What's Different in ISO 14971:2007?

Presented September 13th, 2007

ASQ Biomedical Division

Presented by
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What's Different in ISO 14971:2007?

What's Different in ISO 14971:2007?

What will be addressed:

TOPICS

- **Some Definitions**
  - What is ISO 14971:2007?
  - What is Risk?
  - What is Risk Management?
  - What is "Quality Risk Management"?
- **Quality Management System Considerations**
  - What Do Standards and Regulations Require with Regard to Risk Management?
  - Where in the QMS should a requirement for Risk Management be established?
- **General Requirements of ISO 14971**
- **Differences Between ISO 14971:2000(E) and ISO 14971:2007(E)**
- **Risk Management References**
- **Some Risk Management Tools**

What's Different in ISO 14971:2007?

Some Definitions

- **Some Definitions**
  - What is ISO 14971:2007?
  - What is Risk?
  - What is Risk Management?
  - What is "Quality Risk Management"?

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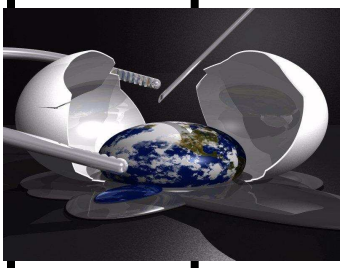
What's Different in ISO 14971:2007?

- **What is ISO 14971:2007?**
  - Source: http://webstore.ansi.org/RecordDetail.aspx?sku=ISO+14971%3a2007
  - ISO 14971:2007 Medical devices - Application of risk management to medical devices
    - ISO 14971:2007 specifies a process for a manufacturer to identify the hazards associated with medical devices, including *in vitro* diagnostic (IVD) medical devices, to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls. The requirements of ISO 14971:2007 are applicable to all stages of the life-cycle of a medical device.

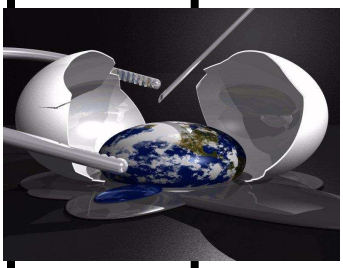
Some Definitions



What's Different in ISO 14971:2007?

- **What is Risk?**
  - Source: http://www.fda.gov/cder/guidance/7153fnl.htm - "Guidance for Industry Q9 Quality Risk Management" and ISO/IEC Guide 51 "Safety aspects — Guidelines for their inclusion in standards" Also: GHTF/SG1/N15: 2006 / SG1(PD)/N44 / SG1/N41R9: 2005 / GHTF/SG3/N15R8 : 2005
  - **Risk**: The combination of the probability of occurrence of harm and the severity of that harm
  - Note: ISO 14971:2007 definition 2.16 is identical

Some Definitions



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Some Definitions

- **What is Risk Management?**
  - Sources: ISO 14971:2007, definition 2.22 "Medical devices -- Application of risk management to medical devices"
  - **Risk Management:** Systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating, controlling and monitoring risk.
  - New in 2007: " monitoring"

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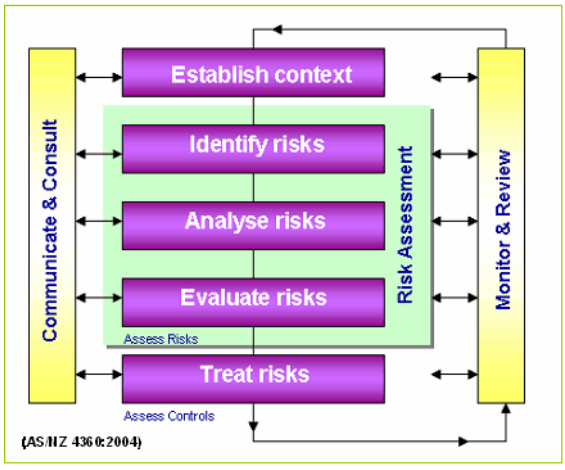
Some Definitions

- **Typical Risk Management Process – Example 1** (http://www.vqpb.vic.gov.au/CA256C450016850B/0/EA22BBF17E386255CA256E3900063F44?OpenDocument)



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Some Definitions

- **Typical Risk Management Process – Example 2 (http://www.tfhrc.gov/pubrds/04jul/06.htm)**

Source: Integrated Risk Management Framework, Treasury Board of Canada, Secretariat, 2001. Reproduced with the permission of the Minister of Public Works and Government Services, Government of Canada, 2004.

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What's Different in ISO 14971:2007?

Some Definitions

- **What is "Quality Risk Management"?**
  - Source: http://www.fda.gov/cder/guidance/7153fnl.htm - "Guidance for Industry Q9 Quality Risk Management"
  - **Quality Risk Management**: A systematic process for the assessment, control, communication, and review of risks to the quality *of the drug product across the product lifecycle.*

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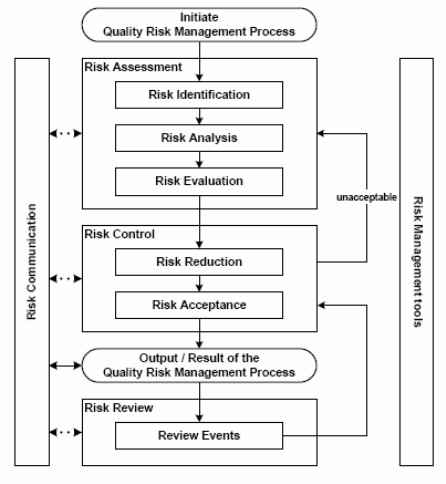
What's Different in ISO 14971:2007?

- **Typical Quality Risk Management Process**
  (http://www.fda.gov/cder/guidance/7153fnl.htm)

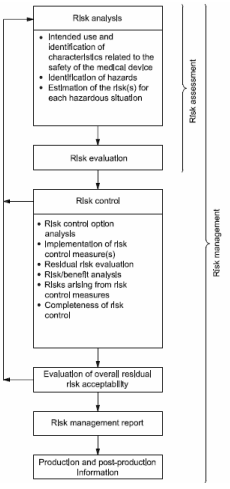
Some Definitions



What's Different in ISO 14971:2007?

- **ISO 14971:2007 Risk Management Process**

Some Definitions



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Quality Management System Considera-tions

- **Quality Management System Considerations**
  - What Do Standards and Regulations Require with Regard to Risk Management?
  - Where in the QMS should a requirement for Risk Management be established?

What's Different in ISO 14971:2007?

Quality Management System Considera-tions

- What Do Standards and Regulations Require with Regard to Risk Management?
  - Many industries have independent Risk Management Standards
  - **Quality Risk Management** is required by ISO 13485:2003 for Medical Devices
  - **Risk analysis** is required by the FDA's Quality System Regulation (QSR) The FDA initiated its risk analysis expectations on June 1, 1996 and requirement June 1, 1997.
  - **Risk Analysis** is also required by Annex I Essential Safety Requirements of the European Union's Medical Devices Directives

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Quality Management System Considera-tions

- What Do Standards and Regulations Require with Regard to Risk Management?(continued)
- **ISO 13485** addresses Risk Management in the process approach defined as:

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What's Different in ISO 14971:2007?

Quality Management System Considera-tions

- What Do Standards and Regulations Require with Regard to Risk Management?(continued)
- **ISO 13485** also specifically addresses Risk Management in the section on Planning of Product Realization as follows:
  - Section 7.1 Planning of product realization
    - Documented requirements for **risk management** throughout product realization and records arising from risk management (reference **ISO 14971** for guidance)

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What's Different in ISO 14971:2007?

Quality Management System Considera-tions

- Where in the QMS should a requirement for Risk Management be established?
  - As part of the Quality Policy
  - In Design Control
  - Throughout the Entire Product Life Cycle
  - For all aspects of Product Realization
  - Specifically for Sterile Packaging at:
    - Design Validation
    - Process Validation
    - Distribution Validation

What's Different in ISO 14971:2007?

Quality Management System Considera-tions

- **Where in the QMS should a requirement for Risk Management be established?**
  - Include ***Risk Management*** as part of the Quality Policy.
  - Establish ***Risk Management Objectives*** that support the Quality Policy.
  - Include ***Risk Management*** on the agenda for ***Quality Management Reviews***.

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Quality Management System Considera-tions

- **Where in the QMS should a requirement for Risk Management be established? (cont'd)**
  - Establish ***Risk Management*** related Quality Metrics within QMS ***Operating Procedures.***
  - When feasible, consider establishing Dashboard requirements within ***Production Procedures, Work Instructions, or Process, Material and Product Specifications.***

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Quality Management System Considera-tions

- **Where in the QMS should a requirement for Risk Management be established? (cont'd)**
  - When products or processes are outsourced, especially for design or validation services, flow requirements for ***Risk Management*** related Quality Metrics to Suppliers via their ***Contracts or Purchase Orders.***

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What's Different in ISO 14971:2007?

ISO 14791:2007(E) General Requirements

- **General Requirements of ISO 14971**
  - General Requirements for Risk Management
    - Risk Management Plan
    - Risk Management File
  - Risk Analysis
  - Risk Evaluation
  - Risk Control
    - Risk Reduction
  - Evaluation of Overall Residual Risk Acceptability
  - Risk Management Report
  - Production and* Post-Production Information

    * New in ISO 14971:2007

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What's Different in ISO 14971:2007?

ISO 14791:2007(E) versus ISO 14791:2000(E)

- **Differences Between ISO 14971:2000(E) and ISO 14971:2007(E)**
  - **2007 adds or modifies definitions for:**
    - ***in vitro* diagnostic medical device IVD medical device**
    - **life-cycle**
    - **post-production**
    - **residual risk (changed from "after protective measures" to "after risk control measures")**
    - **risk estimation**
    - **risk evaluation (eliminated reference to"current values of society")**
    - **risk management (added "monitoring")**
    - **top management**
    - **use error**
    - **verification – significantly expanded to describe confirmation activities**

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What's Different in ISO 14971:2007?

ISO 14791:2007(E) versus ISO 14791:2000(E)

- **Differences Between ISO 14971:2000(E) and ISO 14971:2007(E)**
  - **2007 expands definition for:**
    - **medical device - which now includes:**
      - **implements**
      - **machines**
      - **implants**
      - ***in vitro* reagents**
      - **calibrators**
      - **software (by itself)**
      - **life supporting or sustaining devices**
      - **devices for disinfection of medical devices**
      - **devices that provide information for medical purposes by means of in vitro examination of specimens derived from the human body**

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What's Different in ISO 14971:2007?

ISO 14791:2007(E) versus ISO 14791:2000(E)

- **Differences Between ISO 14971:2000(E) and ISO 14971:2007(E)**
  - **2007 Risk Management Process Schematic expanded to include:**
    - **additional Risk Controls,**
    - **separate block for Residual Risk,**
    - **Risk Management Report and**
    - **Production/Post-Production Information.**

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What's Different in ISO 14971:2007?

ISO 14791:2007(E)

versus

ISO 14791:2000(E)

- **Differences Between ISO 14971:2000(E) and ISO 14971:2007(E)**
  - **2007 dropped Section 3.1 on National or Regional Regulatory Requirements**
  - **2007 added Section 3.2 on the Risk Management Process**

What's Different in ISO 14971:2007?

ISO 14791:2007(E)

versus

ISO 14791:2000(E)

- **Differences Between ISO 14971:2000(E) and ISO 14971:2007(E)**
  - **2007 Risk Management File section 3.5 expanded to include:**
    - **Risk Analysis**
    - **Risk Evaluation**
    - **Implementation and Verification of Risk Control Measures**
    - **Assessment of Acceptability of Residual Risks**

What's Different in ISO 14971:2007?

ISO 14791:2007(E)

versus

ISO 14791:2000(E)

- **Differences Between ISO 14971:2000(E) and ISO 14971:2007(E)**
  - **2007 changed the former section 4.1 titled "Risk Analysis Procedure" to "Risk Analysis Process"**
  - **In 2007, Figure 2 from the 2000 standard, formerly called "Overview of risk management activities as applied to medical devices" has been dropped out**
  - **Section 4.3 changed from "Identification of Known or Foreseeable Hazards" to "Identification of Hazards"**
  - **Section 4.4 changed from "Estimation of the Risk(s) for each Hazard" to "Estimation of the Risk(s) for Each Hazardous Situation"**

What's Different in ISO 14971:2007?

ISO 14791:2007(E)

versus

ISO 14791:2000(E)

- **Differences Between ISO 14971:2000(E) and ISO 14971:2007(E)**
  - **2007 changed 6.2 from "Option Analysis" to "Risk Control Option Analysis"**
  - **In 2007, Figure 2 from the 2000 standard, formerly called "Overview of risk management activities as applied to medical devices" has been dropped out and moved to an Annex (Annex B)**

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What's Different in ISO 14971:2007?

ISO 14791:2007(E)

versus

ISO 14791:2000(E)

- **Differences Between ISO 14971:2000(E) and ISO 14971:2007(E)**
  - **2007 changed 6.6 from "Other generated hazards" to "Risks arising from risk control measures"**
  - **2007 changed 6.7 from "Completeness of risk evaluation" to "Completeness of risk control"**

What's Different in ISO 14971:2007?

ISO 14791:2007(E)

versus

ISO 14791:2000(E)

- **Differences Between ISO 14971:2000(E) and ISO 14971:2007(E)**
  - **2007 changed section 7 from "Overall residual risk evaluation" to "Evaluation of overall residual risk acceptability"**

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What's Different in ISO 14971:2007?

ISO 14791:2007(E)

versus

ISO 14791:2000(E)

- **Differences Between ISO 14971:2000(E) and ISO 14971:2007(E)**
  - **2007 clarifies section 8 to indicate that elements required within the "Risk Management Report" are:**
    - **Appropriate implementation of the Risk Management Plan**
    - **Acceptability of overall residual risk**
    - **Methods to obtain relevant production and post-production information are appropriate and are in place**

What's Different in ISO 14971:2007?

ISO 14791:2007(E)

versus

ISO 14791:2000(E)

- **Differences Between ISO 14971:2000(E) and ISO 14971:2007(E)**
  - **2007 changed Section 9 from "Post production information" to "Production and post-production information"**

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What's Different in ISO 14971:2007?

ISO 14791:2007(E)

versus

ISO 14791:2000(E)

- **Differences Between ISO 14971:2000(E) and ISO 14971:2007(E)**
  - **2007 New/Changed Annex Sections:**
    - **New: Annex A – Rationale for requirements (was Amendment 1, Annex H in 2000 version)**
    - **New: Annex B - Overview of the risk management process for medical devices (contains modification of former figure 2 and elaborations about it from the 2000 version of the standard)**
    - **Changed: Annex E – Examples of hazards, foreseeable sequences of events and hazardous situations (was Examples of possible hazards and contributing factors associated with medical devices in 2000 version – Annex D)**

What's Different in ISO 14971:2007?

ISO 14791:2007(E)

versus

ISO 14791:2000(E)

- **Differences Between ISO 14971:2000(E) and ISO 14971:2007(E)**
  - **2007 New/Changed Annex Sections (cont'd):**
    - **Changed: Annex I – Guidance on risk analysis for biological* hazards (*was toxicological hazards in 2000 version – Annex C)**
    - **New: Annex J – Information for safety and information about residual risk**
    - **Dropped: former Annex G – Other standards that contain information related to the elements of risk management described in this International Standard**

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What's Different in ISO 14971:2007?

- **Risk Analysis (**Avoid ANAL-ysis**):**

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Risk Management References

- **Risk Management References have been cited throughout this presentation. Here are a few worth mentioning or worth mentioning again:**
  - To purchase a copy of ISO 14791-2007: http://webstore.ansi.org/RecordDetail.aspx?sku=ISO+14971%3a2007
  - Dilbertisms: www.comics.com (paid members can sort comics by key words)
  - Definitions: Do a Google search using "Definition of ____" and use the advanced feature to search for results only from *.gov domains (www.google.com)

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What's Different in ISO 14971:2007?

Risk Management References

- **Risk Management References (continued):**
  - The U.S. Food and Drug Administration's Guidance for Risk Management (Q9): http://www.fda.gov/cder/guidance/7153fnl.htm
  - The Global Harmonization Task Force Glossary of Terms: http://www.ghtf.org/steering/inventorysc/SC-PD3-N4.pdf

What's Different in ISO 14971:2007?

Risk Management Tools You can Put To Use Immediately

- **Risk Management Tools**
- **The following free tools will be provided to you via email upon confirmation of your subscription to the CAPAtrak Member List:**
  - **A .pdf file of the two screen per page handout for this presentation**
  - **An MS Word template for an ISO 13485:2000 compliant Risk Management Procedure**
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THANK YOU!
May I answer Your Questions?

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