Introduction to Risk Management

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Definitions

Intended Use:

ISO 14971: “Use for which a product, process, or service is intended according to the specification, instructions, and information provided by the manufacturer.”

Hazard:

Potential Source of Harm

Note: Sources are always there, somewhere.

Hazardous Situation:

Exposure to a Hazard

Note: It is the bridge between a hazard and harm.

Harm:

Physical injury or damage to health of people, property or environment.

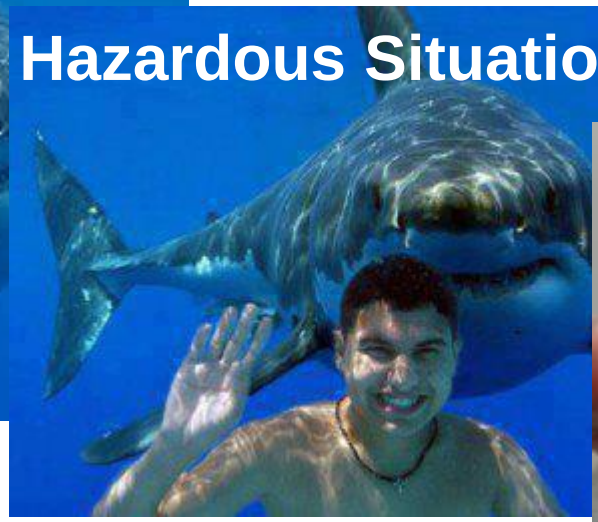
Terminology

Hazard:

Potential Source of Harm.

Always there… but just because it exists doesn't mean there will be Harm..

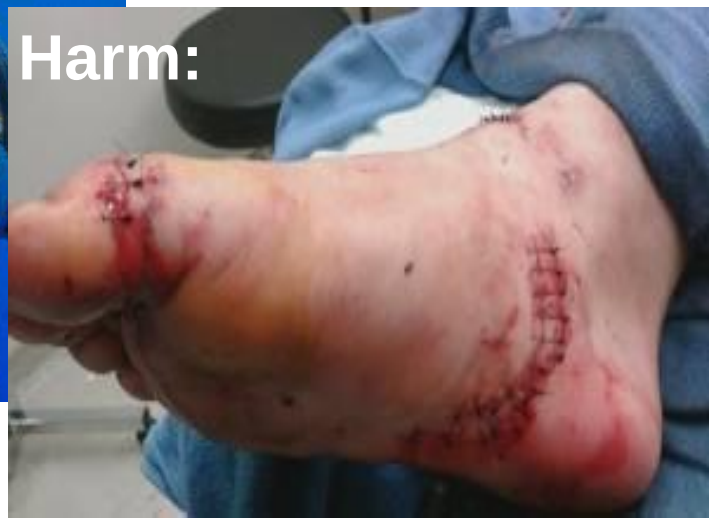
Hazardous Situation:



Exposure to a Hazard.

It's a situation where Harm could happen… It still hasn't happened though..

Harm:



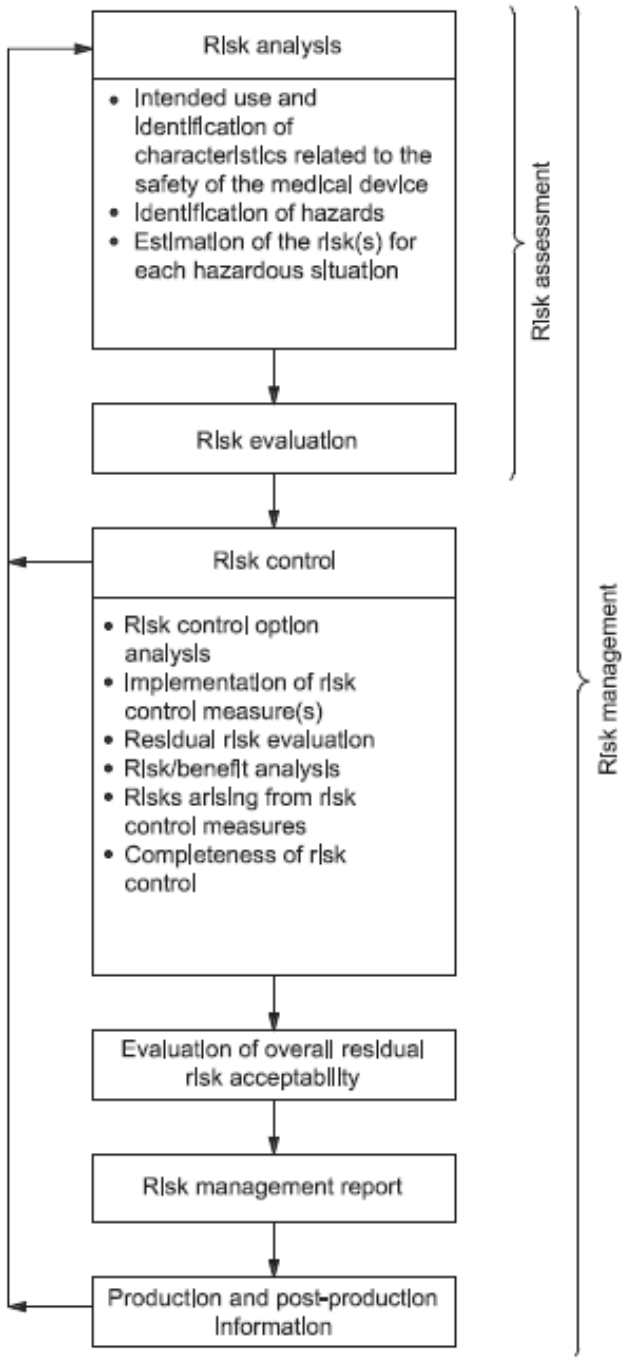
Physical injury or damage to health of people, property or environment.

Ouch.

The Risk Management Process

What does the risk management process look like?

If you read ISO 14971, it looks like this…



4-Step Process

1. What are you trying to do?

2. What can go wrong?

3. What are you going to do about it?

4. Did it work?

Step 1: What are you trying to do?

What is the product's intended use? Risk management can start as soon as you know Intended Use.

What kinds of fluids? There could be different implications for "delivering fluid incorrectly"?

What are the implications of the route?

"Pump is intended to deliver __ fluids, via __ routes, in __ environments, for __ patients, by __ users."

What are the implications of the environment?

Is there something unique about the patients?

Or the users?

Step 2: What can go wrong?

Identify how the product can fail to meet it's Intended Use, and how that can affect patient safety.

Identify Harms, Hazards, Hazardous Situations:

Look at literature, MAUDE, Recalls

Brainstorm causes of failure using Fault Tree Analysis (FTA)

Determine consequences of failure using FMEA

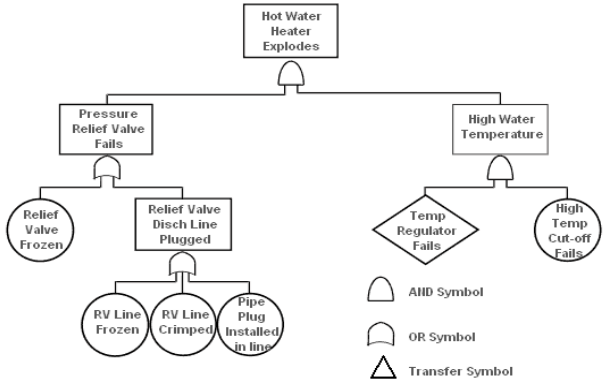
(& other tools)

FTA vs. FMEA

Both FTA and FMEA are tools.

Each tool is good for a particular task; each tool has limitations. No tool is perfect.

FTA is a top-down analysis asking “what can go wrong?”



FMEA is a bottom-up analysis saying “if this goes wrong, what are the consequences?”

Step #	Description	Failure Mode	Cause	Lik.	Sev.	RPN	Score	Mitigation
1	Identify candidate patients (confirmed STEMI)	Too many patients counted	Duplicate records	3	2	6	UNDESIRE	Exclude duplicate records
		Too few patients	Missing STEMI in record	2	3	6	UNDESIRE	No action possible
			Incomplete record because transferred patient	3	4	12	UNACCEPT	Exclude transfers

Step 3: What are you going to do about it?

Can you prevent something from happening? Can you lower the consequences if it does happen? What can you do?

14971 has a preferred order for risk control approaches:

1. Inherent Safety – eliminate the problem
2. Protective measure – protect people from the problem
3. Information for Safety – tell someone about the problem

Risk Control Option: Protective Measures

What can you do to protect the user / patient?

1. Barriers: physical (or software) interventions such as shut-off valves, fences, software lockouts,
2. Detection: Detect and notify an out-of-bounds conditions such as high-temperature alarms, data entry validation, etc.

Note that some of these options could be implemented as manufacturing controls – not all have to be in the design stage.

Examples

Information for Safety

If the hazardous situation cannot be removed by design, and if there are no protective measures, then and only then can you use information as a risk control.

Need to demonstrate the information (e.g. labeling) is effective.

Step 4

Need t e.

Should ted, make s

Step 4: Did it work? - continued

Step 4 continues throughout the product lifecycle through post-market surveillance.

Complaints, MDRs, and other post-market data sources continually feed into “Did it work”, and can trigger NCs or CAPAs to go back and revisit the 4 steps where necessary:

1. What are you trying to do?
2. What can go wrong?
3. What are you going to do about it?
4. Did it work?

References

IEC 14971 – risk management standard for medical devices

- Make sure you read annexes
- ANSI/AAMI/ISO TIR24971 provides additional guidance

IEC 62304 – includes discussion of SW risk management

IEC 62366 – risk management applied to human factors

IEC 61025 – Fault Tree Analysis (FTA)

IEC 60812 – FMEA

IEC 61882 - HAZOP

Useful Papers

VA Center for Patient Safety – Healthcare FMEA (HFMEA):

- http://www.patientsafety.gov/SafetyTopics/HFMEA/FMEA2.pdf
- http://www.patientsafety.gov/SafetyTopics/HFMEA/HFMEAIntro.pdf

Health Care Failure Mode and Effects Analysis for Intravenous Patient-Controlled Analgesia (PCA), ISMP, 2002

ASQ:

- http://asq.org/learn-about-quality/process-analysis-tools/overview/fmea.html

Standards: IEC 60812 Analysis technique for system reliability – Procedure for failure mode and effects analysis (FMEA)

Additional Reading

Interesting concept from aviation – Threat & Error Management:

Captain Dan Maurino, Threat and Error Management (TEM), Canadian Aviation Safety Seminar (CASS), April 2005

Collection of papers regarding safety, regardless of industry

http://www.dependablesos.org/category/dsos

A podcast (yes, seriously, a podcast!)

http://disastercast.co.uk/?feed=podcast\