



EMC and Safety of Medical Equipment

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What is safety?



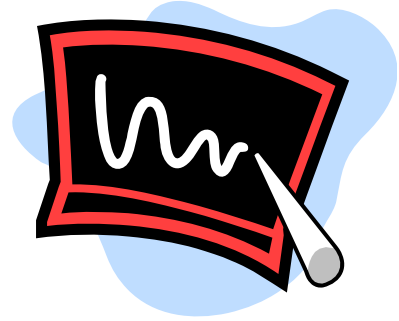
Safety is the freedom of unacceptable risk,
directly caused by physical hazards.

What is a 'risk'?
What is unacceptable?
What is a 'hazard'?



Hazard is a potential source of harm.

What is a 'risk'?
What is unacceptable?
What is a 'hazard'?



Risk is related to:

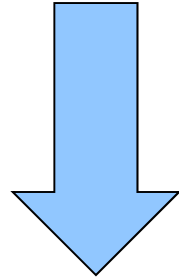
- the probability that harm occurs, and to
- the severity of that harm.

What is a 'risk'?
What is unacceptable?
What is a 'hazard'?



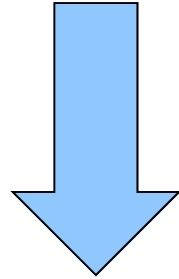
What is acceptable or not,
originates from the core values of a society,
and is regulated by authorities.

Safety is the freedom of unacceptable risk,
directly caused by physical hazards.



To achieve safety,
the risk on harm needs to be acceptably low.

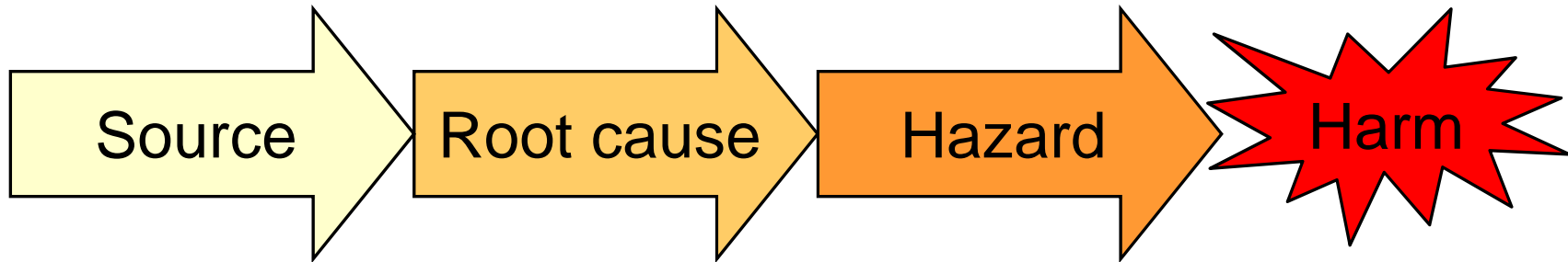
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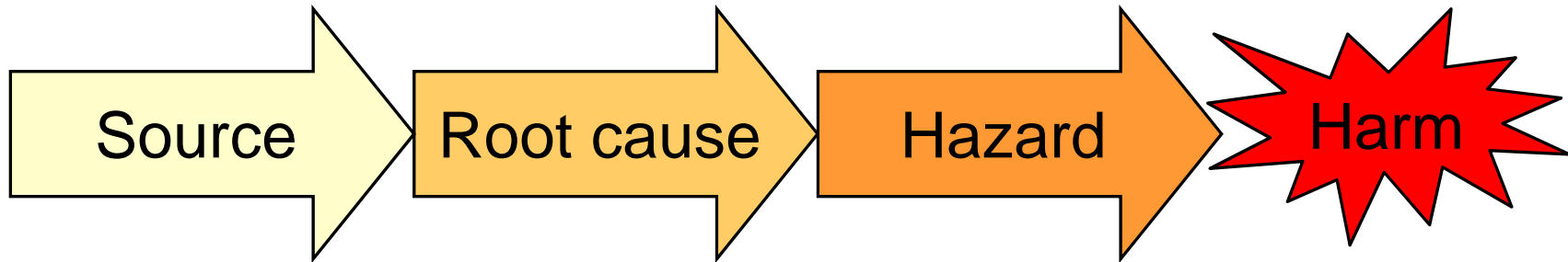
But what causes the risk on harm?

The origin of harm from medical equipment



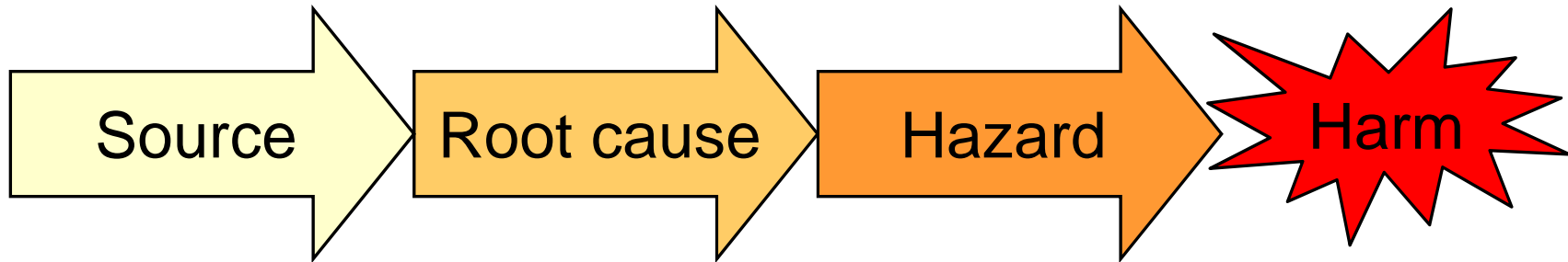
*Electrical
Mechanical
Temperature
Biological
X-ray
Diagnostic
information
Etc.*

The origin of harm from medical equipment



*Leakage current
Movement
Heating
Pollution
Stray radiation
Operating error
Etc.*

The origin of harm from medical equipment



Design
Software
Defect
Instruction
Misuse
EMI
Etc.

EMC for medical equipment is about the prevention of harm

Basic Safety: prevent that the medical equipment creates a hazard

Essential Performance: prevent that the medical equipment fails to provide a function that prevents harm

Performance criteria for EMI immunity testing

- Prevent violation of basic safety
- Provide essential performance

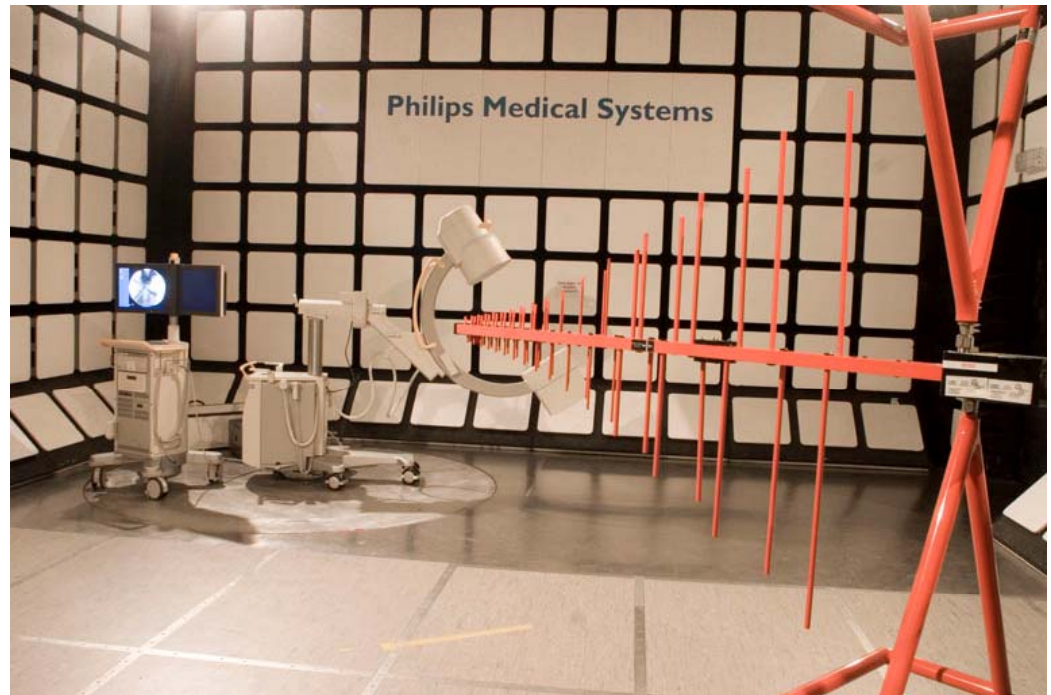


Risk management

- Determine intended use.
- Risk analysis: what could possibly happen due to EMI?
- Risk evaluation: what is acceptable, and what is not?
- Risk reduction: robust concept, fail-safe, instruction.
- Derive performance criteria.

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- Determine intended use.
- Risk analysis: what could possibly happen due to EMI?
- Risk evaluation: what is acceptable, and what is not?
- Risk reduction: robust concept, fail-safe, instruction.
- Derive performance criteria.
- Perform immunity test to demonstrate essential performance and basic safety are achieved.



EMC points of attention for Medical Equipment

- Safety, rather than performance
- Application of modules from other industries
- Patient coupled cables
- Immunity to AED
- Immunity to Electrosurgical knives
- Sensitivity of e.g. EEG-equipment
- MRI systems
- Significant changes to come in medical EMC standard IEC60601-1-2

Summary

- Basic Safety and Essential Performance dominate the EMC aspects of Medical Equipment.
- Risk management will provide specific Performance Criteria.
- For Medical Equipment a number of specific circumstances may apply, like high level disturbances, high sensitivity, involvement of patients, etc.

