LEAN ISO

ASQ North Central PA Section
January 14, 2013
Today’s Objectives

View Quality Management System (QMS) and Lean practices as complementary forces.

1. Integrate Lean practices and the QMS.
2. Use Lean tools to lean out the documentation.
3. Show how to lean out QMS processes.
OBJECTIVES OF AN ORGANIZATION

To:
- Do Everything Right the First Time
- Deliver Every Product/Service Within Spec, as Documented and on Schedule

Thereby:
- Satisfying Customers
- Providing Consistent Top Quality
- Reducing Cost and Increasing Profitability
KEYS TO ANY EFFORT

1. Management commitment, responsibility
   - Strategic planning
   - New ways of thinking
   - Leadership
   - Follow through

2. Understand processes
   - Flow
   - Interactions
   - Effectiveness and efficiency

3. Measure and analyze
   - Facts
   - Improvement
INTEGRATING LEAN AND QMS
Today’s Objective 1 Part 1

- Integrate the QMS with lean practices
  - 8 wastes in the QMS
  - Lean tools applied to the QMS
8 FORMS OF WASTE

- Over production
- Over processing
- Defects
- Transportation
- Motion
- Waiting
- Inventory
- Under utilization of people
# ISO AND THE 8 WASTES

<table>
<thead>
<tr>
<th>LEAN</th>
<th>ISO</th>
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</thead>
<tbody>
<tr>
<td>Overproduction</td>
<td>Too many documents, NVA documents</td>
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<tr>
<td>Over processing</td>
<td>Review &amp; control, multiple approvals</td>
</tr>
<tr>
<td>Defects</td>
<td>Inaccurate documents, uncontrolled documents</td>
</tr>
<tr>
<td>Transportation</td>
<td>Distribution, multiple copies</td>
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<tr>
<td>Motion</td>
<td>Looking for documents</td>
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June '11  Lean ISO
ISO AND THE 8 WASTES

**LEAN**
- Waiting
- Inventory
- Underutilize people

**ISO**
- For revisions, approvals, locating documents
- Keeping lists and controlled copies, multiple locations for same document
- Not letting people determine the need for, content, and use of info
ISO AND THE LEAN TOOLS

LEAN
- 5S
- Standardized work
- POUS
- Quality at source
- Value stream mapping
- Quick changeover (SMED)
- Teams

ISO
- Lean out documentation & ISO processes
- Document and process control
- Information available where used
- Process control
- 4.1 General requirements
- Document control (SMED) Single Minute Exchange of Documents
- Interaction
ISO AND THE LEAN TOOLS

**LEAN**
- Layout
- Visual
- Batch reduction
- Pull /Kanban
- Cellular/flow
- TPM

**ISO**
- Document storage
- Document and process control
- Process flow
- Create only what is needed
- Write documents as flow, store by process
- Perform maintenance on QMS
Today's Objective 1 Part 2

Integrate lean practices with the QMS

- Processes & documents
- Objectives & measures
- System planning
- Management review
- Competency & infrastructure
- Production planning & control
- Internal audits
- Preventive actions
4.1 GENERAL REQUIREMENTS

- Determine processes,
- Determine sequence and interaction,
- Determine effectiveness and ensure control,
- Ensure availability of resources and information,
- Monitor, measure and analyze processes,
- Continually improve.
4.1 GENERAL REQUIREMENTS

- Make value steam mapping (VSM) a work instruction. Link to
  - Quality planning
  - CAPA
  - Management review

- Make 5S a work instruction. Link to
  - Process control
  - Quality planning
  - Internal auditing
  - CAPA
4.2.1.d DOCUMENTATION

- Include lean documents
  - Standard worksheets
  - Kanbans
  - 5S assessment forms
  - Job breakdown sheets
5.4.1 QUALITY OBJECTIVES

- Develop targets for future state value streams such as
  - Space required
  - Walking distance
  - Cycle time
  - Changeover time
  - First pass yield
  - Units per labor hour
- Avoid conflicts with other quality objectives.
5.4.2.b SYSTEM PLANNING

- Lean tools are valuable in planning
  - Value stream map
  - Kaizen event
  - Visual management
  - Gemba walks
5.5.1 RESPONSIBILITY AND AUTHORITY

- Define for
  - Kaizen team leader
  - Lean Champion
  - Value stream manager

- Include job descriptions
5.6.1 MANAGEMENT REVIEW

- Include in management review
  - Daily accountability meetings review parts of the system
  - Gemba walks by top management.

- Include
  - Lean metrics
  - Preventive action plans to eliminate waste
  - Review “lean” changes to sustain actions
6.2 COMPETENCY, TRAINING

- Audit lean training process for effectiveness.
- Integrate lean job breakdown (JB) sheets.
- Use standard work /work instructions.
6.3 INFRASTRUCTURE

- Use to sustain
  - 5S improvements
  - TPM efforts
7.1 PRODUCT REALIZATION (QUALITY PLANNING)

- Lean layout
- Value stream map
- Cellular/flow
- Use the automotive APQP – Advanced Product Quality Planning
- Consider A3
7.5.1.a,b PRODUCTION CONTROL

- Include
  - Kanban cards
  - Standard worksheets
  - Visual instructions
  - Job breakdown sheets
7.5.5 PRESERVATION OF PRODUCT

- Include
  - Kanban levels
  - Continuous flow
  - U-shaped cells
8.2.2.b INTERNAL AUDIT

- Schedule audits of lean processes and their improvements for effectiveness.
- Use to sustain improvements from “lean” actions.
- Train auditors to look for waste. Waste is not effective.
8.2.3 MONITORING AND MEASURING OF PROCESSES

- Monitor and measure waste.
- Supports visual management and lean culture.
- Helps sustain improvements.
8.5.3 PREVENTIVE ACTION

- PA forces root cause analysis (RCA)
- RCA not often done prior to lean activities.
- PA process requires verification of action taken to eliminate root causes of problems.
8.5.3 PREVENTIVE ACTION

- 7 of the 8 wastes are causes of potential nonconformances.
- Which one is not a potential cause of preventive action?
LEANING OUT ISO DOCUMENTATION
Today’s Objective 2

- Use lean tools to lean out documentation
  - 8 wastes
  - 5 S
  - Value Stream Maps (VSM)
  - Single Minute Exchange of Die (SMED)
KISS

- 10 Commandments: 297 words
- Bill of Rights: 463 words
- Gettysburg Address: 266 words
- Federal Directive to Regulate the price of cabbage: 26,911 words
- ISO 9001 QMS documentation
- See ISO section 4.2.1
Everything proceeds in the direction of disorder.

ISO documentation has a tendency to grow more and more.

Our ISO system becomes complex, lengthy, and un-user friendly.
Root Cause Analysis

- Old procedures no longer required.
- Redundancy in many documents.
- Procedures written in batch form.
- External auditor recommendations in the form of OPIs.
- Over interpretation of the requirements.
- Paragraphs instead of bullets or flowcharts.
- Procedures written in detailed “ISO-ese” to impress the external auditor.
ROOT CAUSE

- No control system to keep the QMS from getting out of hand.
USE 5S TO LEAN OUT THE DOCUMENTATION

- Sort
- Set in order
- Shine
- Standardize
- Sustain
GENERAL GUIDELINES

- Never repeat any requirement, procedure, specification, etc. Use references and links.
- Let process operators write procedures/instructions as they actually do them – in process flow. Not for external auditors.
- Reduce the number of procedures. Create only useful documents.
SORT – ELIMINATE WHAT IS NOT NEEDED

- Identify documents or parts of documents that are not used.
- “Red tag” the documents – create temporary folder.
- “Red line” the document contents.
- Start with the quality manual and procedures.
Most manuals duplicate the ISO 9001 standard.
Does anyone read it?
Is it value added?
How does it meet the requirements of ISO section 4.2.2?
4.2.2.a Page 1 In 4-5 paragraphs
- Introduction to the company
- Scope
- Justification for exclusions
- Quality policy

4.2.2b,c Page 2 In a flowchart
- Reference to documented procedures
- Interaction of procedures of the QMS.

Page 3 ?
SORT - PROCEDURES

- Check revision records. Procedures not revised for a “long time” may not be used.
- Documents that do not affect the quality of product, service, or process.
- Contain information only.
- Content is repeated in another document.
- Are “left over” from ISO 1994 and no longer required.
SORT-DOCUMENT SECTIONS

- Redundant paragraphs in the same or other documents.
- How to complete a form.
- Batched info rather than process flow, references, responsibilities, definitions.
- Sections not read.
- Info only or philosophy statements.
SORTING FORMS

- Multiple forms for the same process
- Similar forms with different titles
- Multiple forms with the same information.
SORT - ACTIONS TO TAKE

- Eliminate
- Combine with another document
- Rewrite for ..... (reason)
- Change format to work instruction, form, log, etc.
- Delete sections .....
SET IN ORDER – A PLACE FOR EVERYTHING

- Documents accessible in 2-3 mouse clicks
- Group documents by process rather than type. Link horizontally.
- Documents must be referred to in at least 1 other document.
- Use a logical numbering system. (Numbers are not required.)
SET IN ORDER

- Link procedures, work instructions, and forms and make it easy to trace back to each referencing document. Link vertically.

- Make it easy to find documents. Use titles, numbers can be confusing.
SHINE — KEEP IT CLEAN AND ORDERLY

- Make clearly legible – even in dirty areas – and in readable locations.
- Apply document control to lean documents.
- Use visual standards.
- Ensure documents tell what people really do.
SHINE – KEEP IT CLEAN AND ORDERLY

- Update processes as changes or improvements are made.
- Look for documents being used that are not controlled.
STANDARDIZE – MAINTAIN AND MONITOR

- Maintain the first 3 S’s.
- Make clear definition of
  - Procedure – tells who, what, when, where; involves many people and/or departments.
  - Work instruction – tells how; procedural steps; one person, one task. “to do the job.”
  - Training material – Used for training or reference, but not everyday use.
STANDARDIZE – MAINTAIN AND MONITOR

- Keep documents lean
  - Procedures format–
    - Purpose – why process exists, not why document exists
    - Scope – applies to, or does not apply to
    - Procedure – tell who with a verb; use if or when
    - Revision - latest revision only
STANDARDIZE – MAINTAIN AND MONITOR

- Keep documents lean
  - Avoid batches
    - Responsibilities
    - References
    - Definitions
  - Put these in the defined steps
STANDARDIZE – MAINTAIN AND MONITOR

- Keep documents lean (con’t)
  - Procedure guidelines
    - Three pages or less
    - Avoid redundancy within or between docs
    - Do not attach forms
    - Make forms self-explanatory
    - Refer to other docs at point of use
    - Electronically link
STANDARDIZE – MAINTAIN AND MONITOR

- Keep documents lean (con’t)
  - Work instructions
    - One task, one person, one page steps only
    - Procedural steps only – start with a verb
    - Latest revision only
    - Avoid redundancy within or between docs
    - Refer to other docs at point of use
    - Electronically link
STANDARDIZE – MAINTAIN AND MONITOR

- Use Microsoft Office capabilities.
- Do not duplicate in other “lean” documents, e.g., combination work sheets (CWS) or job breakdown sheets (JBS.)
- Limit access to make changes.
- If using hard copies, standardize their organization.
- Simplify user access to documents. Titles are easier than numbers.
- Standardize desk top access.
SUSTAIN - DISCIPLINE

- Quality and lean must work together to sustain the lean documentation.
- When adding a new document, check for redundancy in existing ones.
- Conduct 5S repeatedly – part of internal audits or process control.
- Make 5S a work instruction. Link to CAPA, internal audits, process control, management review.
REMOVING WASTE FROM THE QUALITY MANAGEMENT SYSTEM
Today’s Objective 3

- Show how to lean out QMS processes
  - Continual improvement
  - Document change control
  - Document structure – files and folders
  - Records control
  - Management review
  - Corrective & preventive action (CAPA)
  - Internal auditing
REMOVE WASTE IN CONTINUOUS IMPROVEMENT PROCESSES

- Many processes with separate leaders/managers, separate departments, and separate goals.
  - Six Sigma
  - Lean
  - ISO
  - Theory of Constraints
  - Balanced Scorecard
  - TQM
  - Innovation Engineering
REMOVE WASTE IN CONTINUAL IMPROVEMENT PROCESSES

- All trying to do the same thing, improve processes and products.
- Competition or collaboration?
- Who gets the credit?
- Processes and measures not aligned.
- Causes waste and confusion.
- Increases costs.
REMOVE WASTE IN DOCUMENT CHANGE CONTROL

- As a result of lengthy approval process
  - System is circumvented
  - System is seen as bureaucratic
  - State of limbo exists
  - People look for reasons to not control documents
    - For reference only
    - Training document
    - Lean document
Why does it take so long? RCA

- Many approvals take time
- No measure of how long it takes
- No goal set for time spent
- Not a priority
- Paper trail approvals
DOCUMENT APPROVAL

- Process owner or value stream manager
- Management representative

That’s it!

- Multiple approvals create waste
- Risk rubber stamping
REMOVE WASTE IN DOCUMENT CHANGE CONTROL

- Improve the process
  - Value stream map and identify
    - Value-added steps
    - Non-value-added steps
REMOVE WASTE IN DOCUMENT CHANGE CONTROL

- SMED
  - Preparation, after approval changes, check existing docs.
  - Changing words, paragraphs, revision record, etc.
  - Review and approval
  - Post training modifications to docs.
REMOVE WASTE IN DOCUMENT & RECORDS CONTROL

- Wall Street Journal
  - People spend 18-36 days a year looking for correct information to do their jobs

- New York Enterprise Report
  - Executives spend six weeks per year looking for misplaced information

- New York Times
  - People spend 10 weeks per year rifling through messy desks.
REMOVE WASTE IN RECORDS CONTROL

- Why? Excess inventory of records
  - Maintain both paper and electronic copies
  - Double entry of data
    - Use electronic storage if possible
  - Records not destroyed as indicated – “minimum retention”
    - Delete/destroy records - 5S?
  - Employees keep additional copies
    - Find out why
  - All records treated equally
    - Confidential, classified, just information
  - No one is responsible or accountable for deleting them
    - 5S or audit storage areas and file cabinets
REMOVE WASTE IN RECORDS CONTROL

- Separate files into
  - Working
  - Reference
  - Archive
- Disposition items in the in box once you read it
- Empty the out box every day
REMOVE WASTE IN RECORDS CONTROL

- Master lists
  - Combine master list of forms and records into one spreadsheet list.
  - Spreadsheet can also serve as the required procedure.
REMOVE WASTE IN MANAGEMENT REVIEW

- Often done as one big batch – see 5.6.2
- Misconceptions
  - Inputs have to be addressed at the same time
  - Inputs have to be addressed at the same frequency
  - The review must be a meeting
  - No other topics should be covered
  - Some topics may have to be covered elsewhere and at the review.
REMOVE WASTE IN MANAGEMENT REVIEW

- An effective management review (MR) process should ensure effectiveness of CAPA and internal audits.
- Review other meetings for MR items covered.
- Lean daily accountability meetings may address MR topics.
- Record minutes, avoid double entry.
- Record decisions and actions.
- Use the same minute form for all meetings.
The most important process

Results may not provide real improvements

Often seen as a “pain in the neck”

Forms hastily completed

Actions not effective
REMOVE WASTE IN (CAPA) CORRECTIVE/PREVENTIVE ACTIONS

- Use the same procedure and forms for both corrective and preventive action.
- Combine ISO and lean forms – e.g., Waste Walk and CAPA.
- Combine CAPA and six sigma forms, Continual Improvement Request?
- Remove old forms
REMOVE WASTE IN (CAPA) CORRECTIVE/PREVENTIVE ACTIONS

- Standardize terms.
  - Observation
    - Avoid term
    - Requires no action
  - Opportunity for improvement
    - A preventive action
    - Requires action
Use preventive action to eliminate waste.
- Forces RCA
- Effectiveness of action is verified.

Manage timely completion of CAPA
- Provide visibility for time lines
- Send e-mail reminders and overdue notices to assignee and supervisor/manager.
- Discuss in meetings.
REMOVE WASTE IN (CAPA) CORRECTIVE/PREVENTIVE ACTIONS

- Downsize paperwork.
  - Consider access database
  - Database can serve as procedure and walk the user through the process.
8.2.2.b INTERNAL AUDIT

- Integrate with gemba walks
  - Seeing waste
  - Following the process
  - Becoming coaches – ask questions
  - Walking regularly (weekly)
  - Follow up on assigned actions
  - Include all levels of management
8.2.2.b INTERNAL AUDIT

- Integrate layered process audits (LPA,) gemba walks and internal auditing.
  - Charts
  - Action lists
  - Communications
  - Lean workplace organization
    - 6.3 infrastructure
    - 6.4 work environment
REMOVE WASTE IN INTERNAL AUDITING

- Do process auditing – follow the process steps.
- Avoid batch auditing.
- Refer to the CAPA procedure and use CAPA form for findings.
- Avoid double entry of info – use 1 form.
REMOVE WASTE IN INTERNAL AUDITING

- Provide competent auditors
- Set auditing objectives and measure effectiveness.
  - Train
  - Retrain
  - Evaluate competence
Today’s Objectives

View Quality Management System (QMS) and Lean practices as complementary forces.

1. Integrate Lean practices and the QMS.
2. Use Lean tools to lean out the documentation.
3. Show how to lean out QMS processes.
Make More Money!!

- Capitalize on the strengths and counteract the weaknesses of both Lean and QMS initiatives.
- Recognize the synergy of combining both.
- Control operations and ensure discipline to adhere to improved processes.