Adopting quality engineering best practices

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ANSI/ISO/ASQ 9000

The ISO 9000 family addresses various aspects of quality management and contains standards and tools for companies and organizations who want to ensure that their products and services consistently meet customer’s requirements, and that quality is consistently improved.
Process Design

Start → Establish Process → Identify Failures → Analyze Effects → Reduce Risk → Document Validate Release
Ishikawa’s Fundamental Tools of Quality

1. Flowcharts
2. Pareto charts
3. Cause/effect diagrams
4. Control charts
5. Check sheets
6. Scatter diagrams
7. Histograms

“as much as 95 percent of all quality-related problems in the factory can be solved with seven fundamental quantitative tools.”

- Kaoru Ishikawa
Process Mapping (Flow Charts)

Goals of process mapping:

- Communications will be understood
- All information and resources for procedure are ready
- That all know who does what when
- All training has been completed
Process Mapping Steps

1. Establish flowchart/map purpose
2. Define map boundaries
3. Observe process
4. Establish gross process flow
5. Develop map details
6. Check for validity/completeness

Additional Resources


asq.org/learn-about-quality/process-analysis-tools/overview/flowchart.html
Failure Identification

Once the procedure is known, walk through each step and identify failures. Common tools include:

• Fault trees
• Activity network diagrams
• Check sheets
• Pareto charts
Fault Trees

Fault trees help people discover, visualize, and communicate logical hierarchical relationships between critical events or objectives.

- Use logical operators, such as AND or OR gates, to connect lower-level events with higher events.
- Once the logic has been described, quantification can take place and risk level assessed.
Fault Trees

• A fault tree does not contain all possible failure modes or all possible fault events that could cause system failure

• Fault trees are capable of considering/modeling human error, hardware and software failures, and environmental causes

• Top level issues typically go into FMEA/FMECAs, while lower levels help identify occurrence probability and opportunities for QA/QC
Activity Network Diagrams

ES: Earliest starting time
EC: Earliest completion time
LS: Latest starting time
LC: Latest completion time

ES, EC, LS, LC

A: Activity

$t$: Activity duration

Critical path

Milestone activity
Process Capacity

- Higher variability processes slow down faster
- Reducing variability (to be discussed later) will improve process capacity
Effects Analysis

During the design phase of the process, it is important to identify potential failures and their causes to eliminate critical failures. Common tools include:

- FMEA
- FMECA
- HAZOP
FMEA/FMECA

• A Failure Mode and Effects Analysis (FMEA) is a process used to detail what errors can occur and what effects they can cause

• Various failures and causes are compared by ranking the occurrence probability, severity, and detection probability

• The product of all three values is the Risk Priority Number (RPN)

• FMECA includes a criticality analysis, the product of occurrence and severity
FMEA Standards and Resources

- Military Standard: MIL-STD 1629A
- Society for Automotive Engineers Standard: SAE J1739
- The Joint Commission: www.jointcommission.org
- Institute for Healthcare Improvement (IHI): www.ihi.org
- AAPM Task Group 100: www.aapm.org
Sample FMEA Form

<table>
<thead>
<tr>
<th>Process function</th>
<th>Potential failure mode</th>
<th>Potential effect(s) of failure</th>
<th>Severity (S)</th>
<th>Class (C)</th>
<th>Potential cause(s)/mechanism(s) of failure</th>
<th>Occurrence (O)</th>
<th>Current process controls</th>
<th>Detectability (D)</th>
<th>RPN</th>
<th>Recommended action(s)</th>
<th>Responsibility and target completion date</th>
<th>Action results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Requirements</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Actions taken</th>
<th>Specify</th>
<th>Design</th>
<th>R. P. N.</th>
</tr>
</thead>
</table>

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Scale Recommendations

- The scale range should be appropriate for the process being evaluated.
- The scale must not vary between failure modes or between individuals.
- When data is less available, scores become more biased by individuals.
- When bias occurs, consider normalization (range scaling, rank-order, etc.)

[Diagram: How worried should you be when various things happen to you?]
Risk Discretization

- Often occurrence and detection are a function of severity
- Try to discretize the distribution as much as possible given the data available
- Consider (at minimum) both the highest severity and highest overall RPN
Palady’s Strategy for FMEA Action

1. Eliminate the occurrence
2. Reduce the severity
3. Reduce the occurrence
4. Improve detection

<table>
<thead>
<tr>
<th>Failure</th>
<th>S</th>
<th>O</th>
<th>D</th>
<th>RPN</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>2</td>
<td>10</td>
<td>5</td>
<td>100</td>
</tr>
<tr>
<td>B</td>
<td>10</td>
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<td>5</td>
<td>100</td>
</tr>
<tr>
<td>C</td>
<td>2</td>
<td>5</td>
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<td>100</td>
</tr>
<tr>
<td>D</td>
<td>10</td>
<td>5</td>
<td>2</td>
<td>100</td>
</tr>
</tbody>
</table>

FMEA Conundrum

What order should these failures be addressed?

SOD Coding Strategy

- A 1-10 scale of S, O, and D only yields 120 possible combinations that are not evenly distributed
- Prioritize failure modes by sorting first by severity, then occurrence, then detectability

Common Deficiencies of FMEAs

- Only as effective as the team’s understanding of the process
- Highlight the highest risks, not the “lowest hanging fruit”
- It is difficult to keep one from getting unmanageably large
- RPNs will not tell you how safe your process is, only how much you are relatively impacting your risk by implementing changes
- An FMEA is not static; it must be repeated after making changes
Risk Reduction Techniques

The preventing faults is accomplished by:

1. Eliminating progenitor causes
   (consider AND/OR gates)

2. Interrupting the propagation
   (add QA/QC)
Risk Reduction Techniques

• Find common faults (i.e. operator error)
• Correct any environmental problems (inexpensive and effective)
• You can never eliminate human error except by eliminating the humans
• Design the process to be *resilient* to human error
Core Components of AAPM TG 100

1. Standardized procedures
2. Adequate training of staff
3. Maintenance of hardware and software
4. Clear lines of communication among staff
5. Adequate resources to perform the job

“Redundancy is not useless duplication”
- Robert Loevinger

“Useless duplication is not redundancy”
- Bruce Thomadsen

## ISMP Order of Effectiveness

<table>
<thead>
<tr>
<th>Type of Action</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Forcing Functions and Constraints</td>
<td>Interlocks, barriers, computerized order entry with feedback</td>
</tr>
<tr>
<td>2. Automation and Computerization</td>
<td>Bar codes, automated monitoring, computerized entry without feedback</td>
</tr>
<tr>
<td>3. Standard procedures and protocols</td>
<td>Checklists, alarms, labels, signs, established communication/escalation pathways</td>
</tr>
<tr>
<td>4. Independent check systems/redundancies</td>
<td>Redundant measurements, independent review</td>
</tr>
<tr>
<td>5. Rules and Policies</td>
<td>Staffing/scheduling, time outs, preventative maintenance inspections, equipment QA</td>
</tr>
<tr>
<td>6. Education and Training</td>
<td>Training, experience</td>
</tr>
</tbody>
</table>

Quality Controls and Assurance

• Quality control and assurance actions are added to a process to reduce risk

• Quality controls focus on reducing the occurrence probability

• Quality assurance increases the detection probability
QA or QC?

- QC typically requires more resources
- QA detection adds time to a procedure as the process must be repeated
- If you are catching many error with QA, move resources to QC
- If you are not picking up error with QA, question its utility or change frequency

Frequency of Errors Caught in Radiotherapy

Ford (2012). IJROBP 84: e263-9
QA Frequency

- QC is conducted every time a procedure is performed.
- QA frequency can vary based on accepted level of risk (FMEA, inspection sampling theory, etc.).
- Full time QA can be considered QC for the downstream process.

Operating Characteristic Curve

- $N = \text{number of runs}$
- $n = \text{frequency of QA}$
- $c = \text{number of QA measurements that are allowed to fail}$
Quality Control Checklists

- Checklists reduce the risk of slips or omissions in a process
- Avoid too much detail; users will "check through" too quickly
- Adding form input to high risk steps causes user to pause, validate
- Checklist should be physical or digital

Additional Resources


Checklist Design

**Poor**

(a) **PRE-INCISION**

(b) □ CHECK BLOOD PRESSURE

(c) □ ALLERGIES?

(d) □ CHECK PULSE

(e) □ CHECK MEDICATION

(f) USE (IF YES, SEE CHECKLIST PAGE c-112)

(g) □ VERIFY SITE, IDENTITY, PROCEDURE, CONSENT

**Improved**

(a) **BEFORE INCISION**

All items must be verbally verified by patient and nurse

(b) □ Patient has confirmed:

- Site
- Identity
- Procedure
- Consent

(c) □ Site marked or not applicable

Allergies

- Yes (list) __________
- No

(d) □ Pulse oximeter in place and working
Statistical Process Control

- SPC is quantitative problem solving, consisting of diagnostic techniques to assist in locating problem sources and prescriptive techniques to help solve problems.
- Control charts are commonly used to compare a measurement to a defined Lower (LCL) and Upper Control Limit (UCL).
- Control limits are either defined using dataset range or variance.
Range Control Chart Example

CBC Turnaround (min) in an ER

<table>
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<tr>
<th>Day</th>
<th>$x_1$</th>
<th>$x_2$</th>
<th>$x_3$</th>
<th>$x_4$</th>
<th>$\bar{x}_i$</th>
<th>$R_i$</th>
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<td>93</td>
<td>80.25</td>
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</tr>
</tbody>
</table>

$\bar{x} = 71.39$ \hspace{1cm} $\bar{R} = 27.05$

Control Charts for Mean and Range

\[ UCL = \bar{x} + A_2\bar{R} = 71.39 + 0.729(27.05) = 91.11 \]
\[ CL = \bar{x} = 71.39 \]
\[ LCL = \bar{x} - A_2\bar{R} = 71.39 - 0.729(27.05) = 51.67. \]
Attribute Control Charts (p-charts)

### Surgical Site Infection Rates

<table>
<thead>
<tr>
<th>Month</th>
<th>Surgeries</th>
<th>Surgical infection</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>57</td>
<td>8</td>
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<tr>
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<tr>
<td>12</td>
<td>69</td>
<td>5</td>
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</tbody>
</table>

### Control Chart for Infection Probability

\[
\text{UCL} = n\bar{p} + 3\sqrt{n\bar{p}(1 - \bar{p})} \\
\text{CL} = n\bar{p} \\
\text{LCL} = n\bar{p} - 3\sqrt{n\bar{p}(1 - \bar{p})}.
\]
Rules for Determining Process Control

1. One point more than $3\sigma$ from the centerline (either side)
2. Seven points in a row on one side of the centerline
3. Six points in a row, all increasing or all decreasing
4. Fourteen points in a row, alternating up and down
5. Two out of three points more than $2\sigma$ from the centerline (same side)
6. Four out of five points more than $1\sigma$ from the centerline (same side)
7. Fifteen points in a row within $1\sigma$ of the centerline (either side)
8. Eight points in a row more than $1\sigma$ from the centerline (either side)

Process and Performance Capability

$C_p$ compares the tolerance (the width of the engineering specifications) with the natural process tolerance. Given Lower (LSL) and Upper Specification Limits (USL):

$$\hat{C}_p = \frac{USL - LSL}{6\sigma}$$
Other Process Capability Indices

1. $C_r$ is the inverse of $C_p$

2. $C_{pk}$ penalizes a process who’s mean is off center:

   $\hat{C}_{pk} = \min \left[ \frac{USL - \bar{x}}{3\hat{\sigma}}, \frac{\bar{x} - LSL}{3\hat{\sigma}} \right]$

3. $C_{pm}$ also considers deviation from a target $T$:

   $\hat{C}_{pm} = \frac{USL - LSL}{6[\hat{\sigma}^2 + (\bar{x} - T)^2]}$
Out of Control Processes

- If the process is out of control, or the true process variance $\sigma^2$ is unknown, the same indices can be used by replacing $\sigma^2$ with the sampled variance $s^2$
- The process index names change from $C_{pk}$ to $P_k$, etc.
Six Sigma

6σ is not a standalone method; rather, it combines the 6σ business strategy with existing quality tools, DMAIC, with the goal of achieving 6σ metrics:

- Process capability indices of $C_p < 2.0$ and $C_{pk} < 1.5$
- 3.4 errors per million opportunities
Six Sigma Metrics

Key References


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