

Medical Device Risk Management ISO 14971

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Speaker Biography

- Dan O’Leary
 - Dan O’Leary is President of Ombu Enterprises, LLC, an education, training, and consulting company focusing on Operational Excellence using analytical skills and a systems approach to operations management.
 - Dan has more than 30 years experience in quality, operations, and program management in regulated industries including aviation, defense, medical devices, and clinical labs.
 - He holds a Masters Degree in Mathematics; is an ASQ certified Biomedical Auditor, Quality Auditor, Quality Engineer, Reliability Engineer, and Six Sigma Black Belt; and is certified by APICS in Resource Management.
- Ombu Enterprises, LLC
 - Ombu works with small manufacturing companies, offering training and execution in Operational Excellence. Focusing on the analytic skills and systems approach of operations management, Ombu helps companies achieve efficient, effective process and regulatory compliance.

Outline

- Status of ISO 14971:2007
- Links to regulatory requirements (QSR & ISO 13485)
- Overview of ISO 14971:2007
- Q&A session
- Summary and Conclusions
- Questions

Our Class

- Our approach is casual
- Write your name on a table tent
- Turn off your cell phones during the class
- Ask lots of questions
- Bring examples from your experience
- Participate
- Have fun!

Participant Introduction

- Your Name
- Your company
- Your job title
- Something about the Risk and Hazard Assessment for Medical Devices issues you face in your company
- Something about Risk and Hazard Assessment for Medical Devices that you want to know

Dan O'Leary's Biography

- Dan has more than 30 years experience in quality, operations, and program management in regulated industries including aviation, defense, medical devices, and clinical labs.
- Dan earned a Masters Degree in Mathematics
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The Current Status of ISO 14971:2007

ISO 14971:2007 Development

- ISO 14971:2007 is the second edition
 - It replaces the year 2000 edition (ISO 14971:2000)
 - It also replaces amendment 1 to the 2000 edition (ISO 14971:2000/Amd 1:2003)
- The second edition was published on March 1, 2007
- ISO 14971 is managed by ISO TC 210 – Quality management and corresponding general aspects for medical devices

FDA Recognition Status

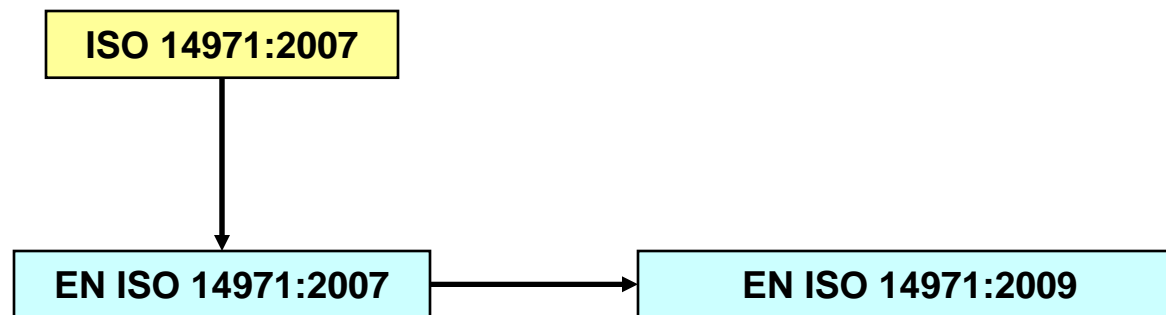
- The FDA recognized the current version on Sep. 12, 2007.
- Their recognition extends to the whole standard
- A declaration of conformity means that
 - (1) a process appropriate for medical devices and their accessories, including in vitro diagnostic devices, has been used to identify hazards and hazardous situations, estimate and evaluate the risks, control those risks including overall residual risk, and monitor the effectiveness of the controls, and
 - (2) criteria based upon applicable national or regional regulations, relevant international Standards, information such as the generally accepted state of the art, and known stakeholder concerns was used to determine risk acceptability.

EN ISO 14971 Status

- EN ISO 14971:2009
 - The current version is EN ISO 14971:2009 Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)
 - Conformity to EN ISO 14971:2007 expired on March 21, 2010

EN ISO 14971 Versions

- Many EN standards start with an ISO version
- Various standards bodies may adopt them, add information, and renumber them.



CEN doesn't sell standards; purchase them through national standards bodies. As a result, the standards are renumbered (again).

I.S. EN ISO 14971:2009

BSI EN ISO 14971:2009

DIN EN ISO 14971:2009

Links to Regulatory Requirements (QSR & ISO 13485)

QSR Requirements for Risk Analysis

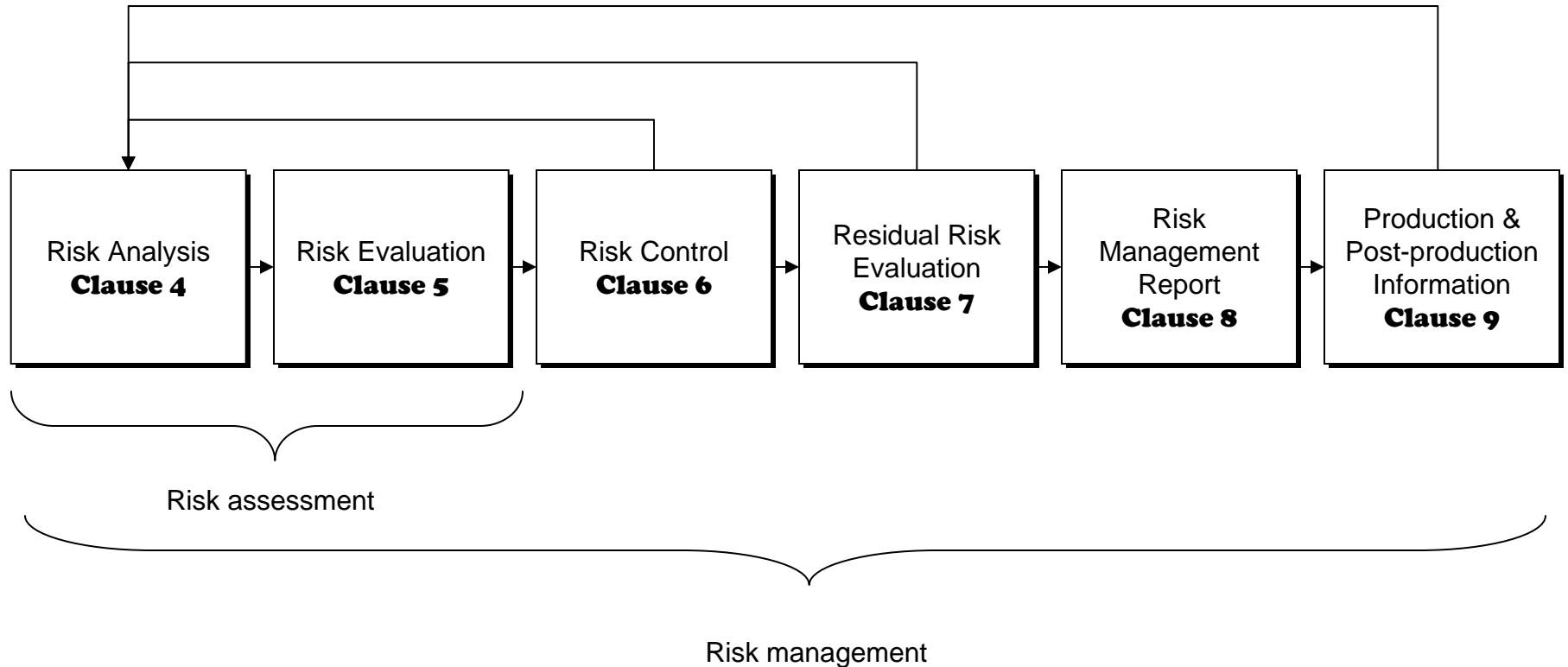
- The FDA requires risk assessment as part of design validation. (820.30(g))
- *Design validation* means establishing by objective evidence that device specifications conform with user needs and intended use(s). (820.3(z)(2))
- Since medical devices need to both safe and effective, risk management, starting in the design phase, is a natural approach.

ISO 13485:2003 & Risk Management

- Clause 7.1 requires, “. . . risk management throughout product realization.”
 - In addition, “Records arising from risk management shall be maintained”
 - The standard recommends ISO 14971 for guidance related to risk management.
- Clause 7.3.2 says that design and development inputs include risk management outputs.

An Overview of ISO 14971:2007

The Risk Management Flow



Adapted from ISO 14971:2007 Figure 1

Risk Management Plan

- Risk management activities need an overall plan
- The risk management plan has standard elements:
 - Scope (including the life-cycle)
 - Responsibilities and authority
 - Review requirements for risk management
 - Risk acceptability criteria
 - Risk verification
 - Production activity data collection and review
 - Post-production activity data collection and review



Risk Management File

- The documents and quality records are maintained in the Risk Management File.
- Think of this as a filing cabinet containing information about the risk management program
 - In practice, it is usually a variety of documents, often in different formats (text files, spreadsheets, *etc.*)
- You must be able to readily retrieve documents and records of the Risk Management File.



Risk Analysis (Clause 4)

- Document both the intended use and foreseeable misuse of the device
- Identify known and foreseeable hazards associated with the device
- Estimate the risk for each hazardous situation

Hazard + Sequence of events → Hazardous Situation

Severity × Probability → Risk

Risk Evaluation (Clause 5)

- The Risk Management Plan defines risk evaluation criteria for each hazardous situation
- Evaluate each hazardous situation, individually, against the criteria in the Risk Management Plan

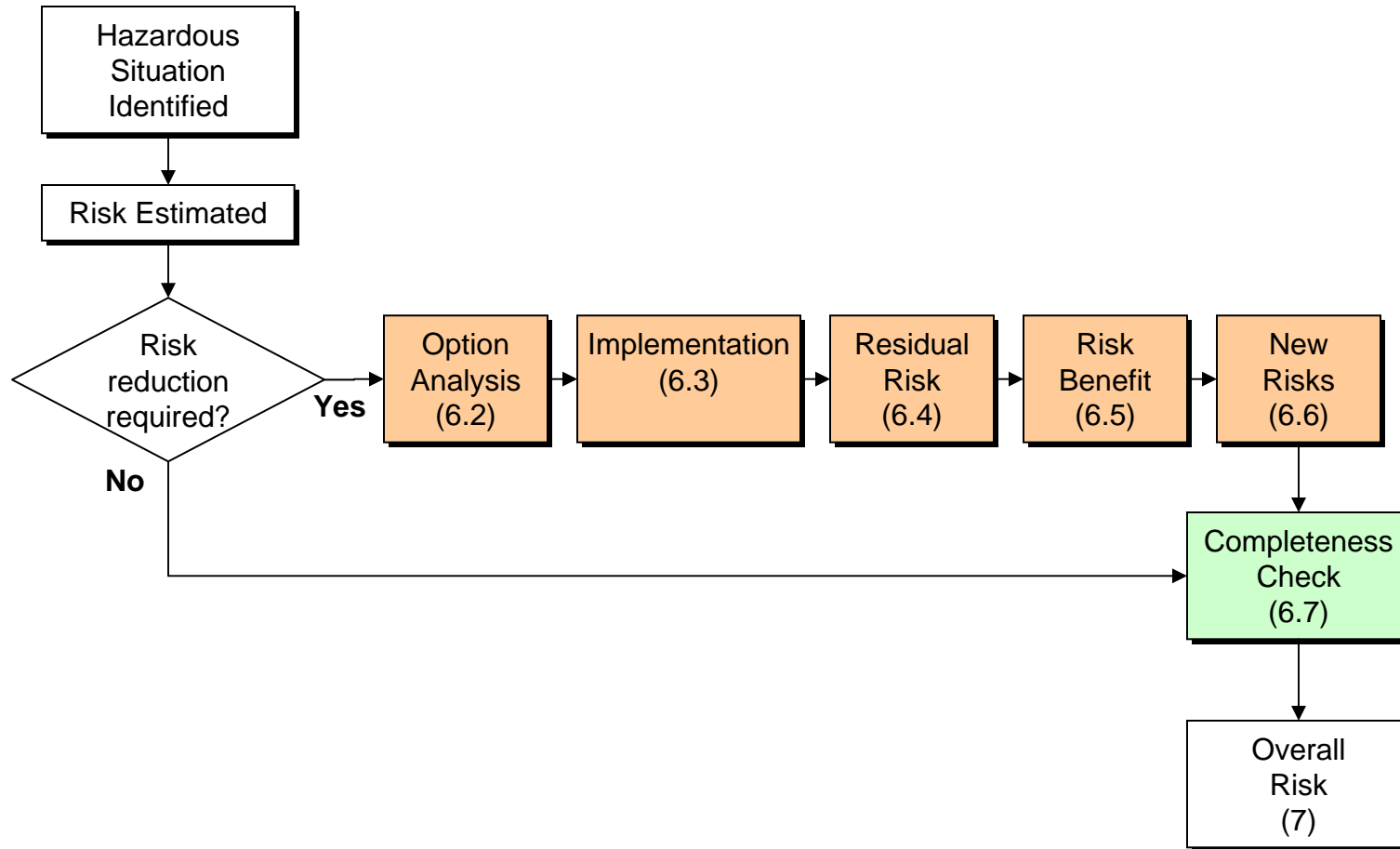
If risk reduction is required, follow clauses 6.2 to 6.6

If risk reduction is not required, go to clause 6.7

Example

- A Risk Management Plan defines five risk levels, 1 to 5, and shows how to calculate them using severity and probability.
- Any risk of level 4 or 5 must be reduced to level 1, 2, or 3.

Risk Control (Clause 6)



Residual Risk Evaluation (Clause 7)

- The Risk Management Plan defines risk evaluation criteria for overall risk
- After the risk control measures are implemented and validated, review the overall risk
- If the overall risk is unacceptable, determine if the medical benefits outweigh the overall residual risk

Risk Management Report (Clause 8)

- Prior to release of the device, you need to review the risk management process.
- The review ensures:
 - The Risk Management Plan is implemented
 - Overall residual risk is acceptable
 - Measures are in place to obtain production and post-production information
- The review's results become the Risk Management Report, and is included in the risk management file

Production & Post-production Information (Clause 9)

- Collect information about your device in the production phase.
 - Review acceptance data
 - Look closely at validated processes and their controls
- In the post-production phase review:
 - Installation and servicing reports
 - Customer complaints
 - New or revised standards
 - Public information, including similar medical devices

An Example to Keep in Mind

The Neonatal Heel Stick

The example helps illustrate the concepts

- Neonates (babies under 1 month of age) are routinely tested for metabolic diseases.
- A nurse draws a sample of blood from the baby's heel, places it on filter paper, and allows it to dry.
- The dried blood spot is sent to a laboratory for testing.

The Heel Stick

- The nurse uses a lancet to draw the blood in a process called a heel stick.
- In this application, the chemical pack is a medical device in the US.

- To make the heel stick easier, the nurse warms the baby's heel, often using a chemical pack.
- The technology is a familiar heat generating chemical pack, activated by squeezing or mixing.



Product Description

- Early in 2009, the FDA published a note describing problems with the heel warmer.
- The Infant Heel Warmer:
 - Is an instant chemical heat pack. It increases capillary circulation in an infant's heel to facilitate blood collection by heel stick.
 - [It is a] nonsterile, single-use, disposable device contain[ing] a nontoxic material.
 - Device activation results in an exothermic reaction with a maximum temperature of around 104°F (40°C) within the first few minutes before it gradually diminishes.
- In the US it is
 - A Class I device
 - For infant use, it requires a 510(k)

Potential Product Problems

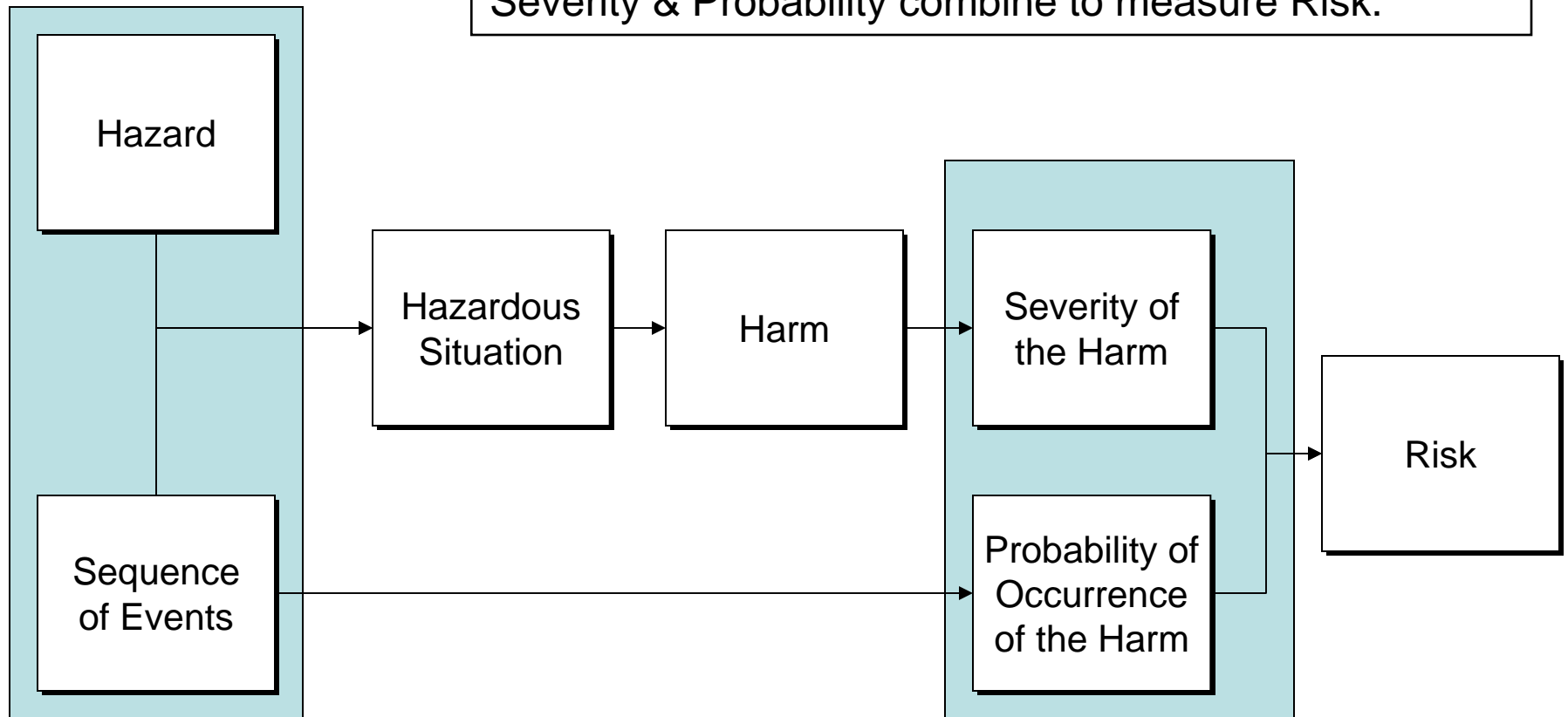
- Based on Medical Device Reports (MDRs), the FDA cited four cases.
 - Case 1: An infant suffered second to third-degree burns to the heel requiring treatment.
 - Case 2: Twins with hyperbilirubinemia were being prepared for a heel-stick procedure. The heel warmer ruptured, its contents covered the infants, and they suffered first and second-degree burns.
 - Case 3: An infant received a second degree burn when the device was reused and reheated contrary to labeling instructions.
 - Case 4: When the nurse activated the infant heel warmer, it burst open and splashed her in her eyes. The infant wasn't hurt, but the nurse required emergency eye wash and ophthalmic antibiotics.

Definitions

Clause 2

The Components of Risk

Hazards, set off by a sequence of events, create Harm. Severity & Probability combine to measure Risk.



Adapted from ISO 14971:2007, Annex E

Definitions – Hazard

Hazard - potential source of harm

Discussion

The manufacturer identifies device hazards. The standard creates a potential 2x2 classification for hazards – they could be known or foreseeable; they could arise in normal or fault condition.

Example

The FDA advice identifies 3 hazards:

- Excessive heat
- Rupture
- Improper reuse

	Known	Foreseeable
Normal Condition		
Fault Condition		

Definitions – Hazardous Situation

Hazardous situation – circumstance in which people, property, or the environment are exposed to one or more hazard(s)

Discussion

A hazard is potential, and doesn't arise until set off by a sequence of events. It then becomes a hazardous situation allowing exposure to the hazard. A hazardous situation can occur in normal operation or in a fault condition.

Example

Postulated sequences allowing a hazardous situation:

- Excessive heat
 - Chemical mix is incorrect
 - Use of a “blanket”, contrary to manufacturer’s instructions
- Rupture
 - Incorrect seal strength
- Improper reuse
 - Reuse of a single use device, contrary to manufacturer’s instructions

Definitions – Harm

Harm – physical injury or damage to the health of people, or damage to property or the environment

Discussion

Harm is the actual injury or damage that occurs from a hazardous situation. Harm arises from a hazardous situation.

Example

- Excessive heat
 - Thermal burn of the skin
- Rupture
 - Thermal burn of the skin
 - Chemical burn of the skin, eyes, *etc.*
- Improper reuse
 - See excessive heat
 - See rupture

Definitions – Severity

Severity – measure of the possible consequences of a hazard

Discussion

When harm occurs, it can have different levels of seriousness. Severity is the measure of seriousness of the harm.

Example

- Thermal Burn
 - First degree
 - Second degree
 - Third degree
- Chemical Burn
 - Skin
 - Eyes



Example

These instance must be converted to the manufacturer's description of severity. This is often a qualitative approach.

Definitions – Probability of Occurrence

Probability of occurrence – the likelihood that the harm occurs with the stated severity

Discussion

Some harms are less likely to occur than others. In addition, harms with different severity usually have different likelihood of happening.

Example

Thermal burn resulting from incorrect chemical mix → Very Low

Thermal burn resulting from use of a “blanket” → Low

Thermal burn resulting from a burst package → Very Low

Chemical burn resulting from a burst package → Very Low

Definitions – Risk

Risk – combination of the probability of occurrence of harm and the severity of that harm

Discussion

Risk combines two factors, usually in a qualitative approach. Risk increases with the severity of the harm. It also increases with the probability of occurrence of the harm. Risk is often expressed as a specialized “multiplication table”.

Example

Burst package results in 3rd degree (thermal) burn of a nurse.
Severity: Significant
Probability: Low
Risk: Medium

		Severity of Harm		
		Negligible	Moderate	Significant
Probability of Occurrence	High	Medium	Medium	High
	Medium	Low	Medium	Medium
	Low	Low	Low	Medium

Developing the Risk Management Plan

Clause 3.4

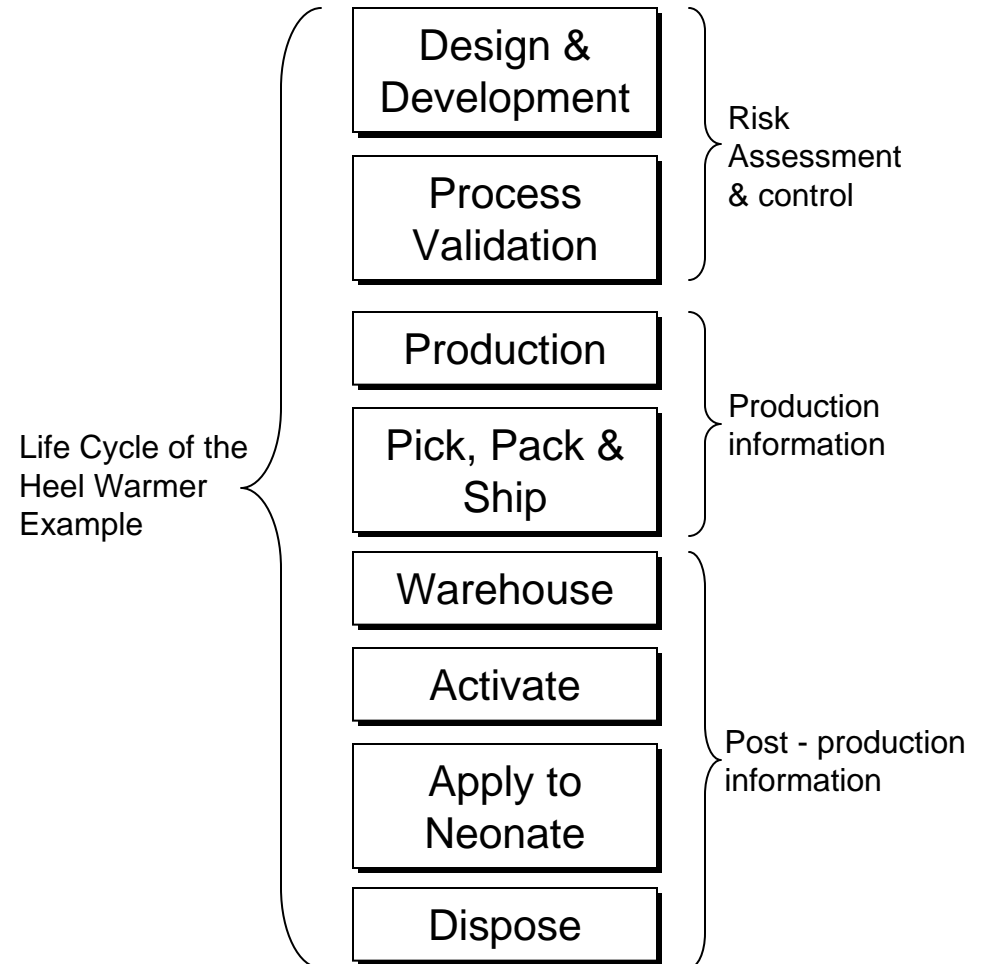
Annex F

Role of the Risk Management Plan

- The Risk Management Plan provides the overarching approach to the managing risk.
- It can take a variety of forms
 - Stand alone document
 - Integrated into QMS documents
 - Refer to other documents
- The structure and detail should relate to the medical device risk.

Scope of the Plan

- The scope needs to identify
 - the medical device (or family)
 - and the life cycle
- The risk management activities are mapped to the life cycle



Assign Responsibility and Authority

Risk Mgmt. Plan

- Assign roles and their responsibilities
- Examples include:
 - Reviewer
 - Approval authority
 - Expert
 - Verification specialist
- Follow the roles and responsibilities in the design project to avoid confusion
- The RASI Matrix is a useful tool for tasks
 - Responsible
 - Support
 - Authority
 - Inform

Criteria for Risk Acceptability

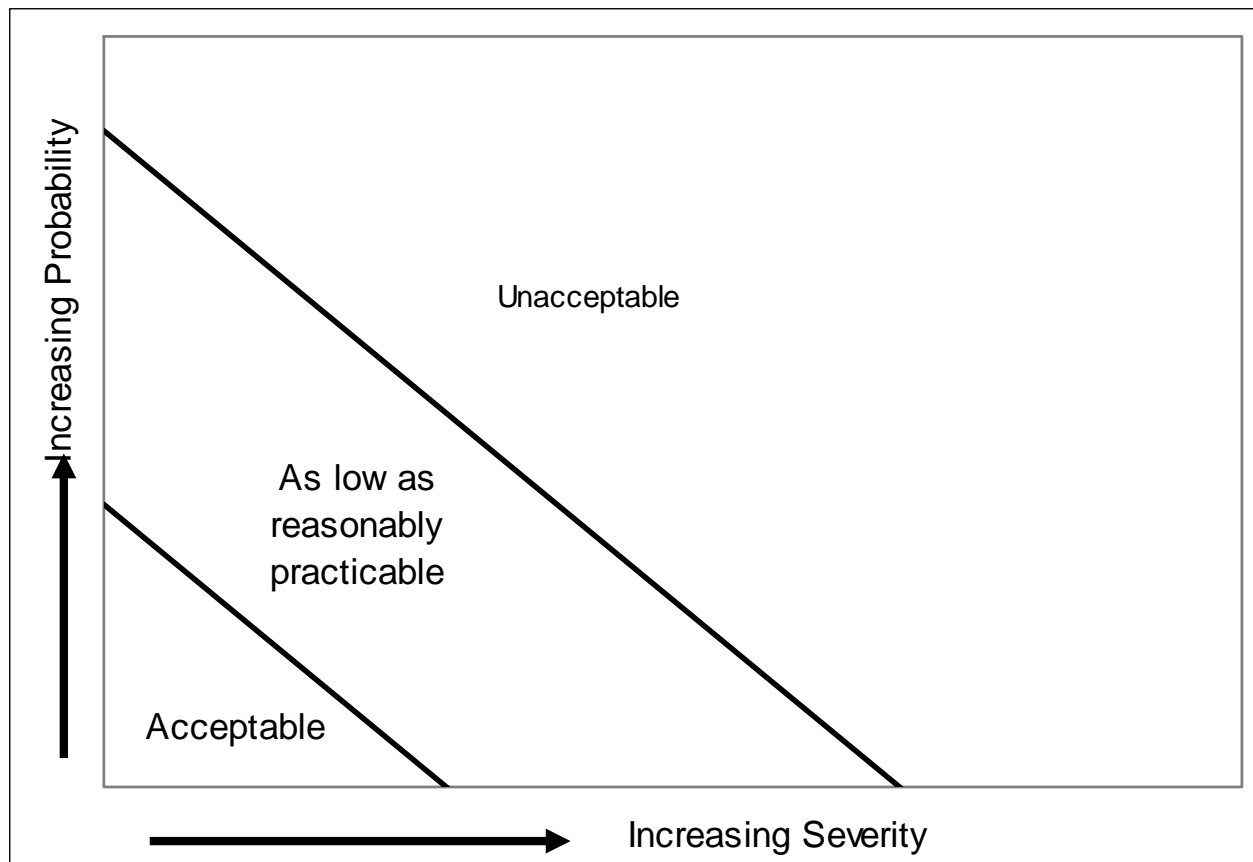
Risk Mgmt. Plan

- The Risk Management Plan needs two sets of criteria
 - One arises from the risk assigned to each hazardous situation
 - The other arises from the overall risk

Concept of Risk

Risk Mgmt. Plan

The concept of risk starts with continuous Probability and Severity dividing the Risk area into regions.



But more often becomes a table

Risk Mgmt. Plan

■ ■ ■

Severity Levels	
Term	Description
Catastrophic	Results in death
Critical	Results in permanent impairment to life-threatening injury
Serious	Results in injury or impairment requiring medical intervention
Minor	Results in injury or impairment not requiring medical intervention
Negligible	Inconvenience or temporary discomfort

Probability Levels	
Term	Description
Frequent	Happens often
Probable	Likely to happen
Occasional	Can happen, but not likely
Remote	Unlikely to happen
Improbable	Highly unlikely to happen

. . . that represents risk

Risk Mgmt. Plan

		Severity Levels				
		Negligible	Minor	Serious	Critical	Catastrophic
Probability Levels	Frequent	R2	R2	R3	R3	R3
	Probable	R2	R2	R2	R2	R3
	Occasional	R2	R2	R2	R2	R3
	Remote	R1	R1	R2	R2	R3
	Improbable	R1	R1	R2	R2	R3

R1 Acceptable risk
R2 As Low As Reasonably Practicable
R3 Unacceptable

Each company must develop its own risk analysis system.

The risk matrix may differ by product. For example, a risk matrix for a heel warmer may not be adequate for an automatic defibrillator.

Overall Residual Risk Evaluation

Risk Mgmt. Plan

- If each risk is low, then the residual risks should be low.
- When residual risk remains, it should be evaluated by specialists with knowledge of the device.
- If the residual risk is too high, it may be offset by the medical benefit.
 - X-rays cause damage to tissue, but the diagnostic benefit outweighs the risk.

Verification Activities

Risk Mgmt. Plan

- The standard says there are two distinct verification activities
 - Ensure the risk control measures are implemented in the final design.
 - Ensure the implemented risk control measures actually reduce the risk.
- The Risk Management Plan explains how to conduct these verifications.

Production Activity – Data Collection and Review

Risk Mgmt. Plan

- The Plan describes how you will collect and review data from production activities
 - Some production activities, if performed incorrectly could increase risk
 - Identify them and monitor process results
 - Pay particular attention to processes that must be validated

- Our example
 - The chemical mix determines the temperature of the heat warmer. Monitor mix parameters.
 - One would expect destructive testing for seal strength and temperature profile. Monitor the results of these tests.

Post-production Activity – Data Collection And Review

Risk Mgmt. Plan

- The plan describes how you will collect and review post-production activity
- Include the following areas in data collection:
 - Customer complaints
 - Installation reports
 - Servicing reports
 - FDA’s Adverse Event reports
 - Professional literature
- For each item collected, review the hazard, hazardous situation, and risk
 - The new information may lead you to update the previous analysis and conclusion

Performing Risk Analysis

Clause 4

Risk Analysis Methodology

- This is a systematic approach to determine risk
 - List every hazard (know or foreseeable)
 - List the associated hazardous situations
 - List the chain of events that creates each hazardous situation
 - Identify the potential harm(s)
 - Estimate the severity and probability
 - Calculate the risk, using the Risk Management Plan

This approach lends itself to a spreadsheet

Hazard	Chain of events	Hazardous Situation	Potential Harms	Severity	Probability	Risk
Pouch bursts	* Operator error setting up sealing machine * Weak seal * Nurse aggressively mixes the pouch	Pouch spills hot contents	Second degree thermal burn	Serious	Occasional	R2
	* Nurse reheats the pouch * Aggressive mixing breaks seal	Pouch spills hot contents	Second degree thermal burn	Serious	Remote	R2

The spreadsheet could contain many rows.
Notice that a hazard could have more than one chain of events.

Identifying hazards can be difficult

- The standard has a number of helpful aids
 - Annex C helps identify device characteristics that may impact safety
 - Table E.1 provides a list of potential hazards
 - Table E.2 offers a list of potential initiating events
 - Table E.3 shows examples of hazards, chain of events, hazardous situations, and harm
 - Annex H provides additional information for *in vitro* diagnostic devices

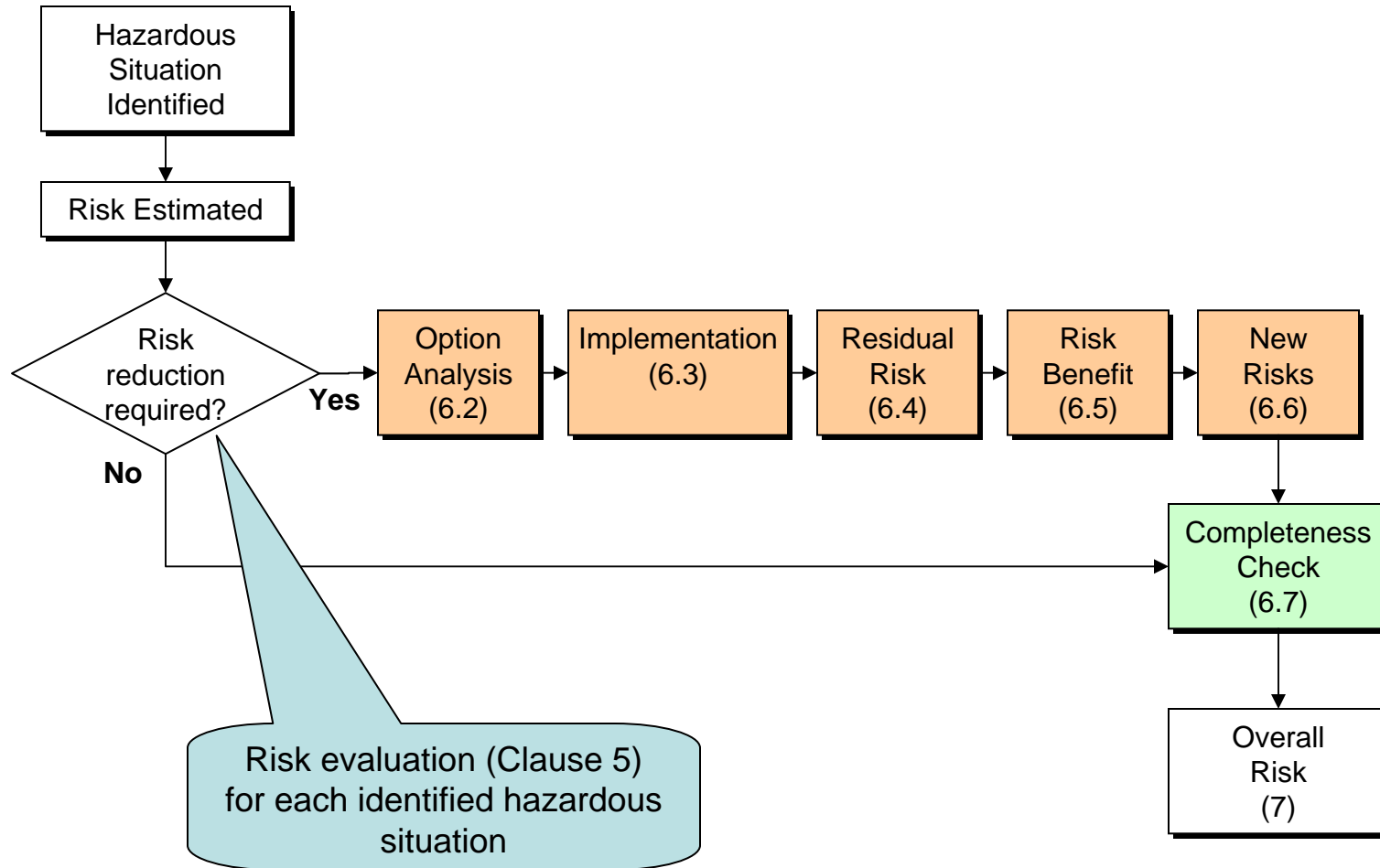
Risk Evaluation

Clause 5

The Prior Work Simplifies Risk Evaluation

- The Risk Management Plan contains the criteria for acceptable risk
- Risk Analysis determined the risk for each hazardous situation
- Application of the criteria to each hazardous situation determines the need for risk reduction

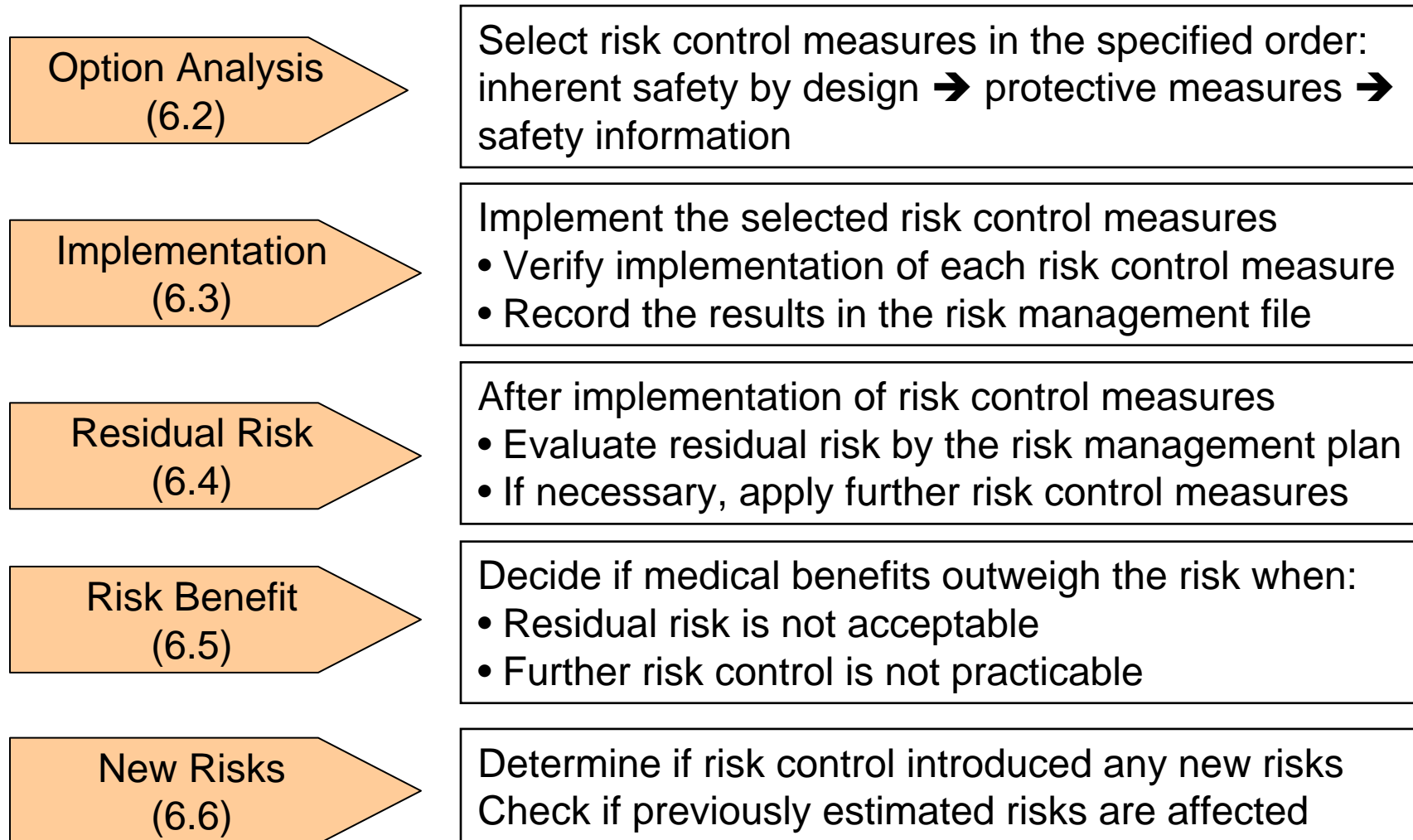
Recall Our Previous Flow Chart



Risk Control

Clause 6

Risk Reduction (when required) Clause 6



Risk Control Completeness Check

Clause 6

Completeness
Check (6.7)

Ensure the risks from all identified hazardous situations are considered.

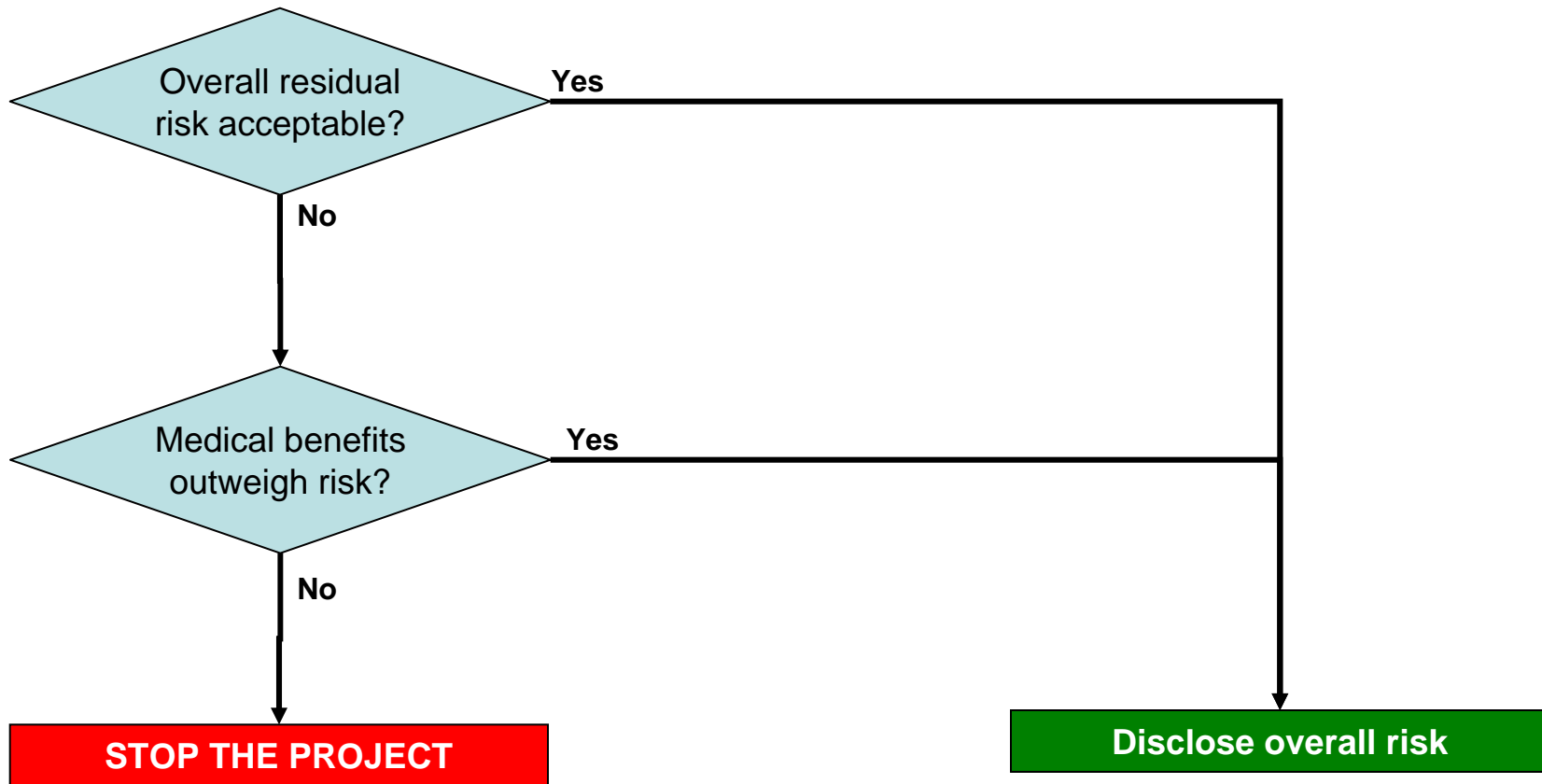
Evaluation of Overall Residual Risk Acceptability

Clause 7

This is a Broad View of Risk

- Previously we evaluated the risk of each hazardous situation
 - If it didn't meet the criteria we reduced the risk
 - We also cycled through all the hazardous situations to evaluate impacts
- Now we take a broader view to evaluate the whole device

Use Expert Opinion to Review and Decide



Disclosing Overall Risk

- Annex J offers guidance on communicating risk
- Information for safety is the least preferred method
 - Recall the priority order: inherent safety by design → protective measures → safety information
- Identify who receives the information and how
- Explain the risk, the consequences of exposure, and how to prevent the harm

The GHTF Guidance

Implementation of risk management principles and activities within a Quality Management System

Purpose and Overview

- The GHTF Guidance focuses on integrating Risk Management into the Quality Management System (QMS).
- The scope of ISO 14971 says
 - “This International Standard does not require that the manufacturer have a quality management system in place. However, risk management can be an integral part of a quality management system.”

Phases of Risk

1st Phase

Acceptable levels of risk

A policy or procedure determines risk acceptability criteria
It is derived from experience and research on currently accepted risk levels

2nd Phase

Risk analysis

Identify hazards in normal use or foreseeable misuse
Estimate the for each identified hazard

3rd Phase

Compare risks to acceptability criteria

Determine the need for risk reduction, if necessary
Determines the appropriate level of required risk reduction

4th Phase

Risk control and monitoring activities

Activities can begin as early as design input, and continues through manufacturing, distribution, installation, and servicing. Activities cover the device life cycle.

The Guidance Covers Areas of the QMS

- Management Responsibilities
- Outsourcing
- Planning
- Design and Development
- Traceability
- Purchasing Control and Acceptance Activities
- Production and Process Controls
- Servicing
- Analysis of Data
- Corrective and Preventive Actions (CAPA)

Two Areas are Worthy of Note

- Design and Development
 - The guidance covers each area of design and development.
 - Annex B contains a detailed flowchart placing risk management activities in the design and development process

- CAPA
 - The guidance contains a detailed flowchart integrating risk management into the CAPA process.
 - The flowchart identifies key quality data points:
 - Service Reports
 - Product Complaints
 - Manufacturing
 - Nonconformities/Defects
 - Engineering
 - Nonconformities/Defects
 - Quality System
 - Nonconformities/Defects

Tools for Risk Management

Failure Modes and Effects Analysis

Fault Tree Analysis

Hazard Analysis and Critical Control Point

Failure Modes and Effects Analysis (FMEA)

- This is a standard reliability technique adapted to risk analysis.
- In risk analysis, there is a very important consideration. Hazards and Harms **do not** require failure!
- Evaluate risk management in normal, single fault, and multiple fault conditions.

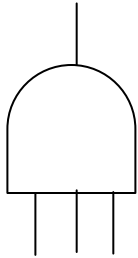
The Standard Method

- A large spreadsheet where each row relates to a hazard.
- Typical column entries include:
 - Function
 - Hazard
 - Harm
 - Mode (Normal, single fault, or multiple fault)
 - Severity
 - Occurrence
 - Detection
 - Risk Priority Number (Determine by severity, occurrence, & detection as defined in the Risk Management Plan)
 - Mitigation
 - Responsibility
 - Verification

Fault Tree Analysis (FTA)

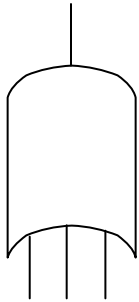
- A Fault Tree is a logic diagram showing the paths to an event
- The event under study is called the Top Event
- The causes of the Top Event are diagrammed using standard logic gate symbols

Logic Symbols



AND

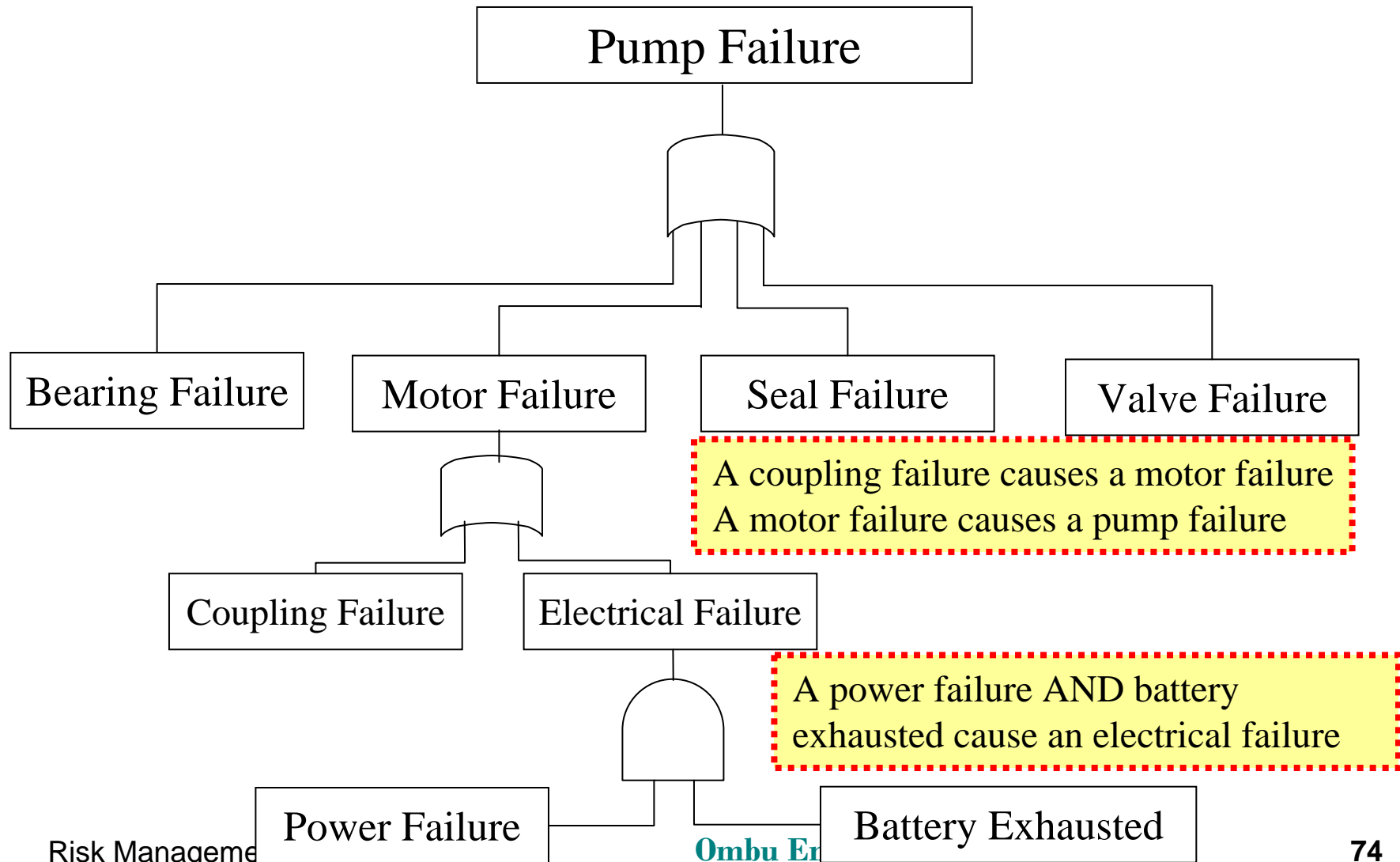
The output event occurs when all input events occur at the same time



OR

The output event occurs when at least one of the input events occur

A Fault Tree



Fault Tree Analysis (FTA) Steps

Fault Tree Analysis usually involves five steps:

1. Define the undesired event to study, the Top Event
 - State the undesired event that can cause risk
2. Understand the system
 - Describe the events that could allow the Top Event to happen. For each event determine the what would cause it. Continue to analyze the system.
3. Construct the fault tree
 - After selecting the undesired event and analyzed the system to identify the causal events, construct the Fault Tree. Describe the events and their relationships using AND and OR gates. More complex gates are also possible.
4. Evaluate the fault tree
 - Evaluate the Fault Tree. Look for possible improvements that can mitigate, reduce, or eliminate the events. Identify all possible hazards affecting in a direct or indirect way the system.
5. Control the hazards identified
 - After identifying the events and hazards, determine methods to decrease the probability of occurrence.

Hazard Analysis and Critical Control Point (HACCP)

- HACCP is a system to prevent problems, rather than finding them by inspection at the end of the production process.
- HACCP is used by US regulatory agencies (FDA and USDA) to help protect the food supply
- HACCP is based on seven principles described in the FDA's *Hazard Analysis and Critical Control Point Principles and Application Guidelines*

HACCP Principles

- Principle 1: Conduct a hazard analysis
 - The hazard analysis develops a list of significant hazards that they are reasonably likely to cause injury or illness if not effectively controlled.
- Principle 2: Determine the critical control points (CCPs)
 - A critical control point is a step at which control can be applied to prevent or eliminate a hazard or reduce it to an acceptable level.
- Principle 3: Establish critical limits
 - A critical limit is a maximum and/or minimum value to which a parameter must be controlled at a CCP to prevent, eliminate or reduce to an acceptable level the occurrence of a hazard. A critical limit is used to distinguish between safe and unsafe operating conditions at a CCP.

HACCP Principles (cont.)

- Principle 4: Establish monitoring procedures
 - Monitoring is a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for future use in verification.
 - Monitoring serves three main purposes.
 - Monitoring facilitates tracking of the operation. If monitoring indicates that there is a trend towards loss of control, then action can be taken to bring the process back into control before a deviation from a critical limit occurs.
 - Monitoring is used to determine when there is loss of control and a deviation occurs at a CCP, *i.e.*, exceeding or not meeting a critical limit. When a deviation occurs, an appropriate corrective action must be taken.
 - Monitoring provides written documentation for use in verification.

HACCP Principles (cont.)

- Principle 5: Establish corrective actions
 - The HACCP system identifies hazards and establishes strategies to prevent, eliminate, or reduce their occurrence. Deviations from established processes may occur, so if there is a deviation from established critical limits, corrective actions are necessary. Specific corrective actions should be developed in advance for each CCP and included in the HACCP plan
 - Corrective actions should include the following elements:
 - (a) determine and correct the cause of non-compliance;
 - (b) determine the disposition of non-compliant product and
 - (c) record the corrective actions that have been taken.

HACCP Principles (cont.)

- Principle 6: Establish verification procedures
 - Verification is defined as those activities, other than monitoring, that determine the validity of the HACCP plan and that the system is operating according to the plan.
- Principle 7: Establish record-keeping and documentation procedures
 - Generally, the records maintained for the HACCP System should include the following:
 - A summary of the hazard analysis, including the rationale for determining hazards and control measures
 - The HACCP Plan
 - Support documentation such as validation records
 - Records that are generated during the operation of the plan

Summary & Conclusions

Summary

- The standard method for medical device risk management is ISO 14971:2007
 - The FDA recognizes it as a consensus standard
 - The EU lists it as a harmonized standard to the MDD, IVD, and AIMD
 - ISO 13485:2003 recommends ISO 14971 for risk management

Summary

- ISO 14971 implementation starts with a Risk Management Plan
- The implementation flows through a series of steps defined in the respective clauses:
 - 4: Risk Analysis
 - 5: Risk Evaluation
 - 6: Risk Control
 - 7: Residual Risk Evaluation
 - 8: Risk Management Report
 - 9: Production & Post-production Information
- Maintain of the information in the Risk Management File

Summary

- The Risk Management File is not a static document
- It should include production information
 - Monitor production processes that contribute to risk factors
 - Validated processes are particularly significant contributors
- It include post-production information
 - Integrate the complaint and post-market surveillance processes

Conclusions

- ISO 14971:2007 is the *de facto* standard for medical device risk management
- Regardless of the marketing region (US, EU, Canada, *etc.*) ISO 14971 is a valuable addition to a medical device QMS
- ISO 14971 is most effective when it is integrated into a company's QMS.



QUESTIONS