PREVENTING MEDICAL DEVICES RECALLS

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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

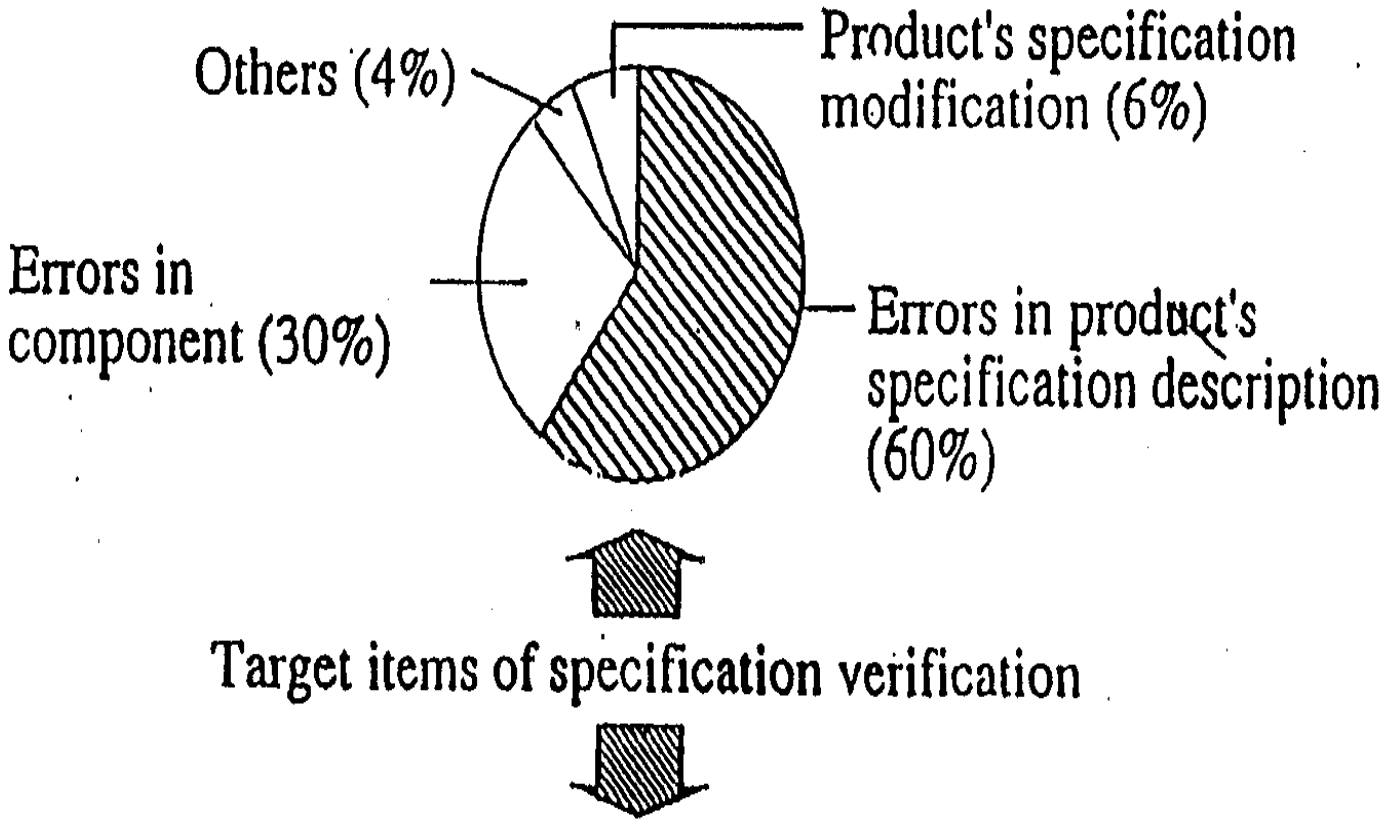
Issues in Medical Device Safety

Adverse Event is not an option

Damage done to patients is very serious

The costs of product recall are enormous

SOURCES OF ERRORS



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

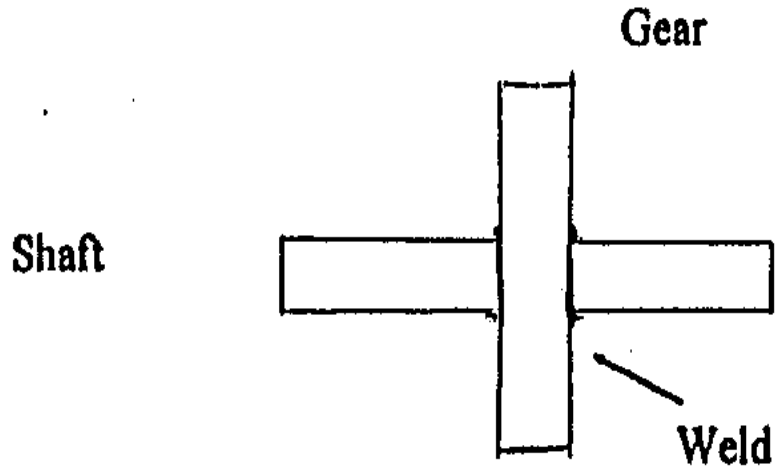
Over 60% reduction in testing

HIGH RELIABILITY COMES AT LOWER PRICE

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 blue print of a gear, press fit on a shaft, and a weld holds the two together. This is shown in the diagram below.

Gear/shaft assembly



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 with15 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

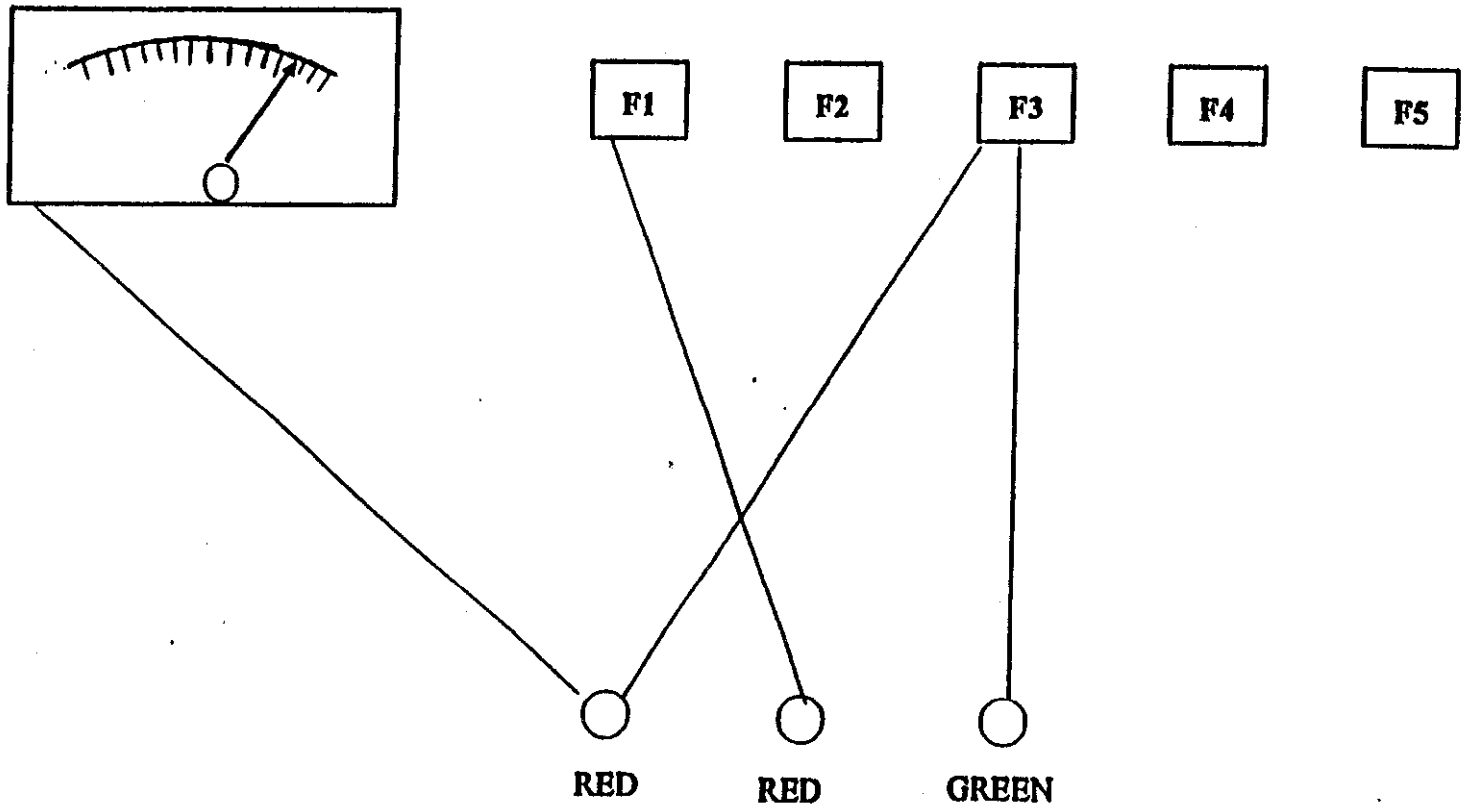
- ***Paradigm 4: Don't Just Design for Reliability, Design for Durability***

- ***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



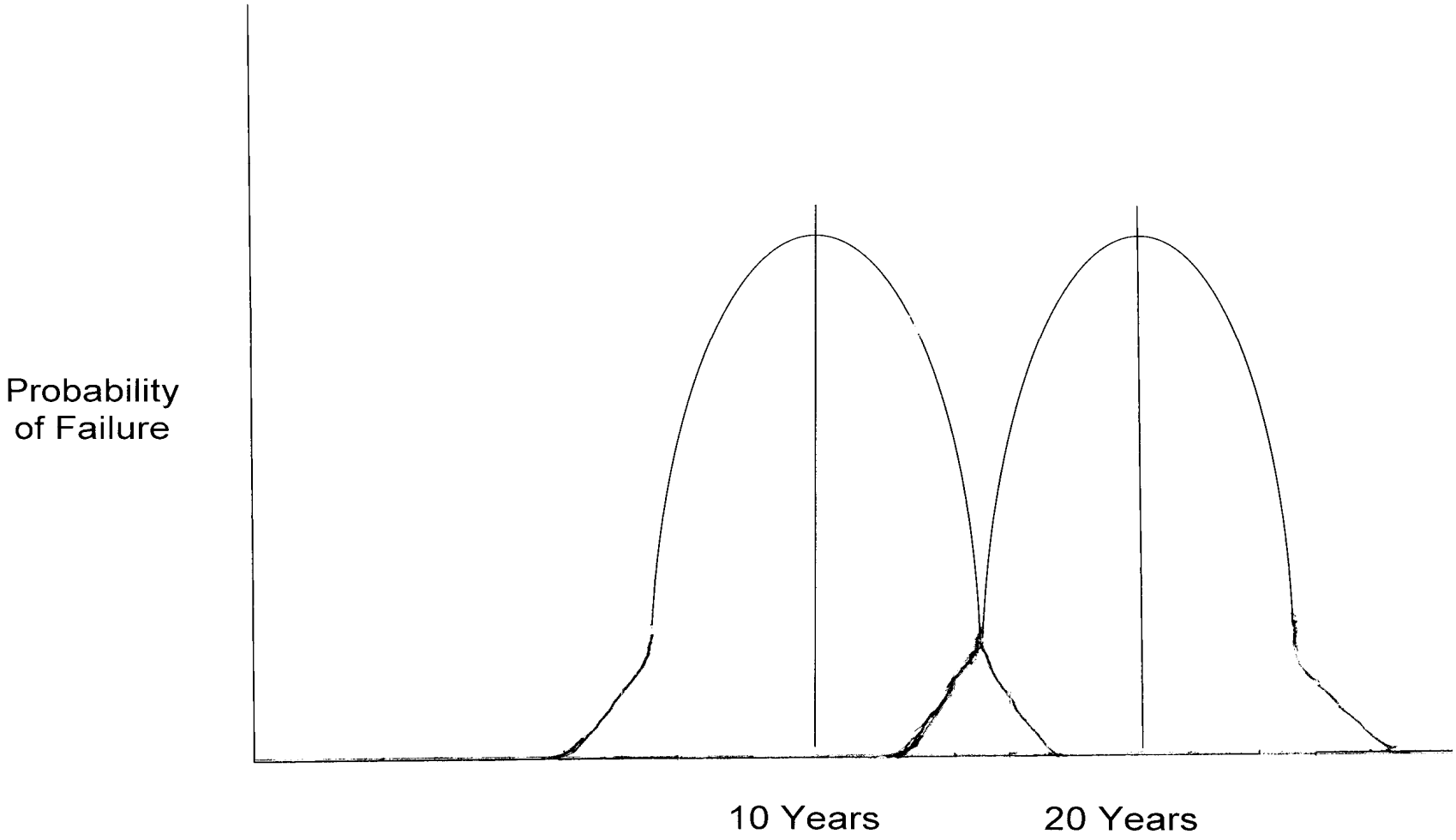
PROCESS FMEA

Product *Panel Assembly Process* Date _____

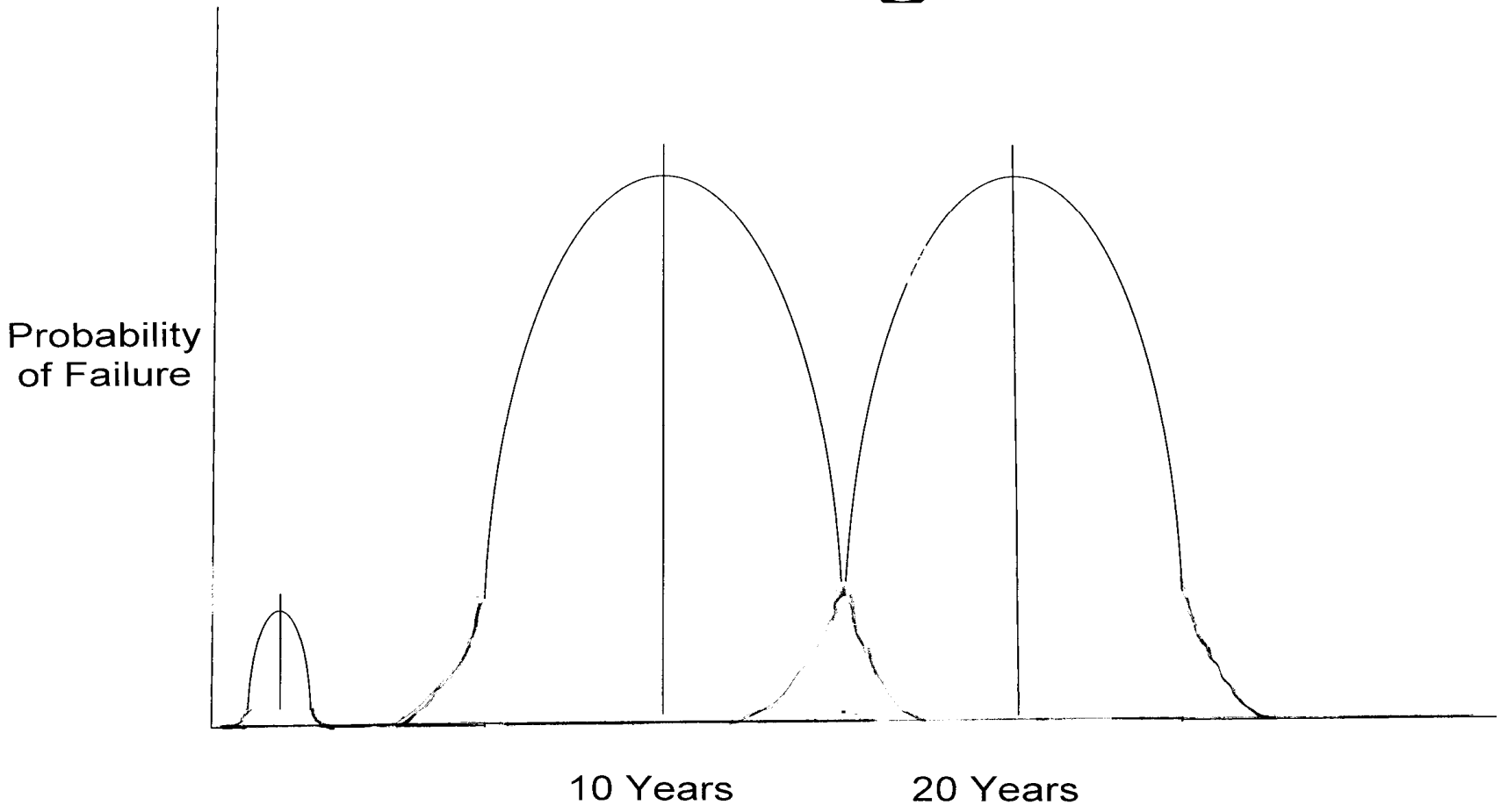
Team Members _____ Page of

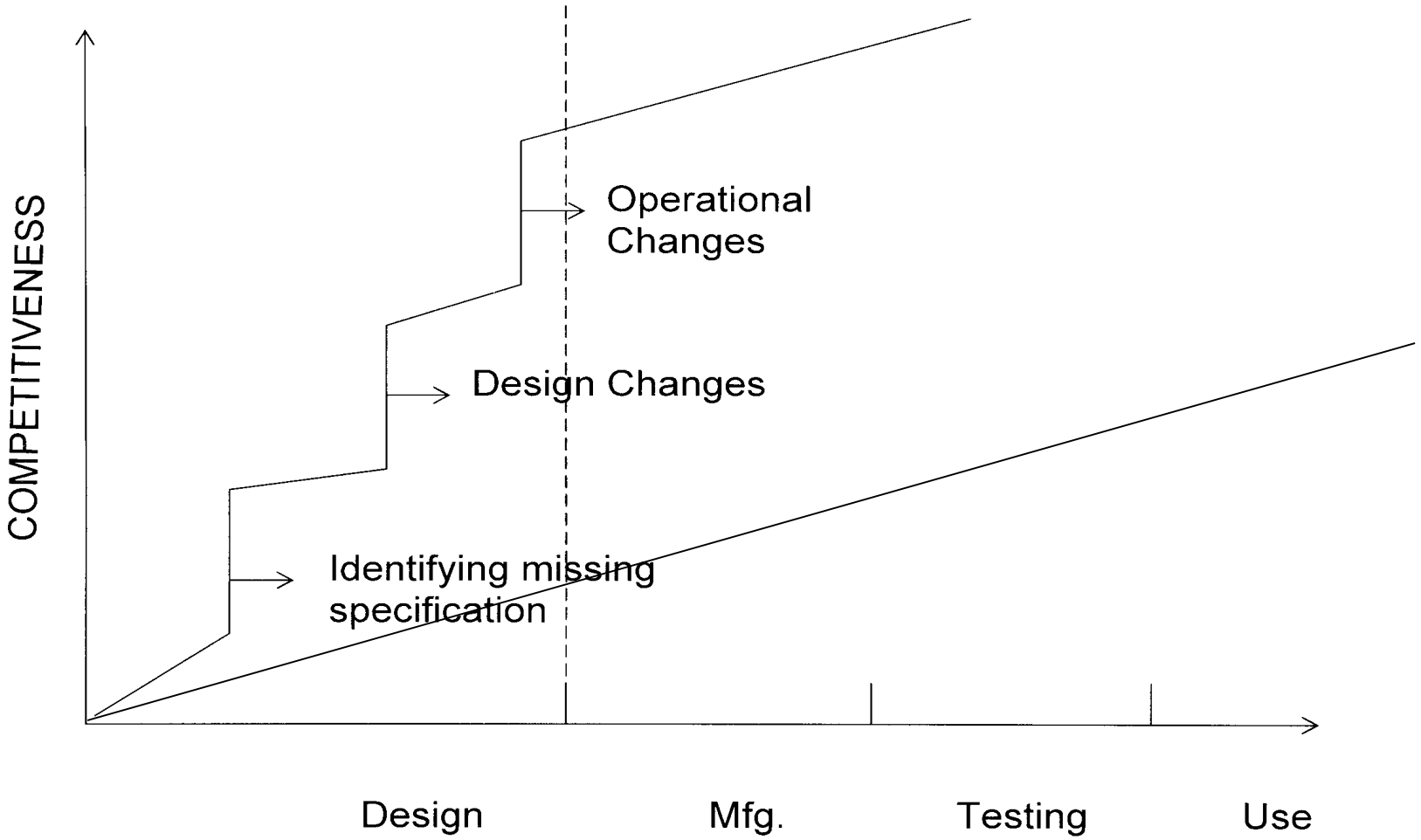
Process Description	Process Function	Failure Mode	Causes	Effects	SEV	FREQ	DET	RPN	Recommended Control
Procure zinc plated plastic panel	Provide conductive surface	Plating may not adhere to plastic surface completely	Dirty parts during plating process	Product malfunction	7	3	10	350	Use carbonized plastic instead of platingl.
Mount fuel gage	To provide fuel reading	Cage may be mounted upside down	Operator error	Customer will need to send product for repair	7	2	2	28	Design the mounting holes in different sized so the gage cannot be mounted wrong.
Assemble functon indicators	To snap in lamp cover in proper sequence	Cover installed in wrong sequence	Operator error	Customer confused and gets false indications	8	4	2	64	Silk screen letters on the panel instead of lamp cover.
Install warning lights	To install warning light in proper location	Warning light cover interchanged with caution lamp cover	Operator error	Customer may not get warning	9	2	2	36	Choose different size socket for warning light.
Make wiring connections	Provide electrical circuit	Wired wrong	Operator error	Product functioning improperly	8	4	10	320	Design harness assembly.

Design Validation



DURABILITY GOALS
Manufacturing Influence




COMPETITIVENESS
Operational
Changes
Design Changes
Identifying missing
specification
Design
Mfg.
Testing
Use

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**