

Risk Management

風險管理

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Disclaimer

- This presentation represents only my view on risk management. It does not reflect the views of any of my previous and current employers.

What Is Risk (危機)?

- Combination of the probability of occurrence of harm and the severity of that harm (ISO/IEC Guide 51:1999, definition 3.2)
- A dangerous (危險) business opportunity (機會)
 - No risk, no gain
 - Possible death from poisoning > New package protection on Tylenol bottles
 - Environment pollution > Electric cars
 - Collision during lane changes > Collision warning and auto stop in cars

Why Is Risk Management Important?

- Reasons
 - **Business Survival and Prosperity**
 - Accountable
 - Liable
 - Achievable
 - Retribution
 - Profitable
- Objective
 - **ALARP** (As Low As Reasonably Practicable)

ALARP

- It is a principle on residual risk.
- Originated in UK: Health and Safety at Work Act 1974
- In *Edwards v. National Coal Board* in 1949, the ruling is that “risk must be insignificant in relation to the sacrifice required to avert it.”
- What is reasonable? It depends on risk tolerance.
- Reasonable person – each person owes a duty to behave as a reasonable person would under the same or similar circumstances.

RM Terms

- **Harm**
 - Physical injury or damage to the health of people, or damage to property or the environment
- **Hazard**
 - Potential source of harm
- **Hazardous situation**
 - Circumstance in which people, property, or the environment are exposed to one or more hazards)
- **Intended use**
 - Intended purpose use for which a product, process or service is intended according to the specifications, instructions and information provided by the manufacturer

RM Terms

- **Objective evidence**
 - Data supporting the existence or verity of something
- **Post-production**
 - Part of the life-cycle of the product after the design has been completed and the medical device has been manufactured
- **Record**
 - document stating results achieved or providing evidence of activities performed
- **Residual risk**
 - Risk remaining after risk control measures have been taken

RM Terms

- **Risk analysis**
 - Systematic use of available information to identify hazards and to estimate the risk
- **Risk assessment**
 - Overall process comprising a risk analysis and a risk evaluation
- **Risk control**
 - Process in which decisions are made and measures implemented by which risks are reduced to, or maintained within, specified levels
- **Risk estimation**
 - Process used to assign values to the probability of occurrence of harm and the severity of that harm

RM Terms

- **Risk evaluation**
 - Process of comparing the estimated risk against given risk criteria to determine the acceptability of the risk
- **Risk management**
 - Systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating, controlling and monitoring risk
- **Risk management file**
 - Set of records and other documents that are produced by risk management
- **Safety**
 - Freedom from unacceptable risk

Risk Terms

- **Severity**
 - Measure of the possible consequences of a hazard
- **Use error**
 - Act or omission of an act that results in a different medical device response than intended by the manufacturer or expected by the user
- **Verification**
 - Confirmation, through the provision of objective evidence, that specified requirements have been fulfilled

The PTP – Foundation of Good Software Quality

- Process
 - Are the right software-related processes in place?
 - Software design, coding standard, system engineering, development, code reviews, anomaly management, V&V, and configuration management
- Tools
 - Does the project has the right tools?
 - Programming languages, requirement database, code coverage analysis, code complexity analysis, test automation, anomaly database, and software build
- People
 - Does the project has the right people?
 - Education, experience, and training

Software That Requires Validation

- Software used as a component, part, or accessory of a medical device
- Software that is itself a medical device
- Software used in the production of a device
- Software used in implementation of the device manufacturer's quality system

FDA Software Validation Guidance

- Least Burdensome Approach
- Risk-Based Software Validation
 - Effort proportional to perceived risk (RPN)
- Manufacturers of final products are primarily responsible for the safety and quality of the products
- Use the guidance/guidelines as references for testing strategy

RM is Continuous in a Product's Life Cycle

- Design Controls
 - Concept
 - Design
 - Implement
 - Verification & validation
 - User confirmation
 - Design Transfer
- Production
- Post-Market Surveillance
 - Limited commercial release
 - Full commercial release
 - Retirement



Risk Management Files

- Risk Management Plan
- Risk Analysis
- Risk Management Report
- Related Documents
 - Requirements
 - Designs
 - Test cases and test results

Risk Analysis

- Identify
 - Hazard (e.g. data error)
 - Corresponding Risk/Risks (e.g. overdoes, underdoes, incorrect therapy, delayed therapy)
 - Potential Cause/Causes (e.g. data retrieval/store error, communication problem)

Suggested Risk Analysis Tools

- Brainstorming sessions
- Fault Tree Analysis
- Failure Mode Effect Analysis (FMEA)
- User Experience sessions

Common Risk Source Data

- In-depth knowledge of the product
- Intended and unintended uses (e.g. [user experience design](#))
- Industrial data (i.e. available data from similar products)
- International standards (e.g. IEEE)
- Independent assessments (e.g. expert opinions)
- Previous risk assessments
- Test anomalies
- Sampling/Inspection data
- Customer feedbacks/complaints
- Field service data

Hazard Types

- Operational Hazards
- Environmental Hazards
- Electrical Hazards
- Hardware Hazards
- Software Hazards
- Mechanical Hazards
- Biological and Chemical Hazards
- User Hazards

Software and System

- Configures a system
- Interfaces between a system & its users and among systems
- Provides operational instructions to a system
- Monitors the performance of a system
- Records data generated by a system
- Reports data generated by a system
- Controls a system

Risk Evaluation

- What is the probability of occurrence?
- What is the probable severity of damage?
- Use historical data if available
 - Test data
 - Performance data
 - Reliability data
- Use statistical analysis on historical data for credible predictions

Risk Evaluation-Probability of Occurrence

<i>Common Terms</i>	<i>Descriptions (Operations)</i>	<i>Weight</i>
Frequent	$\geq 1/1,000$	5
Probable	$< 1/1,000$ and $\geq 1/10,000$	4
Occasional	$< 1/10,000$ and $\geq 1/100,000$	3
Remote	$< 1/100,000$ and $\geq 1/1,000,000$	2
Improbable	$< 1/1,000,000$	1

Note: The chart above is an example only.

Risk Evaluation-Probable Severity Levels

<i>Common Terms</i>	<i>Descriptions</i>	<i>Weight</i>
Catastrophic	Results in patient death	5
Critical	Results in permanent impairment or life-threatening injury	4
Serious	Results in injury or impairment requiring professional medical intervention	3
Minor	Results in temporary injury or impairment not requiring professional medical intervention	2
Negligible	Inconvenience or temporary discomfort	1

Note: The chart above is an example only.

Risk Evaluation

- Risk Probability Number (RPN) = Probability of Occurrence x Probable Severity

Risk Evaluation

		Probability of Occurrence			
Probable Severity	Frequent	Probable	Occasional	Remote	Improbable
Catastrophic	25	20	15	10	5
Critical	20	16	12	8	4
Serious	15	14	9	3	3
Minor	10	8	6	4	2
Negligible	5	4	3	2	1

Note: The chart above is an example only.

Risk Control

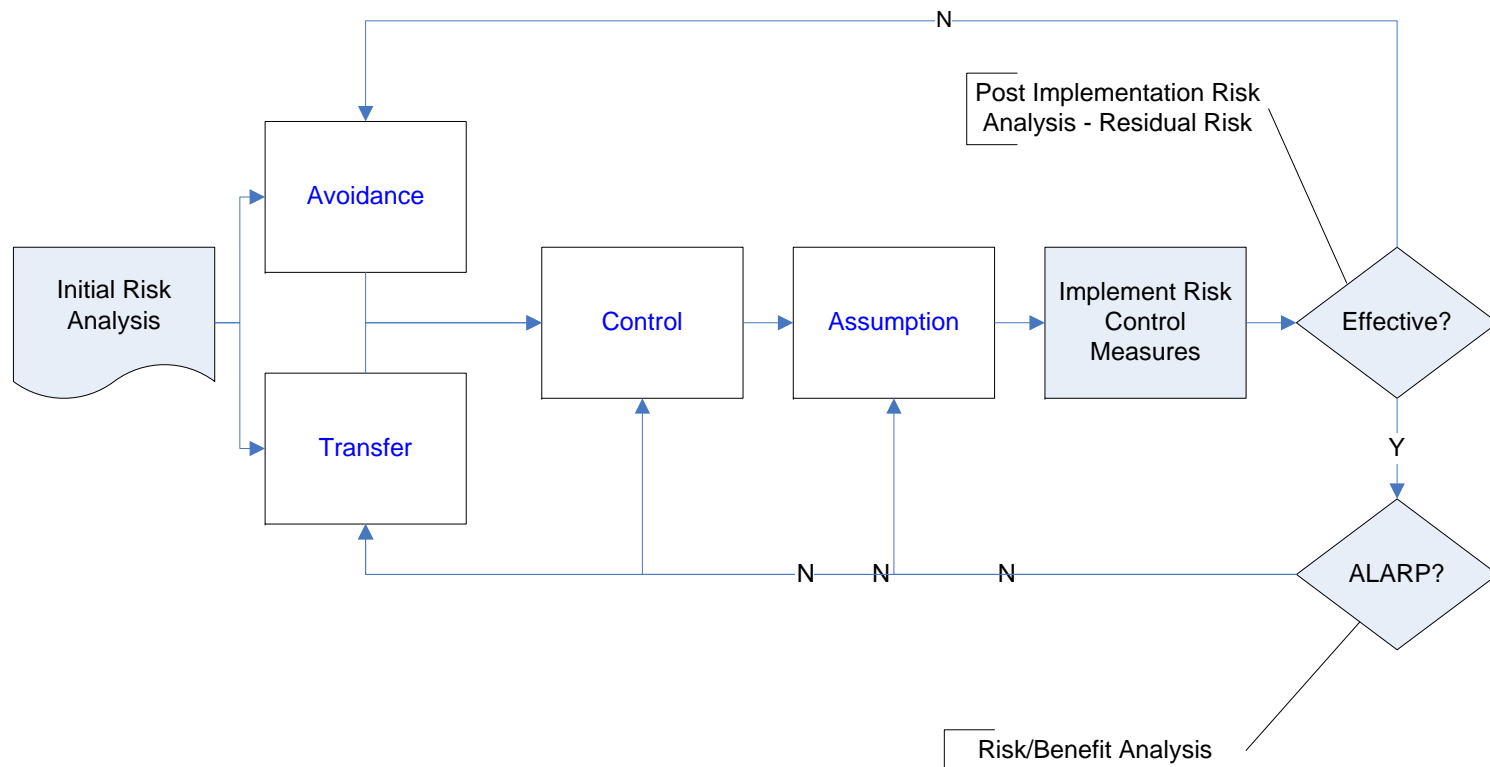
- Technical Analysis

- How can the probable occurrence be prevented or reduced?
- How can the probable severity be eliminated or reduced?
- What is the residual risk after implementing the risk control measures?
- Does the benefit to the users outweigh the risk?

Business Analysis

- Does the benefit to the company outweigh the risk?

Risk Control



Risk Control Examples

Option	Description	Risk Control Measures (Examples only)
Avoidance	Avoid the risk completely	Not implementing a feature
Control	Prevent occurrence and/or reduce harm	<i>Risk-based software development approach (e.g. layered software architecture, clear requirements, good coding standards, reduced code complexity, and training)</i> <i>Start up check</i> <i>Operation can only start after human confirmation</i> <i>Monitor the patient condition to prevent adverse conditions</i> <i>Audible and visual alarms</i> Warning labels on devices Detail cautions, warnings, use, and maintenance instruction in the Direction for Use (DFU) User training Field bulletins Regular software maintenance on field units Disaster management process/team
Assumption	Accept the risk as it is	User training Field bulletins Disaster management process/team
Risk Transfer	Transfer the risk to another party	Contractual agreement to use the medical device as intended Liability insurance

Risk Monitoring

- Purposes
 - To continuously assess effectiveness of risk control measures
 - To identify and mitigate new risks
- Methods
 - Sampling during Production
 - User Trials/Acceptance Testing
 - Field Service Data
 - Customer Relation Management (customer complaints)
 - FDA MAUDE database (adverse event reports)
 - FDA Recalls

A Few Notes on Risk

- Risk management is an integral part of design
- There can be a one-to-many relationship between:
 - Hazard and Risks
 - Risks and Causes
 - Causes and Risk Control Measures
- A risk control measure can create new risks as well as new business opportunities.
- Implementation and V&V starts after initial risk analysis is completed.
- Post implementation (residual) risk analysis starts after V&V is completed.
- New risks can be identified and control measures may change during a product's entire life cycle.

Software-Related Documentation in a 510(k) Submission

- The documentation should:
 - Describe the design of your device
 - Document how your design was implemented
 - Demonstrate how the device produced by your design implementation was tested
 - Show that you identified hazards appropriately and managed risks effectively
 - Provide traceability to link together design, implementation, testing, and risk management.

510(k) Review Checklist

IX. Software

Version:		
Level of Concern:		
	Yes	No
Software description:		
Device Hazard Analysis:		
Software Requirements Specifications:		
Architecture Design Chart:		
Design Specifications:		
Traceability Analysis/Matrix:		
Development:		
Verification & Validation Testing:		
Revision level history:		
Unresolved anomalies:		

Risk Analysis Traceability Matrix

- See example attached to this presentation

3 Be's

- Be Diligent
- Be Prepared
- Be Active

References

- Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management (July 18, 2000)
- General Principles on Software Validation (January 11, 2002)
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005)
- ISO 14971 : Medical devices — Application of Risk Management to Medical Devices, Second Edition 2007-03-01
- Total Product Life Cycle: Infusion Pump – Premarket Notification [510(k)] Submissions (Draft Guidance) (April 23, 2010)
- [Medical Devices Infusion Pump Risk Reduction Strategies for Clinicians](#)
- Premarket Notification [510(k)] Review Traditional/Abbreviated

Future Topics

- Overview of Software Reliability
- Hands-On Software Risk Analysis
- FDA Medical Device Regulations

Q&A

- If you have questions in the future regarding this presentation, please feel free to send me an e-mail at edwutg1@gmail.com.