LSS + ISO 9001:2015 =
Maybe at risk, but not in peril…

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When you change the way you look at things, the things you look at change.

~ Max Planck
Learning Objectives

- What is a framework?
- Introduction to Lean and Six Sigma
- Introduction to quality management systems
- Introduction to Baldrige
- How LSS can engage with other frameworks
- Q&A
What is a framework?

**framework** *n*: a basic conceptual structure (as of ideas)

www.Merriam-Webster.com
What is Six Sigma?

Six Sigma

- Is a philosophy of pursuing process improvement to increase customer satisfaction
- Uses statistical tools to reduce process variation
- Follows the DMAIC problem solving method
- Is often used in conjunction with Lean
History of Six Sigma

Timeline

- 1777-1855: Carl Frederick Gauss introduced the concept of the normal curve
- 1920s: Walter Shewhart introduced the concepts of common cause and special cause variation and 3-sigma process limits
- 1980s: Six sigma developed as a practiced methodology by Motorola
What is Lean?

- Lean is a philosophy that embraces respect for the individual, putting the customer first and the pursuit of perfection in all things.
- Lean is a system of thought meant to stimulate innovation through the elimination of the various wastes that take up valuable time and resources.
- Lean is also a methodology for achieving cycle time reduction.
THE 8 WASTES = D.O.W.N.T.I.M.E.

- Defects
- Over production
- Waiting
- Non-utilization
- Transportation
- Inventory
- Motion
- Excess Processing
Lean drives improvement by reducing process waste and production cycle time

Six Sigma drives improvement by reducing overall process variation and eliminating special cause variation
Quality Management System (QMS)

The quality management system consists of inter-related processes. Understanding how results are produced by this system enables an organization to optimize the system and its performance.

www.iso.org
Baldrige

The Malcolm Baldrige National Quality Award is the highest level of national recognition for performance excellence that a U.S. organization can receive. The award focuses on performance in five key areas:

- Product and process outcomes
- Customer outcomes
- Workforce outcomes
- Leadership and governance outcomes
- Financial and market outcomes
Interlacing Frameworks

Lean Six Sigma shares key elements with QMS’ and Baldrige that help support the goals of organizational continual improvement and risk management.

- philosophy
- cultural enablers
- complementary tools and methods
## Interlacing Frameworks - 2

<table>
<thead>
<tr>
<th>Lean Six Sigma</th>
<th>Quality Management Systems</th>
<th>Baldrige</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respect for the individual</td>
<td><strong>QMP 1</strong> – Customer focus</td>
<td>Leadership</td>
</tr>
<tr>
<td>Use statistical tools to reduce process variation</td>
<td><strong>QMP 2</strong> – Leadership</td>
<td>Strategy</td>
</tr>
<tr>
<td>Eliminate waste and reduce cycle time</td>
<td><strong>QMP 3</strong> – Engagement of people</td>
<td>Customers</td>
</tr>
<tr>
<td>Perfection is attainable</td>
<td><strong>QMP 4</strong> – Process approach</td>
<td>Workforce</td>
</tr>
<tr>
<td>PDCA and DMAIC iterative problem solving approaches</td>
<td><strong>QMP 5</strong> – Improvement</td>
<td>Operations</td>
</tr>
<tr>
<td>Value creation from the perspective of the customer</td>
<td><strong>QMP 6</strong> – Evidence-based decision making</td>
<td>Measurement, Analysis and Knowledge Management</td>
</tr>
<tr>
<td>Leadership must be engaged</td>
<td><strong>QMP 7</strong> – Relationship management</td>
<td></td>
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</tbody>
</table>
How LSS supports the QMS

- LSS demonstrates a proactive data driven approach to improvement
- LSS provides concrete and measurable evidence of improvement activities
- By eliminating wastes, risks and opportunities both become more visible
- Reducing variation creates greater predictability of process outcomes which in turn allows for improved strategic planning
How LSS supports the QMS - 2

- Tools such as process maps, value stream maps, FMEA and SIPOC diagrams all facilitate the use and provide evidence of the process approach.
- The FMEA provides evidence of how risks and opportunities are taken into account during planning and implementation.
- DMAIC and PDCA methodologies provide evidence of a logical and fact based approach to problem solving.
ISO 9001:2015:6.1.1 When planning for the quality management system, the organization shall consider the issues referred to in 4.1 (Understanding the organization and its context) and the requirements referred to in 4.2 (Understanding the needs and expectations of interested parties) and determine the risks and opportunities that need to be addressed to:

a) give assurance that the quality management system can achieve its intended result(s);
b) enhance desirable effects;
c) prevent, or reduce, undesired effects;
d) achieve improvement.
By challenging organizations to plan for “risks and opportunities”, ISO for the first time is explicitly recognizing that there are risks associated with efforts to improve.

The use of risk assessment as part of the LSS project evaluation process specifically addresses the “rewards and opportunity” clause.

Documents such as project charters and reports provide objective evidence of taking risk into account when planning for improvement.
Defining Risk

- **ISO 9001:2015** – the effect of uncertainty
- **ISO 31000:2009** – the effect of uncertainty on objectives
- **ISO 14971:2007** – combination of the probability of occurrence of harm and the severity of harm
# Lean Six Sigma Project Charter

## Six Sigma Project Contract

<table>
<thead>
<tr>
<th>Black Belt Assigned:</th>
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<tbody>
<tr>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Contact:</th>
<th>Start Date:</th>
<th>Anticipated Finish:</th>
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<tbody>
<tr>
<td></td>
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<table>
<thead>
<tr>
<th>Phone:</th>
<th>Location:</th>
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<tbody>
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<table>
<thead>
<tr>
<th>Project Title:</th>
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<tbody>
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</table>

<table>
<thead>
<tr>
<th>Project Abstract:</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Short paragraph description of intent)</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

## Project Risk Assessment

<table>
<thead>
<tr>
<th>LIKELIHOOD</th>
<th>NEGLIGIBLE</th>
<th>MINOR</th>
<th>MAJOR</th>
<th>CRITICAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very Likely</td>
<td>□ M</td>
<td>□ H</td>
<td>□ H</td>
<td>□ H</td>
</tr>
<tr>
<td>Likely</td>
<td>□ L</td>
<td>□ M</td>
<td>□ H</td>
<td>□ H</td>
</tr>
<tr>
<td>Unlikely</td>
<td>□ L</td>
<td>□ L</td>
<td>□ M</td>
<td>□ H</td>
</tr>
<tr>
<td>Very Unlikely</td>
<td>□ L</td>
<td>□ L</td>
<td>□ M</td>
<td>□ M</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>IMPACT</th>
<th>Low Risk (L)</th>
<th>Medium Risk (M)</th>
<th>High Risk (H)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low Risk (L)</td>
<td>□ M</td>
<td>□ H</td>
<td>□ H</td>
</tr>
<tr>
<td>Medium Risk (M)</td>
<td>□ M</td>
<td>□ H</td>
<td>□ H</td>
</tr>
<tr>
<td>High Risk (H)</td>
<td>□ M</td>
<td>□ H</td>
<td>□ H</td>
</tr>
</tbody>
</table>

(C) 2015 Lance B.
## Lean Six Sigma Project Charter cont’d

<table>
<thead>
<tr>
<th>Specific success criteria for this project: (Describe the <em>measurable</em> goals for this project effort)</th>
<th></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Business Impact &amp; Opportunities: (Describe the impact this project will have to higher level business goals and objectives)</th>
<th></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Support Team: (Individuals assigned by project champion to support project)</th>
<th></th>
</tr>
</thead>
</table>

| Has contract been reviewed by a Master Black Belt? | Yes | No |
| --- | --- |

| Has contract and project paperwork been reviewed by Finance? | Yes | No |
| --- | --- |

<table>
<thead>
<tr>
<th>Chartering Manager: Phone number:</th>
<th>Master Black Belt: Phone number:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Finance: Phone number:</th>
<th>Green Belt Assigned: Phone number:</th>
</tr>
</thead>
</table>
Failure Mode and Effects Analysis (FMEA) is a risk management tool used in an attempt to capture every possible failure of a product, design or process and the potential effects of those failures.

- FMEA
- Design FMEA (DFMEA)
- Process FMEA (PFMEA)
- System FMEA (SFMEA)
When do we use FMEA

- Developing a new product or process
- Modifying an existing product or process
- Troubleshooting by reviewing a product or process FMEA, in order to identify failure root cause
- Using an existing product or service in a new application or environment
Why do we use FMEA

- Rate, prioritize, and act on failures using specific criteria
- Ensure that you address potential failure modes with the greatest risk first
- Reduce risk by actively anticipating...
  - What might fail (component, process step, activity, subsystem interaction in a system...)
  - Mode of the failure (the way something fails)
  - Effect of the failure (consequences)
  - Potential options to mitigate the failure
# FMEA Example

## Failure Mode and Effects Analysis

<table>
<thead>
<tr>
<th>Process Function</th>
<th>Potential Failure Mode</th>
<th>Potential Effect(s) of Failure</th>
<th>Severity</th>
<th>Potential Cause(s)/Mechanism(s) of Failure</th>
<th>Occurrence</th>
<th>Current Process Controls</th>
<th>RPN</th>
<th>Recommended Action(s)</th>
<th>Responsibility and Target Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drill Blind Hole</td>
<td>Hole too deep</td>
<td>Break through bottom of plate</td>
<td>7</td>
<td>Improper machine set up</td>
<td>3</td>
<td>3</td>
<td>63</td>
<td></td>
<td>J. Doe 3/1/2016</td>
</tr>
<tr>
<td></td>
<td>Hole not deep enough</td>
<td>Incomplete thread form</td>
<td>5</td>
<td>Improper machine set up</td>
<td>3</td>
<td>3</td>
<td>45</td>
<td></td>
<td>J. Doe 3/1/2016</td>
</tr>
<tr>
<td></td>
<td>Broken Drill</td>
<td>None</td>
<td>5</td>
<td>None</td>
<td>9</td>
<td>225</td>
<td>Install Tool Detectors</td>
<td>J. Doe 3/1/2016</td>
<td></td>
</tr>
</tbody>
</table>
# FMEA and ISO 9001:2015

<table>
<thead>
<tr>
<th>ISO 9001:2015 Clause</th>
<th>How FMEA addresses</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>4.1</strong> The organization shall determine external and internal issues [risks] that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system.</td>
<td>System FMEA can capture overall internal and external risks from the perspective of the customer.</td>
</tr>
<tr>
<td><strong>5.1.2</strong> Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that: b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;</td>
<td>Management commitment is demonstrated by providing resources for training and application of FMEA techniques.</td>
</tr>
<tr>
<td><strong>6.1.2</strong> The organization shall plan: a) actions to address these risks and opportunities;</td>
<td>FMEA is part of the planning process of new and revised products and processes.</td>
</tr>
<tr>
<td><strong>9.1.3</strong> The organization shall analyse and evaluate appropriate data and information arising from monitoring and measurement. The results of analysis shall be used to evaluate: e) the effectiveness of actions taken to address risks and opportunities;</td>
<td>Revising the FMEA when it is determined that all risks have not been capture, due to internal and external feedback, demonstrate data analysis and response.</td>
</tr>
<tr>
<td><strong>10.2.1</strong> When a nonconformity occurs, including any arising from complaints, the organization shall: e) update risks and opportunities determined during planning, if necessary;</td>
<td>Revising the FMEA when it is determined that all risks have not been capture, due to internal and external feedback, directly addresses this cause. Use of FMEA demonstrates a fact based approach to problem solving.</td>
</tr>
</tbody>
</table>
Baldrige 1.1 Senior Leadership

Senior leaders play a central role in setting values and directions, communicating, creating and balancing value for all stakeholders, and creating an organizational focus on action, including transformational change in the organization’s structure and culture, when needed. Success requires a strong orientation to the future; an understanding that risk is a part of planning and conducting operations; a commitment to improvement, innovation, and intelligent risk taking; and a focus on organizational sustainability.
Baldrige 2.0  Strategy

This category asks how you develop strategic objectives and action plans, implement them, change them if circumstances require, and measure progress. It stresses that your organization’s long-term success and competitive environment are key strategic issues that need to be integral parts of your overall planning. Making decisions about your organization’s core competencies and work systems is an integral part of ensuring your organization’s success now and in the future, and these decisions are therefore key strategic decisions. It challenges organizations to understand context when planning
Hoshin Kanri is a strategic planning and management methodology developed to capture strategic goals and distill them down to measurable objectives and targeted action items.

- Hoshin is a Japanese word meaning “compass needle” or “direction”
- Kanri means “management” or “control”
Hoshin Kanri – How it works
Hoshin Kanri

<table>
<thead>
<tr>
<th>Level 1 - Policy Deployment - X Matrix</th>
</tr>
</thead>
<tbody>
<tr>
<td>Objective 1</td>
</tr>
<tr>
<td>1 Mission 1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>RESOURCES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Team 1</td>
</tr>
</tbody>
</table>

- Mission 1: • = strong correlation or team leader
- Mission 2: ° = important correlation or core team member
- Mission 3: • = weak correlation or rotating team member
- Mission 4: ° = weak correlation or rotating team member

- Teams
- Tactical Objectives
- Annual Strategic
- 3-5 Year Objectives

- RESOURCES
- Individuals
- Equipment
- Capital
## Hoshin Kanri

### Level 2 - Strategic Development X-Matrix

<table>
<thead>
<tr>
<th></th>
<th>Objective 6</th>
<th>Objective 5</th>
<th>Objective 4</th>
<th>Objective 3</th>
<th>Objective 2</th>
<th>Objective 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Strategy 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Strategy 2</td>
<td></td>
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<td></td>
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<tr>
<td>3</td>
<td>Strategy 3</td>
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<tr>
<td>4</td>
<td>Strategy 4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>5</td>
<td>Strategy 5</td>
<td></td>
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</tr>
</tbody>
</table>

### METRICS OR TARGETS

<table>
<thead>
<tr>
<th>Name 1</th>
<th>Name 2</th>
<th>Name 3</th>
<th>Name 4</th>
<th>Name 5</th>
<th>Name 6</th>
<th>Name 7</th>
</tr>
</thead>
</table>

### Assignments

- **Strong correlation or team leader**
- **Important correlation or core team member**
- **Weak correlation or rotating team member**

### Goals

1. Objective 1
2. Objective 2
3. Objective 3
4. Objective 4
5. Objective 5
6. Objective 6

### Strategies

1. Strategy 1
2. Strategy 2
3. Strategy 3
4. Strategy 4
5. Strategy 5
Baldrige 3.1 Voice of the Customer

This item asks about your processes for listening to customers and determining their satisfaction and dissatisfaction. The aim is to capture meaningful information in order to exceed your customers’ expectations.
Baldrige 5.1  Workplace Environment

This item asks about your workforce capability and capacity needs, how you meet those needs to accomplish your organization’s work, and how you ensure a supportive work climate. The aim is to build an effective environment for accomplishing your work and supporting your workforce.
ISO 9001:2015:7.1.4 Environment...

Environment for operation of processes: The organization shall determine, provide and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services.

NOTE A suitable environment can be a combination of human and physical factors, such as:

a) social (e.g. non-discriminatory, calm, non-confrontational);
b) psychological (e.g. stress-reducing, burnout prevention, emotionally protective);
c) physical (e.g. temperature, heat, humidity, light, airflow, hygiene, noise).

These factors can differ substantially depending on the products and services provided.
Baldrige 6.1 Work Processes

This item asks about the management of your key programs and services, your key work processes, and innovation, with the aim of creating value for your students and other customers and achieving current and future organizational success.
ISO 9001:2015:0.3 Process Approach

Understanding and managing interrelated processes as a system contributes to the organization’s effectiveness and efficiency in achieving its intended results. This approach enables the organization to control the interrelationships and interdependencies among the processes of the system, so that the overall performance of the organization can be enhanced.

The process approach involves the systematic definition and management of processes, and their interactions, so as to achieve the intended results in accordance with the quality policy and strategic direction of the organization.
Value Stream Map
SIPOC Diagram

SIPOC (supplier-input-process-output-customer) is a diagram used to analyze a process, its inputs, outputs, suppliers and customers. It’s most important purpose is to:

- Establish boundaries or scope
- Define any gaps in knowledge
Don’t collect data if you aren’t going to plot it,
Don’t plot data if you aren’t going to analyze it,
Don’t analyze data if you aren’t going to do anything with what you learn…
The organization shall analyse and evaluate appropriate data and information arising from monitoring and measurement...

..**NOTE** Methods to analyze data can include statistical techniques.
A visual device is an apparatus, mechanism, item or thing that influences, directs, limits or controls behavior by making information vital to the task-at-hand available-at-a-glance, without speaking a word.
Visual (Risk) Management
Control Charts

Why do we use control charts?

• Monitor a process
• Assess process control
Control Charts

General Types
• Variable
• Attribute

Related Charts
• Run charts
• Pre-Control charts
Control Charts

Most commonly used attribute charts:

• P-chart – percentage defective
• NP-chart – number of parts defective
• U-chart – defects per unit
• C-chart – defects within the sample

Most commonly used variable charts

• IMR charts – individual data points
• X-bar/R charts - subgroups
Spotting Adverse Trends
Baldrige 4.0 Measurement, Analysis and Knowledge Management

The aim of performance measurement, analysis, review, and improvement is to guide your process management toward the achievement of key organizational results and strategic objectives, anticipate and respond to rapid or unexpected organizational or external changes, and identify best practices to share.
Key Thoughts Recap

1. Different frameworks or thought systems will support and not compete with one another when they share.
   • philosophy
   • cultural enablers
   • complementary tools and methods

2. Improvement and risk management are two sides of the same coin; improvement reduces risk while the act or improving carries its own risks.

3. Visual Management systems are a powerful tool that helps summarize and present data in a meaningful way to management
Conclusion

By allowing these different thought systems (and their organizational components) to engage with one another, synergies will develop, creating a more effective hybrid philosophy, elevating the continual improvement and risk management processes. Such an evolution will benefit the company, customer, suppliers and the community at large.
Next Steps

- Optimize this and similar experiences
- If you are not in OPEX, use your tools regularly; don’t let them atrophy
- If you are in OPEX, reach across the aisle to quality and ask how you can be of assistance with improving those support processes
- If you are in quality, seek out LSS training even if it is not included in your job description; become a “Big Q” professional
- Promote an individual as well as organizational journey of continual improvement.
- Strive to express your uniqueness upon the world

ASQ
QUESTIONS???