Learning from Other Industries
Tuesday, September 29| 1:15 p.m.–2:15 p.m.

Steven W. Badelt
Managing Partner, Suttons Creek, Inc.
Industry Ambassador, INCOSE
Take-Aways

• Risk management exists outside of Medical Devices and Healthcare
• Risk management is a core discipline of systems engineering
• Risk management in Medical Devices is narrowly focused on safety and efficacy.
• Risk management in Healthcare is not driven top-down the way it would be in aerospace (ref. Defense Acquisition Model)
“BETTER HEALTH CARE AND LOWER COSTS: ACCELERATING IMPROVEMENT THROUGH SYSTEMS ENGINEERING”
## Risk Management - Process Interactions

<table>
<thead>
<tr>
<th>EXTERNAL</th>
<th>REQUIREMENTS</th>
<th>DESIGN</th>
<th>DEVELOPMENT</th>
<th>SYSTEMS</th>
<th>VALIDATION</th>
<th>LIFECYCLE</th>
</tr>
</thead>
</table>

**Source:** FAA
We’re Not So Different, You and I.
The Risk Matrix

Source: NASA
We’re Not So Different, You and I. 
Risk Triplets

RISK = Structure of Scenario, Likelihood and Its Uncertainty, Consequence Severity and Its Uncertainty

Source: NASA
Continuous Risk Management

Source: NASA
Aerospace: Technical Risk Management

- Risk is defined as the combination of (1) the probability that a program or project will experience an undesired event and (2) the consequences, impact, or severity of the undesired event, were it to occur.

- The undesired event might come from technical or programmatic sources (e.g., a cost overrun, schedule slippage, safety mishap, health problem, malicious activities, environmental impact, or failure to achieve a needed scientific or technological objective or success criterion).

- The concept of “value of information” is central to making the determination of what analysis is appropriate and to what extent uncertainty needs to be quantified.

Source: NASA
Risk-Informed Decision Analysis

Source: NASA
Defense Acquisition Management Framework
Defense Buys Top-Down
Defense Buys Top-Down

• The “Prime” is driving requirements, specifying what they will buy. Top-Down
• The “Prime” is specifying how technical program processes, including risk, are driven. Top-down.
“Prime”

Requirements

Process (Risk Management)

“Sub”
Healthcare Does Not Buy Top-Down

• The Vendor (medtech) is driving requirements, specifying what they will build. Bottom-Up.

• The Vendor (medtech) is specifying how technical program process, which is only communicated to regulator agencies.
Integration failure: Alarm Fatigue

1. It's quite alarming...
   Alarm fatigue occurs when hospital staff become desensitized to alarm alerts causing missed alarms or delayed response.

2. 216 deaths
   Between 2005 and 2010, alarm fatigue caused 216 hospital deaths.

3. #1 Hazard
   Voted the top technology hazard of 2012 by ECRI, beating out 2011's radiation exposure.

4. 942 alarms each day
   942 alarms sound off each day in a typical 15-bed unit.

5. 1 alarm every 90 seconds

6. 90% are unanswered
   Alarms are reported to be unanswered 90% of the time.

It's no wonder that alarm fatigue is so prevalent.

Locate
- Locate the source of each alarm

Limit
- Limit active alarms based on patient needs

Volume
- Set volume accordingly

How can alarm fatigue be prevented?

Sources:
- http://www.bostonglobe.com/lifestyle/health/articles/2011/02/13/patient_alarm_above_sound_level/1bed
- http://www.ecri.org/Forms/Pages/EcRi-Institute-10-Hs-Tech-Hazards.aspx
- http://www.chgbeds.com
Integration Failure: Covidien Defib Electrode Incompatibility
Integration Failure: Product Mimicry

• Your product is only one of many…
  – How is your product differentiated from others?

Photo: Patient Safety Authority, 2007
Integration Failure: Luer-Lock
A Systems Engineering Approach to Risk Management

Tuesday, September 30| 8:45 a.m.–10:00 a.m.

Steven W. Badelt
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A lack of practicum to the point of panic.

I want to thank all twenty of you for coming to this mandatory risk management meeting... Let's begin.

How should we evaluate the risk to the patient if a monkey sneaks in and touches a Cheerio to the sterile needle without the patient knowing?

3 hours later...

It looks like we'll need a few more sessions to figure this one out.
“systems engineering is the scientific method of engineering.”
- S. Badelt
SE implementation is about tailoring best practices to your business, not disrupting it.
The WHAT:
21CFR820.30 & Guidance

The HOW:
Systems Engineering
Just cause it needs to be said

• It is no coincidence that manufacturers that generally have poor requirements ... and also have inadequate risk management
What’s wrong with this picture?
Risk Management – Is it in a silo?

Source: FAA
# Risk Management - Process Interactions

Source: FAA
Continuous Risk Management

Source: NASA
Risk Identification: Do Better than Brainstorming

- Risk analysis is required for medical device development and is driven by QbD for pharmaceuticals.
- It is common for teams to identify risks by unstructured brainstorming at the beginning of risk analysis.
- **Unstructured brainstorming fails** because teams suffer from absence blindness.
- Successful **risk analysis** begins first with a rigorous, structured process for **risk identification**.
- The application of this process has improved risk identification rates by a **factor of 10**.
Risk Identification Through SE Best Practices (e.g. Modeling)