Application of Risk Management

to Medical Devices

ISO 14971:2000




Thailand

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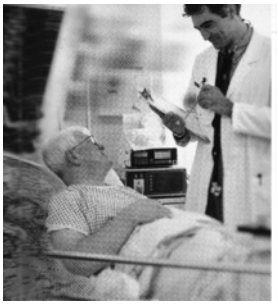
Goals

- Safe products/ Patient safety
- No problems eg recalls / incidents
- Good technical documentation (liability)
- Compliant to Requirments



- First step in coming up with a risk management system in a company

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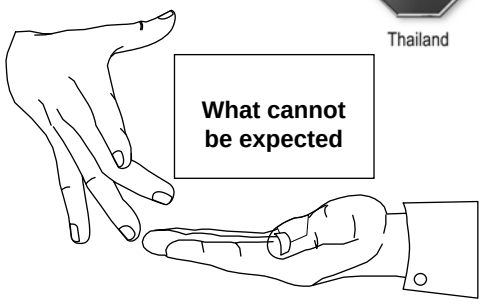

- trained and be expert
- perfect training material
- expert in the application of risk management
- for all Medical Devices
- somebody who knows everything

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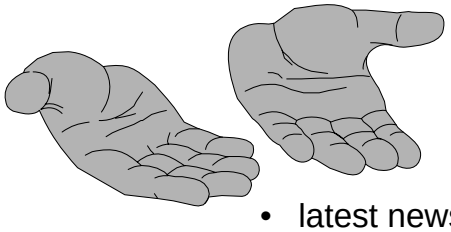

**What can
Be expected**

- latest news about standards
- interpretations
- read the standards
- examples of the real world
- introduction in the subject

Introduction MOTTO

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Introduction MOTTO

After all, Courage is not ignoring RISKS,

it is confronting them and facing them down.

Accepting and embracing them.

NOW that is true COURAGE

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ISO 14971: 2000

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- *Risk Management Overview*
- *Regulatory references*

Lars-Oliver Huber
President
TÜV Thailand Ltd

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Risk Management overview

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The standard

ISO 14971:2000

Medical devices —

Application of risk management to medical devices

Published 2000-12-15


INTERNATIONAL STANDARD

ISO 14971

First edition 2000-12-15

Medical devices — Application of risk management to medical devices

Dispositifs médicaux — Application de la gestion des risques aux dispositifs médicaux

Reference number ISO 14971:2000(E)

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Risk Management Overview

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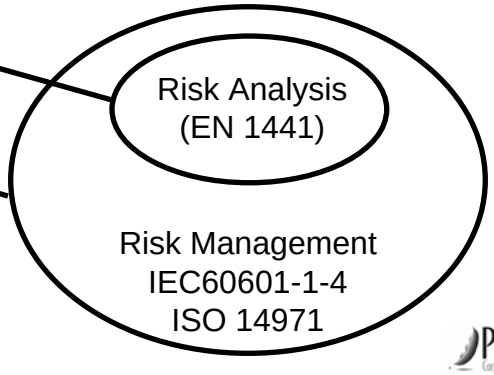
Risk analysis is a subset of risk management



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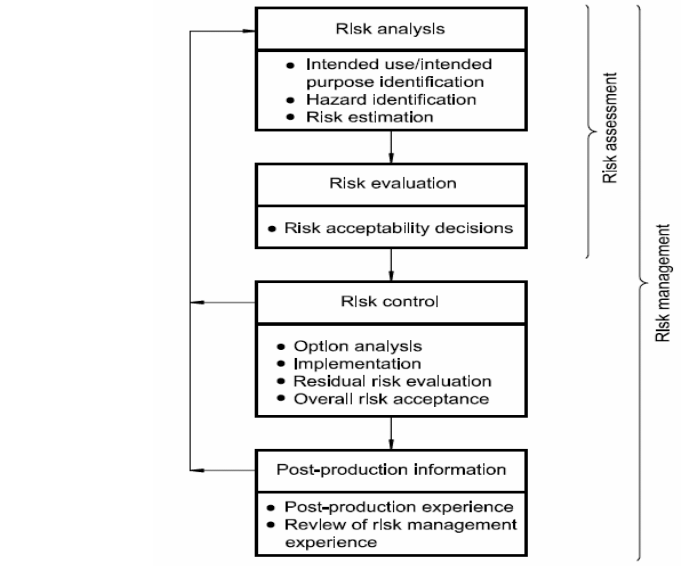

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Risk Analysis Overview

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- Risk analysis means:
  - Identifying potential hazards
    - *Hazard analysis to get foreseeable hazards by intended purpose, annex A & D of ISO 14971,clinical literature, incidents, brainstorming, FMEA, FTA, filed trials, market experience .....*
  - Estimating the risk for each potential hazard:

Risk = Likelihood x Severity

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Risk Management Overview

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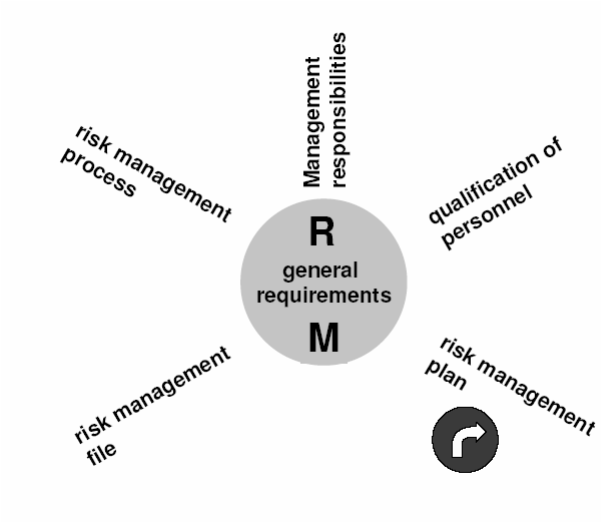
- Risk management includes in addition to the analysis:
  - risk evaluation (decisions about acceptability)
  - risk control
    - risk reduction measures
      - measures : inherent protection, protection system, warnings/cautions
      - implementation
      - verification
  - post production information

Risk Management Overview

Thailand



Real life …

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In 1984, a mechanical engineer in a starch processing factory warned of the risk of dust explosions, recommending regular cleaning to remove dust deposits. The risks of dust explosions are well documented.

The management ignored the warning.

In 1986 a dust explosion occurred killing one, seriously burns to 2 others, with massive damage to the factory.

In the newspaper, management claimed it was a “one in million chance”.

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Real life …

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Risk analysis would have …

- identified the potential hazard
- risk estimation

Risk management would have …

- determined the need to address
- ensured necessary actions are taken (periodic cleaning)

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Why Risk Analysis?

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Why do we need risk analysis?

Because people are BAD at assessing risks based on intuition alone.

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Why Risk Analysis?

Thailand

Why is our intuition wrong?

People assume

low probability = low risk

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Why Risk Analysis?

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Why do we ignore severity?

People cannot easily multiply in their head

very small numbers

X

very big numbers

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Why Risk Analysis?

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Example: road crossing

Chance of a serious accident, if crossing against the lights:

1 in 10,000

or, 99.99% chance of safe crossing

… sounds safe to most people …

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Why Risk Analysis?

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But, if the average serious accident costs US$500,000

Risk severity = *likelihood x* $500,000

= 10^{-4} *x* $500,000

= ***US$50*** *per crossing*

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Why Risk Analysis?

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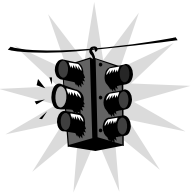
Choice A:
Wait for the lights

Choice B:
Cross against the lights

Pay $50



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Why Risk Analysis?

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People naturally assume :

If it hasn't happened yet … it won't ever happen…

(and if it does, it's just bad luck)

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Why Risk Management?

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- Key reasons:
  - Provide procedures for risk analysis
  - Ensure risk analysis is done at appropriate time/s
  - Ensure persons performing are qualified
  - Ensure implementation
  - Ensure records are retained

Basically ISO9001 controls for risk

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Table of contents of ISO14971:2000

Thailand

1 Scope
2 Terms and definitions
3 General requirements for risk management
4 Risk analysis
5 Risk evaluation
6 Risk control
7 Overall residual risk evaluation
8 Risk management report
9 Post-production information
Annexes, Bibliography

ISO14971: Scope

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1 Scope

This International Standard specifies a procedure by which a manufacturer can identify the hazards associated with medical devices and their accessories, including *in vitro* diagnostic medical devices, estimate and evaluate the risks, control these risks and monitor the effectiveness of the control.

The requirements of this International Standard are applicable to all stages of the life cycle of a medical device.

This International Standard does not apply to clinical judgements relating to the use of a medical device.

It does not specify acceptable risk levels.

This International Standard does not require that the manufacturer has a formal quality system in place. However, risk management can be an integral part of a quality system (see, for example, Table G.1).

ISO14971: Scope

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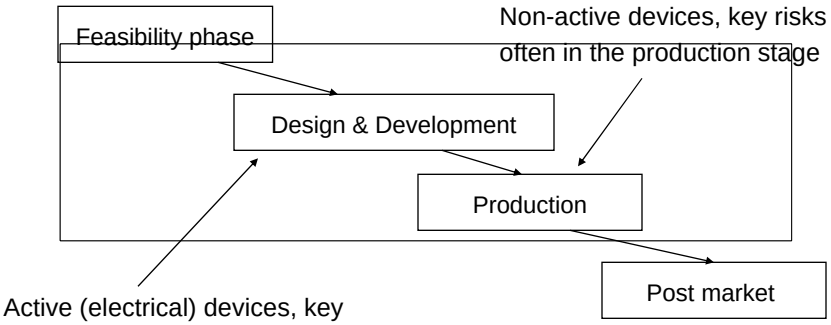
- Scope covers all stages of the life cycle, which includes:



ISO14971: Scope

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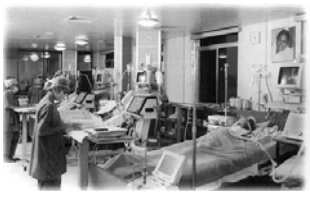

- Scope excludes **clinical judgements**
- Why?
  - clinical side is dealt with separately (for Europe: MDD Annex X, EN540)
  - clinical data (trials) covers risks from side effects, contraindications, these being assessed under “normal condition”
  - risk analysis covers the “abnormal conditions”, and fault conditions, operator mistakes and so on.

ISO14971: Scope

- Standard does not specify **acceptable risk levels**
- Why?

  Different applications have different levels risk tolerance

  Dialyser – reasonable residual risk remains
  Thermometer – negligible risk is possible

Some Terms and definitions

add some real definitions
MDD = European Medical Device Directive
RA = Risk Analysis
RM = Risk Management
EN = European Norm (standard)
IEC = International Electrotechnical Commission (Standards)
ISO = International Organization for Standardization
FMEA = Failure modes and effects analysis
FTA = Fault tree analysis

ISO14971: Application

- Many risks are addressed through common sense, based on device and situation e.g. Glove, Syringe
- Key risks must be well documented but it is not practical to document every risk.

Part 2: Regulatory references

Regulatory references

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- Some regulations have direct references to risk analysis (FDA, MDD, TGA, CMDR)
- Some regulations use ISO13485:2003 (MDD, TGA, CMDR)
- Some regulations list ISO14971 as a recognized standard (such as MDD, TGA)
- Expected that Asia over time will also adopt ISO13485 and possibly MDD like regulations.

Regulatory references

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- ISO13485:2003 specific reference:

The organization shall establish **documented requirements for risk management** throughout product realization.

Records arising from risk management **shall be maintained** (see 4.2.4 and Note 3).

NOTE 3 See **ISO 14971** for guidance related to risk management.

Regulatory references

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- Europe:
  - MDD has a general reference to risk analysis
  - ISO13485:2003 transition period until 31 July 2006, direct reference
  - **EN ISO14971:2000 is harmonized** (superseeded EN1441 on 2004-04-01)

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Regulatory references

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- Australia:
  - Adopted similar regulation to European MDD
  - ISO14971:2000 (AS/NZS 4810.1:2000) is a gazetted standard from Feb 2003

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Regulatory references

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- USA:
  - FDA 21CFR820.30 requires risk analysis
  - Many mentions of risk management in design control guidance document
  - No formal references to ISO14971

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Regulatory references

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- Canada:
  - Regulation requires risk analysis
  - ISO13485:2003 is used
    (transition period until 15 July 2006)

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Definition and Calculation of Risk,

Example of a Process Risk Calculation

„Our world“ has changed

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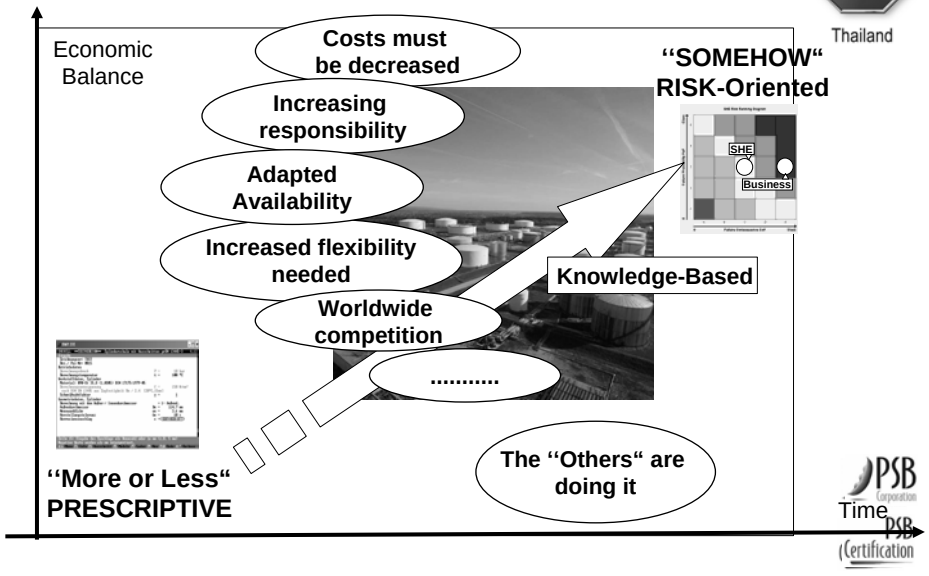

Risk as Deliberate Assessment-Criteria

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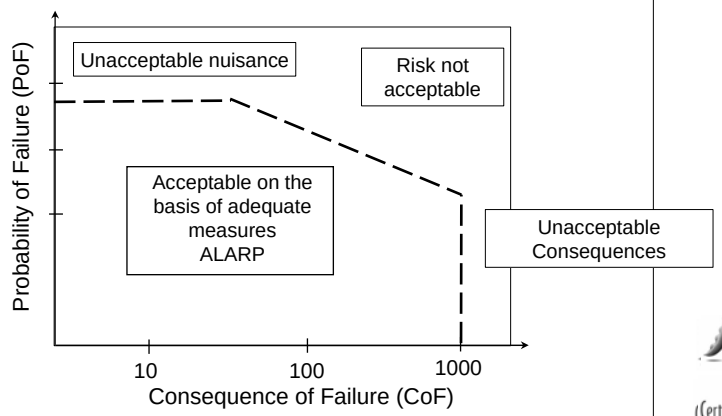
RISK = Probability of Failure x Consequence of Failure



Understanding of Risk

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Risk = Probability of Failure (PoF) x Consequence of Failure (CoF)

What's really new?

Integral Approach

- new, traceable assessment criteria
- risk assessment requires multi-disciplinary team
- all type of equipment considered under one hat

PoF

- more distinctive regarding the identification of damage/deterioration mechanism to address optimized inspection techniques
- introduction of classes not only „good" or „bad"
- confidence related

CoF
SHE-related
Costs-related

- systematic introduction of CoF
- distinction between SHE and Cost/Reliability CoF

Logarithmic Risk Matrix

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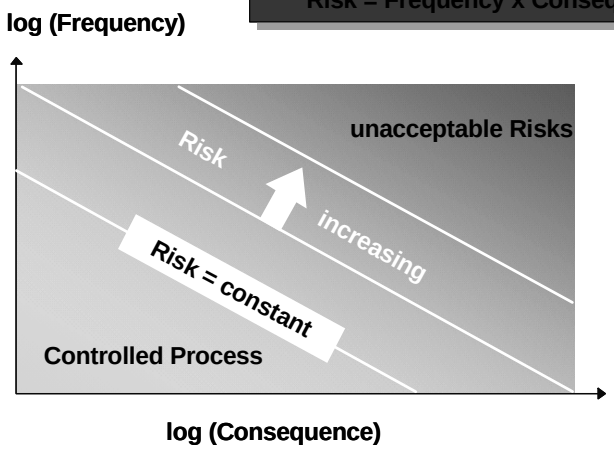
Risk = Frequency x Consequence



Discrete Risk Matrix

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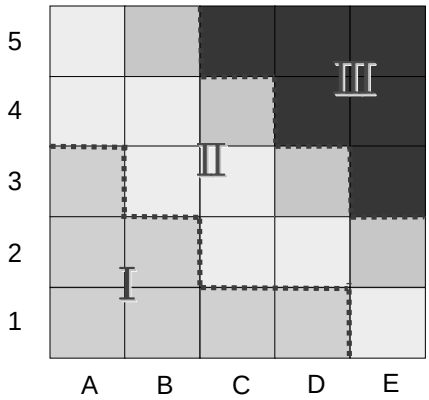

I: Nice to have
Massive reduction of efforts

II: ALARP
(= As Low As Reasonably Practicable)
Minimizing / Optimizing

III: Unacceptable
Change of design, operation etc. necessary
Minimizing risk

Attributing Likelihoods and Consequences

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Extent of damage	Likelihood
Tolerable: Loss of property, 1 slightly injured person	**Almost improbable**: Very low probability of occurrence in a PP-plant
Minor: Only some light casualties	**Low**: Very low probability of occurrence
Serious: 1 or more severely injured persons	**Medium**: low probability of occurrence within lifetime of the plant
Extensive: several severly injured persons or one fatality	**Possible**: Can occur within lifetime of the plant
Catastrophic: several fatalities	**High**: Can reasonably be expected to occur within lifetime of the plant

FEAR

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- After all:

Do you have the COURAGE?

COURAGE

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- After all, Courage is not ignoring RISKS, it is confronting them and facing them down. Accepting and embracing them.
- LET US HELP YOU
- THANK YOU FOR YOUR ATTENTION