Biomedical Division
ASQ
The Global Voice of Quality™

Risk Management

Who are we?

- The Biomedical Division is an industry specific Division of ASQ

- The Biomedical Division is managed by volunteers
  - Elected Officers
  - Standing Committee Chairs
  - Regional Discussion Group Committee Chairs

What are we striving for?

We strive to be your best authority on quality issues in the medical device and in-vitro diagnostics development and manufacturing community

Our Vision and Mission

To be the leading authority on quality issues related to the Biomedical Community

To promote the awareness and the use of quality principles, concepts and technologies in the Biomedical Community

What we see in the industry

- Globalization
- Harmonization
- Interpretation of Regulations
- Interpretation of Standards
- Organizations with Multiple/Single Quality Management Systems
- Organizations with Multiple/Single Notified Bodies

……Communication Challenges

Harmonization/Globalization

- Harmonized
  - Harmonized Standards

    Across multiple countries and governmental systems
  - Harmonized Procedures

    Across multiple sites and/or management systems
  - Why?

    Clear, unambiguous, common language and expectations for both internal and external communications.
  - Why not?

    One size fits most.

Harmonization/Globalization

- Where have you seen this done?
  - Project Management
  - Design Controls
  - Change Controls
  - Supplier Controls
  - …
- Where have you see this done well or to a mutual benefit?
  - Risk Management EN/ISO 14971

ISO 31000

Communications

- Internal
  - Product Development team
  - Sustaining Product teams
  - …….
- External
  - Regulators
  - Notified Bodies
  - Testing/Certification Bodies

Terms

a) Risk

The combination of hazard probability and harm severity.

Do not redefine, use the published definition: combination of the probability of occurrence of harm and the severity of that harm [ISO/IEC Guide 51:1999, definition 3.2]

b) Risk Priority Number

A means for prioritizing work efforts

c) Risk Acceptability

$$a \neq b \neq c$$

Terms

Acceptable Risk / Risk Acceptability

IS

Defined by you in your Risk Management Policy/Plans and is determined by Risk Benefits Analysis. In 14971 § 3.4 d) The plan shall include criteria for risk acceptability, based on the manufacturer's policy for determining acceptable risk, including criteria for accepting risks when the probability of occurrence of harm cannot be estimated;

Safety: freedom from unacceptable risk [ISO/IEC Guide 51:1999, definition 3.1]

IS NOT

Defined by the EN/ISO 14971 standard

Defined as an RPN

Terms

Unacceptable Risk

IS

The converse of acceptable risk as defined by you in your Risk Management Policy.

If safety is defined by freedom from unacceptable risk, an unacceptable risk is therefore not safe.

IS NOT

Defined as Intolerable Risk

Defined as an RPN

Terms

- Intolerable Risk

  Some risks which cannot be reduced, may always be assessed to be intolerable. This may be acceptable risk. Therefore intolerable risk does not equal unacceptable risk.

  Note: This term from the 2000 edition is not in the 2007 edition of the risk management standard.

Terms

- Essential
  - Essential Performance
    (EN/IEC 60601-1)
  - Essential Requirements
    (MDD)
  - Essential Requirements Check List
    (MDD)
  - Essential Design Outputs
    (21CFR820.30)
  - Essential Characteristics
    (? Characteristics the could affect safety)

Terms

FDA's QSR and ISO13485 are harmonized (do not conflict) and meet global requirements for medical devices. The difference in scope:

- FDA's standard of approval is "**safe** and effective"
- EU's standard for CE marking is "**safety** and performance"

Terms

Definition from EN 14971 2nd edition

2.24 safety

freedom from unacceptable risk

Definition from EN 60601-1 3rd edition

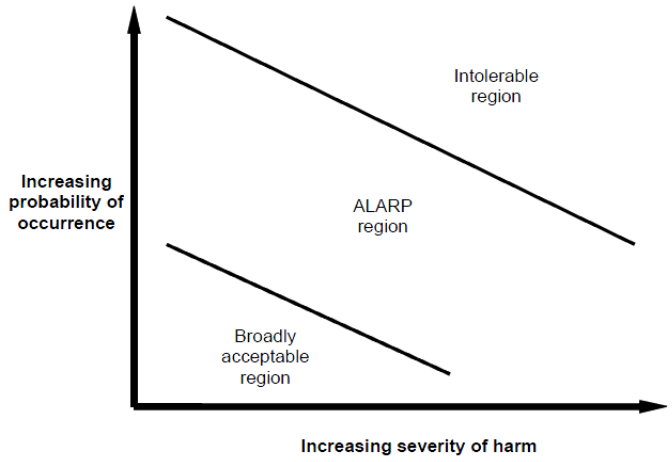
3.27 ESSENTIAL PERFORMANCE

performance necessary to achieve freedom from unacceptable RISK

Note: When substituting the word “safety” for the phrase “freedom from unacceptable risk”, the definition of Essential Performance could be expressed: *performance necessary to achieve safety.*

Methods

- Two embodiments of three region risk Chart (figure E.1 from 14971:2000)



Inverted Scale

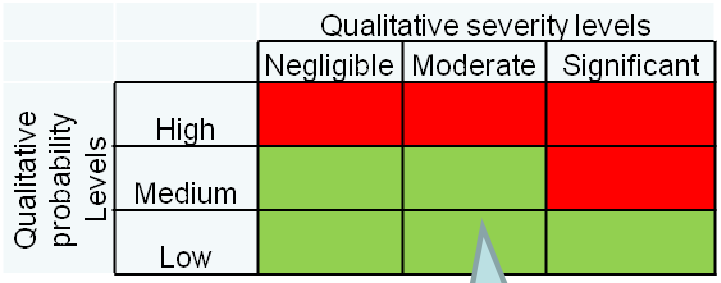
Likelihood	Severity: 5 Catastrophic	4 Critical	3 Minor	2 Marginal	1 Negligible
5 - Routine	C	C	C	C	B
4 - Probable	C	C	C	B	B
3 - Occasional	C	C	B	B	B
2 - Remote	C	B	B	B	A
1 - Improbable	B	B	B	A	A

A	Acceptable Region	Risk/Benefits are supported by PMA 010018 SSEDs.
B	ALARP Region	As Low As Reasonably Practicable region
C	Intolerable Region	As CK is an elective and esthetic procedure for most patients, hazards with Catastrophic and Critical severities do not have benefits that outweigh risks.

Methods

- Qualitative and semi quantitative Charts

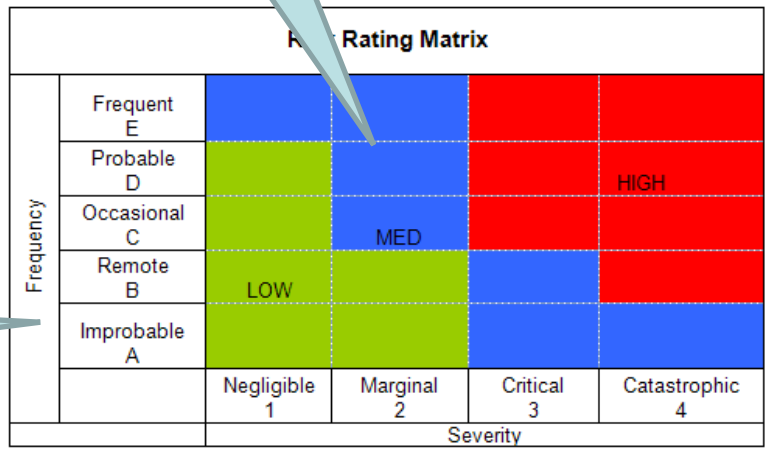
(see figures in Appendix D of 14971:2007)



Two Region

Three Region

Semi quantitative probability levels



Methods

- Probability Estimation
  - Qualitative
  - Quantitative

  - How do you estimate probability of occurrence levels for software issues?

Tools

- FTA

  EN 61025

- HAZOP

  IEC 61882

- HACCP

  ASTM E2590

- FMEA

  EN 60812

  - Design
  - Process
  - …..

Are these top down or bottom up assessment tools?

Case Study

Situation: PFMEA from your Contract MFR's QMS is presented for use as a record in your RMF.

		SEVERITY				
		S-1	S-2	S-3	S-4	S-5
OCCURRENCE	O-10	ACCEPT	UNACCEPT	UNACCEPT	UNACCEPT	UNACCEPT
	O-9	ACCEPT	ALARP	UNACCEPT	UNACCEPT	UNACCEPT
	O-8	ACCEPT	ALARP	ALARP	UNACCEPT	UNACCEPT
	O-7	ACCEPT	ACCEPT	ALARP	ALARP	UNACCEPT
	O-6	ACCEPT	ACCEPT	ALARP	ALARP	UNACCEPT
	O-5	ACCEPT	ACCEPT	ALARP	ALARP	ALARP
	O-4	ACCEPT	ACCEPT	ALARP	ALARP	ALARP
	O-3	ACCEPT	ACCEPT	ACCEPT	ALARP	ALARP
	O-2	ACCEPT	ACCEPT	ACCEPT	ALARP	ALARP
	O-1	ACCEPT	ACCEPT	ACCEPT	ALARP	ALARP

They use a semi quantitative 5x10 three region matrix and you use a semi quantitative 5x4 three region matrix.

What are your options?

Case Study

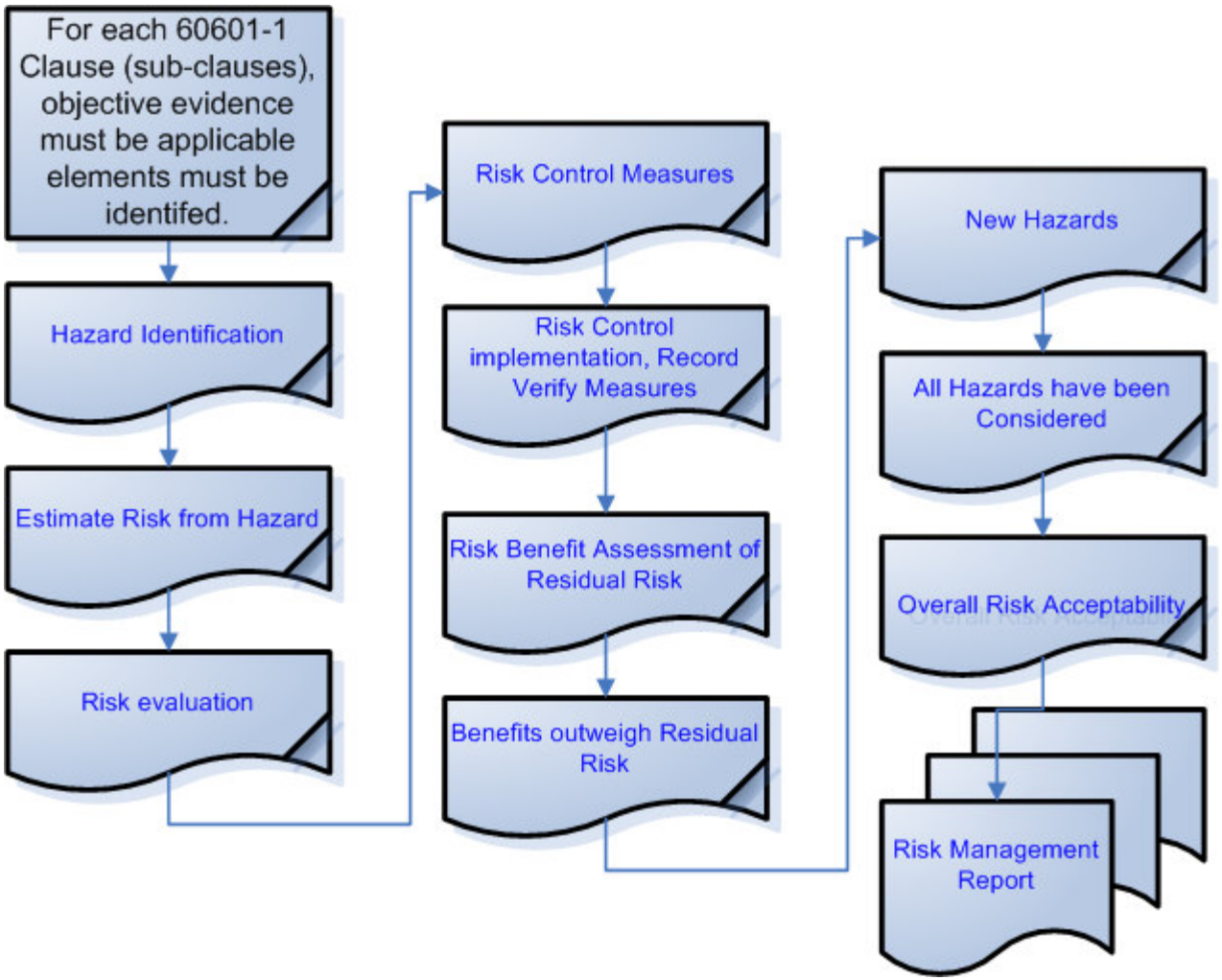
- Options:
  - Accept as is
  - Review and approve
  - Ask them to re-execute using your SOP
  - Translate into you your format
  - Create a conversion algorithm
- Outcome:
  - Some harm severities are not equivalent
  - Some risks assessed as ALARP in one QMS are assessed as unacceptable in another QMS

Case Study

- Differences have been reconciled, reviewed and approved.
- Verification of risk controls
  - How is this demonstrated?
  - How is it recorded?
  - Have all the potential hazarded in 60601-1 been addressed?

Case Study

Hazard Traceability



Case Study

Example Clauses and Sub-clauses

- 5- General requirements for testing MEE
  - 5.7- Humidity preconditioning treatment
- 8- Protection against electrical HAZARDS from ME EQUIPMENT
  - 8.6.3 - Protective earthing of moving parts
- 9- Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS
  - 9.2.2.5 c - Continuous activation

Case Study

- Complete RMF
  - Plan was in place.
  - Report with objective evidence including verification of risk control effectiveness.
- Submit your Medical Equipment for Electrical Safety Marking
  - EN/IEC 60601-1 3rd Edition
  - Required for import into the EU in 2012

RMS Inspection/Certification

- Compliance with ISO 14971 is a requirement to demonstrate compliance with IEC 60601-1 3rd Edition.
- How will this be achieved?
  - Registration by an accredited body
  - System evaluation at time of product testing
  - On-site assessment (audit)
- Are you prepared?

Additional Open Discussion

Thank You

What we do…

- **US Collaborations**
  - Provide Biomedical Tracks for
    - ASQ Divisions
    - ASQ Sections
    - Industry Associations

- **International Collaborations**

Food Drug and FDC Cosmetic Division

ASQ Software Division

FDA

AdvaMed Advanced Medical Technology Association

RAPS

IBEC

IMDA

IQA Institute of Quality Assurance

Management Forum

What we do… Grants

- **RICHARD J. SCHLESINGER** was Co-founded the ASQ Biomedical Division in 1973
  - The Schlesinger Grants promote the awareness and use of quality principles, concepts, and technologies in projects by students within the Biomedical Community
  - Provide project oriented opportunities relating to quality for the worldwide Biomedical Community
  - Encourage consideration of the Quality Profession in the Biomedical Community as a career choice

What we do… Scholarships

- **William J. Feingold** was twice the Chair of the ASQ Biomedical Division in 1988 and 1992 and was a mentor to many of the members.
  - The Feingold scholarship promotes the awareness and the use of quality principles, concepts, and technologies to students within the Biomedical Community
  - Provides learning opportunities relating to quality for the worldwide Biomedical Community
  - Encourages consideration of the Quality Profession in the Biomedical Community as a career choice

CBA History

- >10 years ago
  - Certified Biomedical Auditor
    Developed by ASQ Biomedical Division
    Led by Keith V. Rohrbach, Ph.D.
  - Required a CQA before taking the exam
- Today
  - Stand alone exam
  - Includes BoK from CQA plus Biomedical specific knowledge
  - Supported by the CBA Exam Prep Course

What we do… Discussion Groups

- Managed by a volunteer committee
- Membership demographics is a key driver to establish and maintain a Discussion Group
- Models vary
  - Frequency and Type of Event
    - Round Table meetings
    - One-day Seminars
    - Division conference collaboration

ASQ Biomedical Discussion Groups

- NCDG
- SCDG
- DFWDG
- MWDG
- NEDG

- MADG

ASQ Biomedical Discussion Groups

- Vision / Mission

DISCUSSION GROUP VISION STATEMENT

To be recognized regionally by our members, the industry we serve and regulatory bodies as the leading provider of information and learning opportunities relating to quality in support of the achievement and advancement of individual and organizational excellence.

DISCUSSION GROUP MISSION STATEMENT

To provide a local forum for professionals involved in the development, quality, manufacture and regulation of medical devices and diagnostics, to learn, teach and discuss issues specific to the medical device and diagnostics industry.

DISCUSSION GROUP STRATEGIC OBJECTIVES

To establish Discussion Groups nationally and worldwide in areas having a concentration of medical device constituents.

To promote a symbiotic relationship between industry representatives and regulatory agencies in order to provide information and education to the regional populace in an accurate, timely, and cost effective manner.

To foster a spirit of cooperation and partnership with other industry groups so that members of the medical device community are given easy access to topics and issues essential to the attainment of individual and organizational excellence.

ASQ Biomedical

Division Officers 2012

Chair	*William McLain*
Chair-Elect	*Scott Blood*
Treasurer	*Mary Ellen Delaney*
Secretary	*John Freije*
Vice Chair Discussion Groups	*Richard Vincins*
Past Chair	*Mark Moyer*
Membership Chair	*Teresa Cherry*

Visit our website, www.asq.org/biomed,
for contact information – please contact our Membership Chair for volunteer opportunities