PREVENTING MEDICAL DEVICES RECALLS

Dev Raheja
Product Assurance Consultant
Laurel, Maryland 20708

draheja@aol.com
Outline
Issues in Medical Device Safety
Examples of medical device failures
Improving reliability-the right way
Writing good specifications
Using risk analysis tools
Design for reliability
Design improvement techniques
Process FMEA to design out manufacturing problems
Validation testing
Issues in Medical Device Safety

Adverse Event is not an option

Damage done to patients is very serious

The costs of product recall are enormous
SOURCES OF ERRORS

- Errors in component (30%)
- Errors in product's specification description (60%)
- Product's specification modification (6%)
- Others (4%)

Target items of specification verification
Examples of Device Failures

Wrong dose of radiation
Memory chip failure in the diffusion pump
Faulty leads in defibrillators
Inaccurate results from MRI
Delivering too much radiation
Pacemaker failures in shopping center from the cashier device
Improperly sanitized surgical tools
Maintenance errors on devices
False negatives or positives on lab equipment
Plastic intravenous tubes containing toxic BPA
Device mislabeling
Improving reliability—the right way

- No adverse event goal
- No failure during medical interventions
- No harm to patients
Writing good specifications

Cross functional team
Every team member must challenge the specification to identify missing functions
Conduct negative requirements analysis to identify more missing requirements
Negative Requirements Analysis

• Negate Functions

• Negate Procedures

• Negate performance of critical components
ISO 14971 – Risk Management standard

Preliminary Hazard Analysis
Failure Mode and Effects Analysis
Fault Tree Analysis
HAZOP
HACCP
Design for Reliability (DFR) is a process. If the right process is not followed, results cannot be depended upon to be right.

• Important to get customers involved: They tell us what we don’t know
HOW?

Design for
Twice the Life For Devices
such as the Ventilator assist device

Design For
Fallback Modes
such as
alarms, barriers
Design for Twice the Life is Cheaper!

No warranty costs
Often no testing is needed

No Maintenance
Increased market share
Over 60% reduction in testing
This Life Cycle Costing method is useful in every situation. Let us apply this principle to making decisions on a process selection for higher quality.

Suppose the design engineers gave us a blueprint of a gear, press fit on a shaft, and a weld holds the two together. This is shown in the diagram below.
Design Improvement Techniques

- Predict and eliminate safety failures
- Predict and eliminate design failures
- Predict and eliminate software failures
- Predict and eliminate maintenance failures
- Use human-centered design to counter human errors
World Class Benchmarks for Medical Devices

**Cooper Industries:** Double market share with 15 year warranty

**Toyota:** Prove technology before selling

**Hyundai:** Let long warranty drive business

**Corning:** No tolerance for hidden failures

**Gillette:** Attention to quality at Board level
The Paradigms For Design Improvement

• **Paradigm 1:** Spend Significant Effort on Requirement Analysis

• **Paradigm 2:** Critical Failure is Not an Option for Medical Devices

• **Paradigm 3:** Measure Reliability by Life Cycle Costs
The Paradigms For Design Improvement

• Paradigm 4: Don’t Just Design for Reliability, Design for Durability

• Paradigm 5: Design for Prognostics to minimize surprise failures
Process FMEA to design out manufacturing problems

This analysis is applied to all the processes. The first step is to develop a flowchart for a process so we understand the process. Each block in the flowchart is treated as a component. Then a table similar to Design FMEA is constructed.
CONTROL PANEL PROCESS
FMEA
<table>
<thead>
<tr>
<th>Process Description</th>
<th>Process Function</th>
<th>Failure Mode</th>
<th>Causes</th>
<th>Effects</th>
<th>SEV</th>
<th>FREQ</th>
<th>DET</th>
<th>RPN</th>
<th>Recommended Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procure zinc plated plastic panel</td>
<td>Provide conductive surface</td>
<td>Plating may not adhere to plastic surface completely</td>
<td>Dirty parts during plating process</td>
<td>Product malfunction</td>
<td>7</td>
<td>3</td>
<td>10</td>
<td>350</td>
<td>Use carbonized plastic instead of platingl.</td>
</tr>
<tr>
<td>Mount fuel gage</td>
<td>To provide fuel reading</td>
<td>Cage may be mounted upside down</td>
<td>Operator error</td>
<td>Customer will need to send product for repair</td>
<td>7</td>
<td>2</td>
<td>2</td>
<td>28</td>
<td>Design the mounting holes in different sized so the gage cannot be mounted wrong.</td>
</tr>
<tr>
<td>Assemble function indicators</td>
<td>To snap in lamp cover in proper sequence</td>
<td>Cover installed in wrong sequence</td>
<td>Operator error</td>
<td>Customer confused and gets false indications</td>
<td>8</td>
<td>4</td>
<td>2</td>
<td>64</td>
<td>Silk screen letters on the panel instead of lamp cover.</td>
</tr>
<tr>
<td>Install warning lights</td>
<td>To install warning light in proper location</td>
<td>Warning light cover interchanged with caution lamp cover</td>
<td>Operator error</td>
<td>Customer may not get warning</td>
<td>9</td>
<td>2</td>
<td>2</td>
<td>36</td>
<td>Choose different size socket for warning light.</td>
</tr>
<tr>
<td>Make wiring connections</td>
<td>Provide electrical circuit</td>
<td>Wired wrong</td>
<td>Operator error</td>
<td>Product functioning improperly</td>
<td>8</td>
<td>4</td>
<td>10</td>
<td>320</td>
<td>Design harness assembly.</td>
</tr>
</tbody>
</table>

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Design Validation

Probability of Failure

10 Years

20 Years
DURABILITY GOALS
Manufacturing Influence

Probability of Failure

10 Years  20 Years

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To compete, we require revolutionary change.
NEW DEVELOPMENT

• FDA has introduced a Unique Device Identification system

• Manufacturers are required to label devices with a new device ID each time there is a major engineering change

• The label must include Production ID linked to serial numbers
SUMMARY

• Must develop robust product specifications

• Must conduct Negative Requirements Analysis

• Must use all the ISO 14971 risk analysis tools

• Must eliminate all the foreseeable harm to users