Equipment Safety –
A manufacturer's point of view

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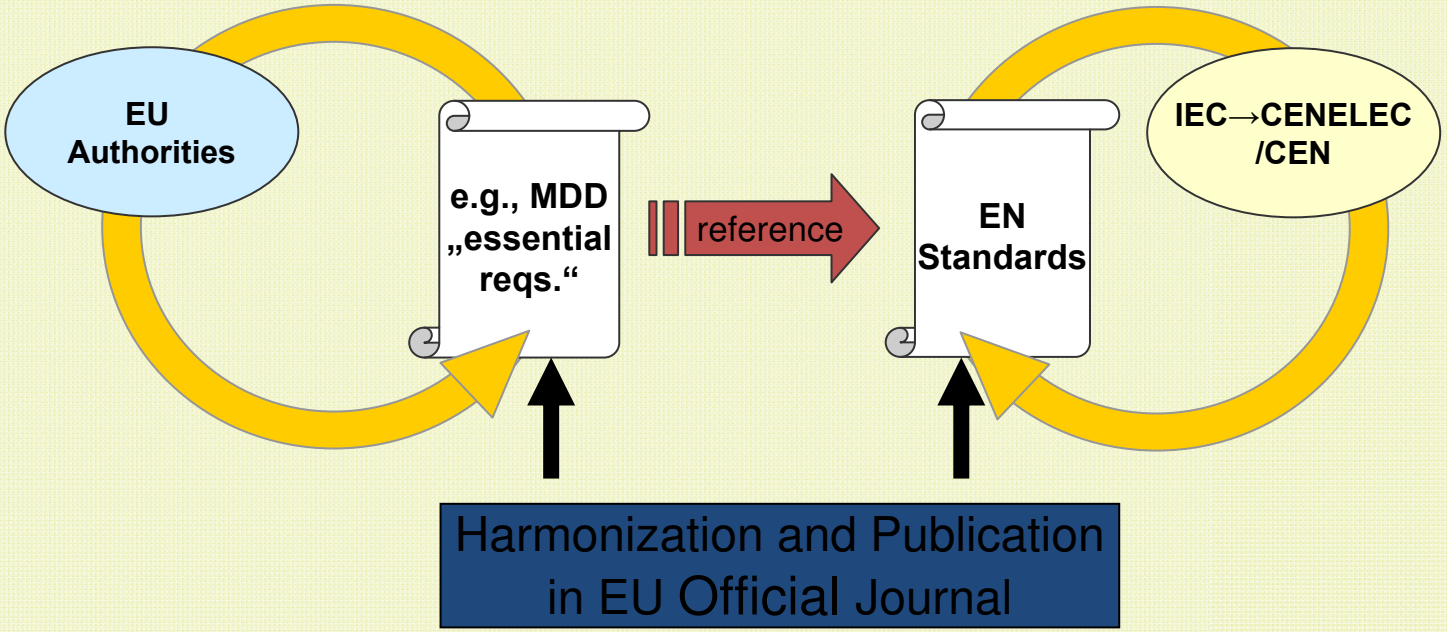
Versailles, France
December 2 - 4, 2009

1. Regulatory Framework for Equipment Safety and Risk Management

2. Implementation of Risk Management
   1. During Product Development
   2. After Product Release

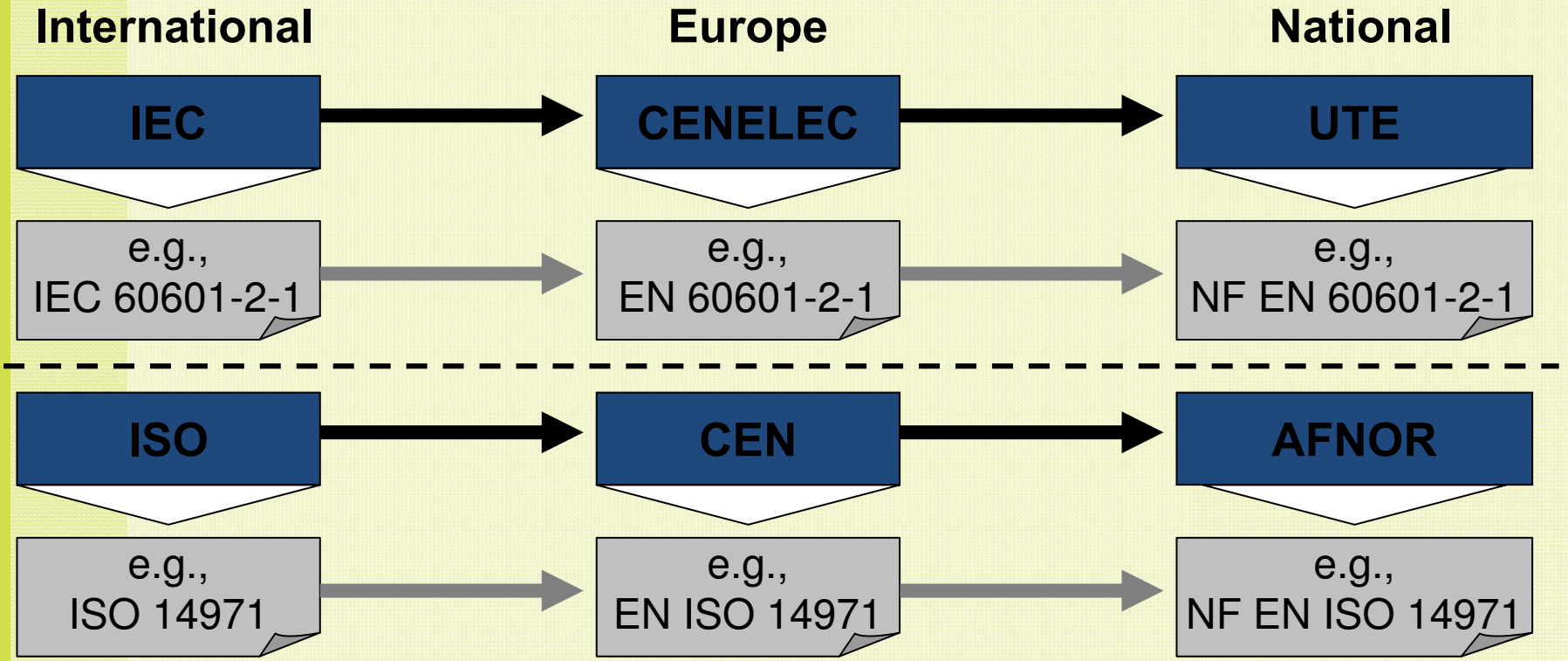

MDD
Council Directive
93/42/EEC
ISO 14971
Risk
Management
to
medical devices
CE
IEC 60601-1
General require-
ments for basic
Safety and
Essential
Performance
3rd edition

A strong link between standards and regulations in the medical mevice market



- Standards detail the regulatory framework
- For “New Approach” directives, the compliance with the “Essential Requirements” is assumed if the products comply with the harmonized standards
- Legal requirements have a life time of approx. 15 years; standards help to describe legal goals in shorter cylces.

Transition of international standards to national standards



- Transition of international standards to **identical** European standards
- Transition of European standards to **identical** national standards
- European standards may be harmonized by the European Commission within the framework of "New Approach" Directives, e.g., Medical Device Directive

The medical market is a regulated market in most countries

- The objective for such regulations is due to the political mandate:
- *To provide people with safe and efficient healthcare*

- Provisions are for instance
- *Market approval* for medical devices
- *For safe use and efficacy*
  - Medical requirements (education, certified medical procedures, guidelines, clinical trial, quality control,…)
  - Technical requirements (basic safety, essential performance, quality assurance, market surveillance,…)
- Technical requirements as prerequisite for reimbursement

Standards play an important role in achieving these goals!

MDD 93/42/EEC

Devices must be designed and manufactured such that … if used for the purpose and under the conditions intended…

- … they will not compromise the condition or safety of patients
- … or safety and health of operators
- … or other persons
- … or any risks associated with the use constitute acceptable risks when weighted against the benefits for the patients

ISO 14971:2007

6.4 Residual risk evaluation

After the risk control measures are applied, any residual risk shall be evaluated using the criteria defined in the risk management plan. The results of this evaluation shall be recorded in the risk management file.

If the residual risk is not judged acceptable using these criteria, further risk control measures shall be applied (see 6.2).

For residual risks that are judged acceptable, the manufacturer shall decide which residual risks to disclose and what information is necessary to include in the accompanying documents in order to disclose those residual risks.

NOTE Guidance on how residual risk(s) can be disclosed is provided in Annex J.

Compliance is checked by inspection of the risk management file and the accompanying documents.

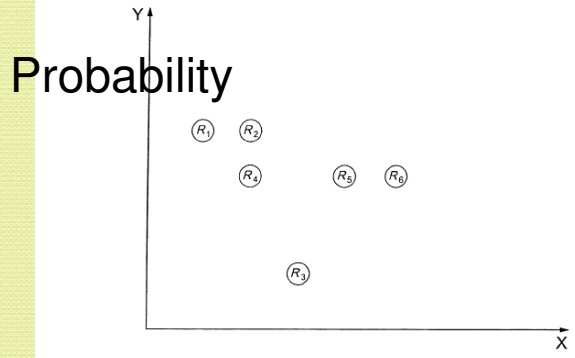


Figure D.1 — Example of a risk chart

Qualitative severity levels

Semi-quantitative probability levels	Negligible	Minor	Serious	Critical	Catastrophic
Frequent					
Probable	R_1	R_2			
Occasional		R_4		R_5	R_6
Remote					
Improbable			R_3		

Key

unacceptable risk

acceptable risk

Figure D.5 — Example of a semi-quantitative risk evaluation matrix

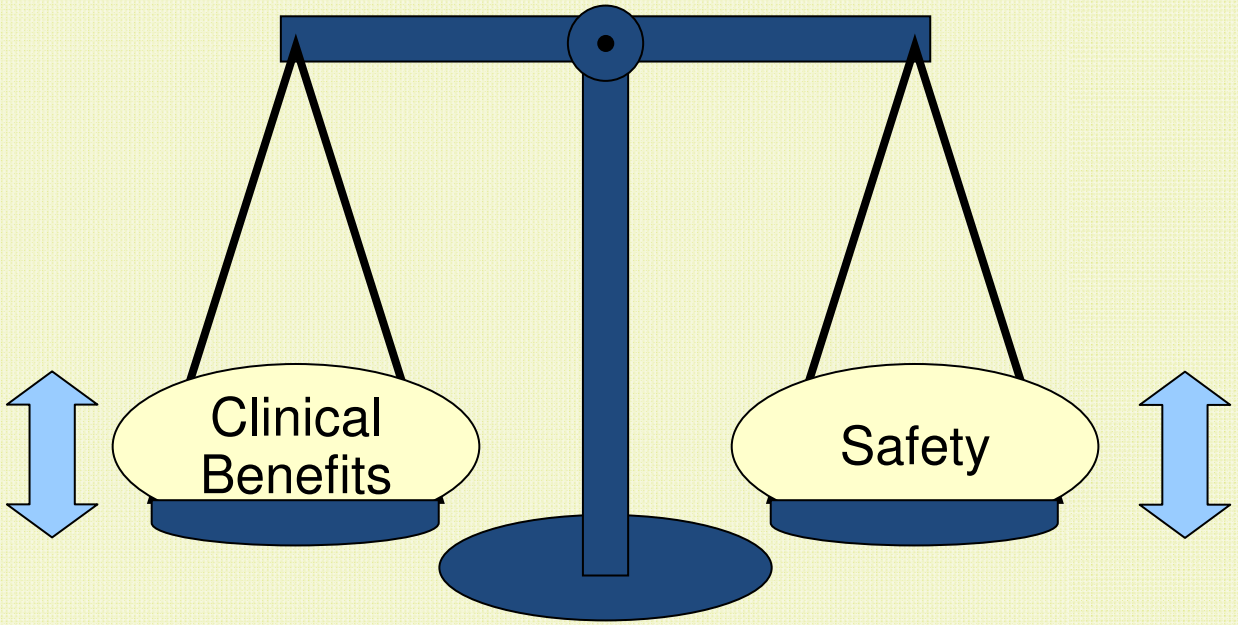
ISO 14971:2007

- After all risk controls are implemented as designed… the manufacturer shall decide if the residual risk is acceptable
- If the residual risk is judged unacceptable, the manufacturer may gather data and review data to determine if the medical benefits… outweigh the residual risk
- For an overall residual risk that is judged acceptable, the manufacturer shall decide which information is necessary to disclose

ISO 14971:2007

- The manufacturer shall establish, document and maintain a system to collect and review information about the medical device… in the production and post-production phases
- When establishing a system…. The manufacturer shall consider:
  - Mechanisms by which the information is presented or processed
  - New or revised standards

Goals of standardization for medical devices



- Find the balance between **clinical benefits** and **safety interests**
- Give a common **technological baseline,** but allow **innovations**
- Describe a framework that is **acceptable for all stakeholders**

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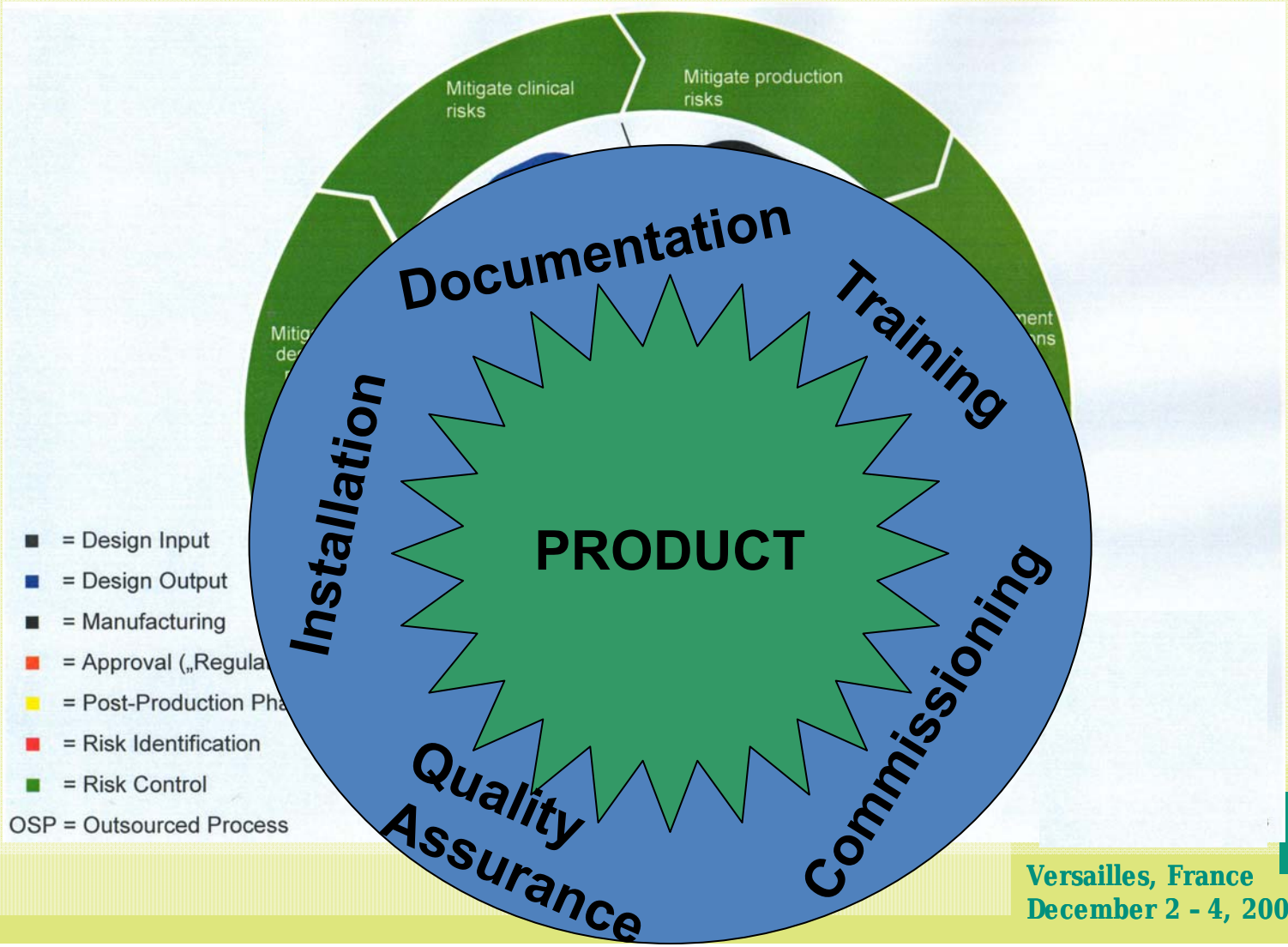
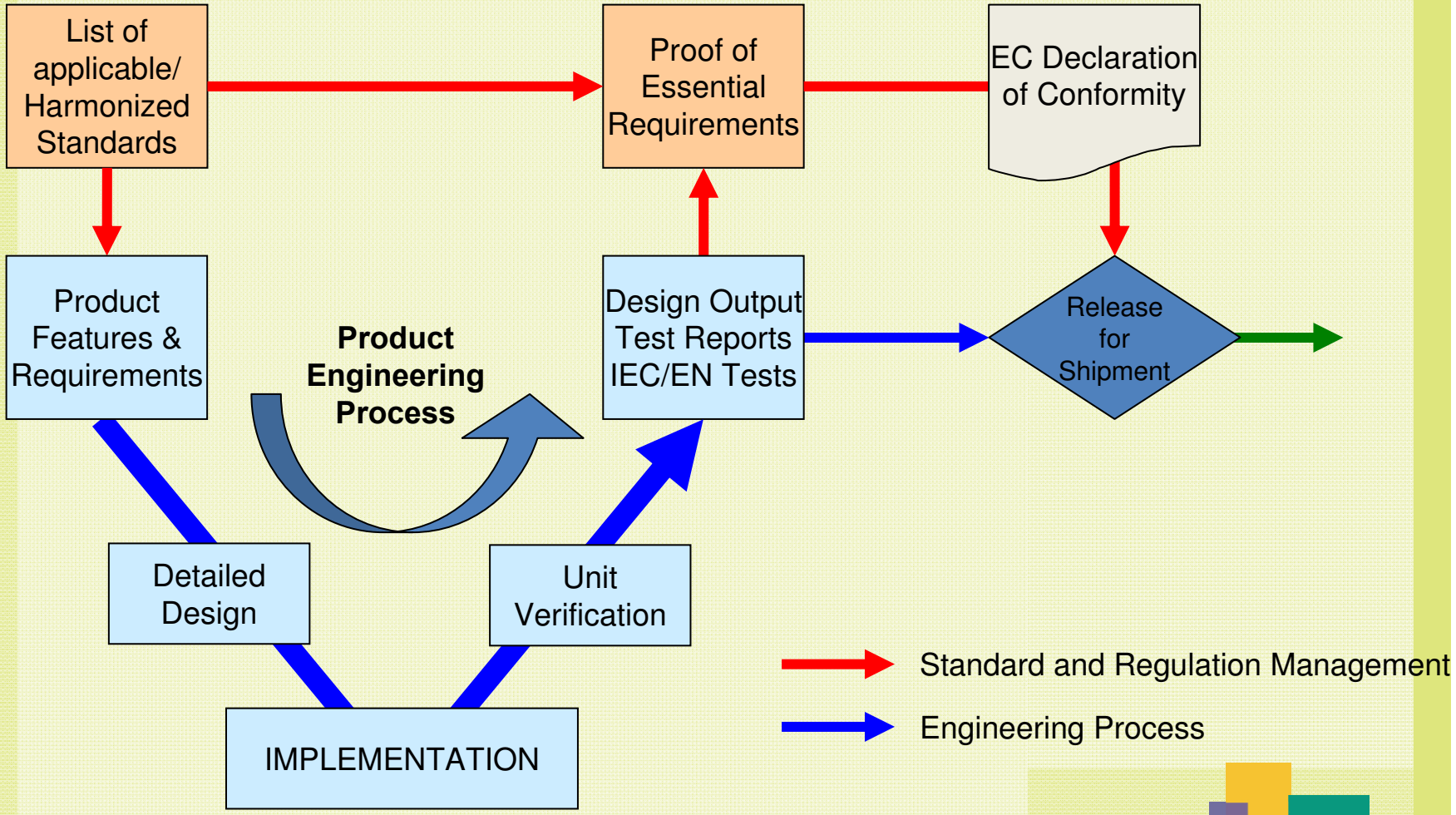
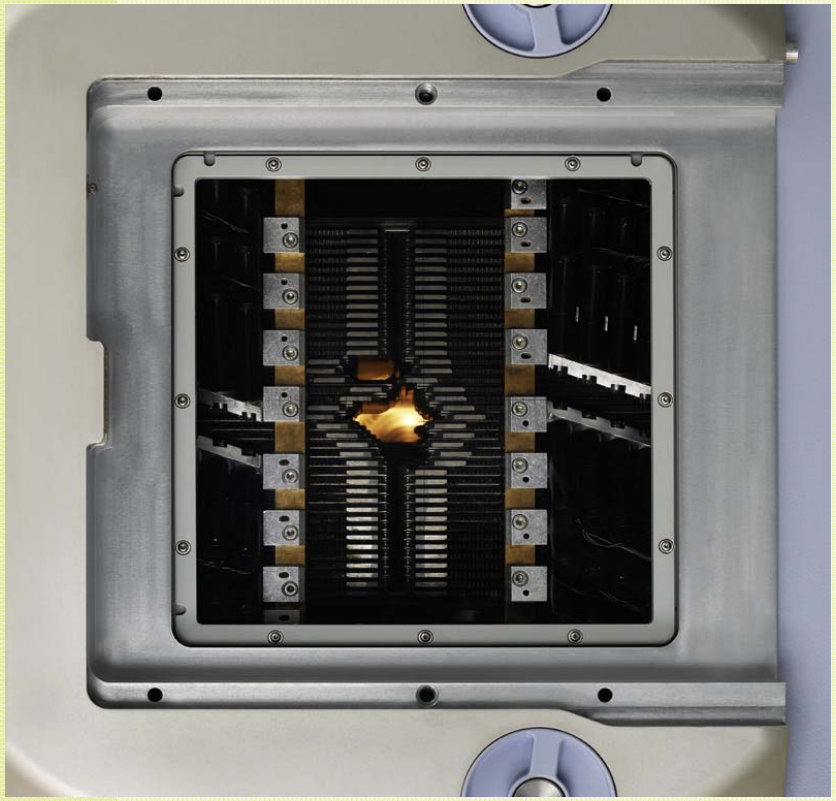
Risk Management within the Product Lifecycle



Ensuring standards compliance in product development



Example: MLC and IEC 60601 – 2- 1



– Multileaf collimators offer the opportunity to adapt the beam to the tumor shape, sparing healthy tissue

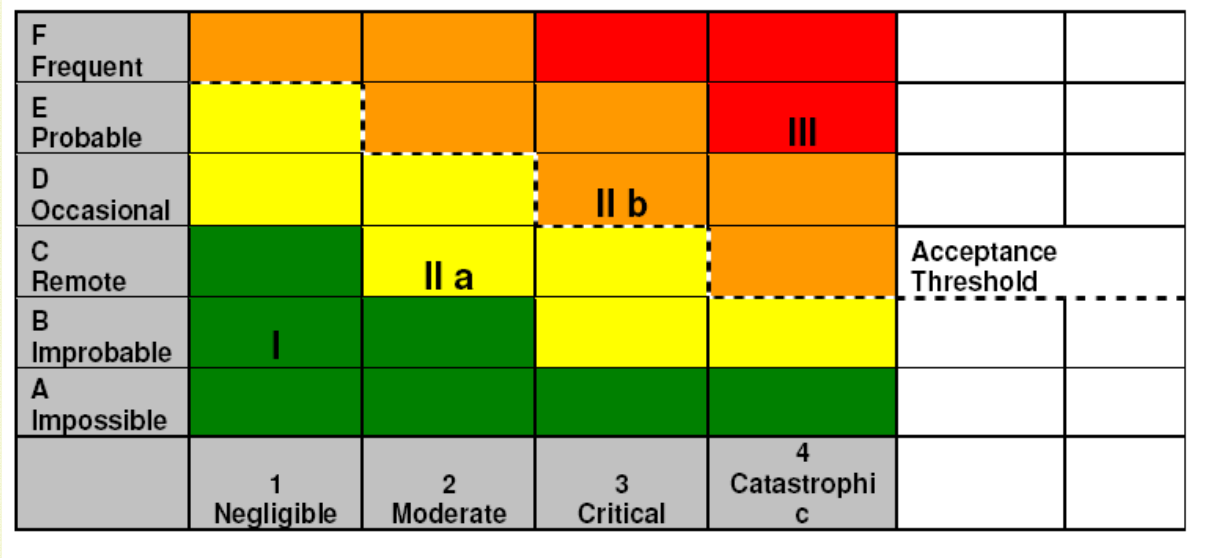
– However, there is some leakage radiation between the leaves

– IEC 60601-2-1 max. X-ray leakage through beam limiting device:

- 1981: 2% (MLC not considered)
- 1998: 5% for MLC
- 2008 (CD): 2.5% (MLC for Intensity-Modulated Radiation Therapy)
- ~~200X: 1%???~~

Implementation of ISO 14971

e.g. OCS – Quality Regulation for Risk Management



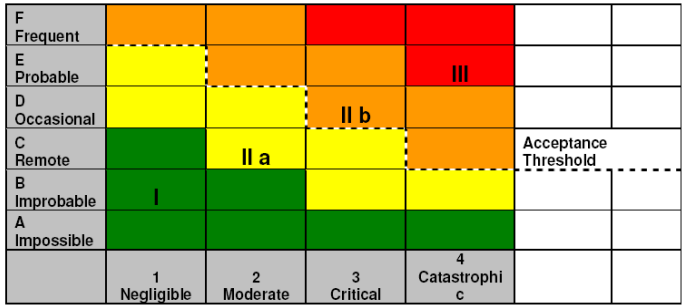
- Low – residual risk acceptable, no active risk control
- Medium – two levels of acceptability:
  - Above acceptability level: risk-analysis to determine how to proceed
  - Below acceptability level: ALARP (as low as reasonably practicable)
- High – risk is intolerable; no risk-benefit analysis is acceptable. Risks must be reduced at least to medium area

Implementation of ISO 14971

Class	1	2	3	4
Severity of Harm	Negligible	Moderate	Critical	Catastrophic
to Persons	Minor injury e.g. slight/insignificant bodily injury which requires no medical treatment	Moderate injury e.g. bodily injury of medium severity which requires medical treatment	Serious injury or death of one person e.g. severe injury / death (of an individual). Necessitates medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure[1].	Serious injury or death of more than one person e.g. severe injury / death (of multiple persons). Necessitates medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure.
to Goods	Damage e.g. Possible damage as the result of a malfunction	Destruction e.g. Possible destruction as the result of a malfunction	Long-term or wide area impact	Not practicable

Degree	Probability*	Definition of Probability*
F	Frequent	Highly likely
E	Probable	Will occur several times
D	Occasional	Will probably occur at least once
C	Remote	Probably will not occur
B	Improbable	Improbable, but not impossible
A	Impossible	By human estimation impossible

* Likelihood



Example

⚠Warning

Wear, damage, or overloading of the accessory holder, accessory trays, and accessory tray locks can result in injury to the patient, due to falling objects.

PHYSICAL INJURY, FALLING OBJECTS

- Regularly inspect these components for signs of wear or damage. Do not exceed the weight limit for block trays or the accessory holder, and replace trays that show discoloration, cracking, or damage.

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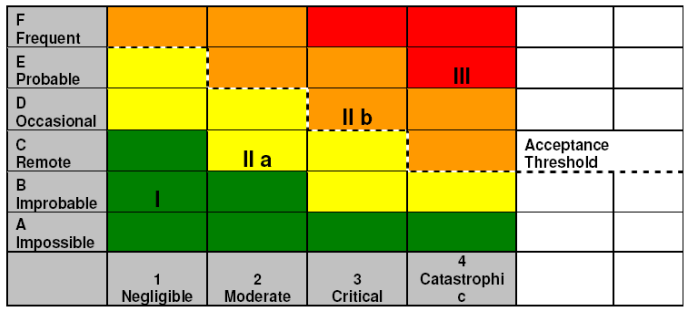
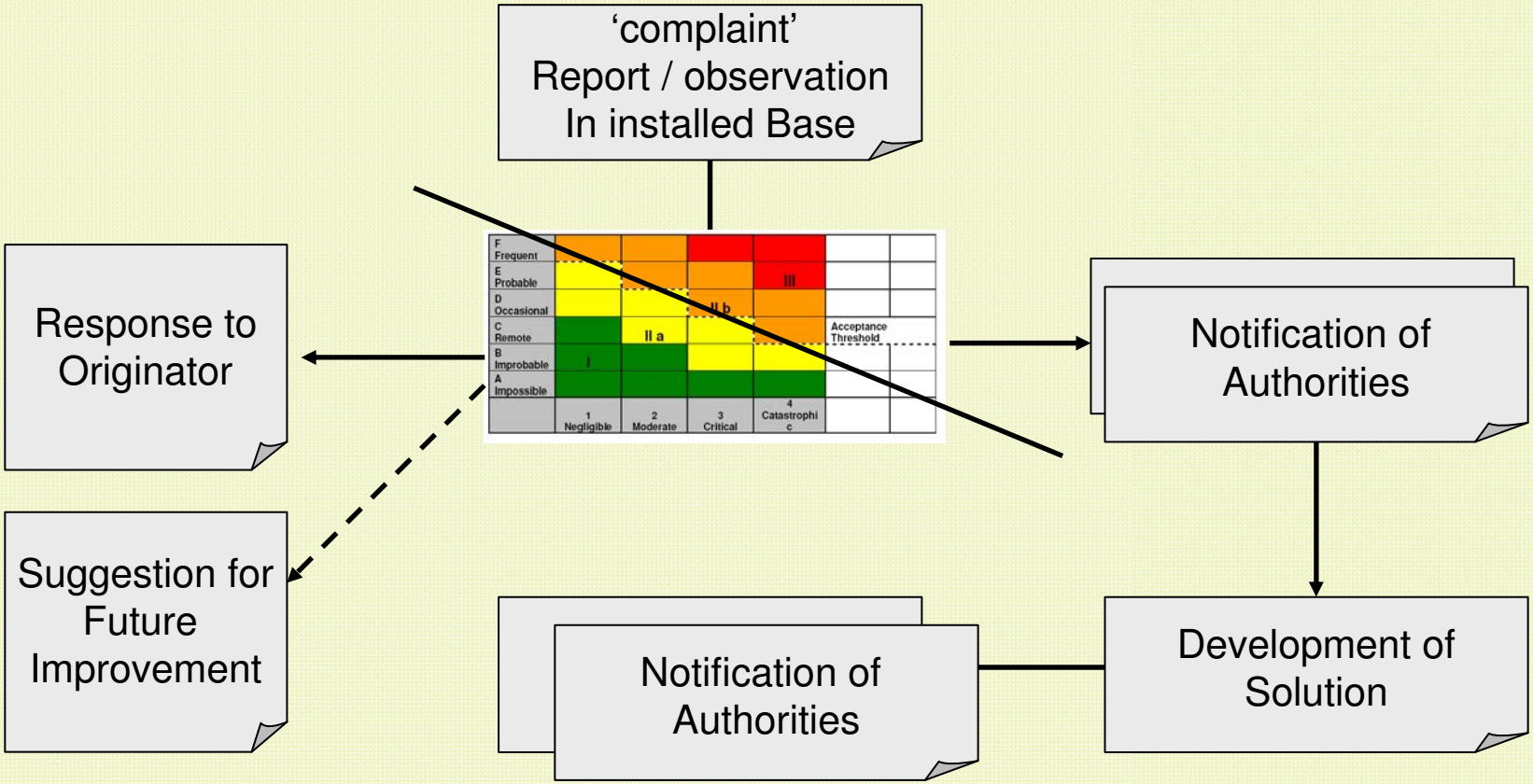


Safety Management in Installed Base



OCS Quality Management System is certified

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TÜV SÜD Product Service

CERTIFICATE

No. Q1N 08 06 33197 015

Holder of Certificate: Siemens Medical Solutions,Inc.
Oncology Care Systems
4040 Nelson Avenue
Concord, CA 94520
USA

Facility(ies): Siemens Medical Solutions,Inc. Oncology Care Systems
4040 Nelson Avenue, Concord, CA 94520, USA

Siemens Medical Solutions OCS Erlangen
Doris Ruppenstein Strasse 4, 91052 Erlangen, GERMANY

Siemens Medical Solutions OCS Heidelberg
Hans-Bunte Strasse 10, 69123 Heidelberg, GERMANY

Certification Mark:

Scope of Certificate: Design, Development, Production, Installation, and Servicing of Radiation Therapy Products and Radiation Therapy Software for Oncology Care Systems

Applied Standard(s): EN ISO 13485:2003/AC:2007
ISO 13485:2003
Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality system which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: NM800884

Valid until: 2011-04-30

Date, 2008-06-10

Reiner Krumme

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TÜV SÜD Product Service GmbH
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TÜV SÜD America

CERTIFICATE

The Certification Body of
TÜV SÜD AMERICA INC.
Management Service Division

hereby certifies that

Siemens Medical Solutions USA, Inc.
Oncology Care Systems
4040 Nelson Ave
Concord, CA 94520

has implemented a Quality Management System in accordance with:

ISO 13485:2003 and ISO 9001:2000

The scope of this Quality Management System includes:

Design, development, production, installation, and servicing of radiation therapy products and radiation therapy software for oncology care systems

Certificate Expiry Date: March 31, 2011

Certificate Registration No: S 951 00 1278

Original Issue Date: October 8, 2002
Effective Date: April 4, 2008

Gary W. Minks
VP, Regulatory Affairs

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