# Medical Device Risk Management

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# Talking points

What are the key areas where we employ medical device risk management?

How has the program resulted in safer medical devices?

What are some lessons learned?

How we used ISO 14971 2nd edition to improve our Risk process.

# What is Risk Management

…The systematic application of management policies, procedures and practices for analyzing, evaluating and controlling risk.

It is a key component of the quality system and is a requirement in the implementation of design controls.

# Definitions

| | |
|---|---|
| Harm: | Physical injury or damage to health, property, or the environment. |
| Hazard: | A potential source of harm. (e.g., sharp object, electrical shock, loss of data…etc.) |
| Hazardous Situation: | Circumstance in which people, property or the environment are exposed to one or more hazard(s) |
| Risk: | Combination of the probability of occurrence of harm and the severity of that harm |

# Definitions

| | |
|---|---|
| Residual Risk: | Risk remaining after risk control measures have been taken |
| Risk Analysis: | Systematic use of available information to identify hazards and estimate the risk |
| Risk Evaluation: | Process of comparing the estimated risk against given risk criteria to determine the acceptability of the risk |
| Risk Assessment: | Overall process comprising a risk analysis and a risk evaluation. |
| Safety: | Freedom from unacceptable harm |

# Definitions

| | |
|---|---|
| Risk Management Plan: | A “product” document describing the risk management activities for the product throughout the life-cycle. |
| Risk Assessment Control Document: | A “product” document containing the results of the Identification of Hazards, risk assessment, risk control and verification activities. |
| Risk Management Summary: | A high-level “product” document that contains a summary of hazards to monitor in post-production & any residual risks. |

# Definitions

| | |
|---|---|
| Risk Management File (RMF): | The Risk Management File (RMF) consists of the records and other documents that are produced by the risk management process for the particular medical device or accessory being considered. The RMF is a subset of the DHF. |
| Severity: | Measure of the possible consequences of a hazard. (Catastrophic, Critical, Serious, Minor) |

# What can Risk Management do for a company?

## We believe it will

- Increase the probability of getting it right the first time by anticipating risks and managing them appropriately
  - If done correctly, this leads to products that are safe and effective
- Reduce field actions by developing more reliable robust products and improving both corrective and preventive actions
  - Less time spent on fixing the product and more time spent on continuous improvement - the fun stuff!
- Improve the efficiency of changes to equipment and processes by ensuring that critical attributes are validated
  - i.e. key risks are managed
- It is a company's knowledge reservoir

# Risk Management in a Quality System

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## Creating a process

- ISO 14971 2nd – Risk Management for Medical Devices
- ISO 13485 – Quality System for Medical Devices
- Product standards (alarms, PEMS, 60601-1 3rd )
- GHTF/SG3/N15R8 – Implementation of risk management principles and activities within a Quality Management System

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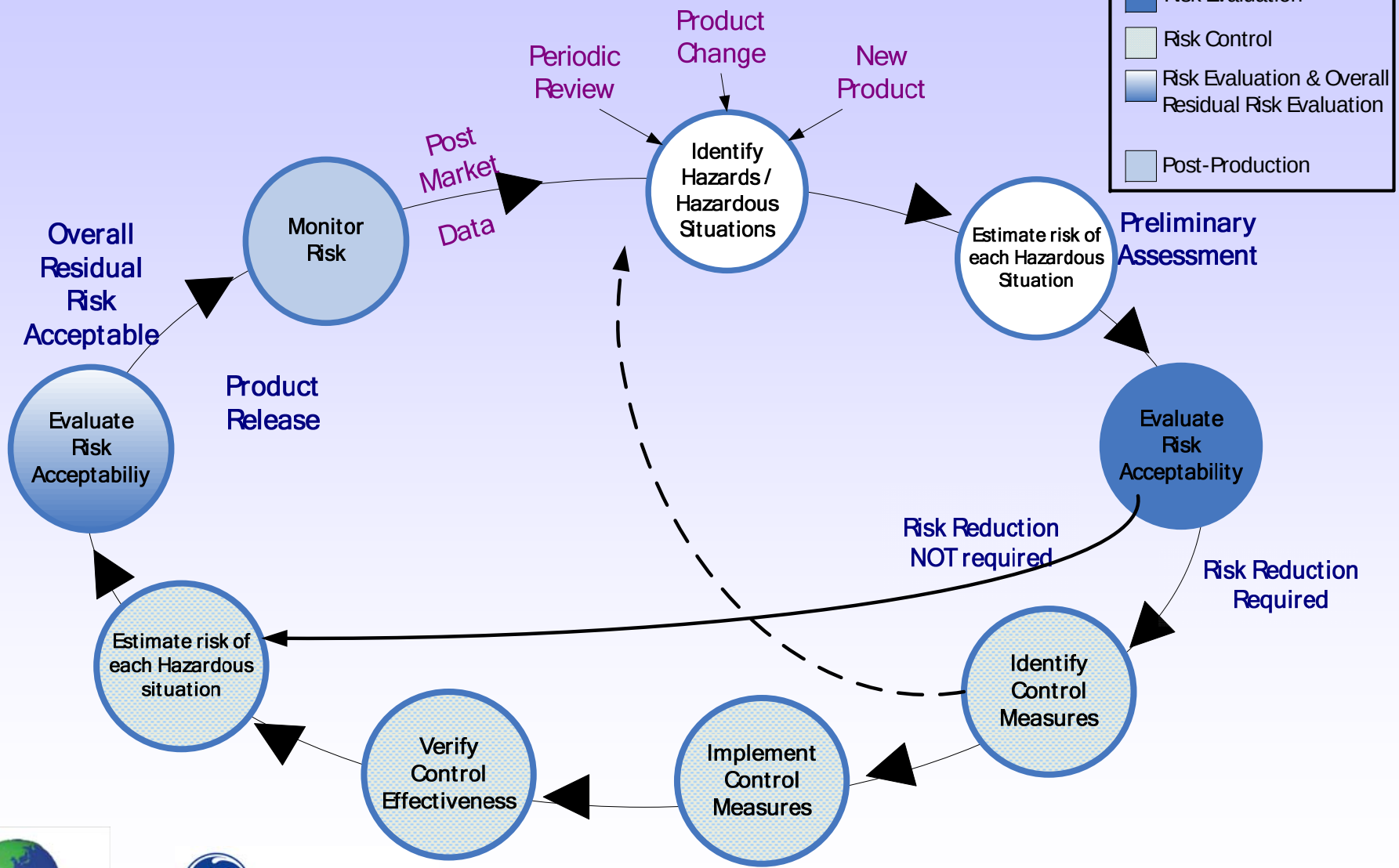
# Risk Process Overview



# Risk Management in Product Development

## Our product teams

- Trained & resourced appropriately
  - Engineers / Scientists
  - Quality
  - Clinical / Medical
  - Regulatory

Training consists of

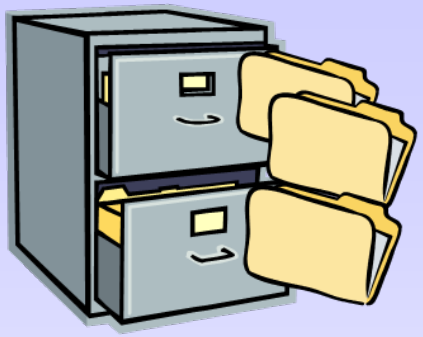
- e-Learning for process & procedure
- Classroom for hands-on experience with case studies

# Risk Management in Product Development

- We follow a structured process for new product introduction

| | |
|---|---|
| Design Inputs | Risk Management Plan<br>Identification of Hazards/Hazardous Situations |
| Design Verification | Preliminary Risk Assessment<br>Identify Risk Control Measures |
| Design Transfer/Validation | Implement Risk Measures<br>Final Risk Assessment<br>Residual Risk Evaluation |

# Risk Management in Product Development



- ✓Develop Risk Management Plan
- ✓Identification of Hazards / Hazardous Situations
- ✓Preliminary Risk Assessment
- ✓Identify Risk Control Measures
- ✓Implement Risk Controls
- ✓Final Risk Assessment
- ✓Residual Risk Evaluation

All outputs are controlled documents in product's Design History File

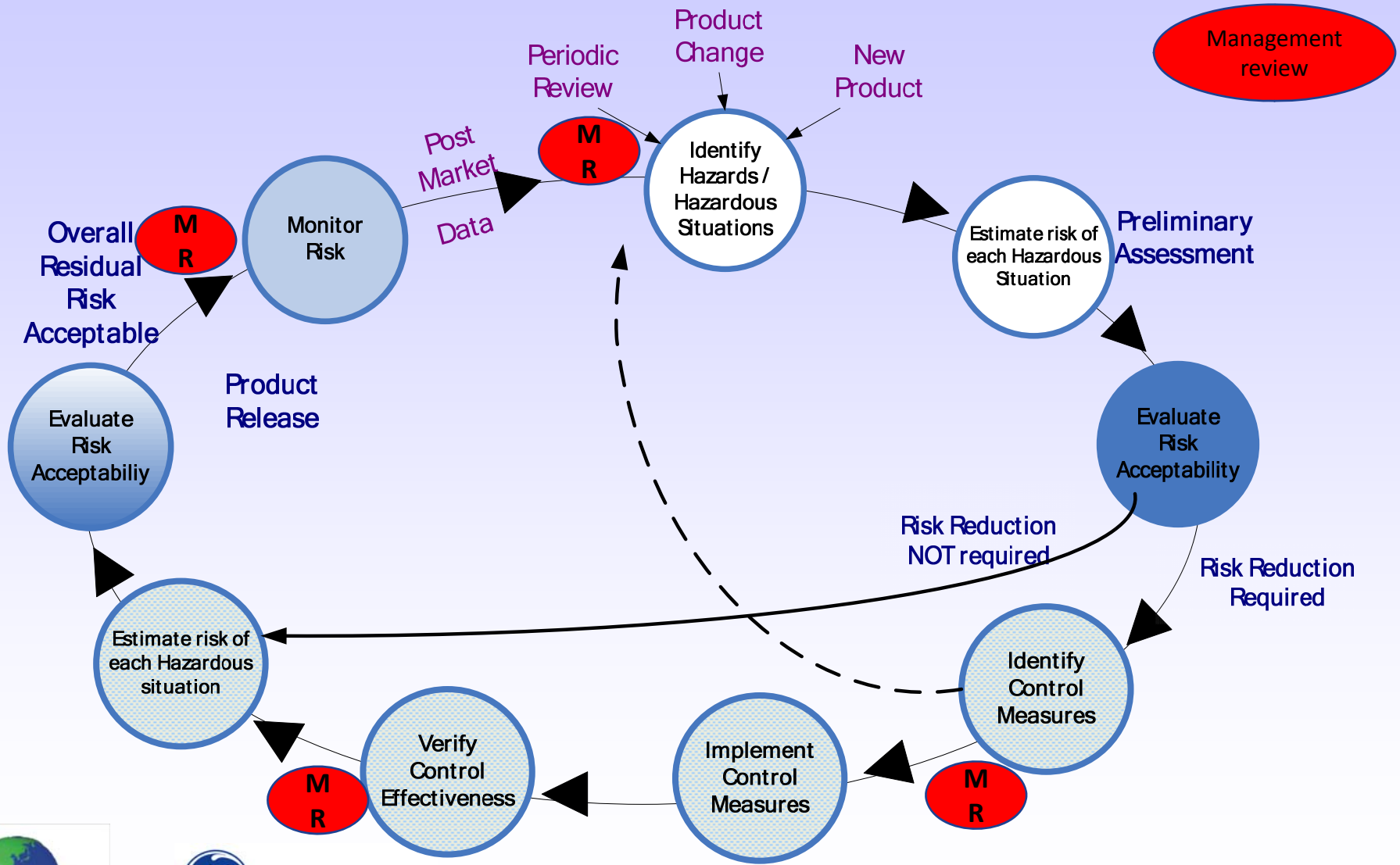
# Risk Management in Product Development

We use basic tools to help identify product and process risk

- Failure Modes and Effects Analysis (FMEA)
  - Design FMEA to understand material choices and part integration
  - Process FMEA to understand manufacturing or assembly critical attributes
- Fault Tree Analysis (FTA) or Usability Task Analysis

Many times we use multiple methods

# Management Review in Risk Process



# Post-Production Risk Management

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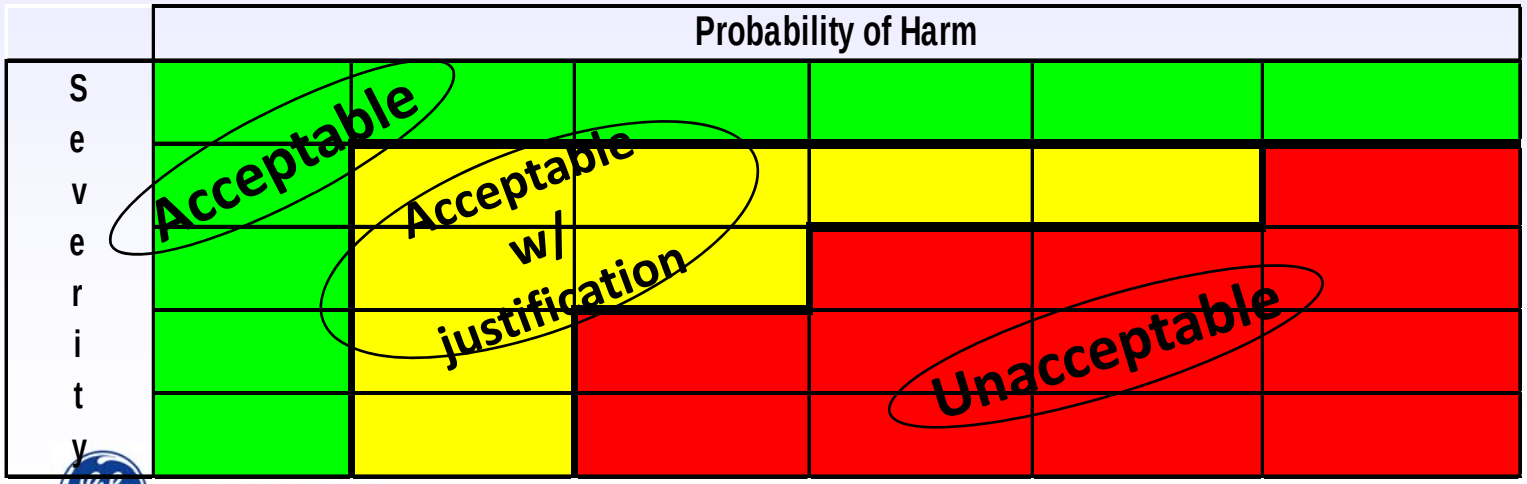
## Procedure includes post-production risk monitoring

### Risk Assessment as part of post-production process

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# Post-Production Risk Management

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## GEHC

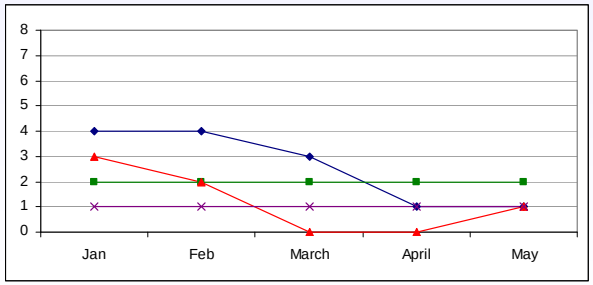
Evaluates all forms of feedback

Develops and monitors trending reports for high risk products

Loop back into the product's Risk Management File

→ Design change

→ Continuous monitoring

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# How this process makes safer products

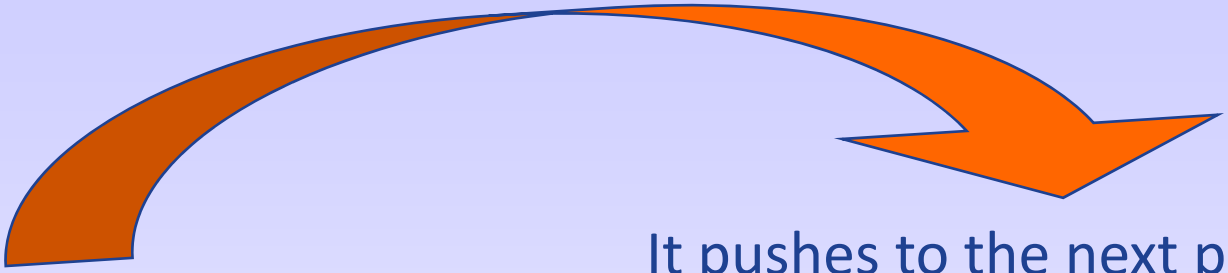
# The process drives safer products

We take all sources of feedback on current design…

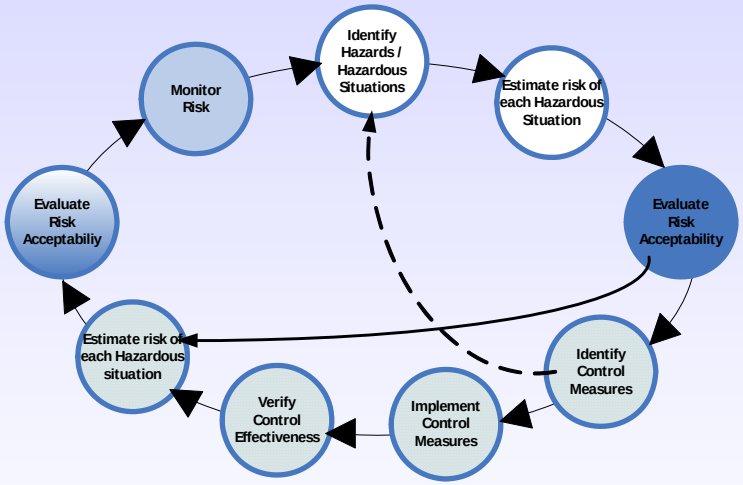
- Voice of customer
- Enhancement requests
- Changes in Industry

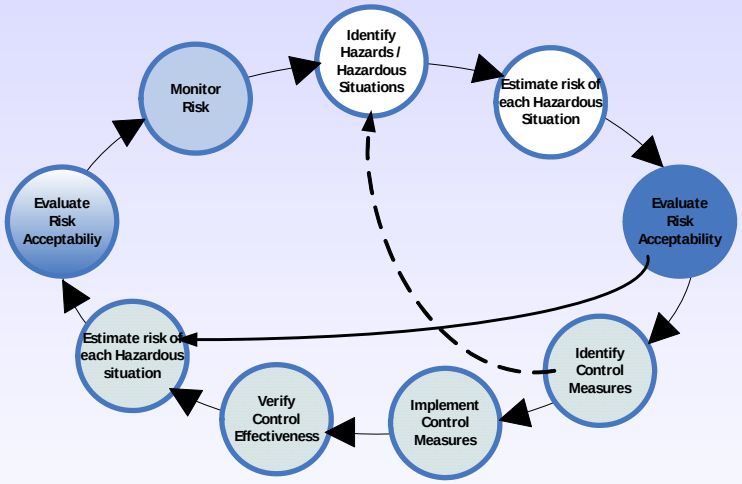
And incorporate that into the next design

# Iterative process



It pushes to the next product




While this process continues…

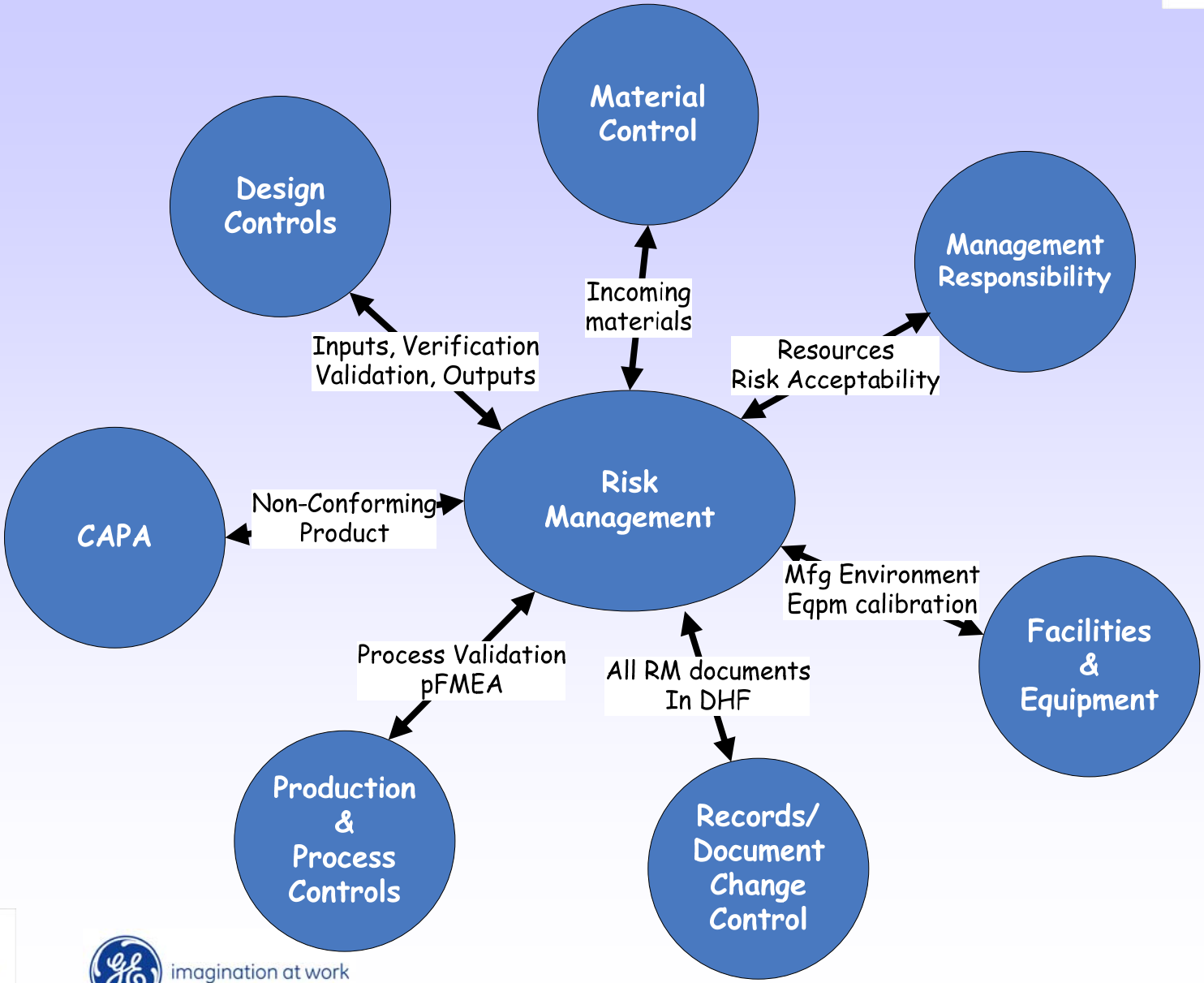
Product A

Product $B_x$

# Medical Device Risk Management

We also make sure all aspects of the Quality System are assessed…

# Quality System and Risk Management

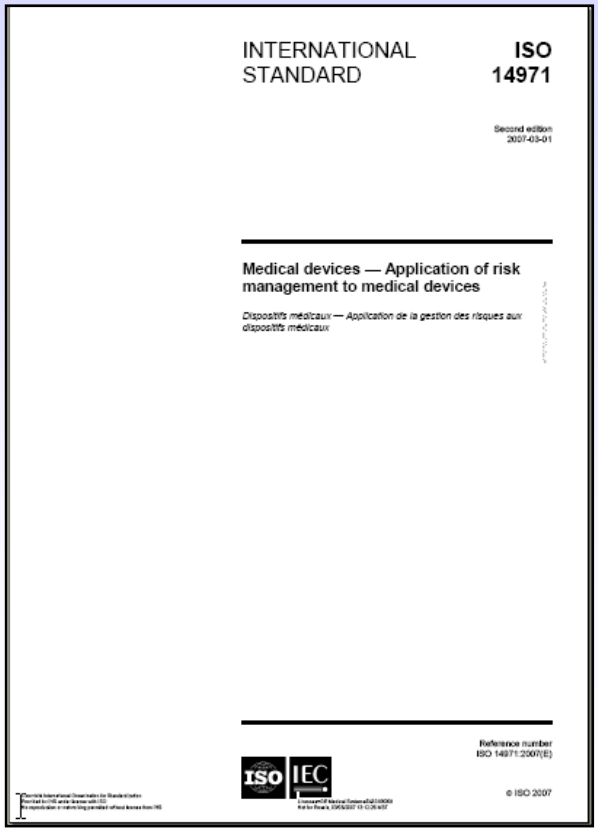


# Lessons learned…

- Continuous improvement of risk management process leads to a more robust system
- Takes a dedicated management team that understands risk management = lower costs (development & production)
- All businesses must be aligned

- **Risk Management is an iterative process**

# ISO 14971 2nd edition



INTERNATIONAL STANDARD

**ISO 14971**

Second edition
2007-03-01

**Medical devices — Application of risk management to medical devices**

*Dispositifs médicaux — Application de la gestion des risques aux dispositifs médicaux*

Reference number
ISO 14971:2007(E)

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# ISO 14971: 2nd edition influences

- Emphasis on hazardous situation rather than just hazards

Exposes workflow failures that may have previously been missed if only looking at hazards

# ISO 14971: 2nd edition influences

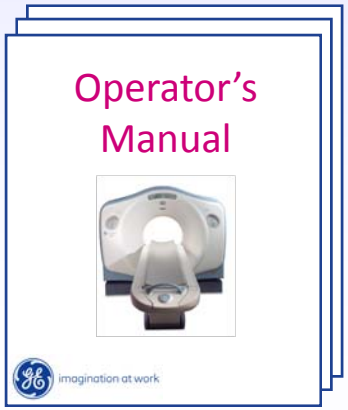
- Added examples for hazardous situations (Annex E)

Used during brainstorming activities for the identification of hazards and hazardous situations

# ISO 14971: 2nd edition influences

- Expanded section on residual risk (Annex J)

Allows us to verify our information for safety is comprehensive



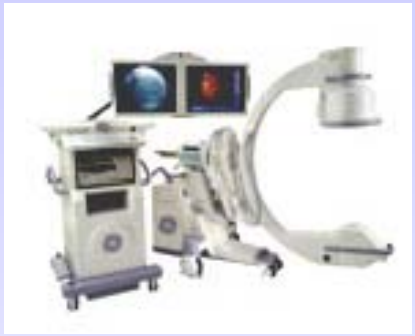
# ISO 14971: 2nd edition influences

- Added severity and probability of harm terms for guidance

  Used to validate the risk assessment process and terminology changes that were in process

  High,Medium → Critical, Serious…

# Post-production input to Risk Management



Design changes

Non Conformances
CAPA

RISK MANAGEMENT

Complaints

Audit Findings

# Responsibilities

- Executive Management
- Lead System Designer
- Engineering
- Product Surveillance Leader
- Medical / Clinical
- Complaint Handling Unit
- QA / QM / RA
- Risk Management Project Team

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# Thank you

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Based on slides from Tracey Holevas

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