State
Editor, *Software Quality Professional*

Previously:

- •Project Manager, Solution Architect, Engagement Manager in Meteorological Research, Telecom, Manufacturing, Software, High Tech 1995-2002
- •Division Head (Director), Software, Green Bank Observatory, 2002-2006
- •Assistant Director (VP) End to End Operations, National Radio Astronomy Observatory, 2006-2009
- •Associate Professor of Data Science & Production Systems, James Madison University, 2009-2018

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1: Systems Thinking

how quality management tackles wicked problems

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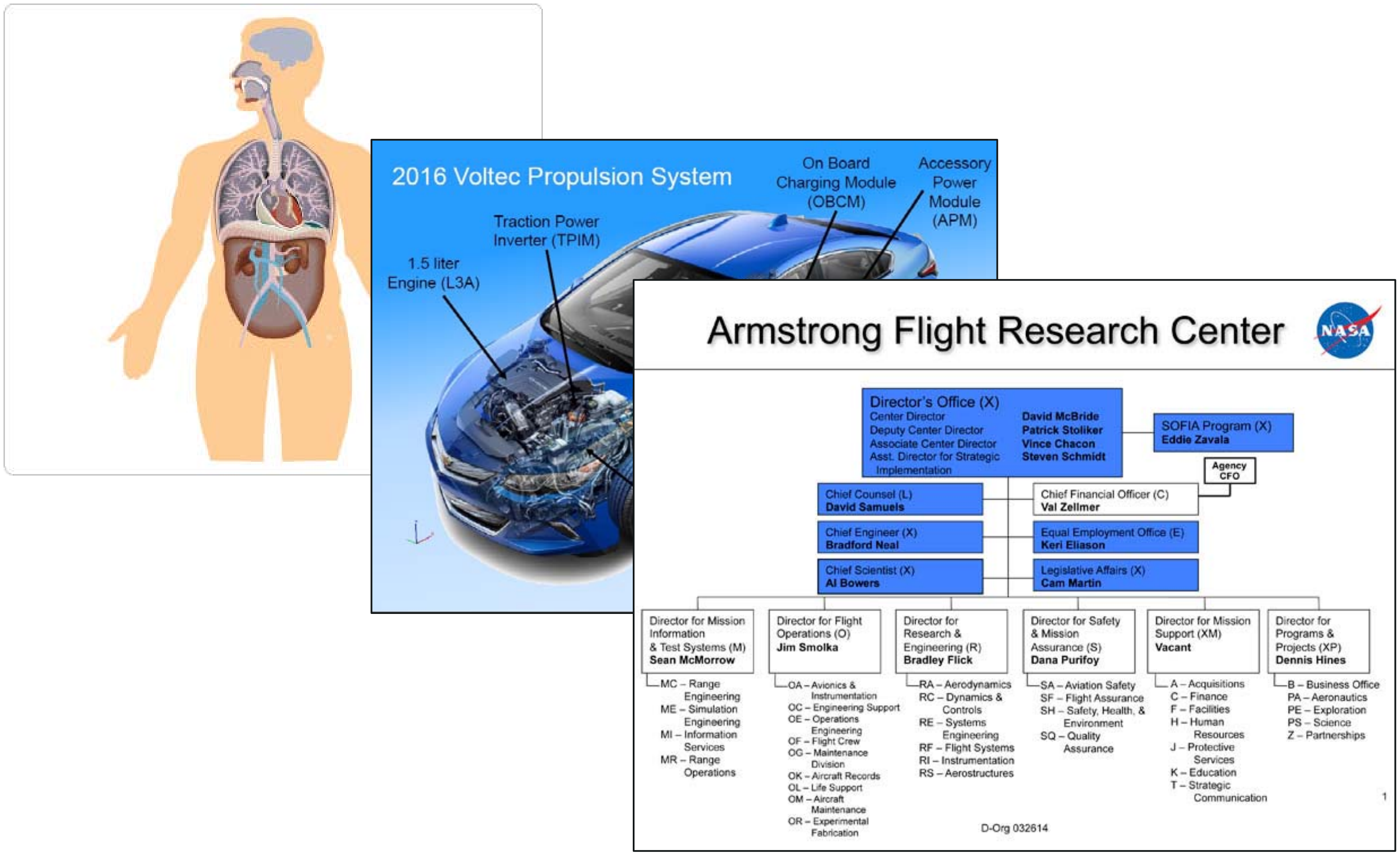
2016 Voltec Propulsion System
On Board Charging Module (OBCM)
Accessory Power Module (APM)
Traction Power Inverter (TPIM)
1.5 liter Engine (L3A)
Armstrong Flight Research Center
NASA
Director's Office (X)
Center Director David McBride
Deputy Center Director Patrick Stoliker
Associate Center Director Vince Chacon
Asst. Director for Strategic Implementation Steven Schmidt
SOFIA Program (X) Eddie Zavala
Agency CFO
Chief Counsel (L) David Samuels
Chief Financial Officer (C) Val Zellmer
Chief Engineer (X) Bradford Neal
Equal Employment Office (E) Keri Eliason
Chief Scientist (X) Al Bowers
Legislative Affairs (X) Cam Martin
Director for Mission Information & Test Systems (M) Sean McMorrow
MC – Range Engineering
ME – Simulation Engineering
MI – Information Services
MR – Range Operations
Director for Flight Operations (O) Jim Smolka
OA – Avionics & Instrumentation
OC – Engineering Support
OE – Operations Engineering
OF – Flight Crew
OG – Maintenance Division
OK – Aircraft Records
OL – Life Support
OM – Aircraft Maintenance
OR – Experimental Fabrication
Director for Research & Engineering (R) Bradley Flick
RA – Aerodynamics
RC – Dynamics & Controls
RE – Systems Engineering
RF – Flight Systems
RI – Instrumentation
RS – Aerostructures
Director for Safety & Mission Assurance (S) Dana Purifoy
SA – Aviation Safety
SF – Flight Assurance
SH – Safety, Health, & Environment
SQ – Quality Assurance
Director for Mission Support (XM) Vacant
A – Acquisitions
C – Finance
F – Facilities
H – Human Resources
J – Protective Services
K – Education
T – Strategic Communication
Director for Programs & Projects (XP) Dennis Hines
B – Business Office
PA – Aeronautics
PE – Exploration
PS – Science
Z – Partnerships
1
D-Org 032614

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What is systems thinking?

Exercise

Two people take 2 hours to dig a hole 5 feet deep.

How deep would the hole be if 4 people dug for 6 hours?

http://www.engineering.iastate.edu/e2020/files/2014/05/rehmann_rover_LCTT_2013.pdf

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More realistic answers?

1. Deeper soil layers might be harder to excavate.
2. The job might not have the proper permit.
3. The people might refuse to work for 6 hours straight.
4. A lack of ladders or shovels or space might prevent progress.
5. They might hit bedrock or the water table (or gold or oil or ancient relics or an underground cable or vicious carnivores).
6. The maximum depth might have been specified as 5 feet.
7. Greenpeace or the neighbors might protest.
8. The workers might not have proper training in ABET outcome d.
9. The work might be scheduled for a religious holiday.
10. The original workers might have had excavating equipment.

http://www.engineering.iastate.edu/e2020/files/2014/05/rehmann_rover_LCTT_2013.pdf

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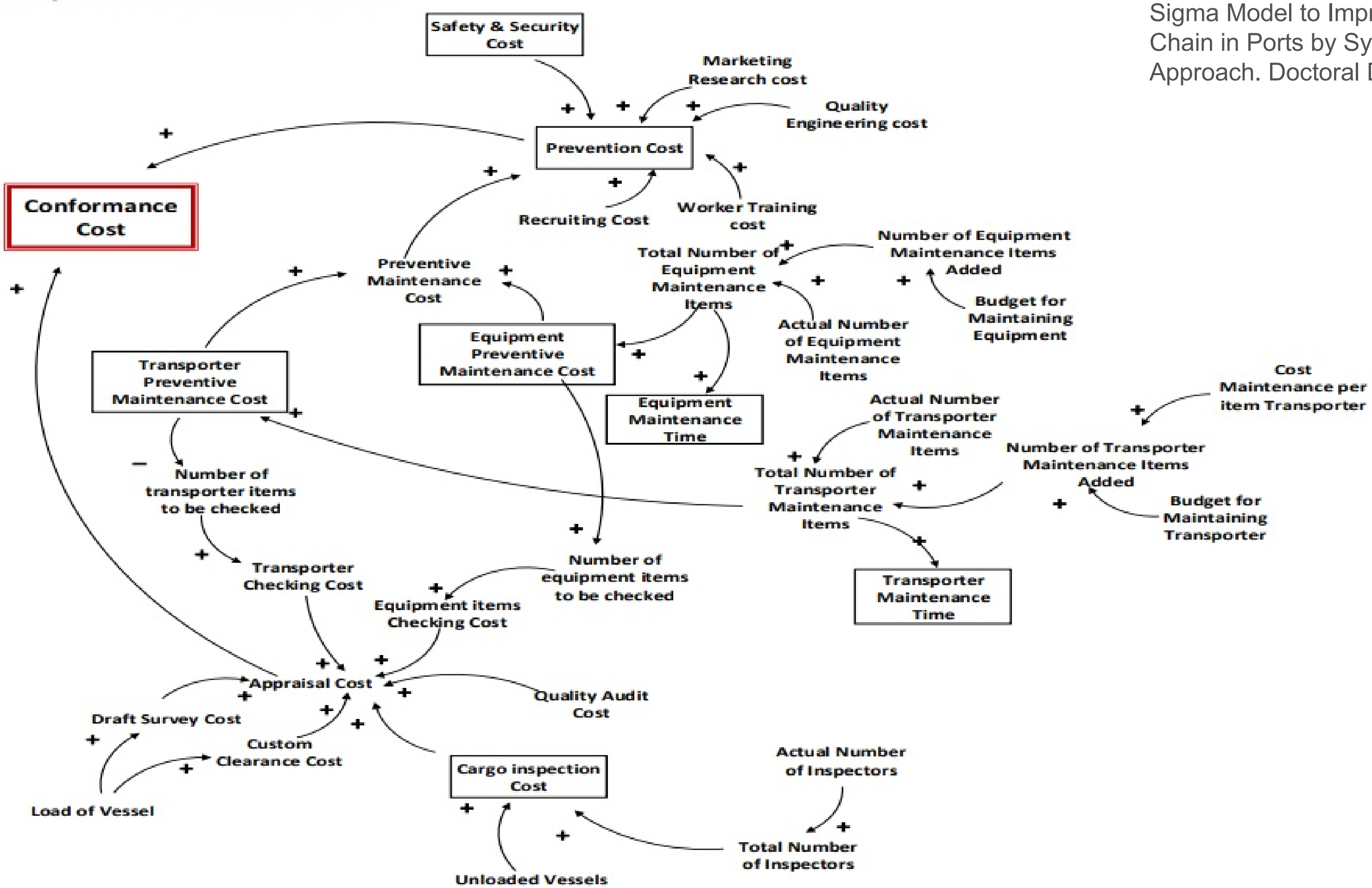
A.4: The CLD of the conformance cost

Ridwan, A., & Tasikmalaya, I. (2016). Six Sigma Model to Improve the Lean Supply Chain in Ports by System Dynamics Approach. Doctoral Dissertation.



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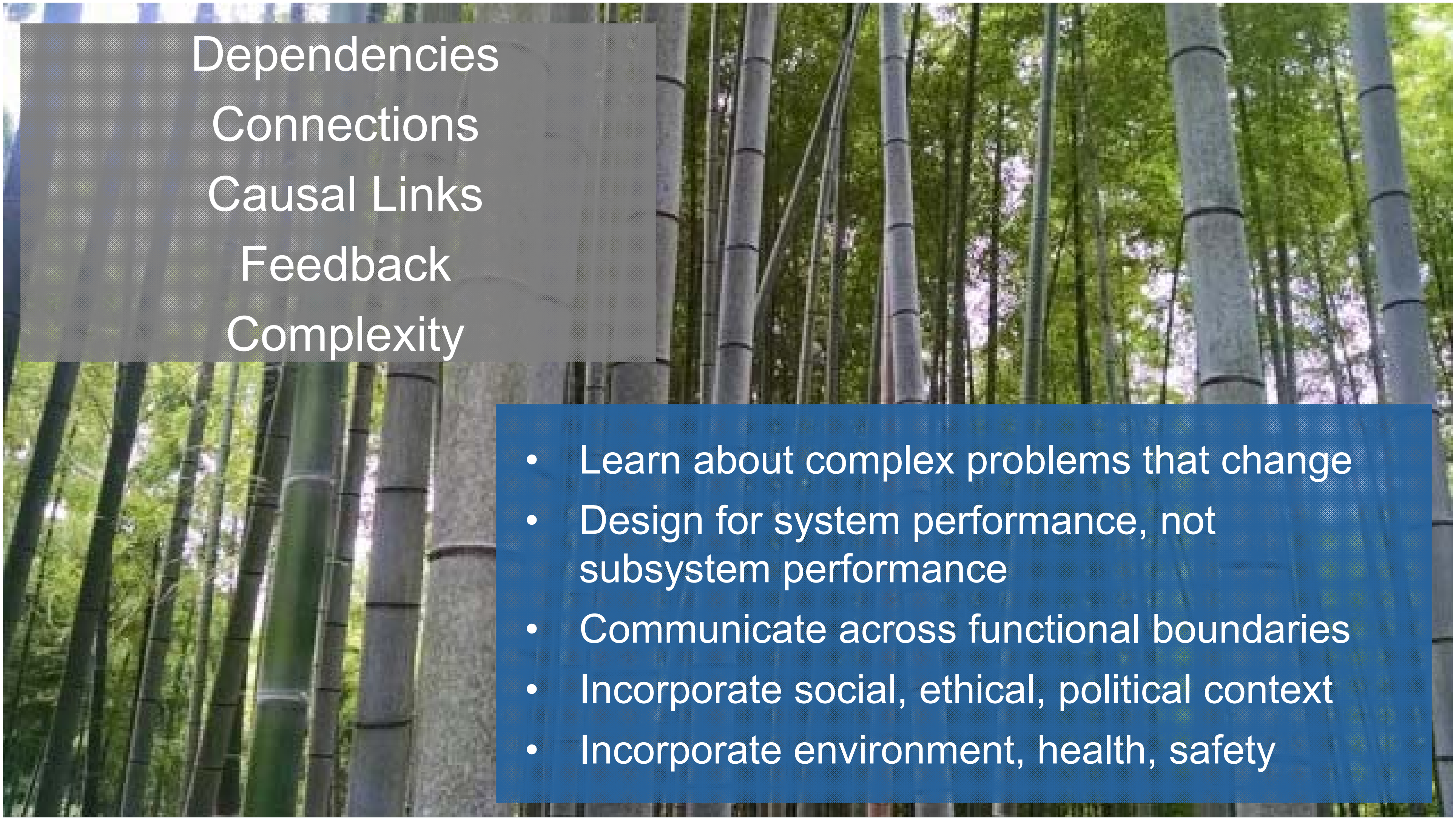
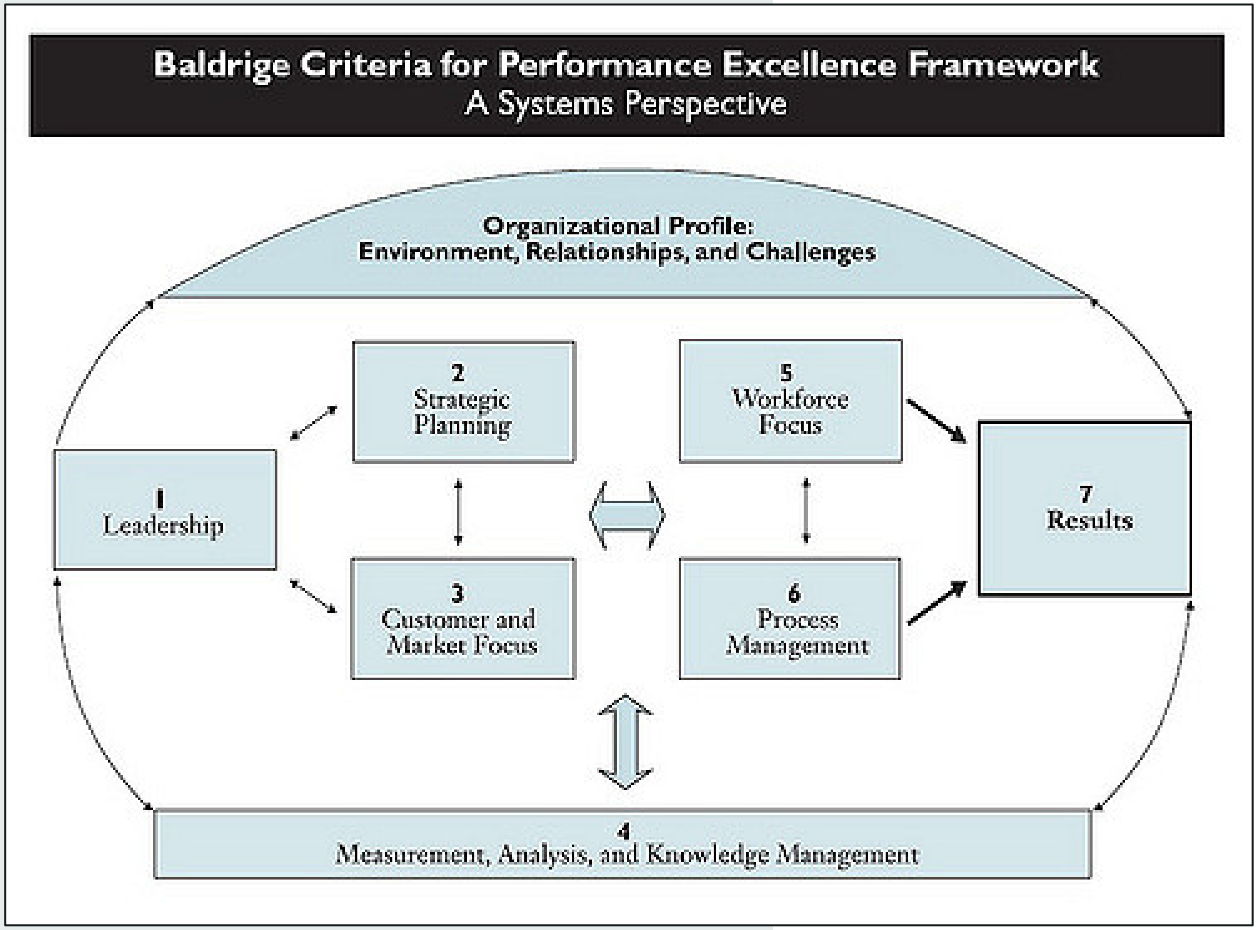


Dependencies
Connections
Causal Links
Feedback
Complexity

- Learn about complex problems that change
- Design for system performance, not subsystem performance
- Communicate across functional boundaries
- Incorporate social, ethical, political context
- Incorporate environment, health, safety



From: Baldrige Criteria for Performance Excellence (2017).

Baldrige Criteria for Performance Excellence (US)

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2: Failure Mode Effects Analysis (FMEA)

figuring out what can go wrong, and fixing or anticipating it

Why do FMEA?

- **The sooner you solve a potential quality or safety problem, the less it will cost – in $$ and reputation.**
- To do this, you have to identify risks and hazards and take actions to address them, so that failures do not occur.
- It's one step towards "zero defects" production.
- FMEA is also used to identify Critical to Quality (CTQ) characteristics and Special Characteristics (SC)

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FMEA Components:
Failure Mode → Effect → Cause → Control

- **Failure Mode**: What bad thing might happen →
- **Effect**: What problems or issues will that bad thing lead to →
- **Cause**: What's the root cause of the bad thing/what will make it go away →
- **Control**:
    - **Prevention**: Can we prevent the thing from happening?
    - **Detection**: Can we provide early awareness that the thing might happen?

Include controls that exist as well as controls that don't exist -- but maybe should.

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Process Step	Potential Failure Mode	Potential Failure Effect	SEV[1]	Potential Causes	OCC[2]	Current Process Controls	DET[3]	RPN[4]	Action Recommended
What is the step?	In what ways can the step go wrong?	What is the impact on the customer if the failure mode is not prevented or corrected?	How severe is the effect on the customer?	What causes the step to go wrong (i.e., how could the failure mode occur)?	How frequently is the cause likely to occur?	What are the existing controls that either prevent the failure mode from occurring or detect it should it occur?	How probable is detection of the failure mode or its cause?	Risk priority number calculated as SEV x OCC x DET	What are the actions for reducing the occurrence of the cause or for improving its detection? Provide actions on all high RPNs and on severity ratings of 9 or 10.
ATM Pin Authentication	Unauthorized access	• Unauthorized cash withdrawal • Very dissatisfied customer	8	Lost or stolen ATM card	3	Block ATM card after three failed authentication attempts	3	72	
	Authentication failure	Annoyed customer	3	Network failure	5	Install load balancer to distribute work-load across network links	5	75	
Dispense Cash	Cash not disbursed	Dissatisfied customer	7	ATM out of cash	7	Internal alert of low cash in ATM	4	196	Increase minimum cash threshold limit of heavily used ATMs to prevent out-of-cash instances
	Account debited but no cash disbursed	Very dissatisfied customer	8	• Transaction failure • Network issue	3	Install load balancer to distribute work-load across network links	4	96	
	Extra cash dispensed	Bank loses money	8	• Bills stuck to each other • Bills stacked incorrectly	2	Verification while loading cash in ATM	3	48	

1. **Severity**: Severity of impact of failure event. It is scored on a scale of 1 to 10. A high score is assigned to high-impact events while a low score is assigned to low-impact events.
2. **Occurrence**: Frequency of occurrence of failure event. It is scored on a scale of 1 to 10. A high score is assigned to frequently occurring events while events with low occurrence are assigned a low score.
3. **Detection**: Ability of process control to detect the occurrence of failure events. It is scored on a scale of 1 to 10. A failure event that can be easily detected by the process control is assigned a low score while a high score is assigned to an inconspicuous event.
4. **Risk priority number**: The overall risk score of an event. It is calculated by multiplying the scores for severity, occurrence and detection. An event with a high RPN demands immediate attention while events with lower RPNs are less risky.

From https://www.isixsigma.com/resource-pages/avoid-failure-when-using-failure-modes-and-effects-analysis-fmea/

From Lockton, D., Harrison, D., & Stanton, N. A. (2010). The Design with Intent Method: A design tool for influencing user behaviour. Applied ergonomics, 41(3), 382-392.

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"… a 'card-returned-then-cash-dispensed' ATM dialogue design was at least **22% more efficient (in withdrawal time)** and resulted in **100% fewer lost cards (i.e. none)** compared with a 'cash-dispensed-then-card-returned' dialogue design."

Zimmermann, C. M., & Bridger, R. S. (2000). Effects of dialogue design on automatic teller machine (ATM) usability: transaction times and card loss. Behaviour & Information Technology, 19(6), 441-449.

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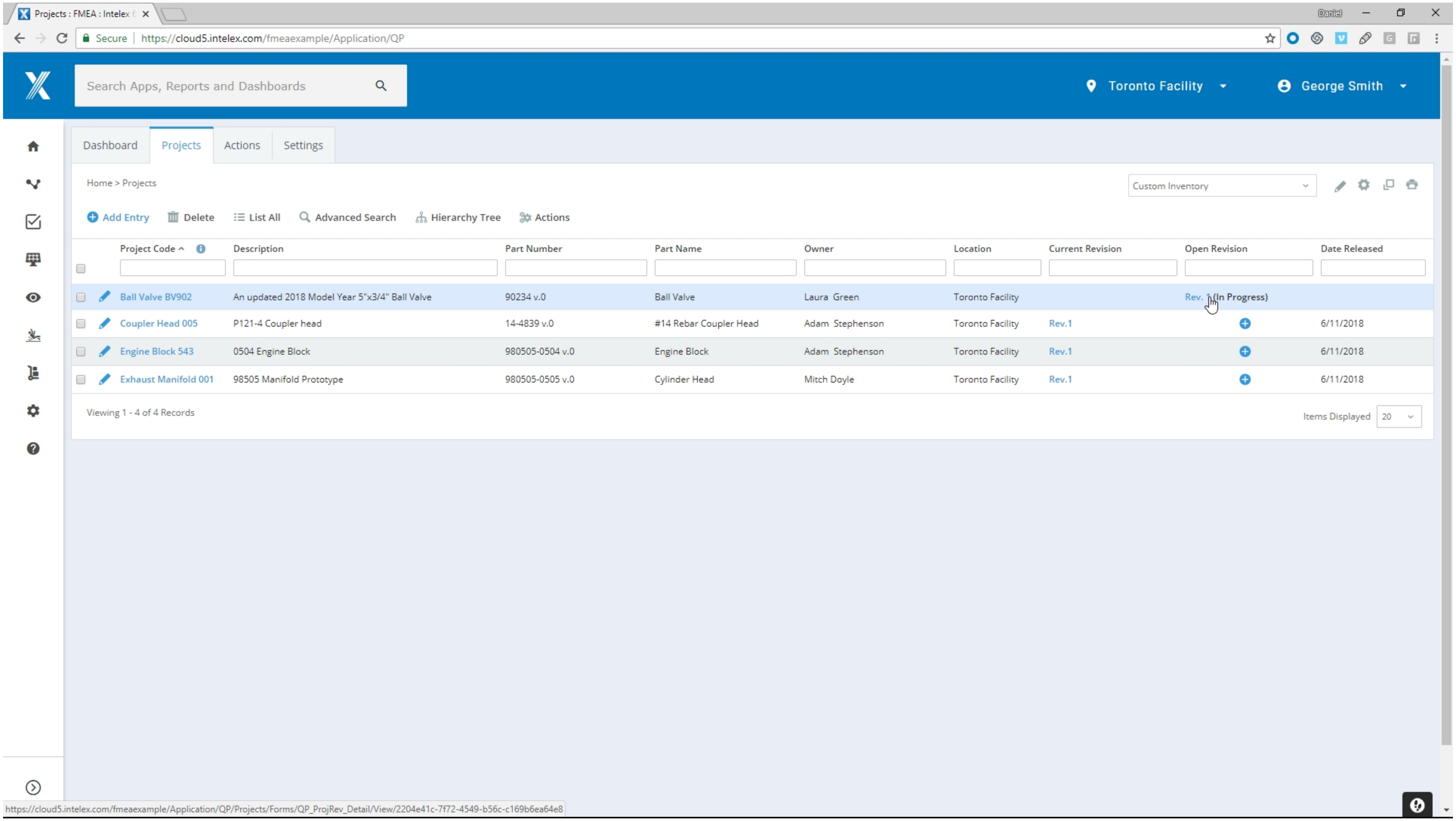
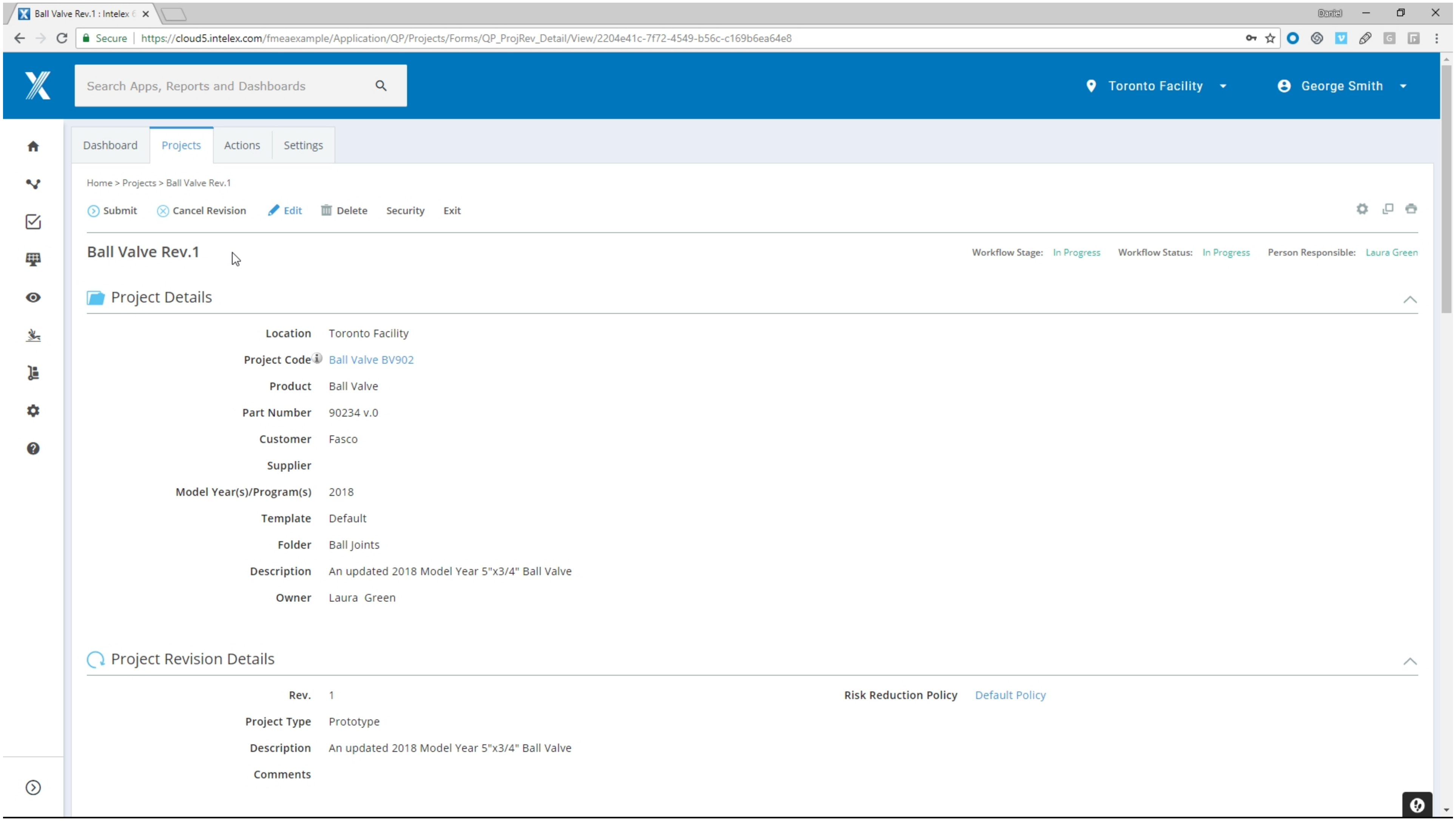
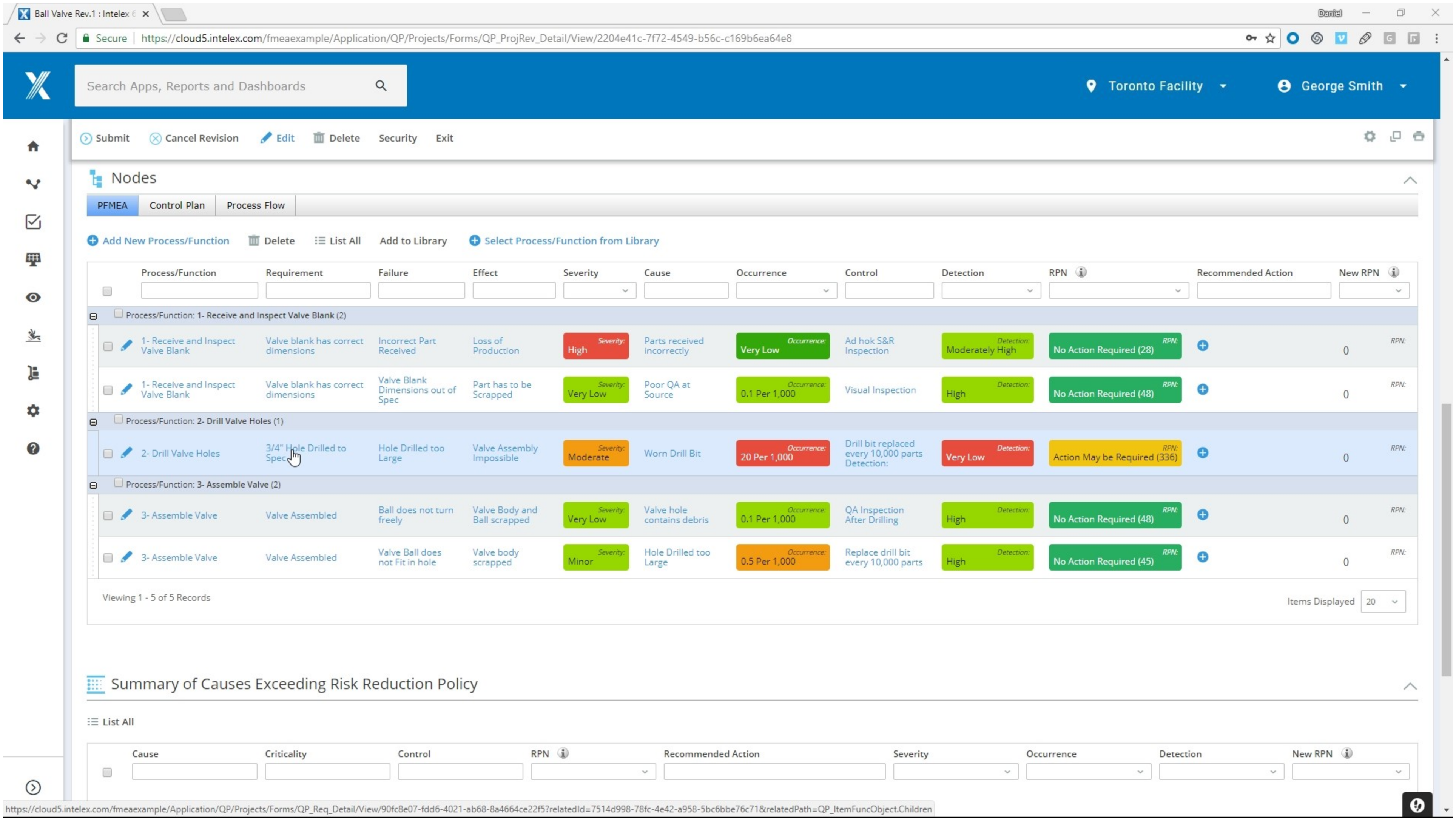
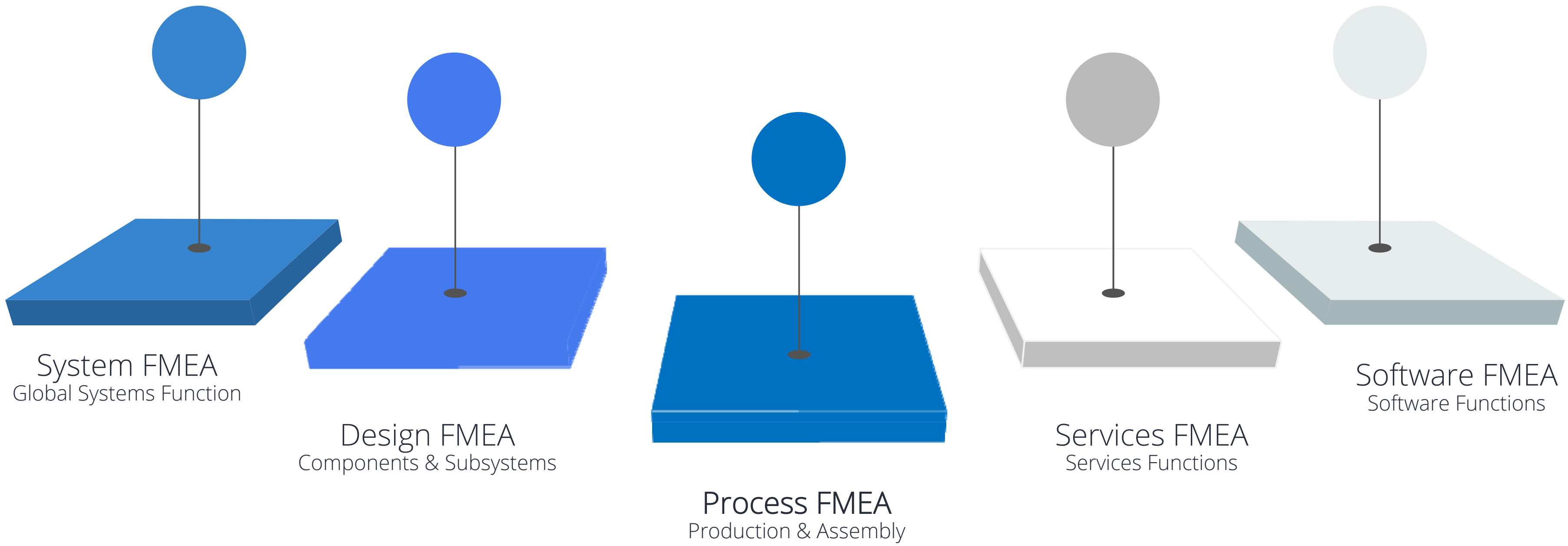

Projects : FMEA : Intelex
Secure https://cloud5.intelex.com/fmeaexample/Application/QP
Search Apps, Reports and Dashboards
Toronto Facility
George Smith
Dashboard
Projects
Actions
Settings
Home > Projects
Custom Inventory
Add Entry
Delete
List All
Advanced Search
Hierarchy Tree
Actions
Project Code | Description | Part Number | Part Name | Owner | Location | Current Revision | Open Revision | Date Released
Ball Valve BV902 | An updated 2018 Model Year 5"x3/4" Ball Valve | 90234 v.0 | Ball Valve | Laura Green | Toronto Facility | | Rev. 1 (In Progress) |
Coupler Head 005 | P121-4 Coupler head | 14-4839 v.0 | #14 Rebar Coupler Head | Adam Stephenson | Toronto Facility | Rev.1 | | 6/11/2018
Engine Block 543 | 0504 Engine Block | 980505-0504 v.0 | Engine Block | Adam Stephenson | Toronto Facility | Rev.1 | | 6/11/2018
Exhaust Manifold 001 | 98505 Manifold Prototype | 980505-0505 v.0 | Cylinder Head | Mitch Doyle | Toronto Facility | Rev.1 | | 6/11/2018
Viewing 1 - 4 of 4 Records
Items Displayed 20
https://cloud5.intelex.com/fmeaexample/Application/QP/Projects/Forms/QP_ProjRev_Detail/View/2204e41c-7f72-4549-b56c-c169b6ea64e8


Ball Valve Rev.1 : Intelex
Secure
https://cloud5.intelex.com/fmeaexample/Application/QP/Projects/Forms/QP_ProjRev_Detail/View/2204e41c-7f72-4549-b56c-c169b6ea64e8
Search Apps, Reports and Dashboards
Toronto Facility
George Smith
Dashboard
Projects
Actions
Settings
Home > Projects > Ball Valve Rev.1
Submit
Cancel Revision
Edit
Delete
Security
Exit
Ball Valve Rev.1
Workflow Stage: In Progress
Workflow Status: In Progress
Person Responsible: Laura Green
Project Details
Location Toronto Facility
Project Code Ball Valve BV902
Product Ball Valve
Part Number 90234 v.0
Customer Fasco
Supplier
Model Year(s)/Program(s) 2018
Template Default
Folder Ball Joints
Description An updated 2018 Model Year 5"x3/4" Ball Valve
Owner Laura Green
Project Revision Details
Rev. 1
Risk Reduction Policy Default Policy
Project Type Prototype
Description An updated 2018 Model Year 5"x3/4" Ball Valve
Comments


Ball Valve Rev.1 : Intelex
Secure https://cloud5.intelex.com/fmeaexample/Application/QP/Projects/Forms/QP_ProjRev_Detail/View/2204e41c-7f72-4549-b56c-c169b6ea64e8
Search Apps, Reports and Dashboards
Toronto Facility
George Smith
Submit
Cancel Revision
Edit
Delete
Security
Exit
Nodes
PFMEA
Control Plan
Process Flow
Add New Process/Function
Delete
List All
Add to Library
Select Process/Function from Library
Process/Function
Requirement
Failure
Effect
Severity
Cause
Occurrence
Control
Detection
RPN
Recommended Action
New RPN
Process/Function: 1- Receive and Inspect Valve Blank (2)
1- Receive and Inspect Valve Blank
Valve blank has correct dimensions
Incorrect Part Received
Loss of Production
Severity: High
Parts received incorrectly
Occurrence: Very Low
Ad hok S&R Inspection
Detection: Moderately High
RPN: No Action Required (28)
()
RPN:
1- Receive and Inspect Valve Blank
Valve blank has correct dimensions
Valve Blank Dimensions out of Spec
Part has to be Scrapped
Severity: Very Low
Poor QA at Source
Occurrence: 0.1 Per 1,000
Visual Inspection
Detection: High
RPN: No Action Required (48)
()
RPN:
Process/Function: 2- Drill Valve Holes (1)
2- Drill Valve Holes
3/4" Hole Drilled to Spec
Hole Drilled too Large
Valve Assembly Impossible
Severity: Moderate
Worn Drill Bit
Occurrence: 20 Per 1,000
Drill bit replaced every 10,000 parts Detection:
Detection: Very Low
RPN: Action May be Required (336)
()
RPN:
Process/Function: 3- Assemble Valve (2)
3- Assemble Valve
Valve Assembled
Ball does not turn freely
Valve Body and Ball scrapped
Severity: Very Low
Valve hole contains debris
Occurrence: 0.1 Per 1,000
QA Inspection After Drilling
Detection: High
RPN: No Action Required (48)
()
RPN:
3- Assemble Valve
Valve Assembled
Valve Ball does not Fit in hole
Valve body scrapped
Severity: Minor
Hole Drilled too Large
Occurrence: 0.5 Per 1,000
Replace drill bit every 10,000 parts
Detection: High
RPN: No Action Required (45)
()
RPN:
Viewing 1 - 5 of 5 Records
Items Displayed 20
Summary of Causes Exceeding Risk Reduction Policy
List All
Cause
Criticality
Control
RPN
Recommended Action
Severity
Occurrence
Detection
New RPN
https://cloud5.intelex.com/fmeaexample/Application/QP/Projects/Forms/QP_Req_Detail/View/90fc8e07-fdd6-4021-ab68-8a4664ce22f5?relatedId=7514d998-78fc-4e42-a958-5bc6bbe76c71&relatedPath=QP_ItemFuncObject.Children

Tailored FMEA

Specific solution approaches tailored to the needs of the business



A new method has been added in automotive with AIAG-VDA-5: **FMEA for Monitoring and System Response (FMEA-MSR)** which "is intended to maintain a safe state (i.e. safety) or state of regulatory (i.e. environmental) compliance during customer operation."

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Why Incorporate Risk-Based Thinking with FMEA?

To **make better decisions** in uncertain environments:

- Reduce frequency of losses
- Reduce likelihood of losses
- Reduce costs of losses
- Improve response time
- Reduce stress
- Increase communication
- Enhance learning
- Capture opportunities for improvement

From Willumsen, P., Oehmen, J., Rossi, M., & Welo, T. (2017). Applying lean thinking to risk management in product development. In Proc. 21st Intl. Conf. on Engr. Design (ICED 17), Vancouver, 269-278.

"… in the end it is all about how organizational insights and knowledge are turned into strategic insights and advantage."

Harry Hertz, Director Emeritus Baldrige Performance Excellence Program

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3: Statistical Process Control (SPC)

finding process problems before they impact the product

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Value

The earlier problems are detected, the less they contribute to Cost of Quality (CoQ).

Catching a process-related problem early means you can minimize problems with products or services:

- Prevent defects/recalls
- Reduce waste/rework
- Improve productivity
- Improve response time

SPC can provide other benefits like added engagement in continuous improvement, and shifting perceptions in the organization from reactive to proactive.

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What Can Happen?

Is the variation I'm observing **OK**, or is there a problem?

	There really was a problem	There was no problem
I detected a problem	Great!	False Alarm
I found no problem at all	Non-detection	Great!

Is the process under **control**?

ASK CONTINUOUSLY DURING PRODUCTION

Is the process **capable** of meeting customer requirements?

ASK DURING PROCESS DESIGN & CONTINUOUS IMPROVEMENT ACTIVITIES

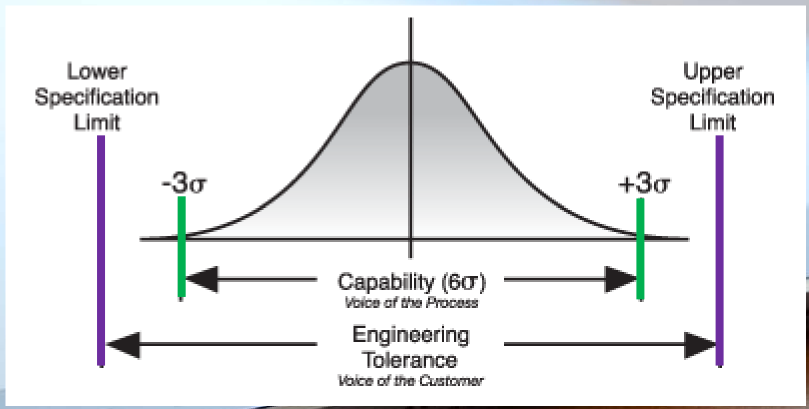

Chart Source: InfinityQS

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EXAMPLE: HUMAN BODY TEMPERATURE

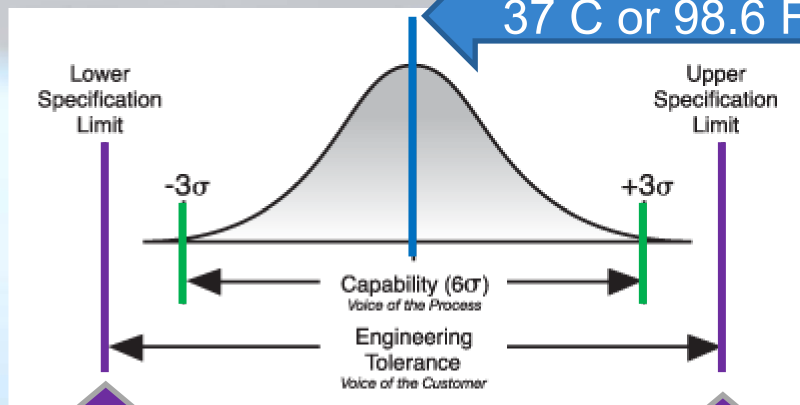
Is the process under **control**?

THAT IS, NOT CREEPING UP OR DOWN IN A SYSTEMATIC WAY

Is the process **capable** of meeting customer requirements?

YOUR CUSTOMER REQUIREMENT = AVOID DEATH

37 C or 98.6 F



35 C
95 F

40 C
105.8 F

35.58 C
96.05 F

40.25 C
100.45 F

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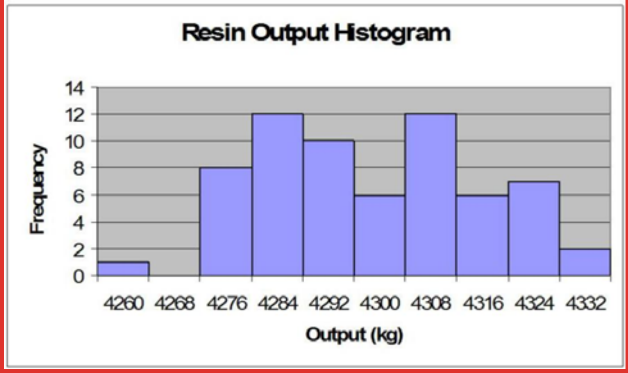
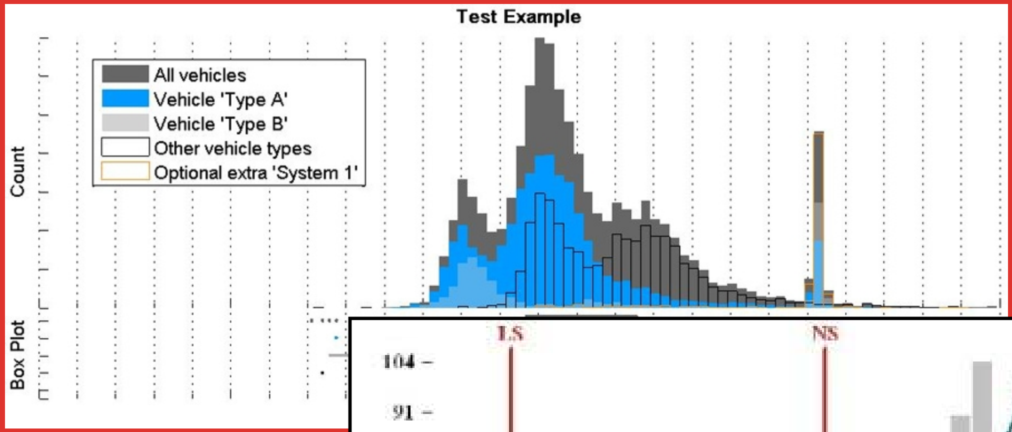
Distributions are Not Always Normal (Bell Shaped)



http://www4.asq.org/blogs/statistics/statistical_thinking_tools/histogram/



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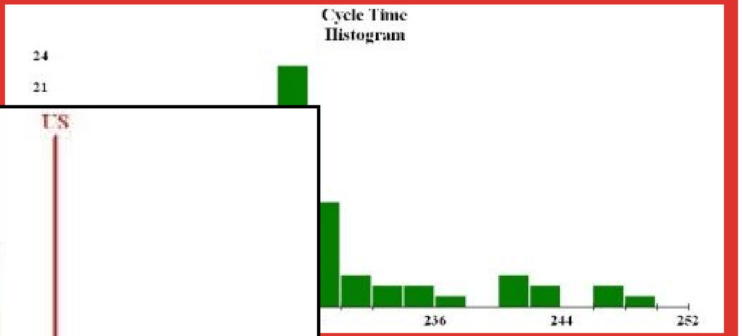
automotive-manuf



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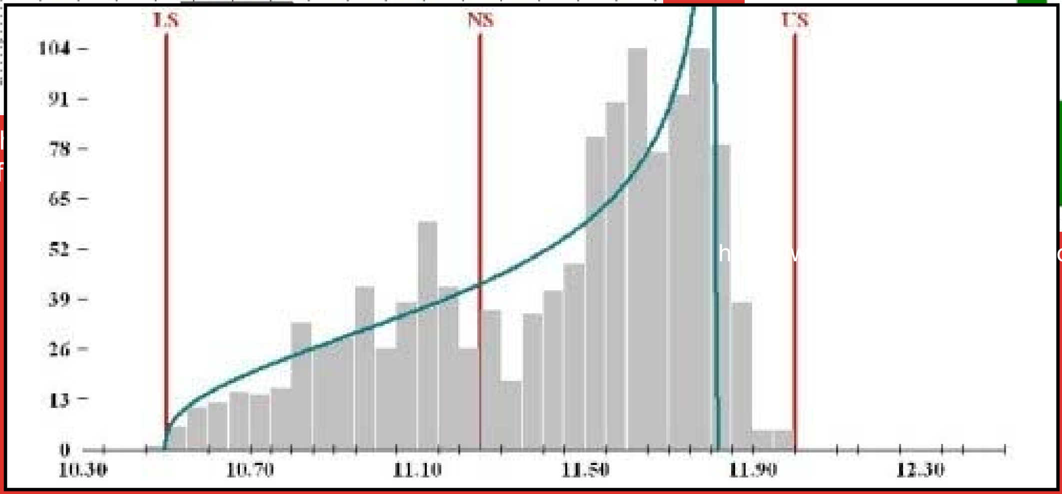

https://www.quality-assurance-solutions.com/histogram-examples.html

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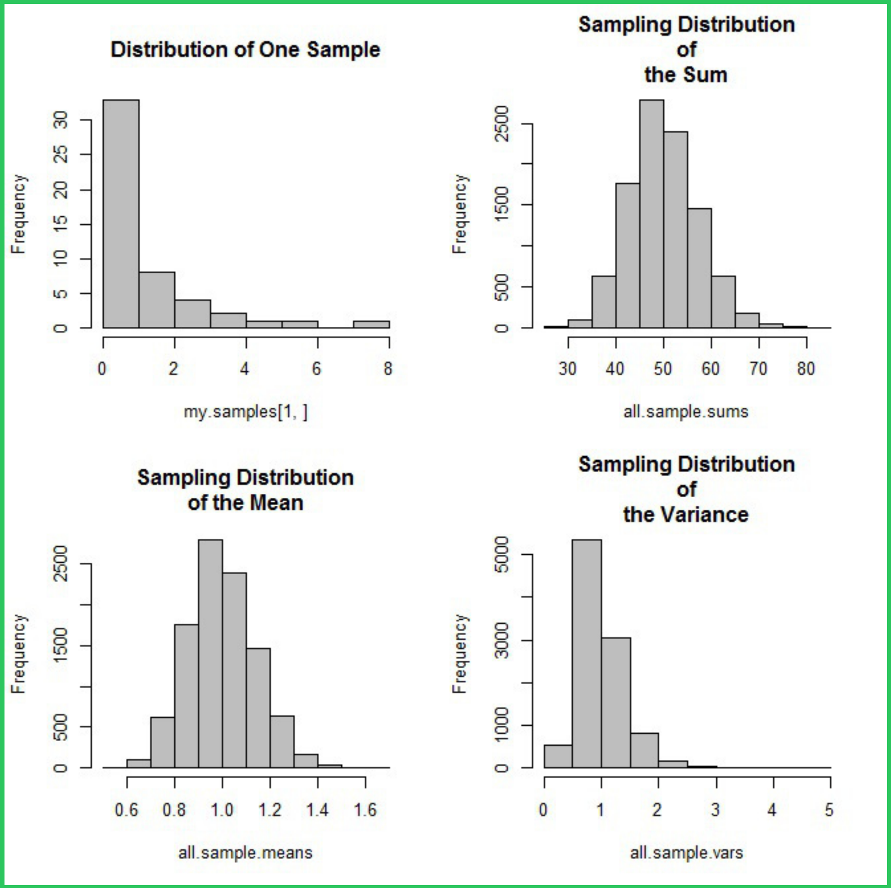

Non-Normal Data?

No Problem: Take the average or sum of a batch of measurements and voila… bell-shaped(*)

Chart Source: Radziwill (2017). Statistics (The Easier Way) With R, 2nd Ed.

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1. SPC Preparation
2. SPC in Operations

SPC Preparation

1. Start with **flow chart** for producing **“part”**
2. Figure out **what’s important to measure**
   - FMEA, CTQ Trees, Design of Experiments (DOE), Principal Component Analysis (PCA)
3. Figure out **what instrument will be used** to measure it
   - Is the instrument calibrated? Make sure you have documentation that it is!
   - MSA-I (Gage Capability)
4. Determine **which people** will measure **which parts**
   - MSA-II (Gage R&R) can call out whether there are training or technique issues
5. Pick **rational subgroups** and devise a **sampling plan**
6. Record this control strategy in the **control plan**

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CONTROL PLAN

Control Plan Number ABC101-23	Key Contact/Phone John Stone - Mfg Engineer, x5412	Date (Orig.) 1/1/10	Date (Rev.) 12/11/11
Part Number/Latest Change Level Sub-Assembly 987-00	Core Team C. Stone, J. Leard, D. Moores, G. Boyd, S. Miller	Customer Engineering Approval/Date (If Req'd.) N/A	
Part Name/Description Leg, Support, and Armrest Asm	Supplier/Plant Approval/Date 12/9/11	Customer Quality Approval/Date (If Req'd.) N/A	
Supplier/Plant In-House (Kansas City) — Supplier Code N/A	Other Approval/Date (If Req'd.) Ed Stumpek, Eng VP (12/10/11)	Other Approval/Date (If Req'd.) N/A	

PART/ PROCESS NUMBER	PROCESS NAME/ OPERATION DESCRIPTION	MACHINE, DEVICE JIG, TOOLS FOR MFG.	CHARACTERISTICS			CTQ?	METHODS					REACTION PLAN
			NO.	PRODUCT	PROCESS		PRODUCT/PROCESS SPECIFICATION/ TOLERANCE	EVALUATION/ MEASUREMENT TECHNIQUE	SAMPLE SIZE	SAMPLE FREQ.	CONTROL METHOD	
1	Place leg, support, and armrest in assembly fixture	Fixture 987-01F1	1D		Parts placed properly in fixture per drawing 987-00	N	Parts oriented correctly (reference drawing 987-00 with any questions)	Error proofed - parts cannot be mis-oriented	N/A	N/A	Error proofed	None required
2	Drive two screws to secure side support	Electric screwdriver 987-01A1	2D	Final screw depth		N	Screw heads sub-flush	Flush gage	5	Hourly	P-Chart	Re-inspect all product since last inspection and rework if needed
			2P		Drive torque on screw	Y	Torque between 10 in-lb and 13 in-lb	Automatically monitored with electric screwdriver - **alarm will sound if torque is out of range**	100%	N/A	100% monitoring	If torque alarm sounds, stop production, verify proper screws, check pilot hole diameter. If correct, contact maintenance and engineering.
3	Drive three screws to secure arm rest	Pneumatic screwdriver 987-01A2	2D	Screws seated sub-flush		N	Screw heads sub-flush	Slide flushness gage over screw locations - must move freely	5	Hourly	P-Chart	Re-inspect all product since last inspection and rework if needed

http://www.dmaictools.com/wp-content/uploads/2011/12/control-plan-complete3.png

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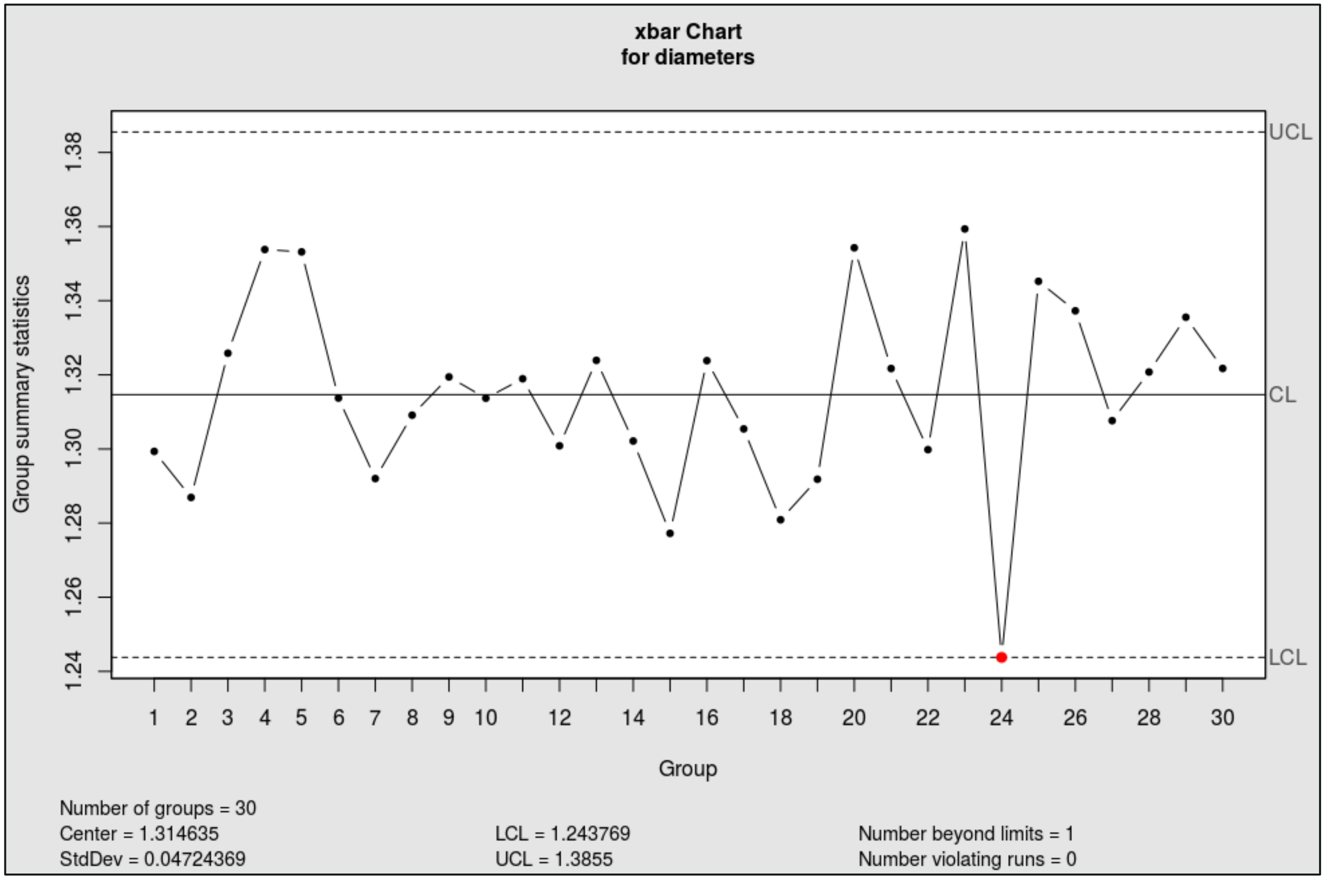

xbar Chart
for diameters
Group summary statistics
1.24
1.26
1.28
1.30
1.32
1.34
1.36
1.38
UCL
CL
LCL
1
2
3
4
5
6
7
8
9
10
12
14
16
18
20
22
24
26
28
30
Group
Number of groups = 30
Center = 1.314635
StdDev = 0.04724369
LCL = 1.243769
UCL = 1.3855
Number beyond limits = 1
Number violating runs = 0

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Variable Data

Numbers that can be measured on a **continuous** scale (1.2, 8.3, 4.5, 2.3) or as **discrete** values (1, 2, 3, 4):

•Height, width, thickness

•Temperature

•Weight, density

•Force, torque

•Time, cycle time, interarrival time

Attribute Data

Categories that describe a process. Record the # or % of items in a category, or the rate (# or % divided by a period of time):

- Number of defects
- Defects per unit, box, pallet, etc.
- Defects per shift, day, week, month, etc.
- Quality Good/Quality Bad
- Pass/Fail
- Go/No-Go
- Audit points

Often there are only **two categories**.

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- 7 heads
- 200 ml pouches (manually affixed)
- Produce 6 groups (42 pouches) per hour
- Two 8-hour shifts
- 672 juice pouches per day
- 20 machines just like this one

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- 7 types of cookies
- Cookie plate consists of 50 cookies, nearly evenly distributed across cookie types
- How could you assess the quality of these cookies?

http://www.gaylesbakery.com

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Attribute Data for Rare Events

- Days between “Never Events” in healthcare, such as wrong site surgeries
- Days between infection outbreaks
- Product liability lawsuits over threshold
- Production line stoppages

Crosses boundaries into safety management:

- Patient falls (healthcare)
- Days between safety incidents
- Days since last accident
- Accidental deaths or severe injuries

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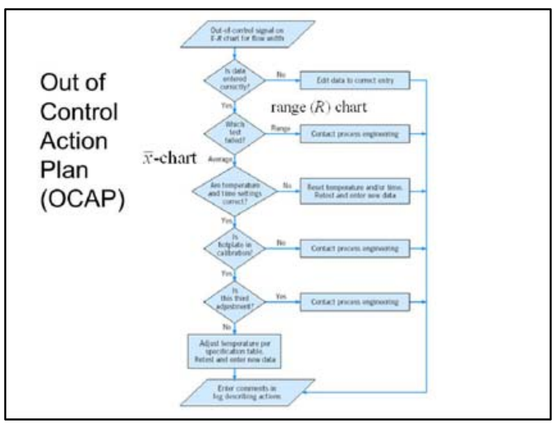
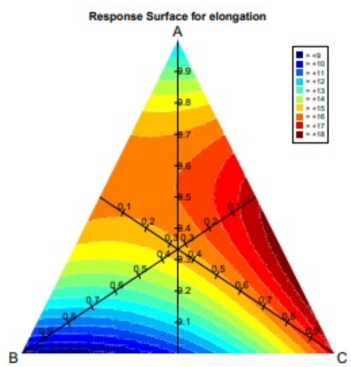
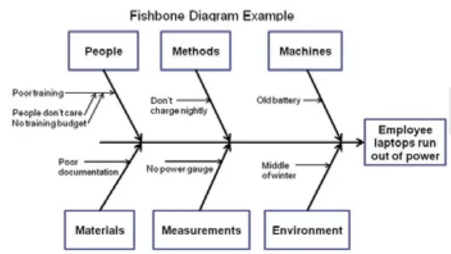
SPC in Operations

Now that you know what to measure for a particular part:

1. Select an appropriate **control chart**
2. Take 20-30 groups of observations and calculate **control limits**
3. Continuously **monitor the process**
4. If something deviates from those limits, **take action**







Corrective and Preventive Action (CAPA) Report

Customer: Address: Phone:	CAPA Number: CAPA-11-000N
Item Description: Number Supplier Part Description: ()	PO # Order #:

CAPA Owner: (Supplier)___________ Supplier CAR/CAPA #: __

CAPA Owner: Complaint Action Report (CAR Num): CAR-000N

Issued Date: _/__/2011 Salesforce Case #:NNNN

Status: ☐ Open ☐ Close

Risk rating: Major___ Moderate___ Minor__x__ Opportunity for improvement___

Category: Audit observation Procedure___ Preventive Action/Safety___ Mgt Review____ Email from QA Customer_x__ Maintenance Other: phone call

Description of problem

Alleged injury description and associated information: None

Reasons: None

Section 2: Immediate Action

Medical Device/Vigilance Reportable? ☐ Yes X☐ No

Document notification date and place report in file.

Date Reported: __NA_________

Performed By: NA	Date: NA

Have you collected all the information to allow you to do an investigation as required? Yes ____ No___

Doc Num: N CONFIDENTIAL Page 1 of 4

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Common Cause Variation (Do Nothing!)

The measurements typically bounce around a little bit, but it's OK because we expect to see:

- Variability in materials
- Variability in environmental conditions (e.g. temperature, humidity)
- Variability between machines
- Variability between operators
- Machine wear

Special Cause Variation (Do Something!)

The production process needs help!

- Supplier materials are out of spec and your acceptance sampling didn't catch it
- A machine is failing or about to break down
- The operator is doing something wrong (either inappropriate technique, insufficient training, or just having a very bad day)
- There has been a change in the way the measurements are being made
- A "process shift" has occurred: operator, materials, methods, tools, machines, or environment has changed(*)

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Reaction Plans (OCAP)

OCAPs (Out-of-Control Action Plans) provide **work instructions for "special cause" events**:

1. Continue process but monitor closely
2. Discontinue automation, run process manually with close observation
3. Follow alternative instructions
4. Stop process, make (and log) specified adjustments, resume
5. Stop, launch **corrective action**/ root cause analysis process, and resume

OCAPs should be linked to what specific rule was violated, e.g. an out-of-control point or a trend violation.

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OCAP

Often referenced on Control Plan:

Control plan for project Mail Rerouting

CONTROL PLAN

Process: Handling & reworking rerouted mail

Version: 2.3

Process owner: Mrs. Hendrickx

Measurement	*Who*	*How*	*Where*	*When*	*Reporting*	*Norm / spec.*	*Lower control limit*	*Which OCAP*
Correct sticker use	Regional manager	Sampling with measurement form	Output stream of each team	Monthly	Senior dept. controller	95%	85%	OCAP HPB2
Machine processed rerouted mail	Senior dept. controller	System data	Input stream of sorting machines	Monthly	Manager Sorting hub	85%	80%	OCAP HPS2

From Kemper, B. P., Koning, S., Luijben, T. C., & Does, R. J. (2011). Quality quandaries: Cost and quality in postal service. *Quality Engineering*, *23*(3), 302-308.

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4: Quality Architecture

systems, interactions, connections

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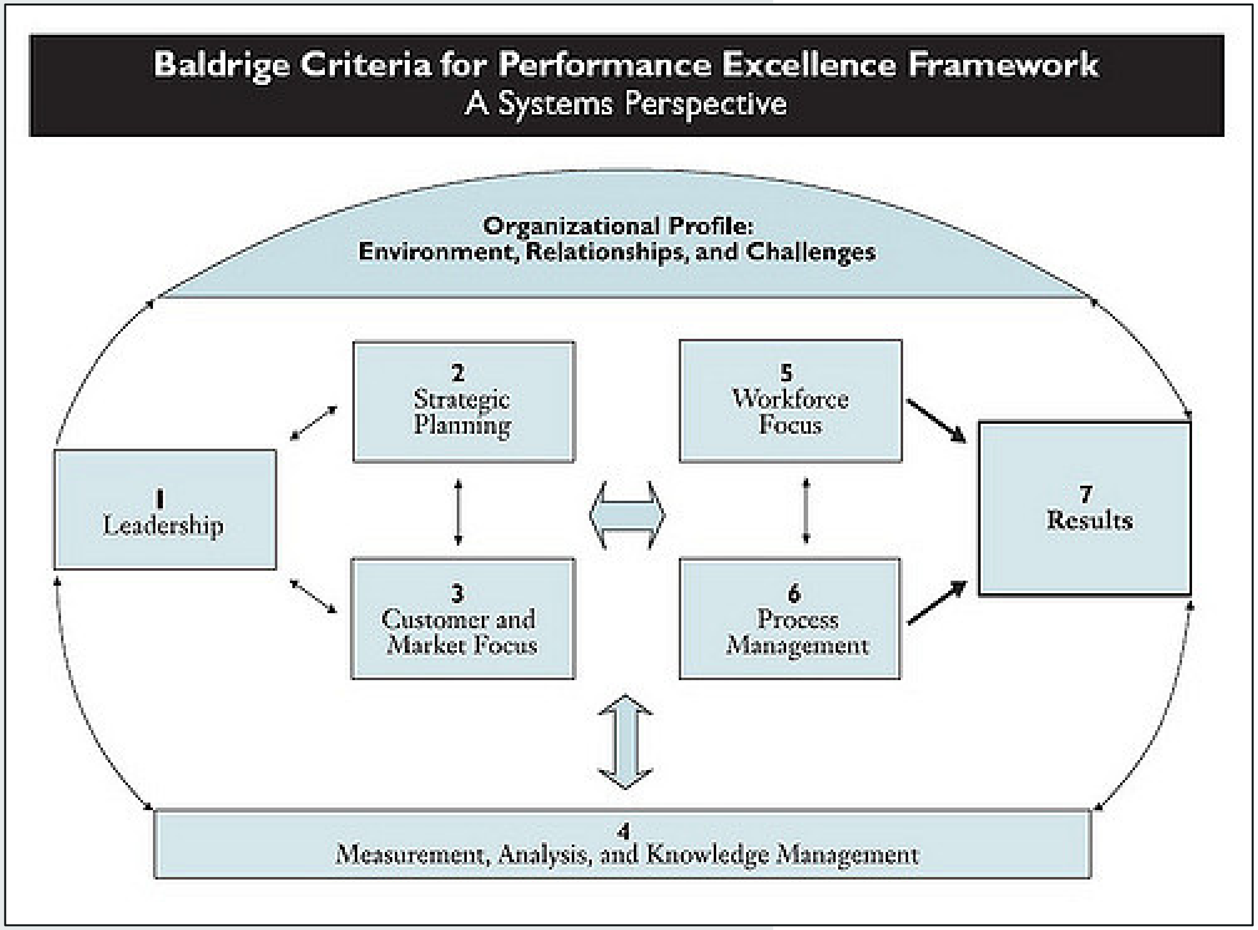

From: Baldrige Criteria for Performance Excellence (2017).

Baldrige Criteria for Performance Excellence (US)

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Quality Planning	Quality Assurance/ Quality Control	Quality Improvement

• Establish quality goals
• Understand organizational context (mission, vision, values, strategy, position, capabilities)
• Understand business environment
• Identify customer & stakeholder needs – Voice of Customer (VoC)
• Design products/services to meet needs
• Design processes for consistent production & related **controls**
	• Evaluate process performance
	• Compare performance with quality goals
	  • **Manage quality events,** update **controls**
	    • Audits
	    • Management reviews
	    • Nonconformances
	    • Incidents/near misses
	    • Complaints
	• Out-of-control production
	• Act to close the gaps
	← Integrate lessons learned into Quality Planning
		• Build capabilities (people and technical)
		• Build infrastructure
		• Identify and justify needs and gaps
		• Conduct improvement activities and establish **controls** to maintain them
		  • Quick wins (PDCA)
		  • Process improvement (DMAIC, Lean)
		  • Process design or redesign (DMADV)
		  • Business process mgmt (BPM) or Robotic Process Automation (RPA)
		• Confirm/Validate changes

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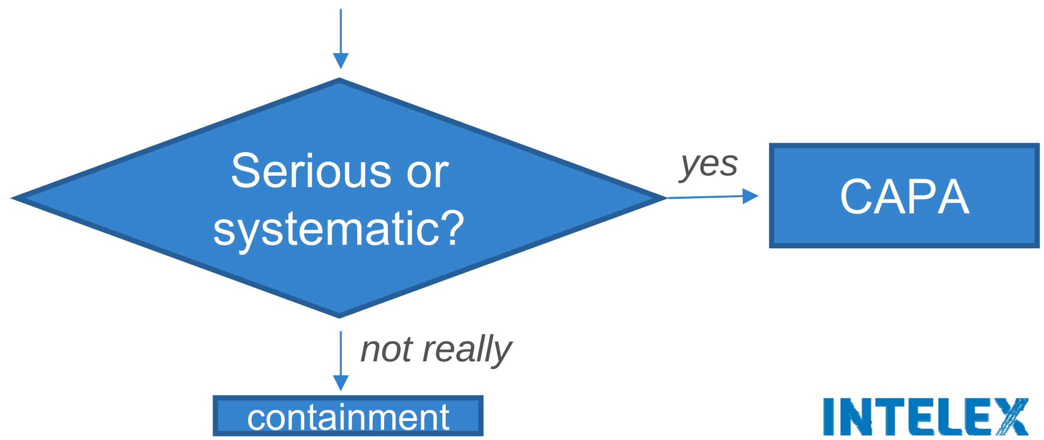
Quality Events

indicate that quality goals are not being met and action is needed

- Nonconforming product
- Incidents/near misses
- Customer complaints
- Recalls/warranty calls
- Deviations (from SOP)
- Out-of-control Action Plans
- Industry-specific events (e.g. MDRs)



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Quality Controls

to prevent or correct unwanted or unexpected change → add stability and consistency

- Calibrations
- Maintenance
- Inspections
- Sampling incoming parts
- Process validation
- Mistake-proofing
- In-situ process monitoring
- Environment monitoring
- Professional testing/ competency assessment
- Training programs and reminders
- Corrective actions taken
- Information security/ network security

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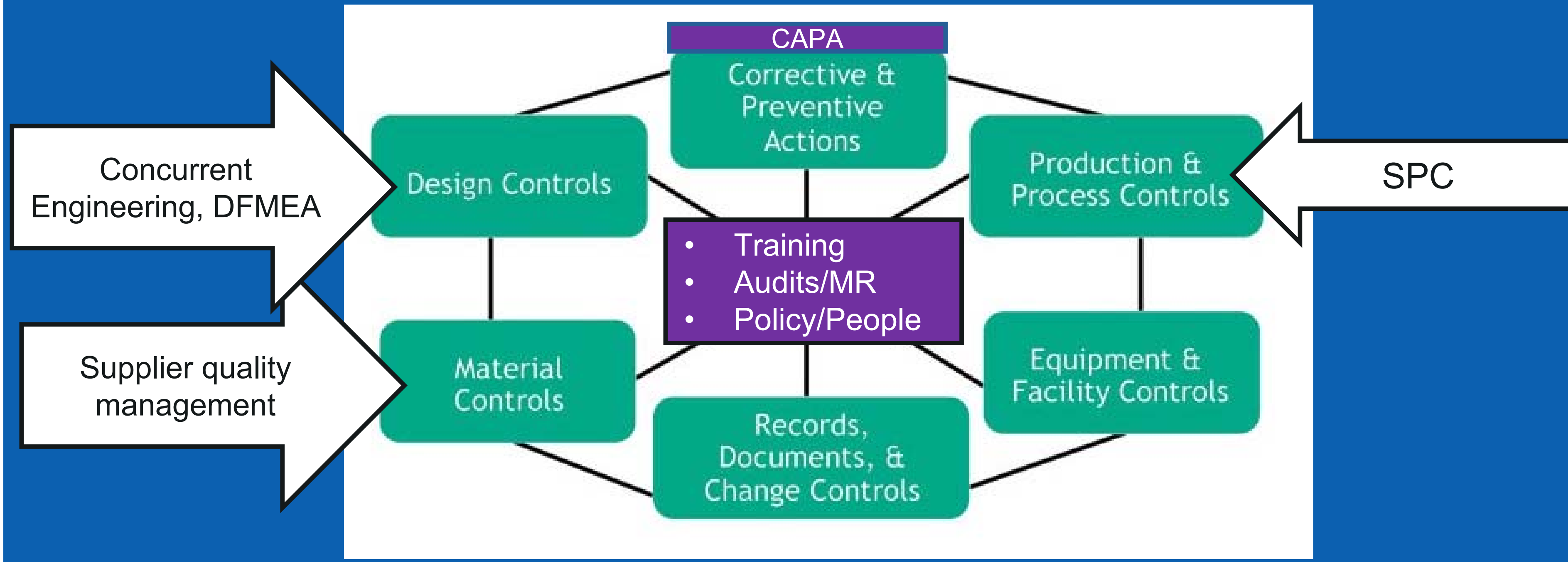
The FDA Model for QMS Components



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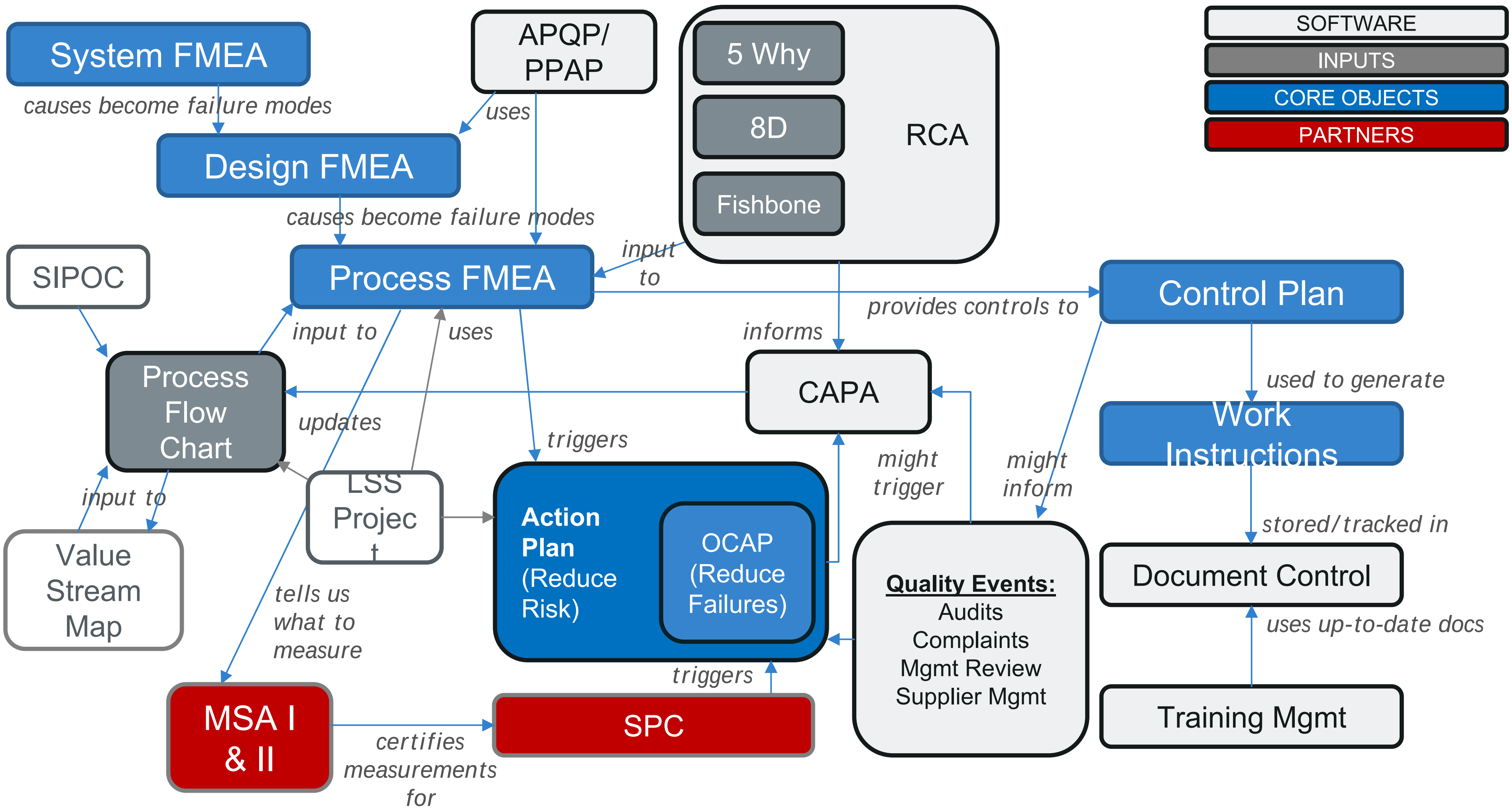

QMS REFERENCE ARCHITECTURE INTELEX

Process Design:
we don't have a process yet, but we need to *develop* one that meets specifications and achieves quality goals

Root Cause Analysis/ Corrective Actions:
we need to *fix a problem* to restore our ability to satisfy quality goals

Process Improvement:
everything is going OK but *it could be better*

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Value is in the integration points:

- Keeping track of Reaction Plans/OCAPs and when they change
- Managing linkage between FMEA and SPC monitor points
- Keeping records for when Reaction Plans/OCAPs are triggered
- Traceability through problem-solving process (e.g. RCA, 8D), corrective action(s), and observed outcomes
- Updating FMEAs after corrective actions, and flowing that down to SPC Control plan

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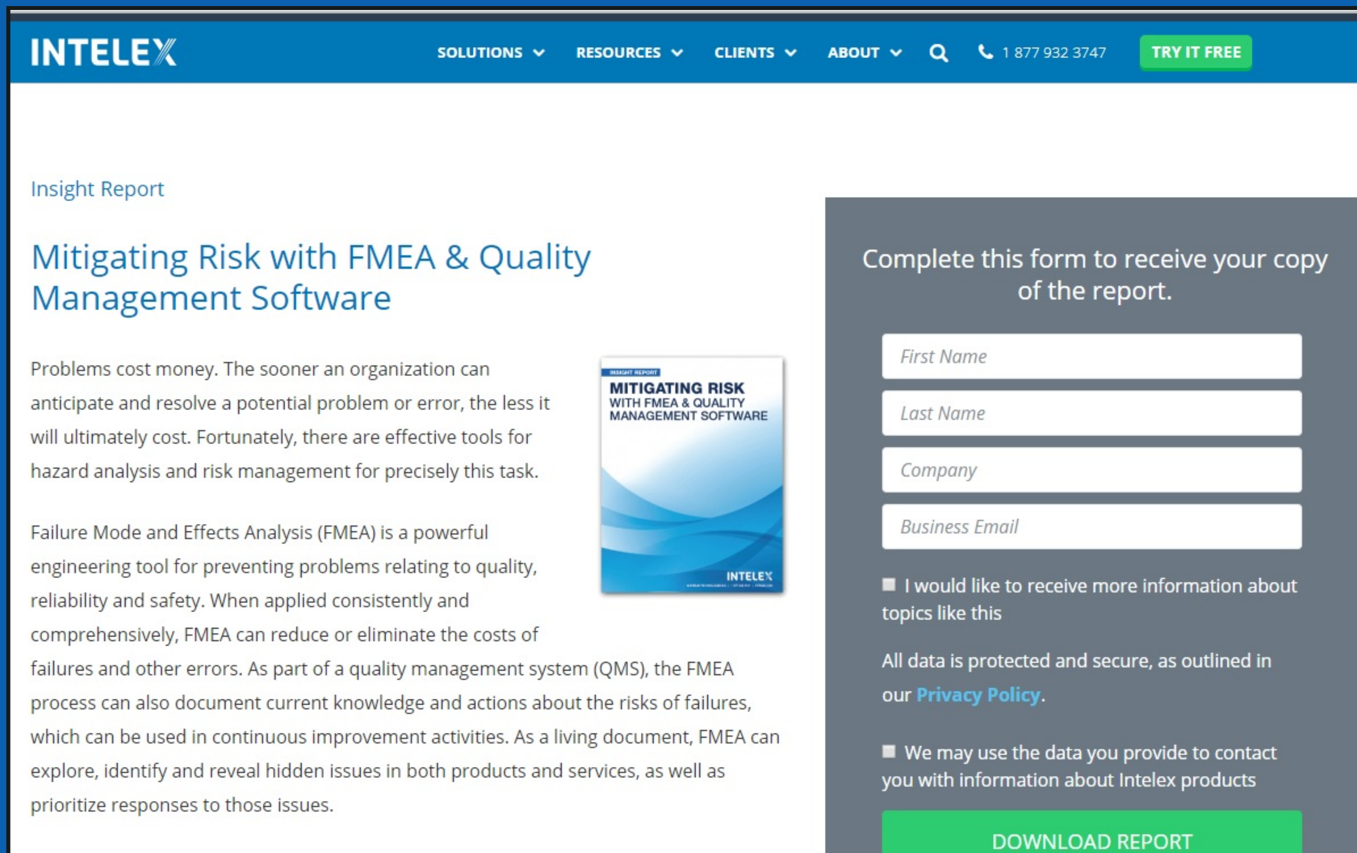
https://www.intelex.com/resources/insight-report/mitigating-risk-fmea-quality-management-software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Insight Report

Mitigating Risk with FMEA & Quality Management Software

Problems cost money. The sooner an organization can anticipate and resolve a potential problem or error, the less it will ultimately cost. Fortunately, there are effective tools for hazard analysis and risk management for precisely this task.

Failure Mode and Effects Analysis (FMEA) is a powerful engineering tool for preventing problems relating to quality, reliability and safety. When applied consistently and comprehensively, FMEA can reduce or eliminate the costs of failures and other errors. As part of a quality management system (QMS), the FMEA process can also document current knowledge and actions about the risks of failures, which can be used in continuous improvement activities. As a living document, FMEA can explore, identify and reveal hidden issues in both products and services, as well as prioritize responses to those issues.

MITIGATING RISK WITH FMEA & QUALITY MANAGEMENT SOFTWARE

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Supplemental Slides

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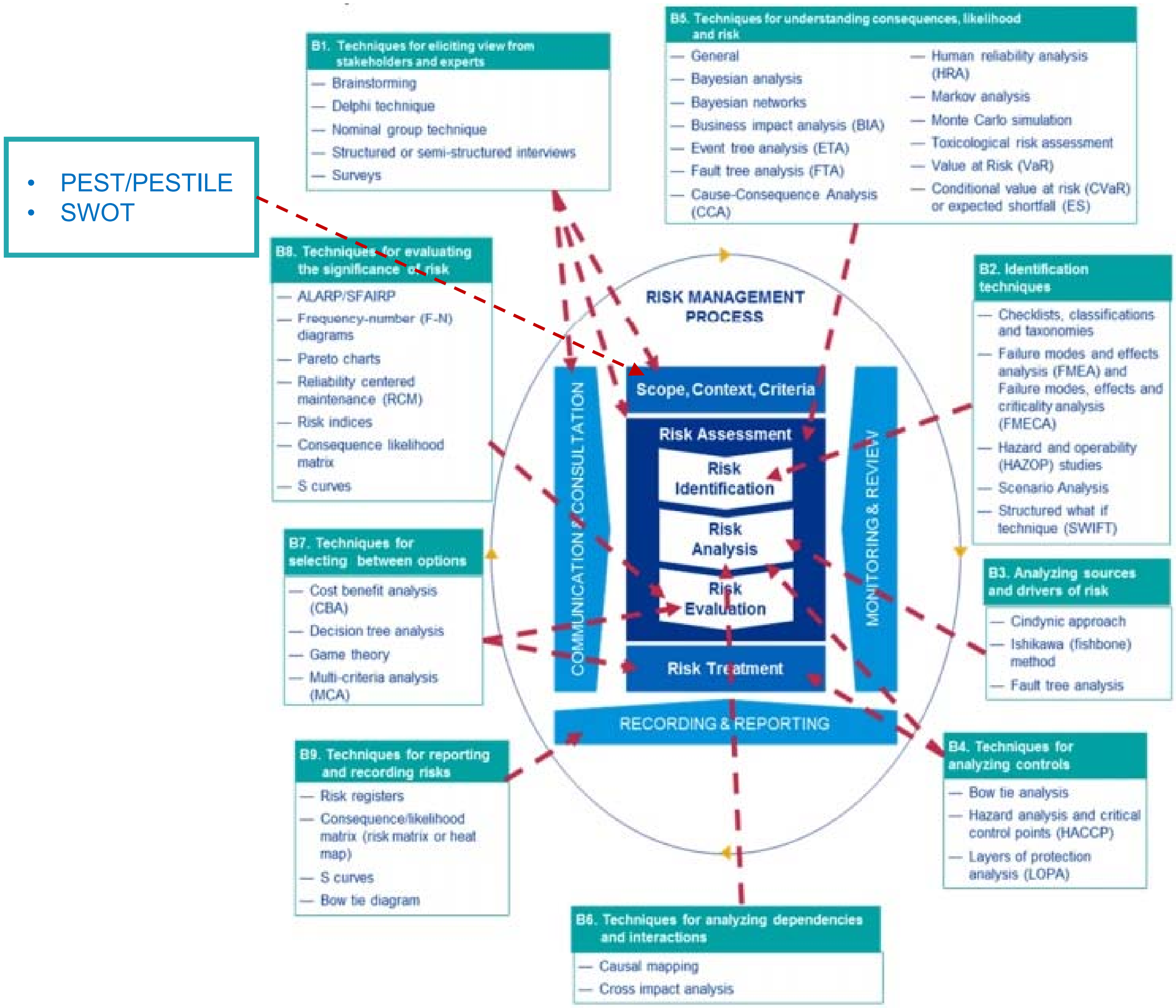

From Cross, J. (2017). ISO 31010 Risk assessment techniques and open systems. *Sixth Workshop on Open Systems Dependability*, Tokyo, October 21.

For more methods, consult the text of ISO/IEC 31010 Risk management methods

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Variable Charts

Subgroup Size	Chart Type(s)	Choose this when…
1	I-MR	• Data is difficult or expensive to collect (e.g. in a blast furnace, destructive testing) • Production is in small-volume production runs or runs that take a lot of time (e.g. brewing lager or kombucha) • Measurements can’t be taken in groups (e.g. temperature of a tank)
Small (2-10) and does not change	Xbar-R	• Measurements tend to cluster around a mean (normally distributed) with consistent variability • Inspection process doesn’t change often
Large (>10) and changes	Xbar-S	
Any	CUSUM, EMWA	• Tiny variations in the process need to be detected

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Attribute Charts

Subgroup Size	Chart Type(s)	Choose this when…
Any, but stays the same	np	• Monitoring **number of defects** = nonconforming (failed) items in a batch
Any, and can change	p	• Monitoring **proportion of defects** = nonconforming (failed) items in a batch divided by batch size
Any, but stays the same	c	• Monitoring **total number of defects in each unit/product**, or total number of some event that occurs per unit time
Any, and can change	u	• Monitoring **average number of defects per unit/product**, or rate of occurrence of some event that occurs per unit time
N/A	g	• Monitoring **number of events between** rarely-occurring errors or nonconforming incidents
N/A	T	• Monitoring **passage of time between** rarely-occurring errors or nonconforming incidents

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