



What's Different in ISO 14971:2007?

Presented September 13th, 2007




Biomedical
Division
ASQ
AMERICAN SOCIETY FOR QUALITY

**Presented by
Diane Kulisek**




www.capatrak.com
805-522-5005 O
805-320-7879 C
dkulisek@capatrak.com
2493 Pinewood Place
Simi Valley, CA 93065



What's Different in ISO 14971:2007?

Dilbert by Scott Adams




The comic strip shows Dilbert reporting to his boss. Dilbert: "AS REQUESTED, I DID A 'RISK MANAGEMENT' ASSESSMENT." Boss: "I CONCLUDED THAT THERE WAS NO RISK OF ANY MANAGEMENT." Dilbert: "DO YOU HAVE ANYTHING TO ADD?" Boss: "I'LL GET BACK TO YOU."

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2




What's Different in ISO 14971:2007?

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 will be addressed:

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Some Definitions

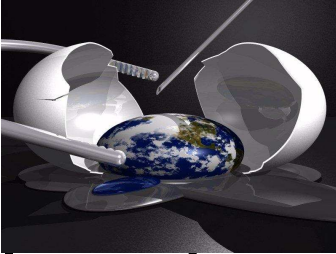
- **Some Definitions**
 - What is ISO 14971:2007?
 - What is Risk?
 - What is Risk Management?
 - What is "Quality Risk Management"?

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What's Different in ISO 14971:2007?

Some Definitions



- **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.

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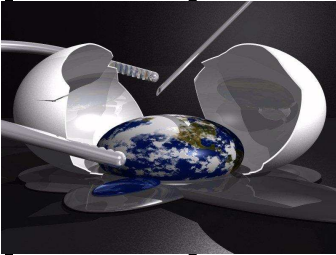
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5

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Some Definitions



- **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

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6

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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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7

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Some Definitions

- **Typical Risk Management Process – Example 1**
(<http://www.vgpb.vic.gov.au/CA256C450016850B/0/EA22BF17E386255CA256E390063F44?OpenDocument>)

(AS/NZ 4360:2004)

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

Some Definitions



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 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.*

Some Definitions

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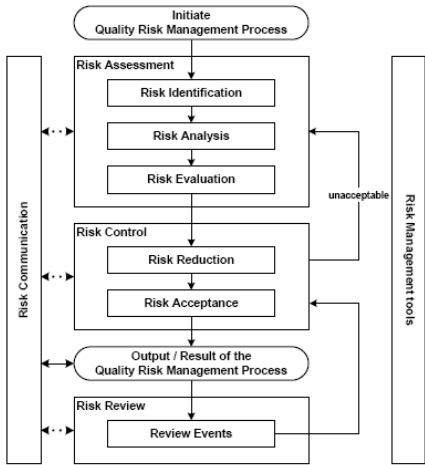
10



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


**Some
Definitions**



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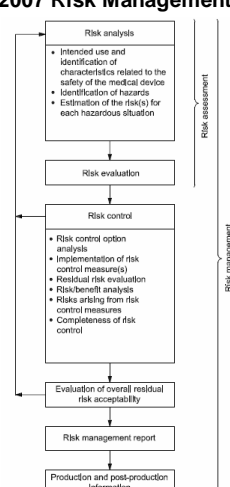
11



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


**Some
Definitions**



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12




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Quality Management System Considerations

- **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?

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Quality Management System Considerations

- 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 Considerations

- 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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15

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Quality Management System Considerations

- 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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16




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Quality Management System Considerations

- 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

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Quality Management System Considerations

- 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 Considerations


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- 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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19



Quality Management System Considerations


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- 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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20



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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21



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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22



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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23



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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24



What's Different in ISO 14971:2007?


ISO 14791:2007(E)
versus
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- 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

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25



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

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26



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"

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27



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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28



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”

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29



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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30



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

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31



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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32

 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)

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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 (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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- **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 14971-2007: <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 (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/inventorystc/SC-PD3-N4.pdf>

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37

Risk Management References



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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
- Please be sure to let me know that you were at this evening's presentation by return email when I thank you for joining the CAPAtrak community.
- To subscribe, please go to www.capatrak.com and click on the blue button that says: "sign up now" on any page of the website.

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38

Risk Management Tools You can Put To Use Immediately

THANK YOU!
May I answer Your
Questions?

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www.capatrak.com
805-522-5005 O
805-320-7879 C
dkulisek@capatrak.com
2493 Pinewood Place
Simi Valley, CA 93065