European Training Network on Electromagnetic Risks in Medical Technology

Deliverable: D.5.3– ETERNITY SS/Workshops

Start date of the project: 1st March 2021

Duration: 48 months

Deliverable summary

The aim of this document is to provide an overview on ETERNITY SS/Workshops held in EMC Europe 2022 Gothenburg, Sweden.

D.5.3. – ETERNITY SS/Workshops

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Revision history

Revision	Date	Description	Author (Organization)
V0.1	22/09/2022	Table of content + complete draft of the deliverable	KU Leuven, Tu/e
V0.2	29/09/2022	Feedback and pictures for annex 1	UPC

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Acronyms

EC	European Commission
PO	Project Officer European Commission
CA	Consortium Agreement
GA	Grant Agreement
DoA	Description of the Action
PCDP	Personal Career development plan
NWE	Network Wide Event
SB	Supervisory Board
MT	Management Team
PM	Project manager
RC	Recruiting Committee
NWE	Network Wide Event

Beneficiaries' short names

TU/e	Technische Universiteit Eindhoven
UT	Universiteit Twente
PMS	Philips Medical System Nederland B.V.
KUL	Katholieke Universiteit Leuven
UPC	Universitat Politècnica de Catalunya
IDNEO	Idneo Technologies SAU
PLUX	Plux -Wireless Biosignals S.A.

Partner Organizations' short names

PMC	Plasmacure
UMCU	Universitair Medisch Centrum Utrecht
EUF	Eurofins
BARCO	Barco
FCT	Faculdade de Ciências e Tecnologia
MST	Medisch Spectrum Centrum
ASEPEYO	Asepeyo hospital

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Table of Contents

This project has received funding from the European Union's EU Framework Programme for Research and Innovation Horizon 2020 under Grant Agreement No. 955.816.

1. Title of the Workshop

Risk-based EMC implementation with examples. (EMC Europe 2022 Gothenburg, Sweden).

2. Organizers' Information

- ESR11, Nandun Senevirathna (Nandun.Senevirathna@philips.com), Philips Medical Systems Nederland B.V., Best, The Netherlands.
    - Mentored by dr. ir. Anne Roc'h (a.roch@tue.nl), Eindhoven University of Technology, Eindhoven, The Netherlands and Rob Kleihorst (Rob.Kleihorst@philips.com), Philips Medical Systems Nederland B.V., Best, The Netherlands.
- ESR12, Geon George Bastian (geon.george@nextium.com), Nextium by Idneo Technologies, Barcelona, Spain.

Mentored by Dr. Jordi Vila Planas (jordi.vila.planas@nextium.com), Nextium by Idneo Technologies, Barcelona, Spain and Prof. Mireya Fernández (mireia.fernandez@upc.edu), Universitat Politècnica de Catalunya (UPC), Barcelona, Spain

3. Speakers' Information

Speaker	Affiliation(s)	Email
Prof. dr. Frank Leferink	University of Twente THALES, the Netherlands.	frank.leferink@utwente.nl
Prof. Dr.-Ing. Frank Sabath	Bundeswehr Research Institute for Protective Technologies and CBRN Protection (WIS), Leibnitz University Hannover, Germany.	frank.sabath@ieee.org
Ir. Rob Kleihorst	Philips Medical Systems Nederland B.V., Best, The Netherlands.	rob.kleihorst@philips.com
Prof. dr. Davy Pissoort	Katholieke Universiteit Leuven, Belgium.	davy.pissoort@kuleuven.be
Dr. Anne Roc'h	Eindhoven University of Technology, the Netherlands.	A.Roch@tue.nl

4. Primary and Secondary Audience

- Primary Audience: Industry professionals and researchers who are interested in an introduction to the risk-based approach on EMC in Europe.
- Secondary Audience: Researchers and industry professionals who are interested in getting introduced to the PETER and ETERNITY networks and their ongoing research.

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5. Summary of the Workshop

The recent European Blue Guide [1] (regarding the implementation of EU product rules) has stipulated a risk-based approach (rather than the conventional, rule-based approach) mandatory for the EMC compliance of any new piece of electronic equipment with applicable EU Directives – including the LVD and the EMCD [2], [3].

Many manufacturers in the industry as well as the users of electronic systems may not be familiarized with this novel risk-based EMC approach to the full extent, as there is a lack of understanding and no clearly prescribed risk-assessment methodologies available yet. Particularly, the small and medium scale enterprises (SMEs), may need assistance to adapt to this major shift in approach.

In this workshop, we presented the EMC risk-based approach, emphasizing its contrast to the traditional rule-based EMC approach. We focused on two examples of implementation of risk-based EMC approach in both military and medical contexts. The workshop also addressed an example of systematic analysis of EMI Risks.

There is not only a need for formalization, but also for trained specialists having the capability to deal with the complexity of systems, and all the stakeholders (individuals and institutions) involved. We introduced two large European networks, **ETERNITY** - **European Training Network on Electromagnetic Risks in Medical Technology**, and **PETER - Pan-European Training, research and education network on Electromagnetic Risk management** that are currently training 29 Early-Stage Researchers focusing on the development and implementation of risk-based EMC methodologies [4], [5].

- Risk-based EMC (military application example) – Frank Leferink
- Systematic Analysis of EMI Risks – Prof. Dr.-Ing. Frank Sabath
- EMC Risk-based Approach within Philips Medical Systems – Rob Kleihorst
- Presentation of the European Training Network PETER – Davy Pissoort
- Presentation of the European Training Network ETERNITY – Anne Roc'h

6. Duration of Workshop (subject to TPC's final discretion)

6.1. 2.5 hours total timing (Q&A included)

Hour 1:

- (30 minutes) – **Systematic Analysis of EMI Risks – Frank Sabath**
- (Questions 10 min)
- (30 minutes) – **Risk-based EMC – Frank Leferink**
- (Questions and discussions 10 min)

Hour 2:

- (20 minutes) – **Risk-based EMC Approach within Philips Medical Systems – Rob Kleihorst**
- (Questions 10 min)
- (15 minutes) - **Presentation of the European Training Network PETER (*Pan-European Training Network on Electromagnetic Risks)* – Davy Pissoort**
- (Questions 5 min)

This project has received funding from the European Union's EU Framework Programme for Research and Innovation Horizon 2020 under Grant Agreement No. 955.816.

- (15 minutes) - **Presentation of the European Training Network ETERNITY (*European Training Network on Electromagnetic Risks in Medical Technology*) – Anne Roc'h/Marc Kopf**
- (Questions 5 min)

7. References

[1] Publications Office of the European Union, "Commission Notice — The 'Blue Guide' on the implementation of EU products rules 2016, 2016/C 272/01." https://op.europa.eu/en/publication-detail/-/publication/ca3224fa-5303-11e6-89bd-01aa75ed71a1/language-en (accessed Feb. 28, 2022).

[2] European Commission, "Low Voltage Directive (LVD)." https://ec.europa.eu/growth/sectors/electrical-and-electronic-engineering-industries-eei/low-voltage-directive-lvd_en (accessed Feb. 28, 2022).

[3] Publications Office of the European Union, "Study on the evaluation of the Electromagnetic Compatibility Directive 2014/30/EU (EMCD)." https://op.europa.eu/en/publication-detail/-/publication/45cfa024-1440-11ec-b4fe-01aa75ed71a1/language-en (accessed Feb. 28, 2022).

[4] "Eternity Project." https://eternity-project.eu/ (accessed Feb. 28, 2022).

[5] "Pan-European Training, Research and Education Network on Electromagnetic Risk Management." https://etn-peter.eu/ (accessed Feb. 28, 2022).

8. Annex 1 (Some photos and all 5 presentations)

This project has received funding from the European Union's EU Framework Programme for Research and Innovation Horizon 2020 under Grant Agreement No. 955.816.


PHILIPS
Risk-based EMC at Philips
EMC system engineering
Rob Kleihorst
Philips IGT-Systems
EMC Europe workshop WS15 - September 5, 2022
innovation + you


Questions & Discussion
SYSTEM THINKING AND EMC RISK CONTROL

EMC Europe 2022
September 5-8 Gothenburg Sweden

Risk-Based EMC implementation with Examples

5th September 14:00h

Location: Room R6

02:00 PM	Welcome & Motive of workshop
02:05 PM	• Systematic Analysis of EMI Risks – Prof. Frank Sabath • Risk-based EMC with military examples – Prof. Frank Leferink
03:40 PM	Coffee Break
04:10 PM	• Risk-based EMC Approach within Philips Medical Systems – Rob Kleihorst • Presentation of the European Training Network PETER – Prof. Davy Pissoort • Presentation of the European Training Network ETERNITY – Marc Kopf
05:50 PM	End of Workshop

SYSTEMATIC ANALYSIS OF EMI RISKS

Frank Sabath
Bundeswehr Research Institute for Protective Technologies and CBRN Protection

BUNDESWEHR

OUTLINE

- Introduction
- EMI Risk & Risk Management
- Model of EMI Scenario
- Uncertainties of EMI Scenario
- EMI Risks Evaluation
- Conclusion – Take Home Messages

INTRODUCTION

Definition of Electromagnetic Compatibility (EMC)

(Directive 2014/30/EU)

- Electromagnetic Compatibility (EMC) means the ability of equipment to function satisfactorily in its electromagnetic environment without introducing intolerable electromagnetic disturbances to other equipment in that environment;
- Electromagnetic Disturbance means any electromagnetic phenomenon which may degrade the performance of equipment

Objective of EMC:

- **ensure the function of equipment**
- **prevent performance degradation of other equipment**

TYPES OF EMC

a) Rule based EMC: prevention of EM interferences by

- in keeping with the EMC Design Guidelines (best practice)
- compliance with standardized emission and immunity levels

b) Risk based EMC: interruption of potential EM interferences by

- Defining the EM environment
- Identifying potential EM threats and coupling paths (source victim matrix)
- adapted requirements and installation guidelines and EMC measures
- Customized validation and verification plan

c) EMI Risks Management: maintaining functionality and managing consequences

- Integrated risk management process
- Analyzing strength and likelihood of EM threats and consequences
- Evaluation resilience and acceptability of consequences

OUTLINE

- Introduction
- **EMI Risk & Risk Management**
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DEFINITION RISK

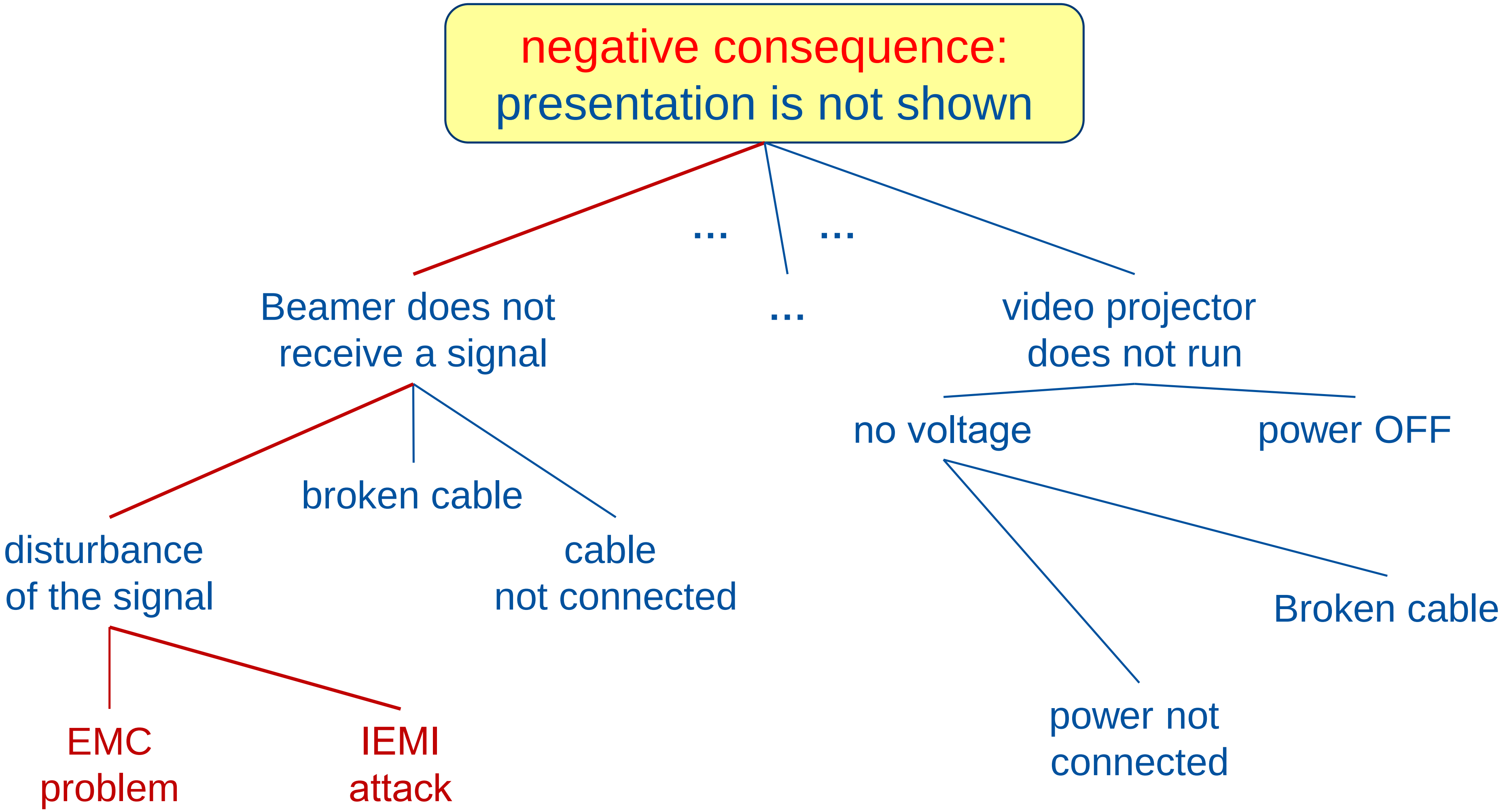
The risk

- is the description of a future event
  with the possibility of negative consequences.
- is the impact of uncertainty/uncertainty on goals.

risk = ⟨consequence, likelihood ⟩

$$r_i = \langle c_i, p(c_i) \rangle$$

EMI RISK


negative consequence:
presentation is not shown
...
...
Beamer does not receive a signal
...
video projector does not run
no voltage
power OFF
broken cable
disturbance of the signal
cable not connected
Broken cable
power not connected
EMC problem
IEMI attack

EMI RISK

Aspects of EMI risk

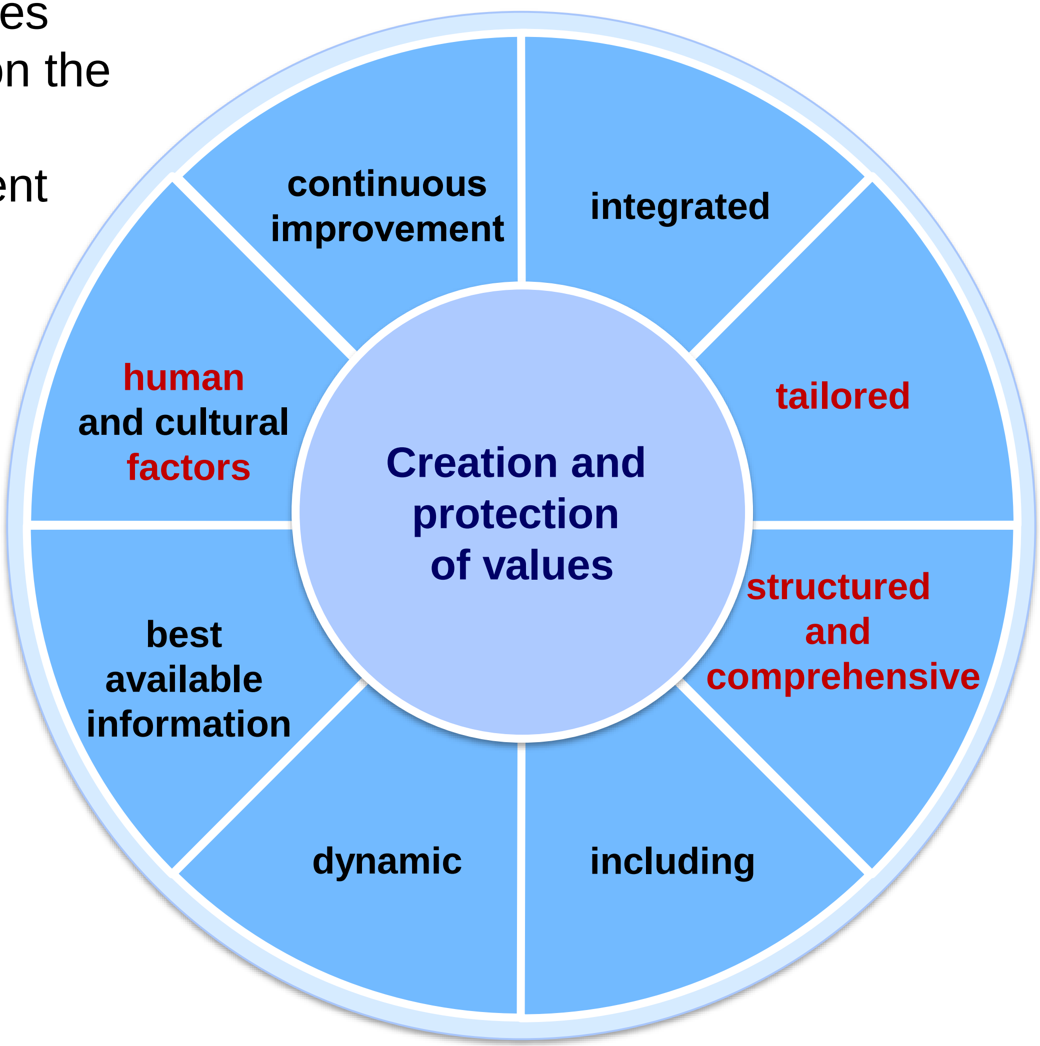
- What can happen? (Scenario)
- What are the consequences?
- How likely can this (scenario & consequences) occur? (uncertainty)

risk = ⟨scenario, consequence, likelihood ⟩

$$r_i = \langle s_i, c_i, p(s_i \cap c_i) \rangle$$

PRINCIPLES OF THE RISK MANAGEMENT

The shown principles provide guidance on the characteristics of effective and efficient risk management, communicate its value and explain its intention and purpose.



These principles form the basis for dealing with risks and should be taken into account when developing the framework and risk management processes.

Source: ISO 31000:2018, Kap. 4

PRINCIPLES OF THE RISK MANAGEMENT (2)

a) **integrated**

Risk management is an integral part of all the activities of an organization.

b) **structured and comprehensive**

A structured and comprehensive risk management approach contributes to consistent and comparable results.

c) **tailored**

The framework and the processes of risk management are adapted to the external and internal context of an organization and are suitably connected with the objectives of the organization.

d) **including**

The appropriate and timely participation of stakeholders allows for the consideration of their knowledge, views and perceptions.

PRINCIPLES OF THE RISK MANAGEMENT (3)

e) dynamic

Risks can arise, change, or disappear as the external and internal context of an organization changes. These changes and events are **appropriately** and **timely** anticipated, recognized, confirmed and addressed by risk management.

f) best information available

The input into risk management is based on historical and current information as well as future expectations. Risk management expressly takes into account all restrictions and uncertainties associated with such information and expectations. Information should be timely, understandable and available to relevant stakeholders.

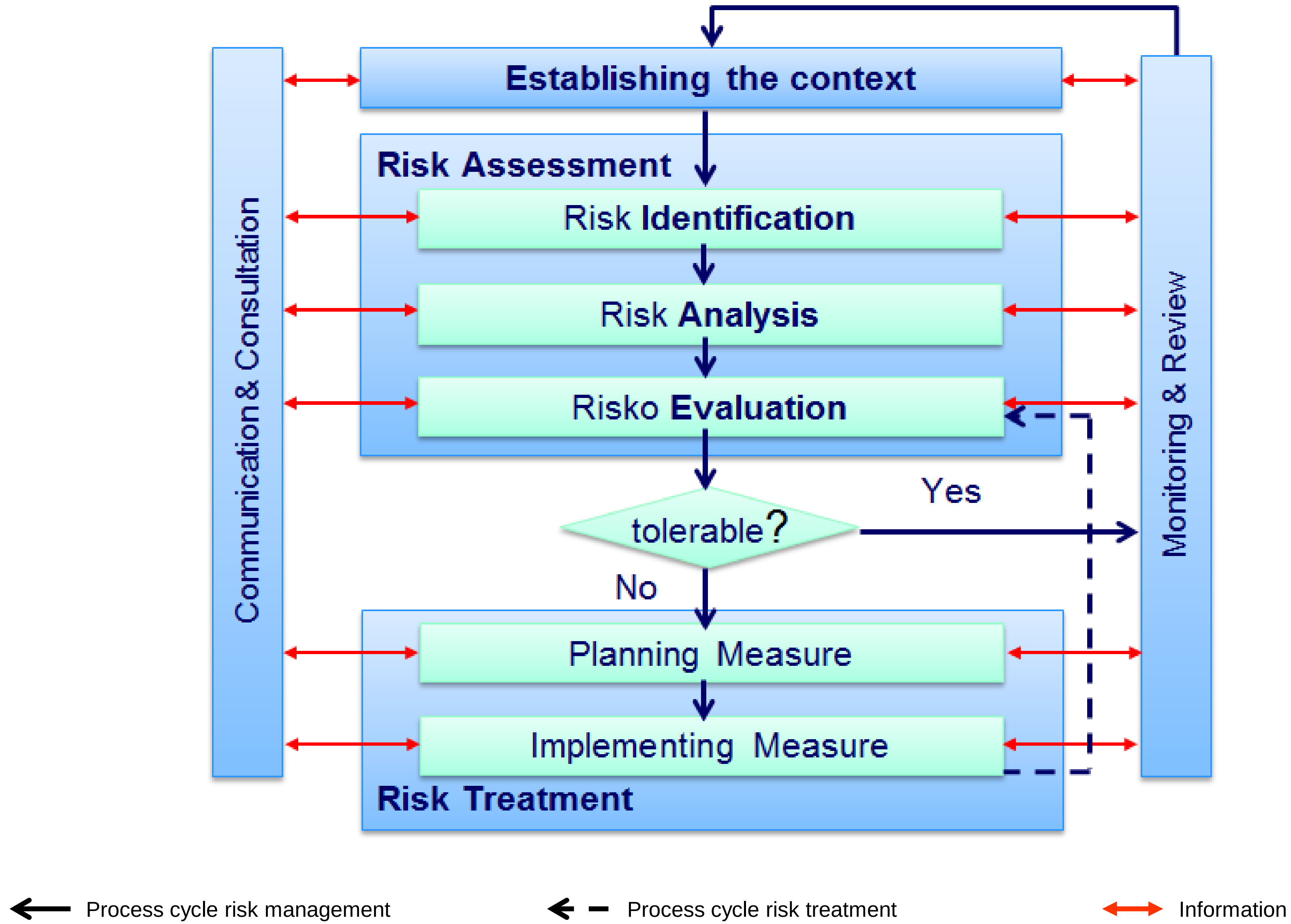
g) human and cultural factors

Human behavior and culture have a significant impact on all aspects of risk management at all levels and at every stage.

h) continuous improvement

Risk management is continually improved through learning and experience.

RISK MANAGEMENT: ISO 31000 PROCESS



ESTABLISHING THE CONTEXT

The context of the EMI risk management must clearly be articulated before the risk assessment starts.

Important aspects are:

- objective and scope (e.g. goals, system)
- external relationships
  (e.g. environmental conditions, interfaces)
- internal relationships of the organization/system
  (e.g. specifications)
- requirements for the EMI risk management process
- EMI risk criteria for the remaining process

MANDATE AND COMMITMENT

What to achieve:

Objectives, Performance criteria

What should it be achieved **with**:

Resources

How to achieve it:

Strategy

Who should reach it:

Responsibilities

COMMUNICATION AND CONSULTATION

Communication and consultation with external and internal stakeholders should take place at all stages of the risk management process.

Essential information is:

- Risk
- Risk cause
- Consequences and impacts
- Necessary measures

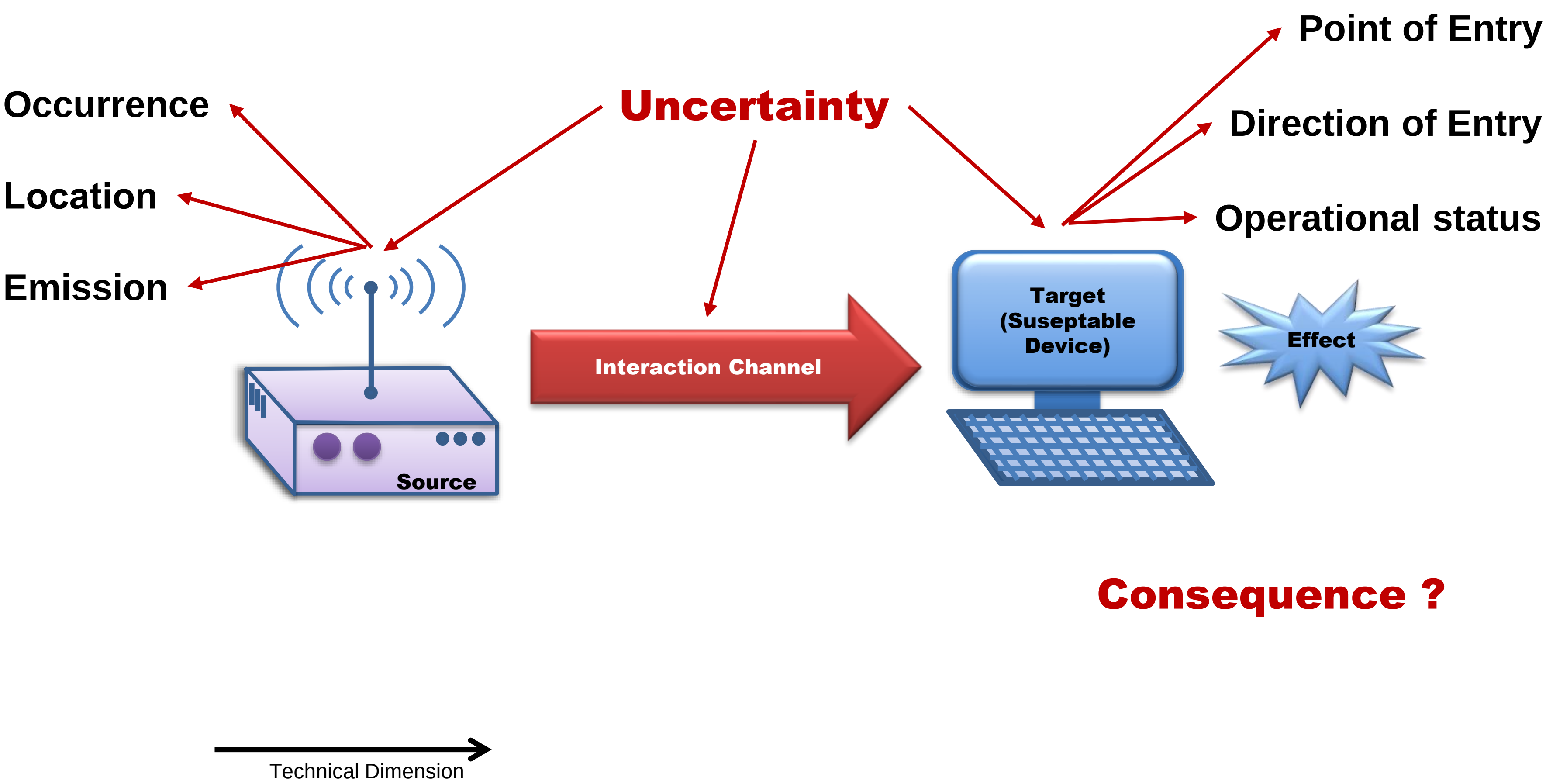
THREAT SCENARIO, EFFECT AND CRITICALITY ANALYSIS (TSECA)

1. Define the EMI threat scenario
2. Construct scenario interaction model and system structure model
3. Determine effects and failure modes
4. Evaluate each failure mode and assign a severity classification category
5. Identify failure detection methods
6. Identify corrective measures for failure modes
7. Documentation

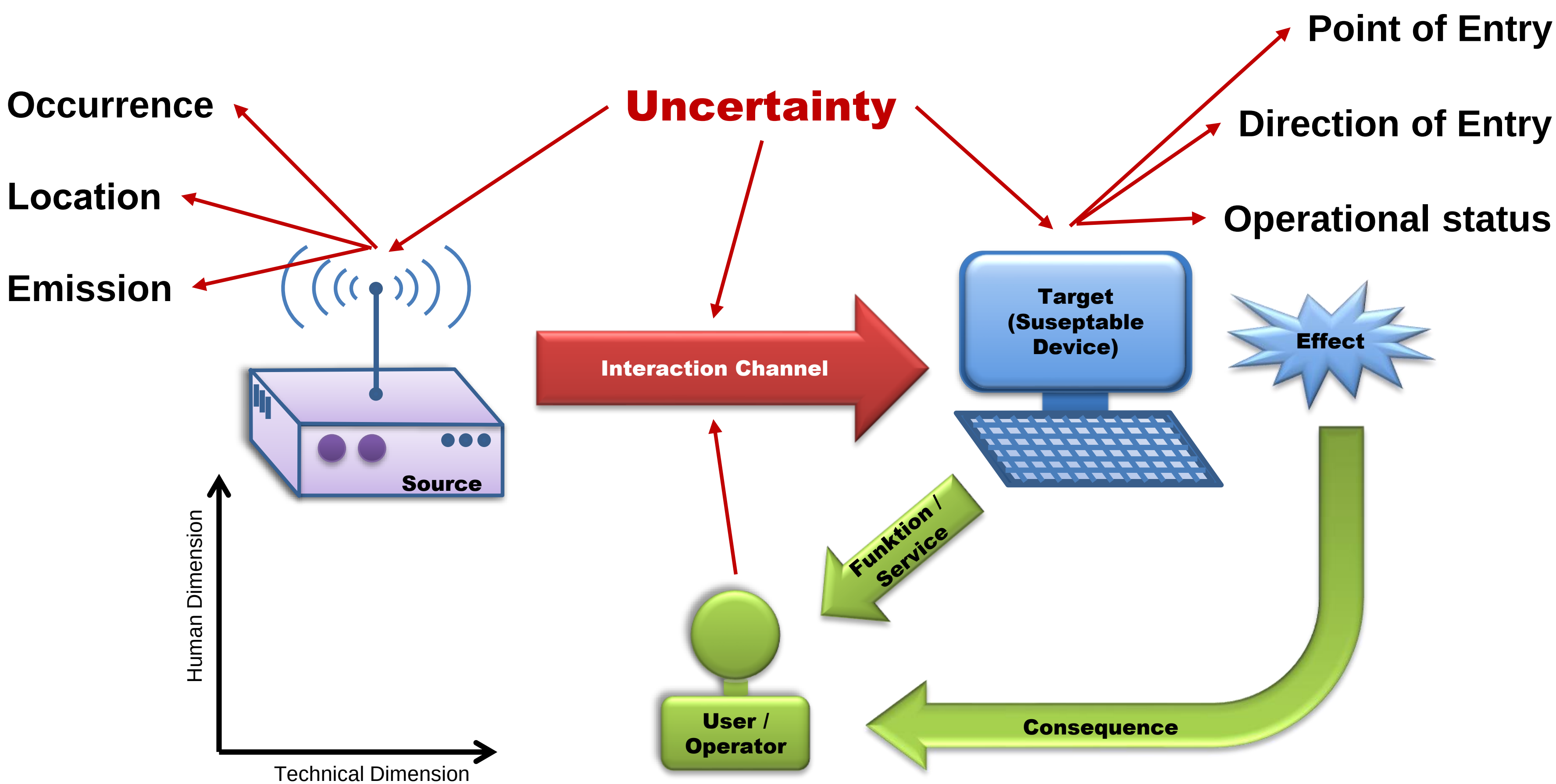
Source: F. Sabath and H. Garbe, "Concept of stochastic modeling for High-Power Electromagnetics (HPEM) risk analysis at system level," 2013 IEEE International Symposium on Electromagnetic Compatibility, Denver, CO, 2013, pp. 401-406, doi: 10.1109/ISEMC.2013.6670446

OUTLINE

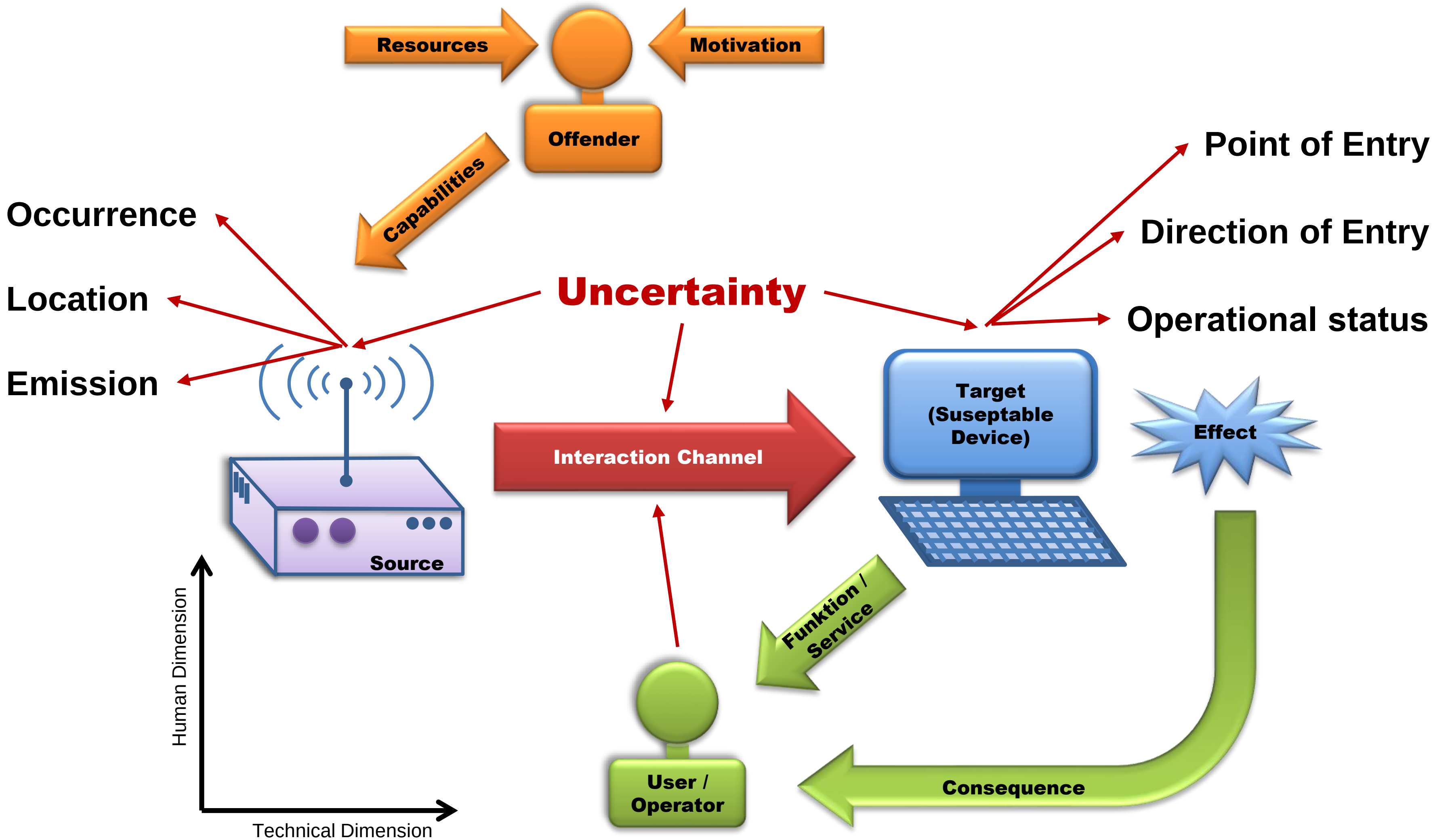
MODEL OF EMC SCENARIO



MODEL OF EMI SCENARIO



MODEL OF IEMI SCENARIO



OUTLINE

Introduction

EMI Risk & Risk Management

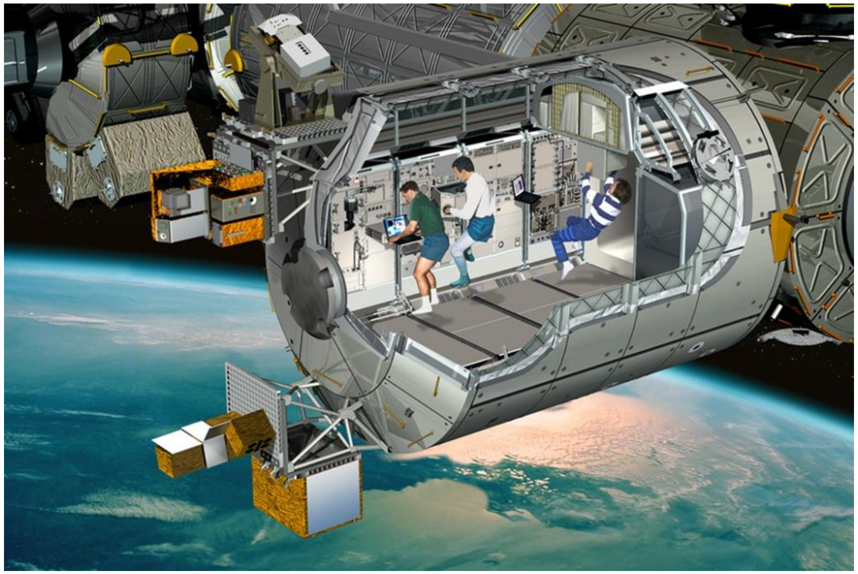
Model of EMI Scenario

Uncertainties of EMI Scenario

EMI Risks Evaluation

Conclusion – Take Home Messages

UNCERTAINTIES: SYSTEM DESCRIPTION



Divergences from documented Construction State

- audio / video systems / IT networks
- ad-hoc retrofits
- „aging“

Current Construction State

≠ documented construction state

≠ qualified construction state

= construction state in use

UNCERTAINTIES

- uncertainties of the **(I)EMI Scenario**
  - Source EM Environment
  - (I)EMI Source Location
  - Duration of (I)EMI exposure
- uncertainties of the **system description**
  - System status
  - Component Susceptibility
  - Target Location
- the stochastic nature of **key parameters**
  - Likelihood of occurrence of IEMI Sources
  - Component Susceptibility

$\Rightarrow$ Solution: **appropriate stochastic models**

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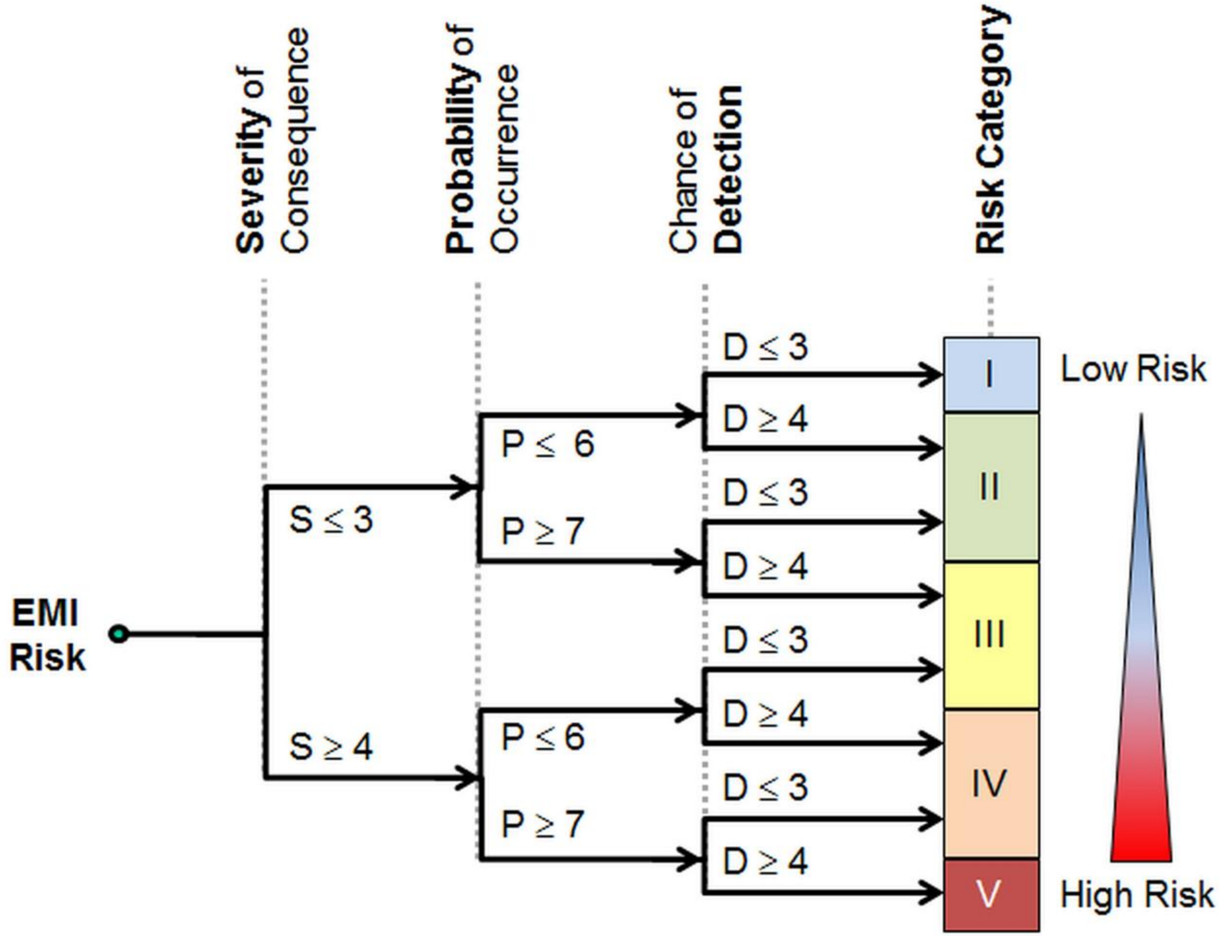
OBJECTIVE OF EMI RISKS EVALUATION

- **Classification** of identified risks
  - risks that can be tolerated
  - risks that require further analysis
  - risks that need to be addressed/mitigated
  - by comparing evaluation criteria and scales with the risk criteria determined during risk analysis
- **Prioritizing** necessary risk management measures

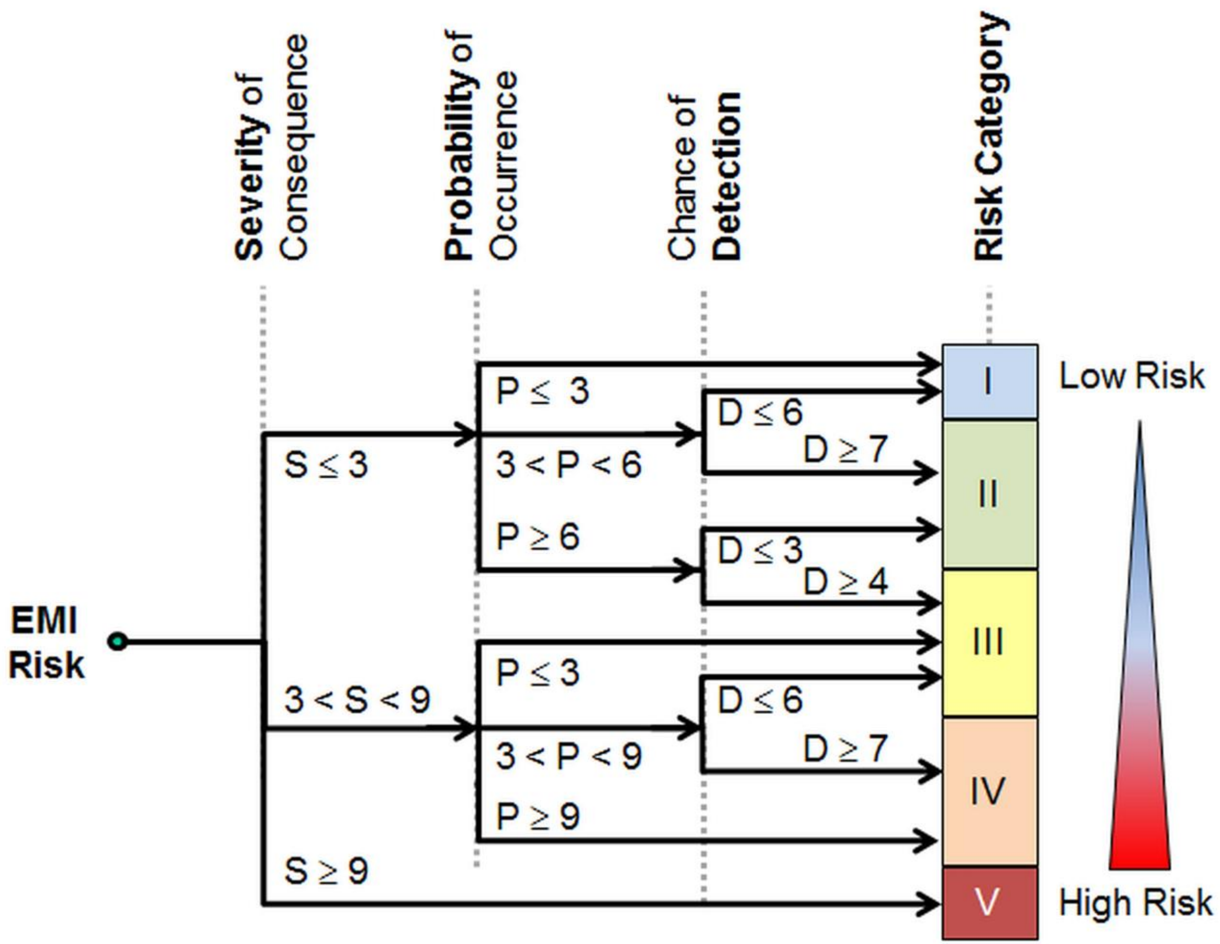
CHARACTERISTICS OF EMI RISKS

- **Probability / frequency of occurrence**
  - How often / likely does the consequence (effect, failure) occur when the system is exposed to an EMI environment (EMI attack).
- **Severity of Consequence**
  - How big is the potential damage or loss?
  - What is the significance of the potential damage and/or loss of functionality to the user of the system?
- **Chance of Detection**
  - Can the cause of error (EMI exposure) be detected in a timely manner (before secondary sequences occur)
- **Resilience**
  - Ability of the system to avoid permanent damage and capability to maintain and/or recover main functionality in a timely manner.

EMI RISK GRAPH



TAILORED EMI RISK GRAPH



OUTLINE

Introduction

EMI Risk & Risk Management

Model of EMI Scenario

Uncertainties of EMI Scenario

EMI Risks Evaluation

Conclusion – Take Home Messages

CONCLUSION – TAKE HOME MESSAGES

- EMI Risk Analysis and Management considers the scenario, uncertainties and consequences.
- An effective and efficient EMI Risk Management
  - is characterized by nine principles
  - Take human factors into account
- EMI Scenario has a technical and human dimension
- Threat Scenario, Effect and Criticality Analysis (TSECA) is capable to analyze EMI Risks
- Uncertainties of EMI Scenario require appropriate stochastic models
- Identified EMI Risks need to be evaluated if they are tolerable

THALES
Building a future we can all trust

Risk Based EMC

(EMC in the THALES development process)

Frank Leferink

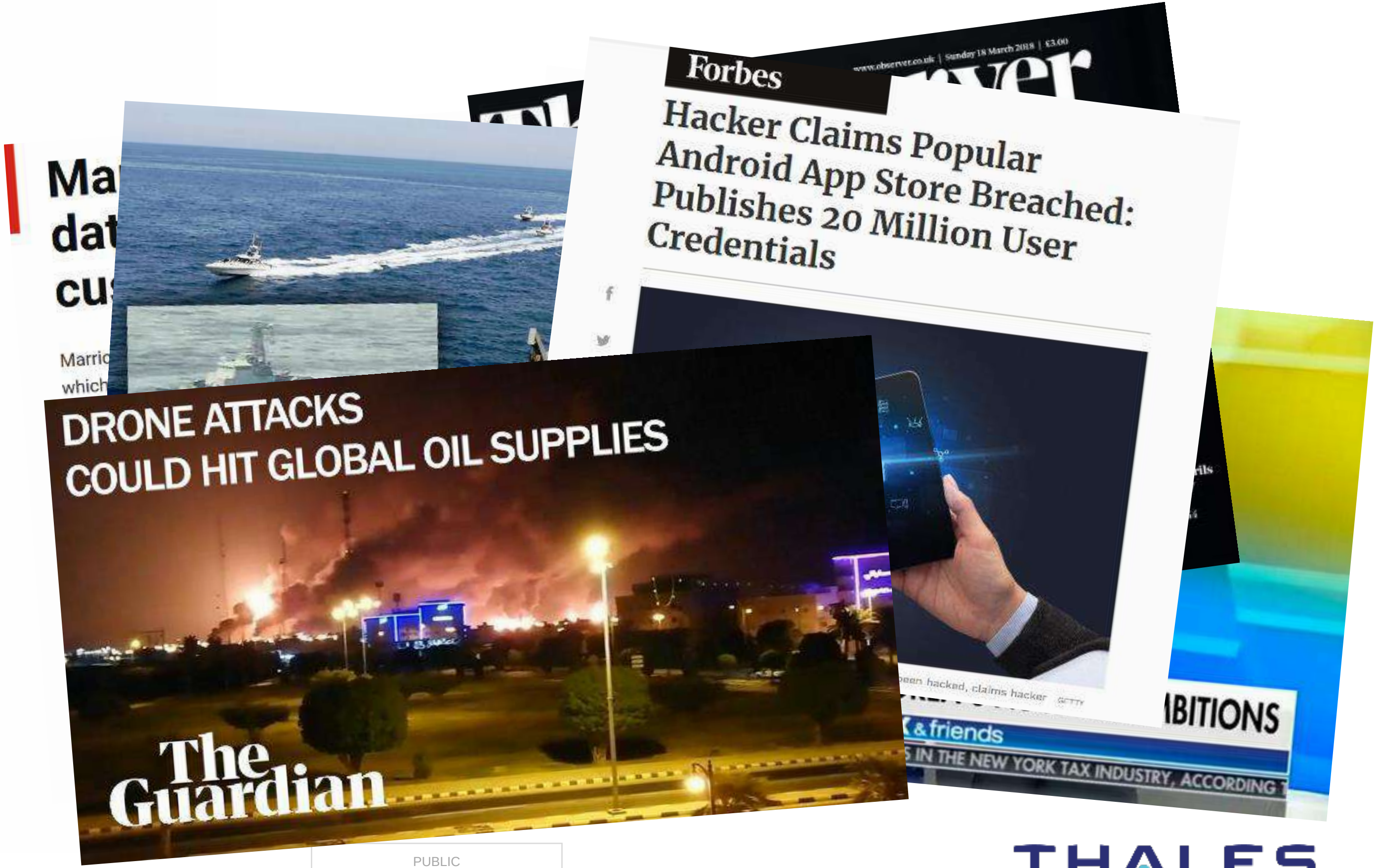
OPEN

About Thales

The people we all rely on to make the world go round, they rely on Thales

In a world that is increasingly fast moving, unpredictable – and full of opportunities,
they come to us with big ambitions: to make life better, to keep us safer.

Building a future we can all trust



PUBLIC
Presented at the MSCA PETER Network Wide Event, April 2021

THALES
Building a future we can all trust

Mastering ever greater complexity

Defence and Security

Digital Identity and Security

Aerospace

Space

Transportation

← Critical decision chain →

Sensing and data gathering 〉 **Data transmission and storage** 〉 **Data processing and decision making**

Sensors, mission systems, communication, command and control systems

Defence and Security

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Digital Identity and Security

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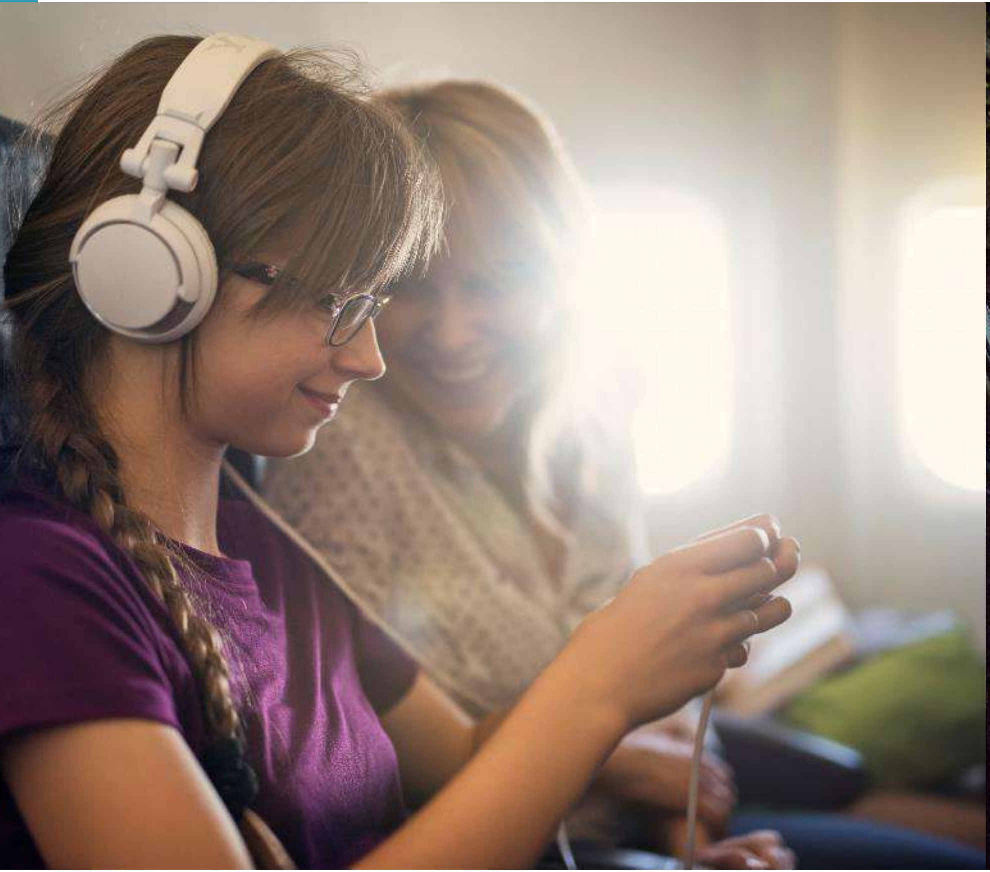
Aerospace



Space

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Transportation

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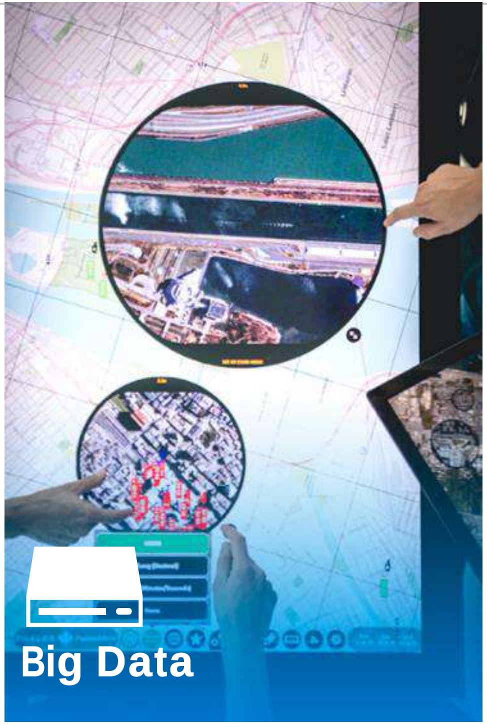
Key Digital Technologies



We help our customers think smarter and act faster - mastering ever greater complexity and every decisive moment along the way. **Whatever it takes.**

About Thales Worldwide

Over **82,000**
employees

68
Countries
Global presence

1bn €
Self-funded R&D*
* Does not include externally financed R&D

Sales in 2019
18.4 bn €

THALES
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About Thales in the Netherlands

Sales
€ 459 million

Export
€ 303 million

R&D
€ 138 million

Non-defence
11%

Employees
+/- 2250

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Presented at the MSCA PETER Network Wide Event, April 2021

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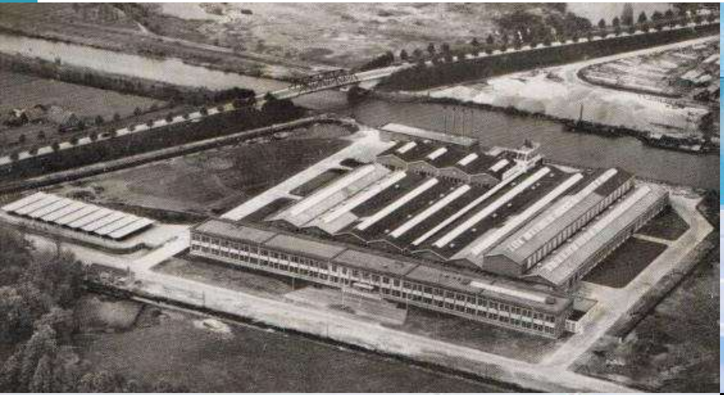
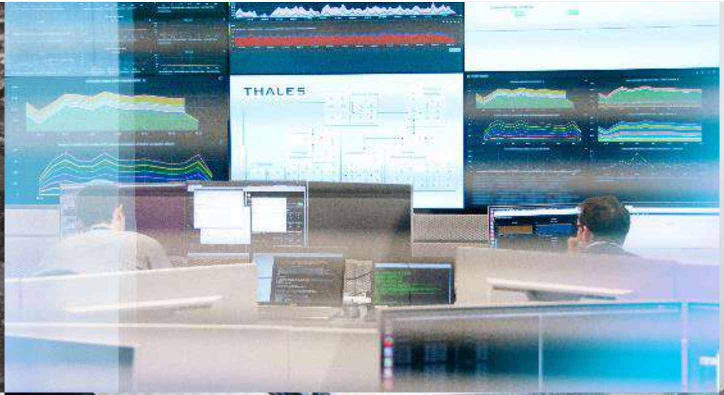
Thales History in the Netherlands

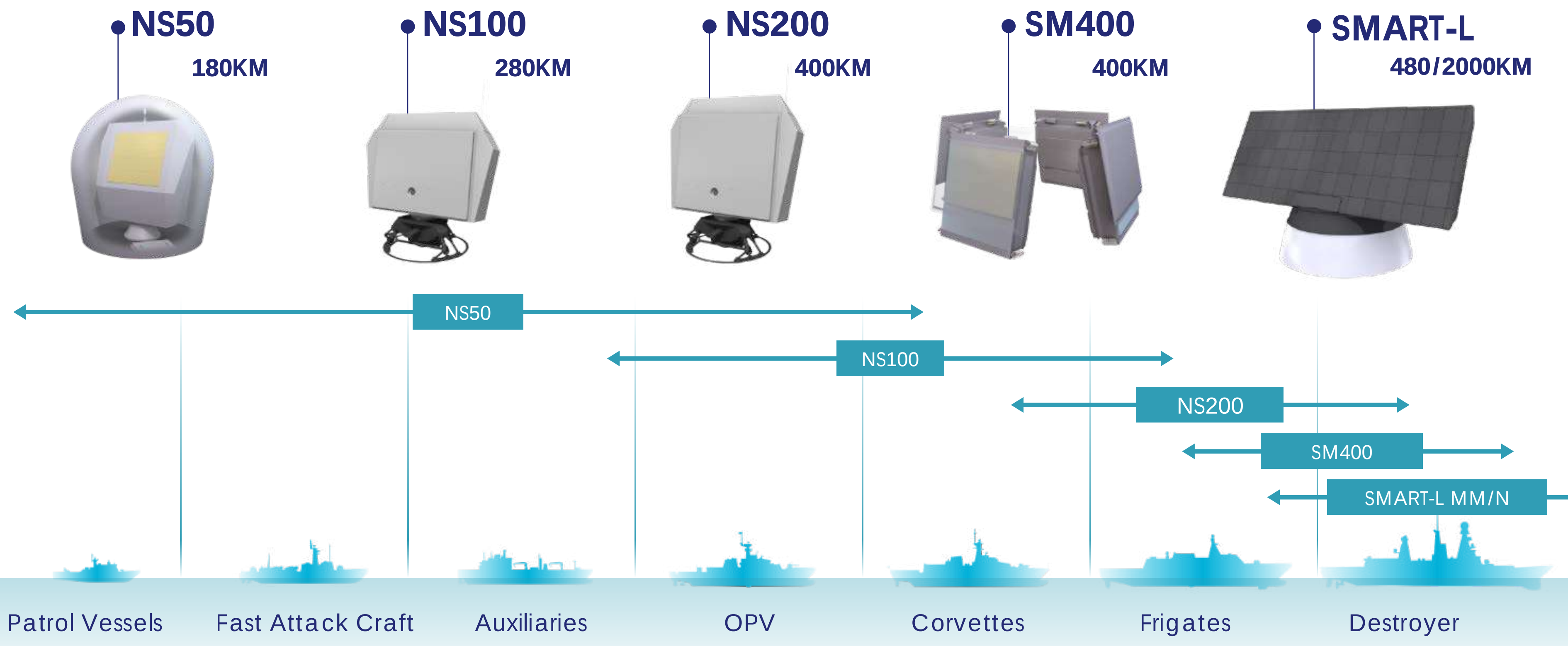




The company was founded in **1922** as NV Hazemeijers fabriek van Signaalapparaten, for the development of naval systems. In **1956** the majority of Signaal shares were purchased by Philips. In **1990** Philips decided defence was not a core activity and sold Signaal to Thomson-CSF. In **2000**, Thomson-CSF changed his name in Thales.

Nowadays, Thales in the Netherlands is active in Defence, Cybersecurity and Transportation.

Naval radar development



EMC

New technology: telephone …….EMI

Reichs-Gesetzblatt.

№ 21.

Inhalt: Gesetz über das Telegraphenwesen des Deutschen Reichs. S. 467

(Nr. 2015.) Gesetz über das Telegraphenwesen des Deutschen Reichs. Vom 6. April 1892.

Wir Wilhelm, von Gottes Gnaden Deutscher Kaiser, König von Preußen rc.

verordnen im Namen des Reichs, nach erfolgter Zustimmung des Bundesraths und des Reichstags, was folgt:

§. 1.

Das Recht, Telegraphenanlagen für die Vermittelung von Nachrichten zu errichten und zu betreiben, steht ausschließlich dem Reich zu. Unter Telegraphenanlagen sind die Fernsprechanlagen mit begriffen.

§. 12.

Elektrische Anlagen sind, wenn eine Störung des Betriebes der einen Leitung durch die andere eingetreten oder zu befürchten ist, auf Kosten desjenigen Theiles, welcher durch eine spätere Anlage oder durch eine später eintretende Aenderung seiner bestehenden Anlage diese Störung oder die Gefahr derselben veranlaßt, nach Möglichkeit so auszuführen, daß sie sich nicht störend beeinflussen.

§. 15.

Die Bestimmungen dieses Gesetzes gelten für Bayern und Württemberg mit der Maßgabe, daß für ihre Gebiete die für das Reich festgestellten Rechte diesen Bundesstaaten zustehen und daß die Bestimmungen des §. 7 auf den inneren Verkehr dieser Bundesstaaten keine Anwendung finden.

Urkundlich unter Unserer Höchsteigenhändigen Unterschrift und beigedrucktem Kaiserlichen Insiegel.

Gegeben im Schloß zu Berlin, den 6. April 1892.

(L. S.) Wilhelm.

Graf von Caprivi.

Power and communication systems are both using earth (ground) as return current path:

Interference

‘ § 12

As far as possible, electric equipments must be designed in a way that interferences do not occur.’

From: Frank Sabath/ Heyno Garbe

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Presented at the MSCA PETER Network Wide Event, April 2021

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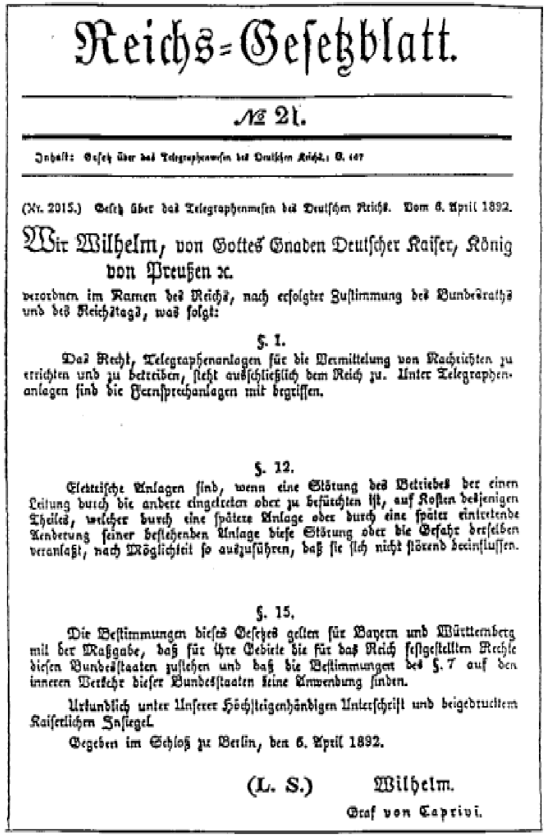
New technology: telephone …….EMI



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Das Recht, Telegraphenanlagen für die Vermittelung von Nachrichten zu errichten und zu betreiben, steht ausschließlich dem Reich zu. Unter Telegraphenanlagen sind die Fernsprechanlagen mit begriffen.

§. 12.

Elektrische Anlagen sind, wenn eine Störung des Betriebes der einen Leitung durch die andere eingetreten oder zu befürchten ist, auf Kosten desjenigen Theiles, welcher durch eine spätere Anlage oder durch eine später eintretende Aenderung seiner bestehenden Anlage diese Störung oder die Gefahr derselben veranlaßt, nach Möglichkeit so auszuführen, daß sie sich nicht störend beeinflussen.

§. 15.

Die Bestimmungen dieses Gesetzes gelten für Bayern und Württemberg mit der Maßgabe, daß für ihre Gebiete die für das Reich festgestellten Rechte diesen Bundesstaaten zustehen und daß die Bestimmungen des §. 7 auf den inneren Verkehr dieser Bundesstaaten keine Anwendung finden.

Urkundlich unter Unserer Höchsteigenhändigen Unterschrift und beigedrucktem Kaiserlichen Insiegel.

Gegeben im Schloß zu Berlin, den 6. April 1892.

(L. S.) Wilhelm.

Graf von Caprivi.

Power and communication systems are both using earth (ground) as return current path:

Interference

‘ § 12

As far as possible, electric equipments must be designed in a way that interferences do not occur.’

Already in 1892

From: Frank Sabath/ Heyno Garbe

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Presented at the MSCA PETER Network Wide Event, April 2021

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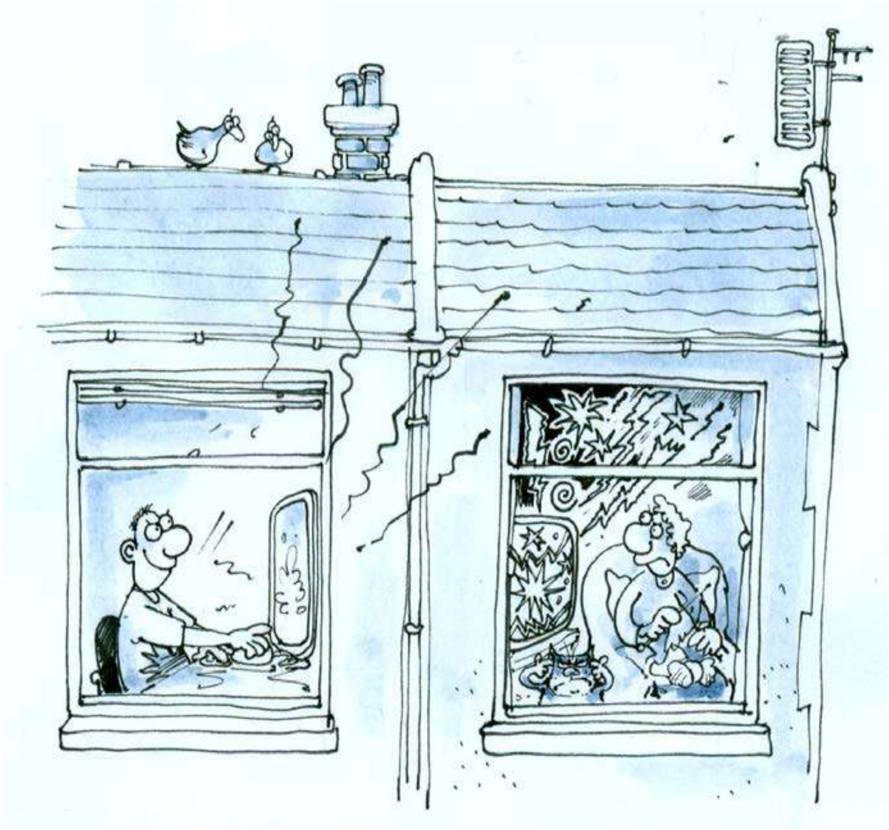
New technology: radio, TV … EMI



Cartoons made by Rupert Beasley for University of Twente

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THALES
Building a future we can all trust

New technology: radio, TV … EMI

https://www.professionalpensions.com/analysis/1013269/-stricter-rules-updating-scheme-rules-deeds

Basic solution

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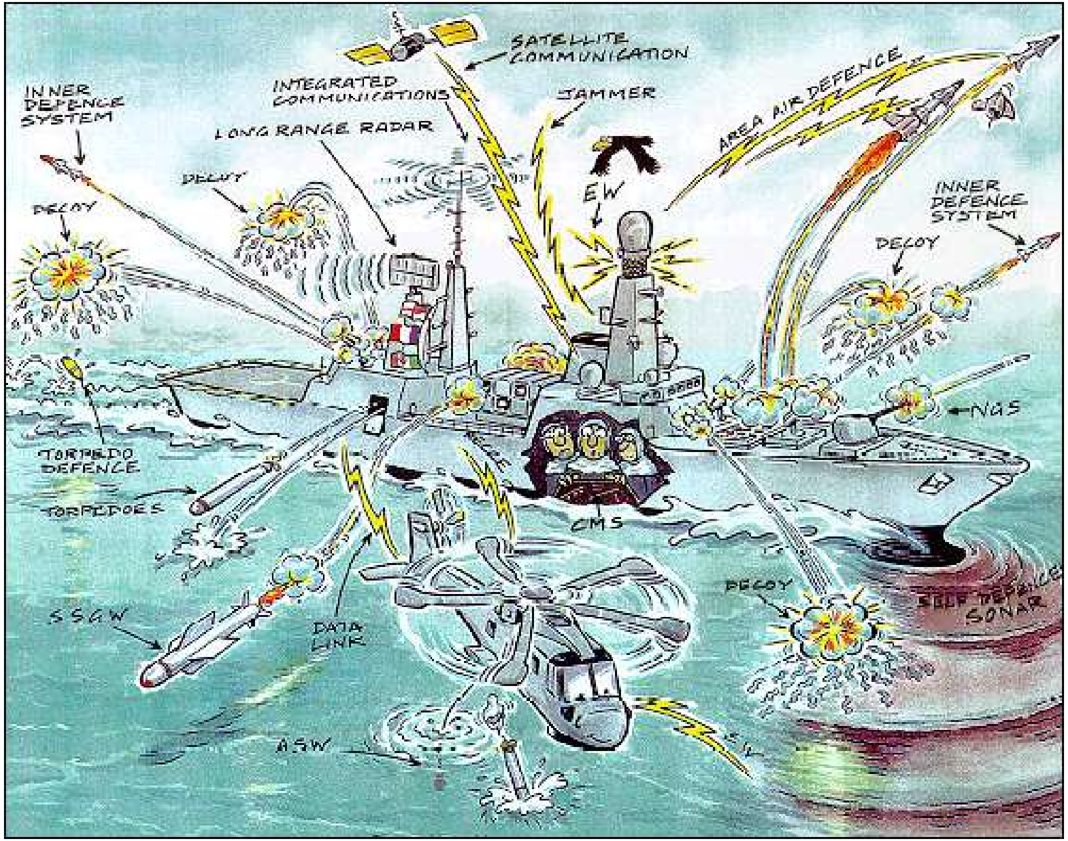
Is that the smart way, also for complex systems?



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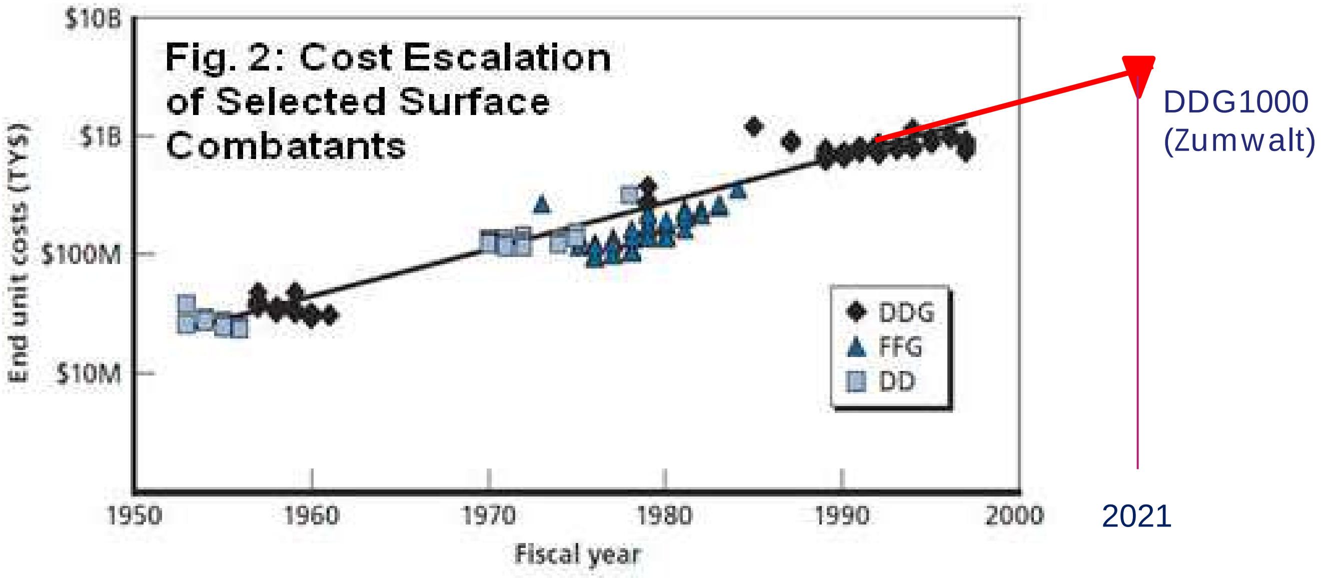
USA: *'Documents for Ship Cost Reduction'*

Initiative by VADM McCoy:

- *"Ships cost too much!"*
- *"We don't know the cost of our specs and standards"*
- *"Find stuff we no longer need or no longer can afford"*

USA: '*Documents for Ship Cost Reduction*'

'The cost of Navy ships is escalating at an unsustainable rate'



'A surprisingly large part of this escalation is attributable to ***Standards*** *and* ***Specifications****'* **(~ rules)**

M. Arena et. al., 'Why has the cost of Navy ships risen?', RAND National Defense Research institute, prepared for the US Navy, 2010

USA: *'Documents for Ship Cost Reduction'*

Top 10 of cost-driver standards,

3 out of them are EMC

- *'MIL-STD-461E Electromagnetic Interference (EMI)'*
- *'MIL-STD 464A Electromagnetic Environmental Effects (E3) Requirements for Systems'*
- *'MIL-STD-469B Radar Engineering Interface Requirements, Electromagnetic Compatibility – Frequency Spectrum Guide for Radar'*

M. Arena et. al., 'Why has the cost of Navy ships risen?', RAND National Defense Research institute, prepared for the US Navy, 2010

Solution (?)

Rules and Standards

Yes, it solved most interference problems

Solution (?)

Rules and Standards

Yes, it solved most interference problems

But increasing costs

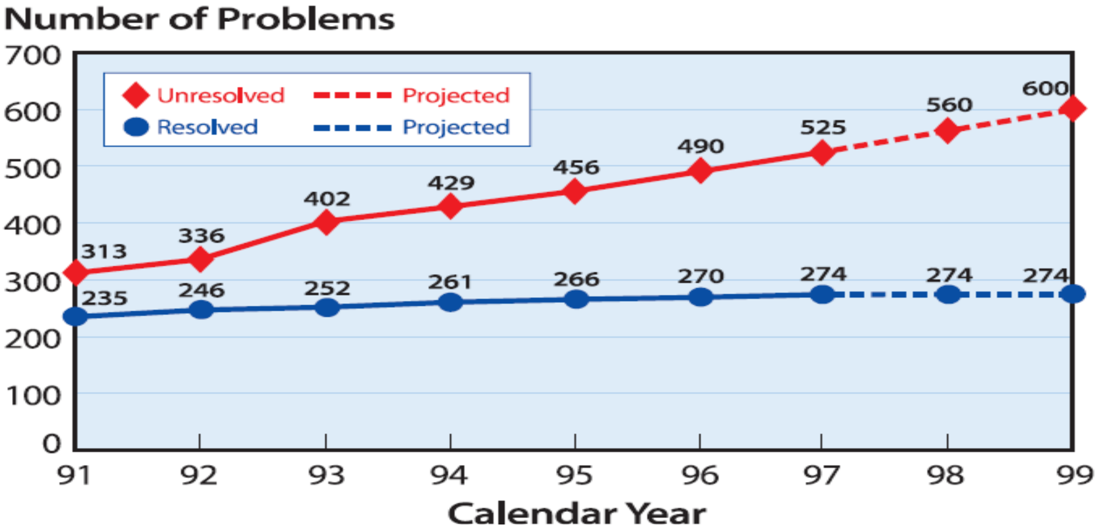
Solution (?)

Rules and Standards

Yes, it solved most interference problems

But increasing costs

And did it help?



No!!

SEMCIP problem history

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Solution (?)

Rules and Standards

Yes, it solved most interference problems

But increasing costs

Why?

Stupid managers believing that sticking to rules solves all problems

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Solution (?)

Rules and Standards

Yes, it solved most interference problems

But increasing costs

Can we do it better for complex systems?

Risk based approach for naval ships

Assessment of:

- the expected actual EM environment,
- immunity and emission characteristics of equipment

Then: Implement necessary measures (incl. non-technical)

No expensive hardening and testing of <u>all</u> individual equipment to very specific standards (i.e. rule based)

Integrating COTS the wrong way: LCS

Report of the
Defense Science Board
Task Force on Integrating
Commercial Systems into the DOD,
Effectively and Efficiently

For these reasons, the commercial advantages were not fully realized in the initial production, although eventual benefits are anticipated. Each ship is estimated to cost more than $500 million, more than doubling the original cost requirement of $220 million.

Risk based approach for naval ships

Thus:

- Instead of hardening <u>all</u> equipment,
  we specify and control the EM environment
- That means we accept the EMC performance of most equipment as it is, but put effort in controlling the EM environment and hardening of only some equipment
- And **keep in control** during the process

M C I V EMC FOR FUTURE SHIPS

It is even requested….

MIL-STD-461G
11 December 2015
SUPERSEDING
MIL-STD-461F
10 December 2007

DEPARTMENT OF DEFENSE
INTERFACE STANDARD

REQUIREMENTS FOR THE CONTROL OF ELECTROMAGNETIC INTERFERENCE CHARACTERISTICS OF SUBSYSTEMS AND EQUIPMENT

1.2.2 Tailoring of requirements.
Application-specific environmental criteria may be derived from operational and engineering analyses on equipment or subsystems being procured for use in specific systems or platforms. When analyses reveal that the requirements in this standard are not appropriate for that procurement, the requirements may be tailored and incorporated into the request-for-proposal, specification, contract, order, and so forth, prior to the start of the test program. The test procedures contained in this document are generic test methods and should be adapted as necessary for each application, while maintaining the intent of the test, and should be approved by the procuring activity. The adapted test procedures should be documented in the Electromagnetic Interference Test Procedures (EMITP) (see 6.3).

From 'rule based' to 'risk based'

How can we do this? M-C-I-V:

- EMC **M**anagement (what, when, who)
- EMC **C**ontrol (risk management)
- EMC **I**mplementation (how)
- EMC **V**erification (check)

M C I V EMC FOR FUTURE SHIPS

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From ‘rule based’ to ‘risk based’

How can we do this? M-C-I-V:

- EMC **M**anagement (what, when, who)
- EMC **C**ontrol (risk management)
- EMC **I**mplementation (how)
- EMC **V**erification (check)

Lloyd’s Register

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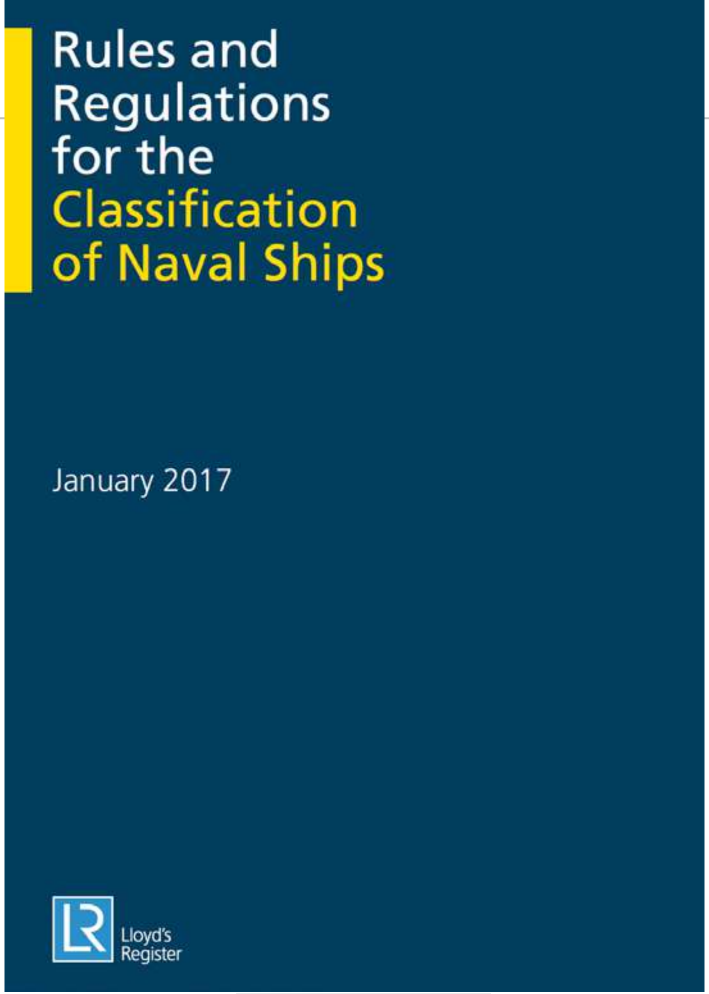

Rules and Regulations for the Classification of Naval Ships
January 2017
Lloyd's Register

3.3.12 **Electromagnetic compatibility (EMC)** *See Vol 2, Pt 1, Ch 3, 4.13 Electromagnetic compatibility (EMC).*

(a) The following set of EMC documents is to be submitted and is to include, but not be limited to:

(i) an EMC Management Plan which details the ships operational role and defines the EM (Electromagnetic) environment, requirements and responsibilities;

(ii) an EMC Control Plan, which defines the design and mitigation measures to be taken to achieve EMC in the agreed EM threat environment. These are to include, but are not limited to the following:

- the EM threats, *see Vol 2, Pt 1, Ch 3, 3.3 Calculations and specifications 3.3.12*(b) below;
- the zoning concept used;
- a declaration of the emission levels;
- a declaration the minimum immunity levels;
- shielding techniques and requirements;
- cabling requirements; and
- filtering requirements.

(iii) an EMC Implementation Plan, which defines the techniques to be used to mitigate the Electromagnetic (EM) threats and the requirements of the EMC Control Plan, including the installation techniques to be applied, *see Vol 2, Pt 1, Ch 3, 4.13 Electromagnetic compatibility (EMC) 4.13.4*; and

(iv) an EMC Test Plan, which defines the verification and validation requirements, which are to include the analysis, inspection, demonstration and testing requirements, *see Vol 2, Pt 1, Ch 3, 4.13 Electromagnetic compatibility (EMC) 4.13.3.*

Note Based on the submissions required above, LR will conduct appropriate inspections to verify the processes and techniques defined have been applied correctly.

(b) the EM Threats are to be defined using the most appropriate method for the assigned ship type and vessel ConOps, *See Vol 1, Pt 1, Ch 2 Classification Regulations*, and one of the following methods:

- applying the requirements and guidelines of IEC 60533, *Electrical Installations in Ships, Electromagnetic Compatibility*; or
- applying Naval Authority requirements, as defined in an appropriate naval standard acceptable to LR; or
- conducting an EM threat assessment which, so far as is reasonably practicable:
  - identifies all the EM threats and associated hazards;
  - identifies all the process, procedures and mitigation requirements which are to be applied to achieve the required EMC in the EM threat environment; and
  - has been agreed between shipbuilder and Naval Authority, and is acceptable to LR.

(c) The ship design must be demonstrated to have taken adequate measures to ensure the required performance of Ship Type and Mobility systems are maintained under all normal and reasonably foreseeable abnormal conditions, *see Vol 2, Pt 1, Ch 3, 4.13 Electromagnetic compatibility (EMC).*

Is this new?

Is this new?

No!!!

this is the
‘EMC engineering’
approach, as written several decades ago in
MIL-HDBK 237,
VG95370,
DEF-STAN 59-411 etc.

Risk vs. Rule based

- In military and other professional (for instance aerospace) domains this is called 'EMC Engineering'

- **But rule-based remains often the default, due to lack of competences (incompetent managers and procurement people), and resulting in exploding costs, see the introduction**

Risk vs. Rule based

- In military and other professional (for instance aerospace) domains this is called ‘EMC Engineering’

- **But rule-based remains often the default, due to lack of competences (incompetent managers and procurement people), and resulting in exploding costs, see the introduction**

- Trending now also in civil domains
  1. European Directive EMC 2014: see ‘’Blue Guide’’ 2016
  2. Medical: IEC 60601-1-2: Medical electrical equipment - EMC Requirements and (EMI) tests, full implementation 2019
  3. Guide for the EMCD (Directive 2014/30/EU), March 2018

Risk vs. Rule based, EMC Directive

- Equipment in the EU shall fulfil the essential requirements of the EMC-Directive:


29.3.2014 EN Official Journal of the European Union L 96/97

ANNEX I

ESSENTIAL REQUIREMENTS

1. **General requirements**

Equipment shall be so designed and manufactured, having regard to the state of the art, as to ensure that:

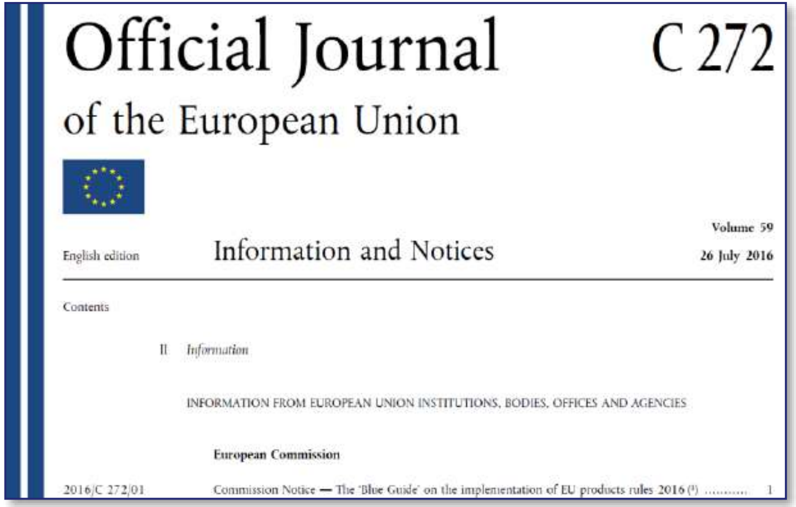
(a) the electromagnetic disturbance generated does not exceed the level above which radio and telecommunications equipment or other equipment cannot operate as intended;

(b) it has a level of immunity to the electromagnetic disturbance to be expected in its intended use which allows it to operate without unacceptable degradation of its intended use.

- *'Equipment shall be so designed and manufactured, having regard to the state of the art, as to ensure that:*
  - *(a) the electromagnetic disturbance generated does not exceed the level above which radio and telecommunications equipment or other equipment cannot operate as intended;*
  - *(b) it has a level of immunity to the electromagnetic disturbance to be expected in its intended use which allows it to operate without unacceptable degradation of its intended use'*

1: Risk vs. Rule based, Blue Guide

- Common approach of most suppliers:
  follow the harmonized EN/IEC standards (‘’rules’’):
  results in ‘presumption of conformity’.
- The European Commission ‘’Blue Guide’’ of 2016 gives a clear explanation on using Harmonised Standards (next page)


Official Journal of the European Union C 272

English edition Information and Notices Volume 59 26 July 2016

Contents

II *Information*

INFORMATION FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND AGENCIES

European Commission

2016/C 272/01 Commission Notice — The ‘Blue Guide’ on the implementation of EU products rules 2016 (¹) 1

1: Risk vs. Rule based, Blue Guide

European Commission Blue Guide 2016:

*'Harmonised standards **never replace** legally binding essential requirements. A specification given in a harmonized standard is not an alternative to a relevant essential or other legal requirement but only a possible technical means to comply with it.*

In risk related harmonisation legislation this means in particular that a manufacturer always, even when using harmonised standards, remains fully responsible for assessing all the risks of his product in order to determine which essential (or other) requirements are applicable.'

Harmonised standards never replace legally binding essential requirements. A specification given in a harmonised standard is not an alternative to a relevant essential or other legal requirement but only a possible technical means to comply with it. In risk related harmonisation legislation this means in particular that a manufacturer always, even when using harmonised standards, remains fully responsible for assessing all the risks of his product in order to determine which essential (or other) requirements are applicable. After this assessment a manufacturer may then choose to apply specifications given in harmonised standards to implement 'risk reduction measures' ([166]) which are specified by harmonised standards. In risk related harmonisation legislation harmonised standards most commonly provide certain means to reduce or remove risks while manufacturers remain fully responsible for risk assessment to identify applicable risks and to identify applicable essential requirements in order to select suitable harmonised standards or other specifications.

1: Risk vs. Rule based, Blue Guide

- European Commission Blue Guide 2016:
  'Harmonised standards ***never replace*** *legally binding essential requirements. A specification given in a harmonized standard is not an alternative to a relevant essential or other legal requirement but only a possible technical means to comply with it.*
  In risk related harmonisation legislation this means in particular that a manufacturer always, even when using harmonised standards, remains fully responsible for assessing all the risks of his product in order to determine which essential (or other) requirements are applicable.'

- **So risk-based should already be a default approach**

2: Risk vs. Rule based, Guide for the EMCD

March 2018

Guide for the EMCD (Directive 2014/30/EU)

4.2 Risk analyses and risk assessment

The conformity assessment procedures for apparatus require the manufacturer to establish technical documentation. This documentation shall make it possible to assess the conformity of the apparatus to the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). In EMCD the concept of risk refers to risks in relation to the electromagnetic compatibility protection aims specified in Annex I "Essential Requirements" and not to safety. On basis of the knowledge of the relevant EMC phenomena for the apparatus and its intended operating environments the EMC assessment according to chapter 4.3 can be performed. This EMC assessment is considered to be an adequate analysis and assessment of the risk(s). See also Blue Guide section 4.1.1 "Definition of essential requirements".

2: Risk vs. Rule based, Guide for the EMCD

After having identified the risks of the apparatus, three methods are possible for the EMC assessment:

a) Application of EMC harmonised standards having checked whether the chosen harmonised standard(s) covers all the phenomena relevant to the product.

b) An EMC assessment where no harmonised standards have been applied and the manufacturer applies his own methodology (other technical specifications).

c) Mixed assessment, combining the two previous methods. For example, one could use the harmonised standards to cover emission phenomena and a detailed technical EMC assessment for immunity aspects.

2: Risk vs. Rule based, Guide for the EMCD

After having identified the risks of the apparatus, three methods are possible for the EMC assessment:

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c) Mixed assessment, combining the two previous methods. For example, one could use the harmonised standards to cover emission phenomena and a detailed technical EMC assessment for immunity aspects.

To re-iterate - **the EMC assessment is the sole responsibility of the manufacturer**; it is never the responsibility of a third party such as a Notified Body or an EMC test laboratory[27].

March 2018

Guide for the EMCD (Directive 2014/30/EU)

The EMCD does not regulate the safety of equipment in respect of people, domestic animals or property[5]. According to Article 1, the EMCD covers exclusively the electromagnetic compatibility of equipment. However, it should be noted that other directives may require higher requirements for EMC phenomena in order to satisfy their specific safety provisions.

The EMCD is therefore not a safety related Directive.

Functional safety aspects based on electromagnetic disturbances are regulated for instance by the Machinery Directive 2006/42/EC, the Low Voltage Directive 2014/35/EU and the General Product Safety Directive 2001/95/EC.

Is this new?

No!!!

this is the
‘EMC engineering’
approach, as written several decades ago in
MIL-HDBK 237,
VG95370,
DEF-STAN 59-411 etc.

Not invented here…. Based on MIL-HDBK-237

W-15-75

MIL-HDBK-237A
2 FEBRUARY 1981

SUPERSEDING
MIL-HDBK-237
20 APRIL 1973

+ interim notice 1 (Navy)

MILITARY HANDBOOK

ELECTROMAGNETIC COMPATIBILITY MANAGEMENT GUIDE FOR PLATFORMS, SYSTEMS AND EQUIPMENT

THIS DOCUMENT CONTAINS 137 PAGES.

FSC EMCS
AMSC NUMBER N3132

0166 E-5

MIL-HDBK-237
INTERIM NOTICE 1 (NAVY)

CONTENTS

Supersedes page iv of 2 February 1981

iv

MIL-HDBK-237A
INTERIM NOTICE 1 (NAVY)

CONTENTS (continued)

TABLES

Also VG

- Similar approach

Bundesamt für Wehrtechnik und Beschaffung	Electromagnetic compatibility **Management control procedures** Procedures for equipment	VG 95 374 Part 5

Elektromagnetische Verträglichkeit; Programme und Verfahren;
Verfahren für Geräte

This standard must be used, although it has not been adequately tested in practice. It is requested that experience and proposal for modification should be communicated to the Normenstelle Elektrotechnik, Kardinal-Krementz-Straße 18, 5400 Koblenz, by 31. December 1986.

Contents

And many other documents, like Def-Stan

UK OFFICIAL

Ministry
of Defence

Defence Standard 59-411 Part 5

Issue 2 **Date: 31 March 2014**

Electromagnetic Compatibility

Part 5: Code of Practice for Tri-Service Design and Installation

5 EMC Management and Planning

5.1 General

Experience has shown that major interference problems and considerable additional
if EMC requirements are not taken into account at all stages of projects for the des
equipment and systems. It is therefore essential to implement suitable EMC manage
reference must be made to **Part 1** of this Standard; Management and Planning.

The aims of EMC planning may be summarised as follows:

a) Co-ordinating the EMC tasks in design, manufacture and quality assurance;

b) Integrating EMC with other requirements such as cost, reliability, maintaina
environmental conditions;

c) Monitoring changes in equipment design and performance deficiencies and communicating the EMC implications to all the parties involved;

d) Assessing the need for changes in EMC requirements and implementing these as necessary;

e) Maintaining liaison between all relevant parties (see **Clause 5.2**).

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And NATO AECTP100

Although laboratory testing is a valuable tool in the materiel development process, there are certain inherent limitations that must be recognised when applying AECTP 100 through 500. The test methods in AECTP 300 through 500 do not include all possible forcing functions that may affect system performance or integrity in its service use. These methods are limited to those currently developed for laboratory testing and cannot apply all known possible stress combinations present in natural field/fleet service environments. Therefore, caution must be used in extrapolating laboratory test results to predict the performance, durability and suitability of materiel in actual service use. AECTP 100 through 500 were not developed specifically to cover the following applications, but in some cases they may be applied:

THALES: in place (whole Group) since 90’s

1990’s:

- More collaboration within the THALES Group
- One action: bring together best practices
- EMC Management (Control) Plan

MODULE No 15 - HARDWARE DEVELOPMENT

METHODOLOGY

EMC CONTROL PLAN

Ref. paper Leferink et. al. 1996

Key table

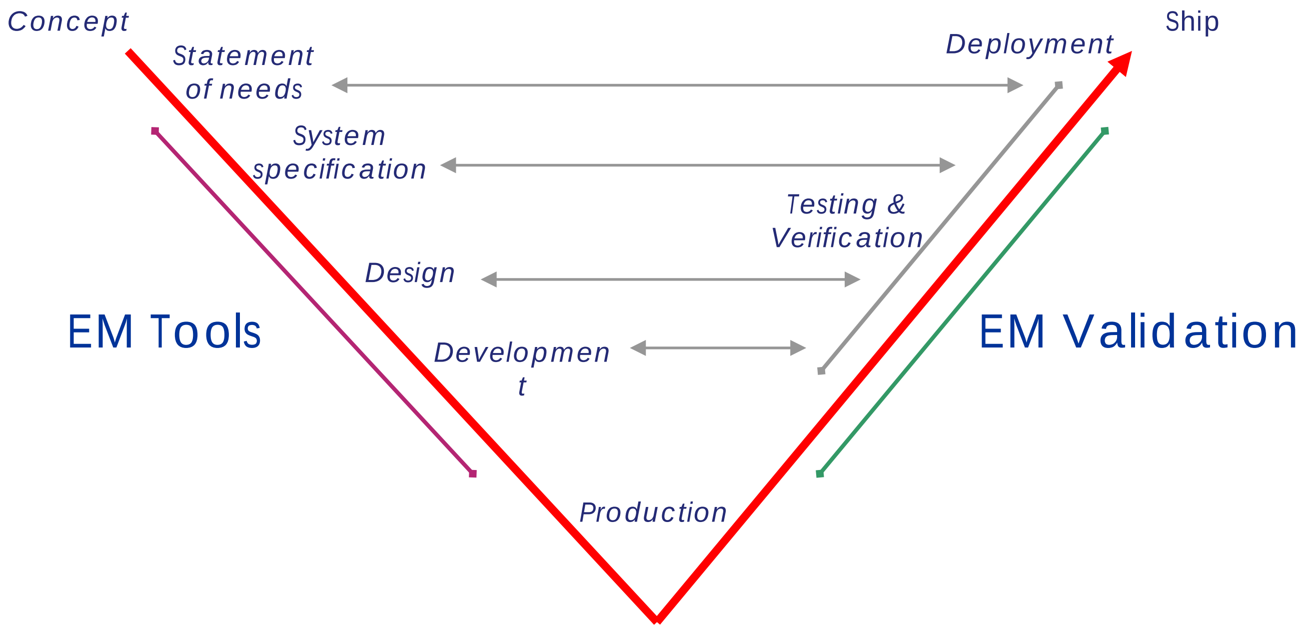
3.1.2.1. Synoptic

MCPA Step Review	Statement of needs	System specification SSR	System design SDR	Development PDR CDR PRR	Production and deployment	Operational support
Activity	- Legal requirements	- Explicit EMC requirements - Implicit EMC requirements - Induced EMC requirements - Critical function analysis - EMC Margins - EMRH	- Analysis of the system architecture - EMC Topology - Risk analysis - Compatibility with other constraints - Establish the EMC protection concept - Derive the requirements	- Tailor the EMC protections (shielding, filters, specific Interfaces) - Technological choices - EMC Design approval - Partial tests on risk elements - EMC Qualification, subsystems, equipment - Follow up engineering changes - EMC inspection during equipment integration	- EMC performance assurance	- Preventive and corrective actions
Doc.		- EMC Requirements into SSDD - EMC Control Plan	- EMC Analysis Report - EMC Requirements into PIDS	- EMC Test plan - Qualification Plan - Qualification Report		Maintenance Documents

de V

These activities have to be conducted in consistency with other engineering specialities such as reliability, maintainability, testability, safety, thermal management.

EMC Management plan



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Presented at the MSCA PETER Network Wide Event, April 2021

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Example, sensor development

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EMC Management Plan

NSxx

PROGRAM 103AL

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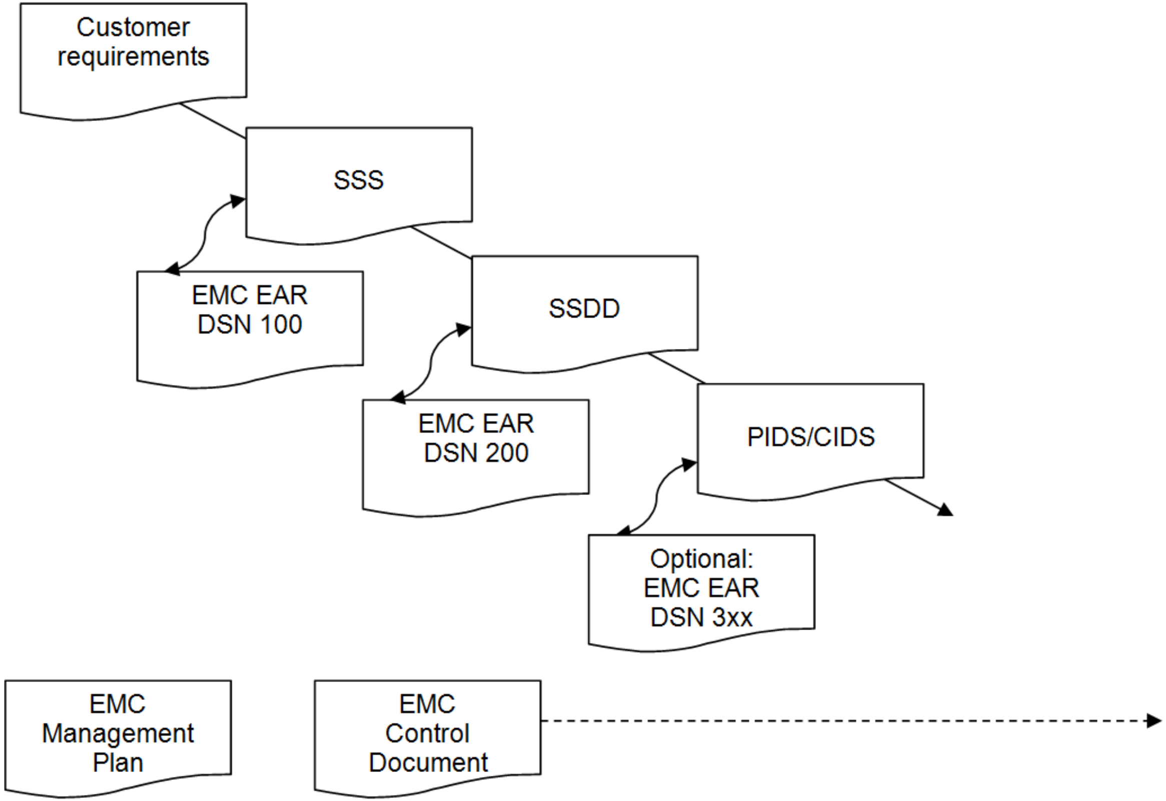
Maturity Order: PRELIMINARY → DRAFT → APPROVED

Document Ident	Type	DCI	UNCLASSIFIED	Status
9505 330 438 xx001	EMD	00.001	Marking	PRELIMINARY - IN PROCESS

4.1. Requirement allocation



Example, sensor development

Table 2: Deliverables

Document	PDM	SEM	DM	PTM	PEM	PQM	ILSM
EMC Management Plan	R				a	a	
EMC Requirements into SSS		R			a		
EMC Control Plan		a	a		a		a
EMC Requirements into SSDD		R			a		
EMC Requirements into HRS and BSP			R		a		
EMC Analysis Report			a		R		
EMC Engineering Test Report			a		R		
Design Qualification Plan, incl. EMC Test Plan		a	a	R	a	a	
EMC Qualification Test Results (QTR+QCR)		a	a	R	a	a	
Maintenance Documents					a		R

R Responsible
a actor

Name:	Type:	DSN:
EMC Management Plan	EMP	DSN 001
EMC Control Plan	ECP	DSN 001
EMC Analysis Report for SSS	AR	DSN 100
EMC Analysis Report for SSDD, incl. decomposition	AR	DSN 200
EMC Analysis Reports for PIDs/BSPs	AR	DSN 3x0
example:		
antenna system	AR	DSN 300
antenna array pack, for PID or BSP	AR	DSN 310
radar signal generator, for PID	AR	DSN 320
multi channel receiver	AR	DSN 330
solid state transmit receive modules, for PID	AR	DSN 340
drive and pedestal	AR	DSN 4x0
drive control cabinet	AR	DSN 4x0
processing	AR	DSN 4x0
EMC Analysis Reports, other	AR	DSN 5xx
EMC Engineering Test Reports	ETR	DSN 6xx
Design Qualification Plan (by P&E), incl. ETP	DQP	
EMC Test Plan	ETP	DSN 700
EMC Qualification Test Reports	QTR	DSN 7xx
EMC Final Analysis Report	FAR	DSN 900
Compliance with EMC Directive – CE marking	FAR	DSN 910

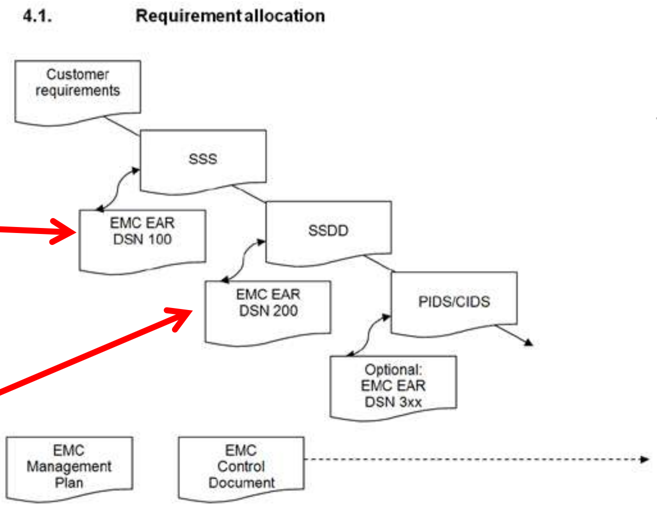
Example, sensor development, what

EAR DSN 100

- EM environment
- Functional requirements
- Leading and/or typical customer requirements
- Market expectations
- Testability
- Economical constraints
- RESULT: Requirements for SSS

EAR DSN 200

- Zoning
- Decomposition
- Output: Requirements at major component level



Example, sensor development, EM environment

- Lightning (direct, indirect)
- Nuclear EMP
- Radiation Hazards (personnel, fuel, ordnance)
- EM Coexistence, mutual interference
- Spectrum (ITU)
- Emission Control (radar silence)
- Power Quality
- Intentional EMI
- TEMPEST
- Etc.

Example, sensor development, Verification methods

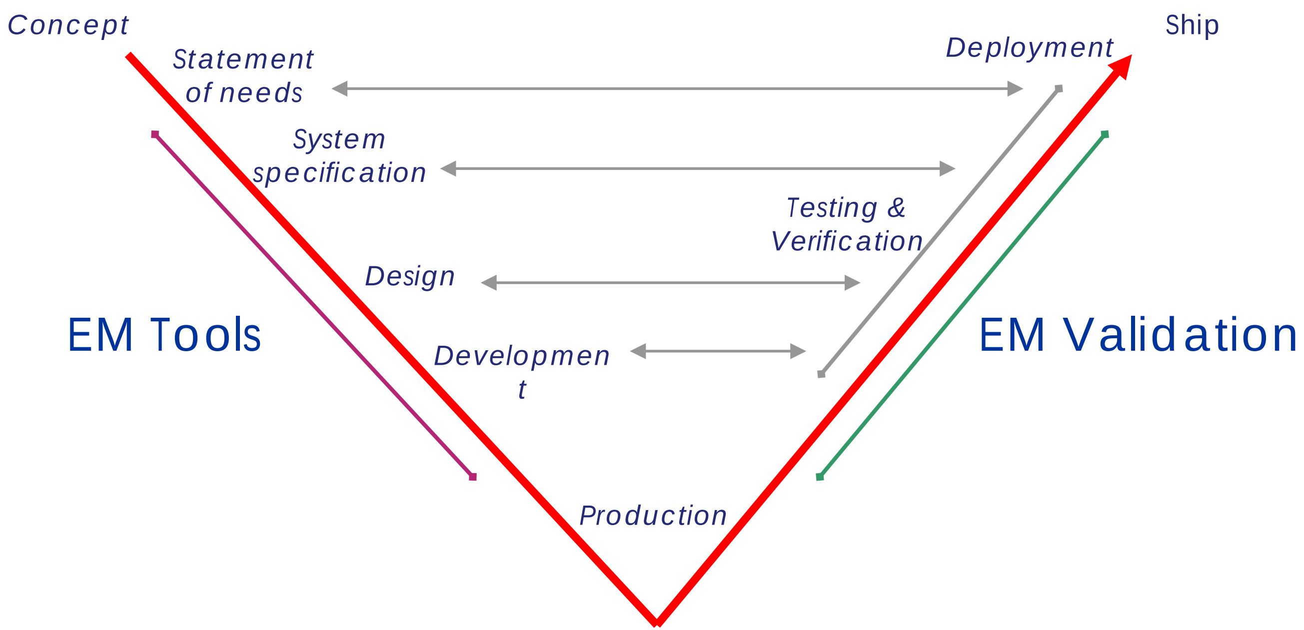
1. Inspection
2. Demonstration
3. Test
4. Analysis

Example, naval ship

Mentioned before:

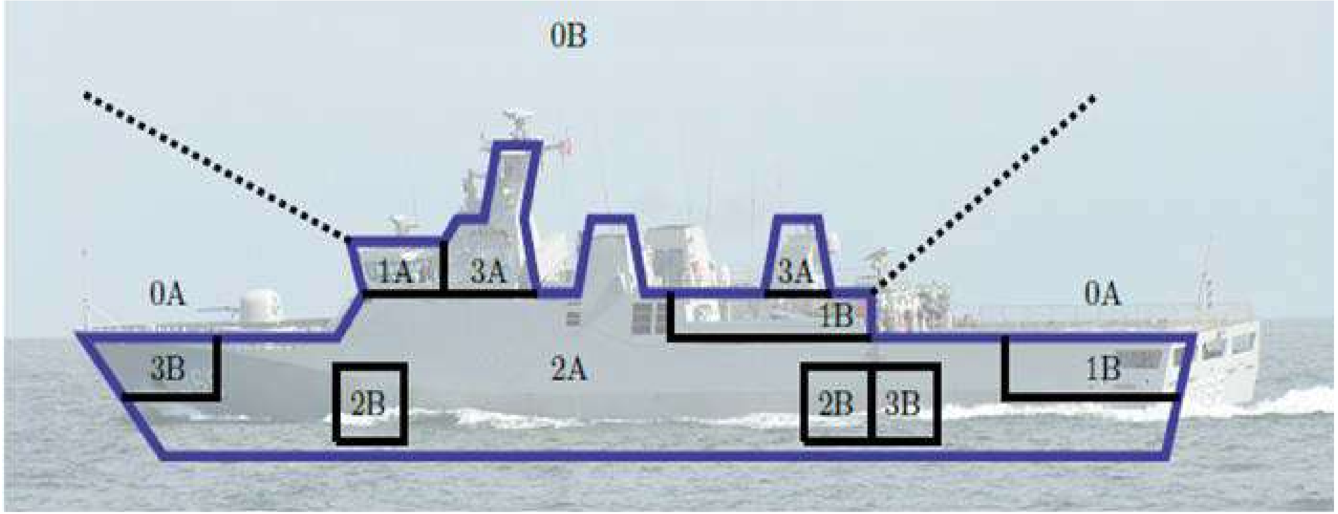
- EMC Management (what, when, who)
- EMC Control (risk management)
- EMC Implementation (how)
- EMC Verification (check)

EMC Management plan



EMC Control, Risk Analysis above deck

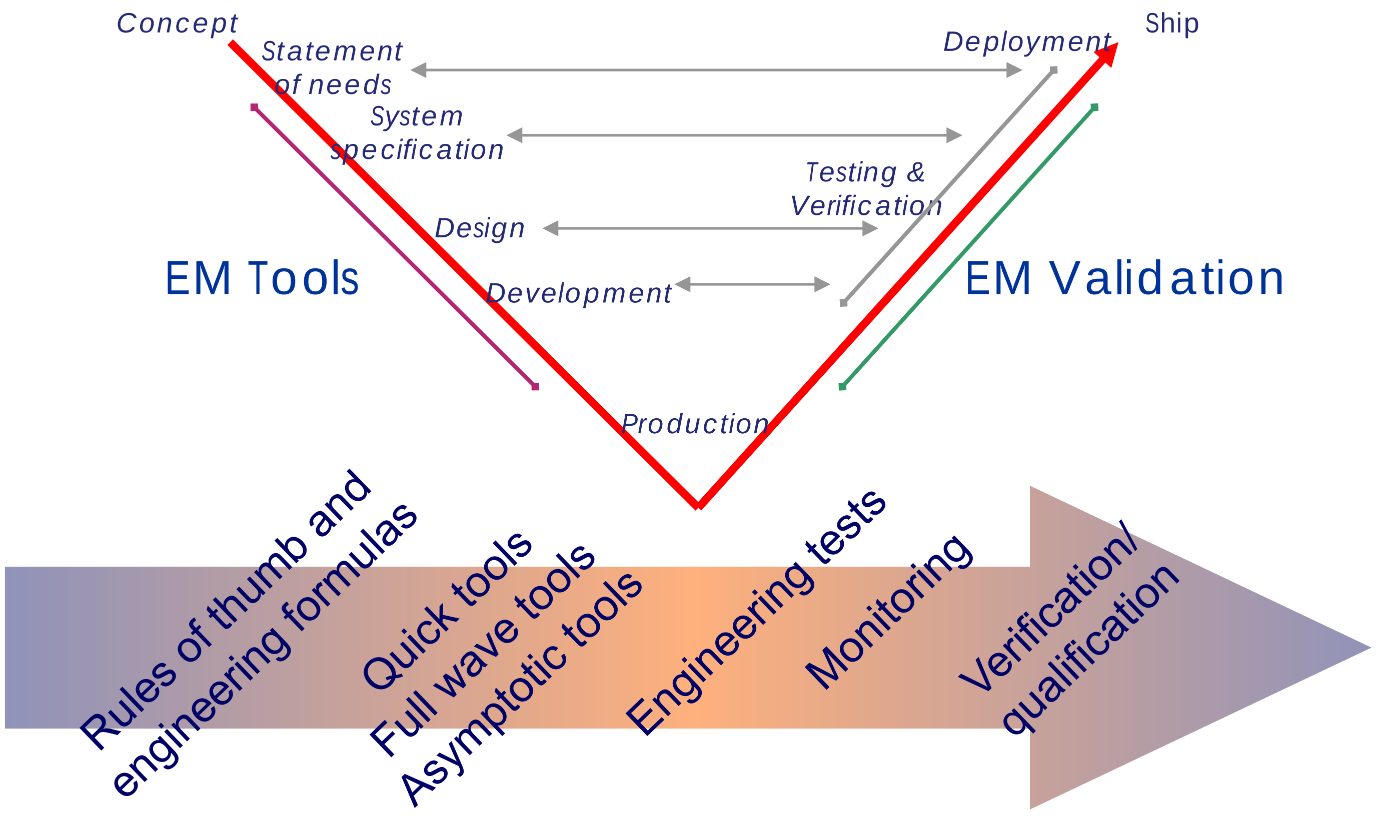
Risk Analysis in EMC control plan, above deck (zone 0)



0A: General outer deck
0B: Antenna zone
1A: Bridge and similar
1B: Hangar and similar

2A: General inner deck
2B: Industrial area
3A: Special zone sensitive
3B: Special zone disturbing

EMC Control, Risk Analysis above deck



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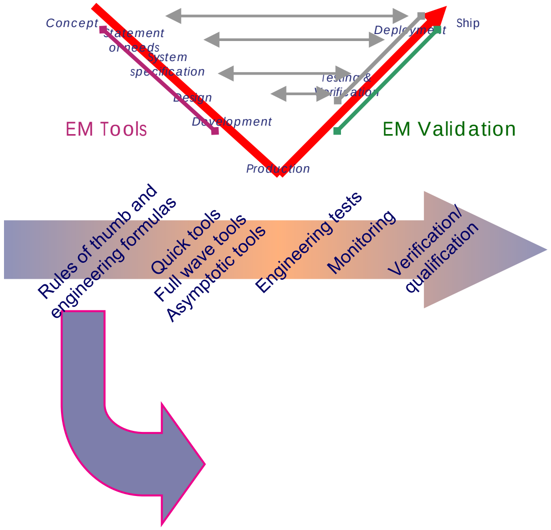
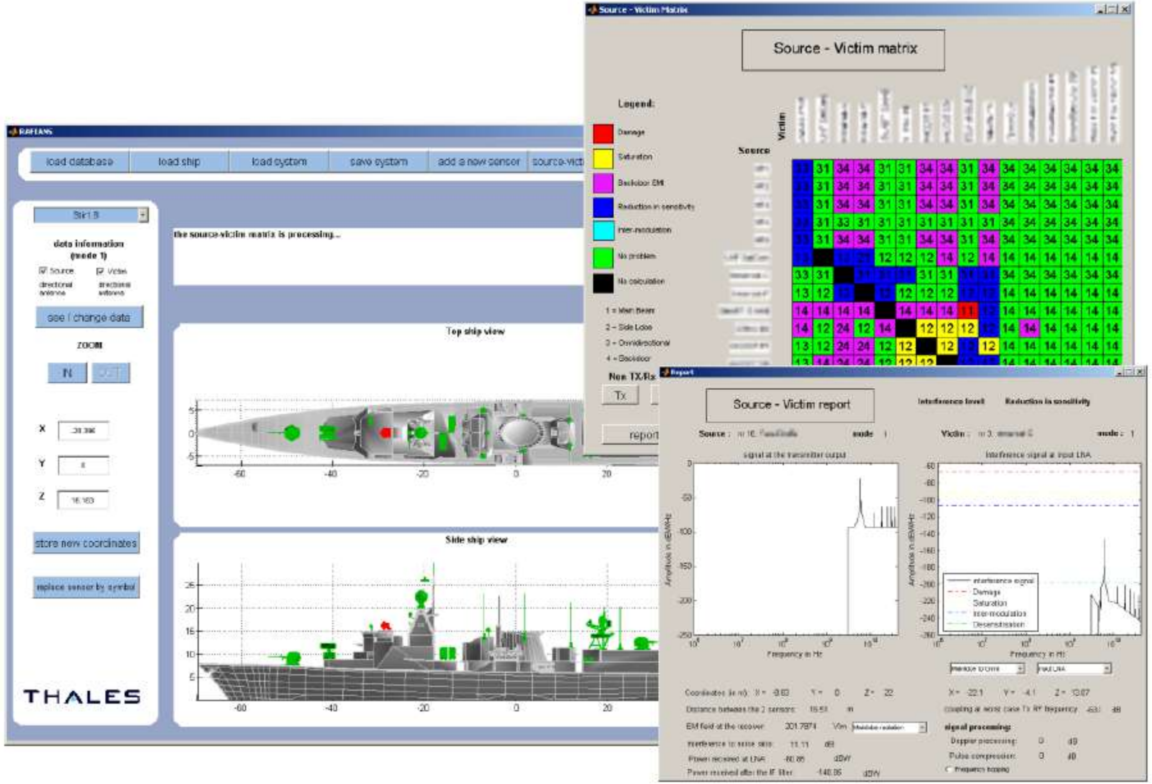
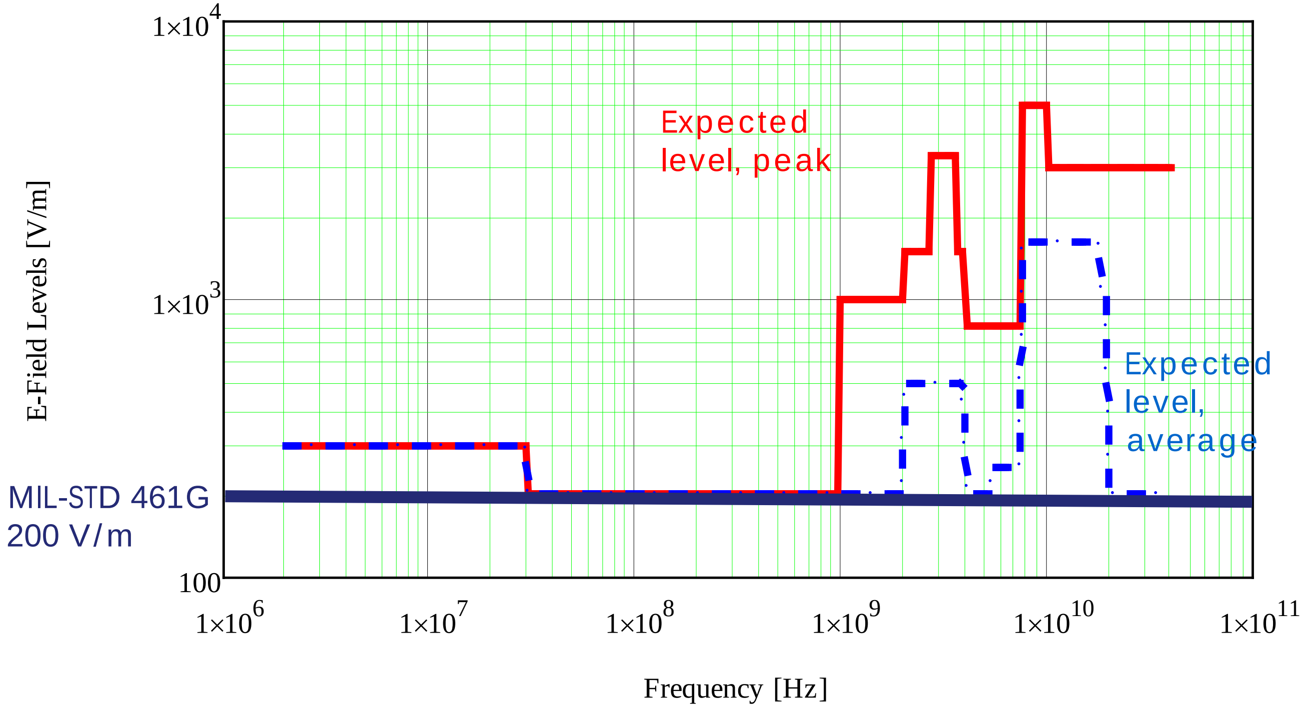
Topside design: Risk Analysis





Topside design: Risk Analysis

Possible field strength levels due to radars and communication systems on a ship



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Topside design: Risk Analysis

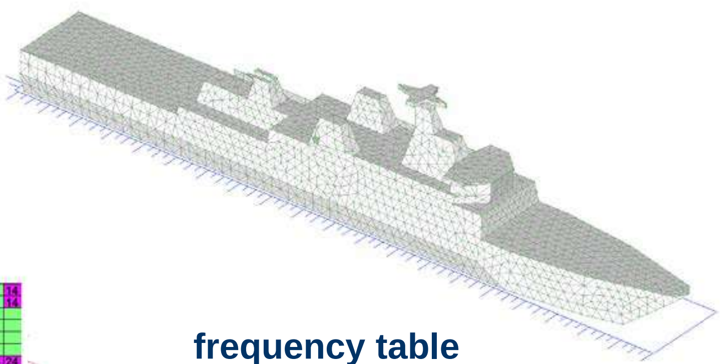
Possible field strength levels due to radars and communication systems on a ship

Topside design: Example 1

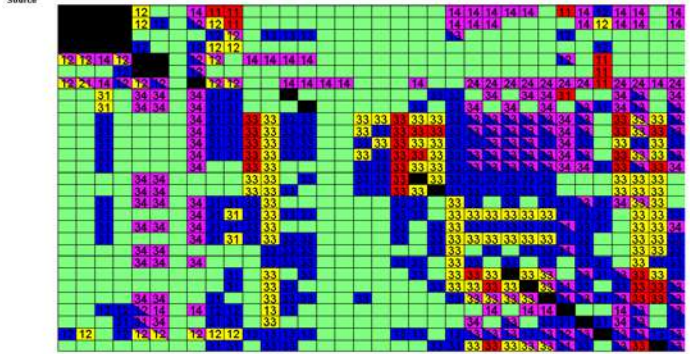

Source: Photograph by SNS / Van der Kloet

New ship project
All THALES sensors i.c.w. 3rd party equipment

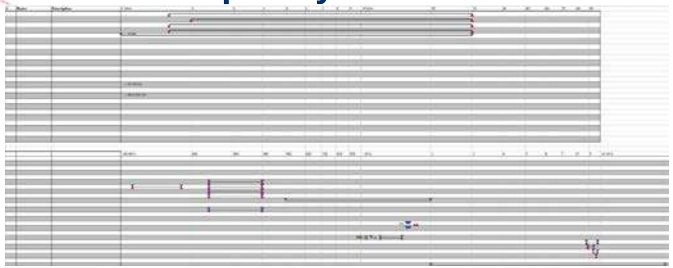
Topside arrangement
Field level prediction (EMI, RadHaz)
Performance prediction (blocking)



source-victim matrix



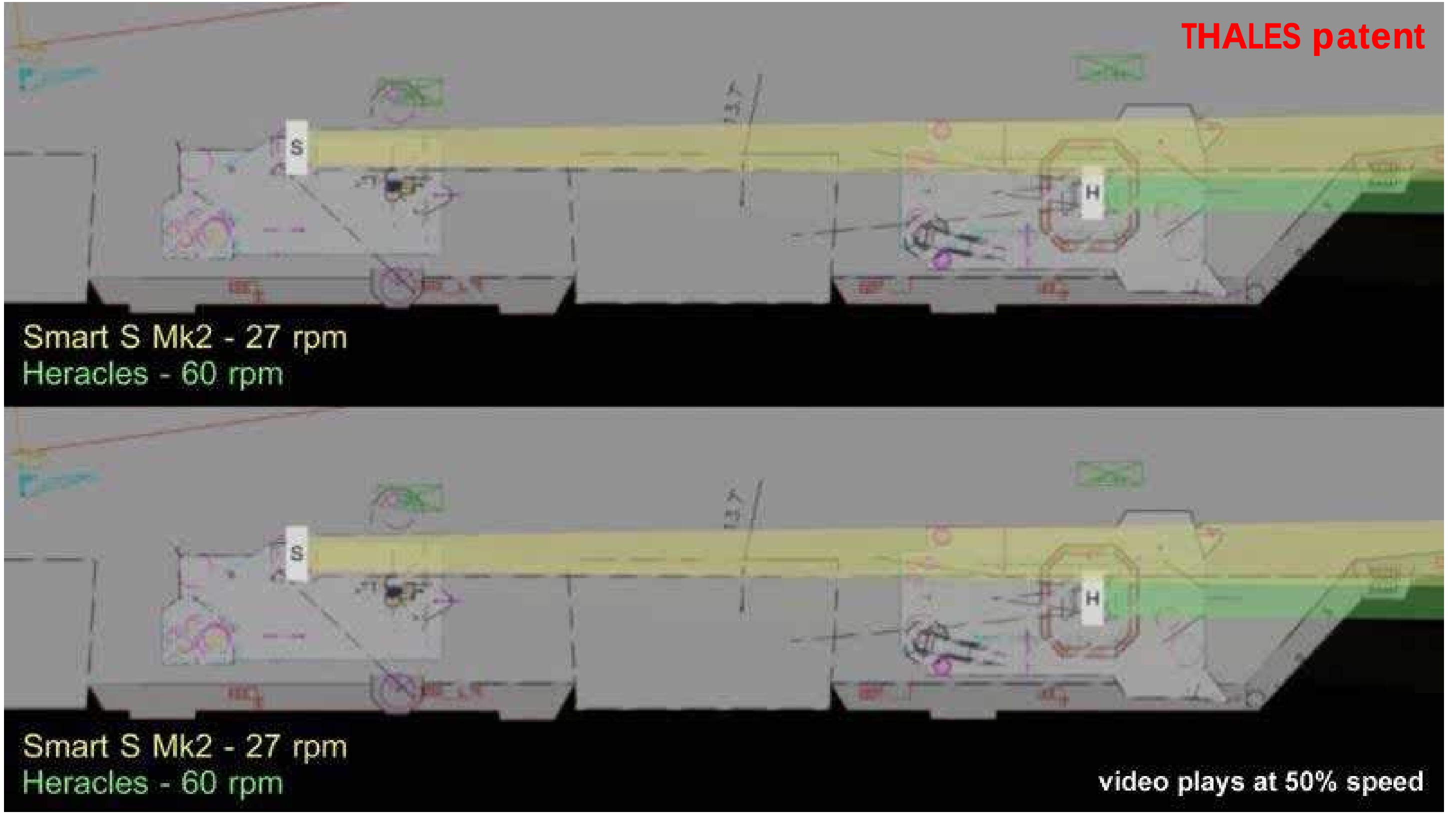
frequency table



Topside design: Example 2

Prediction of possible interference between two S-band radars on aircraft carrier

EMC: no hardening, adaptive rotation



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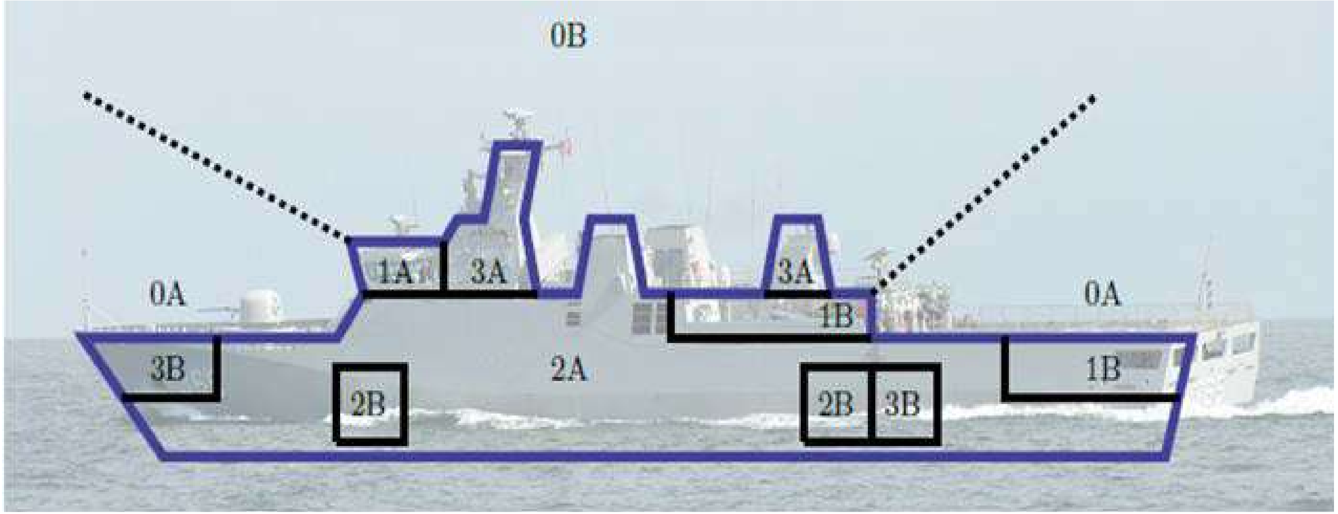
EMC Control, Risk Analysis below deck

Below deck: zoning



0A: General outer deck
0B: Antenna zone
1A: Bridge and similar
1B: Hangar and similar

2A: General inner deck
2B: Industrial area
3A: Special zone sensitive
3B: Special zone disturbing

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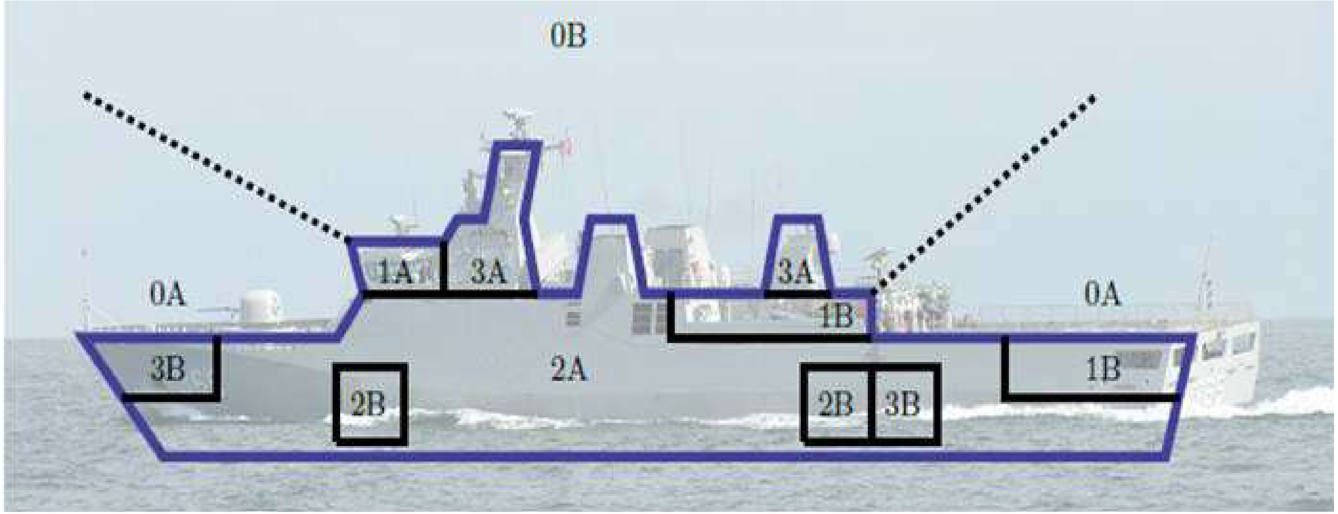
EMC Control, Risk Analysis below deck

Below deck: zoning

When don properly, then in most ''sheltered'' areas Commercial of the Shelf (COTS) can be used

No hardening!!



0A: General outer deck
0B: Antenna zone
1A: Bridge and similar
1B: Hangar and similar

2A: General inner deck
2B: Industrial area
3A: Special zone sensitive
3B: Special zone disturbing

EMC Implementation

❑ EMC-Multi Cable Transits

❑ EMP-protection

❑ Doors / hatches

EMC Zone protection measures

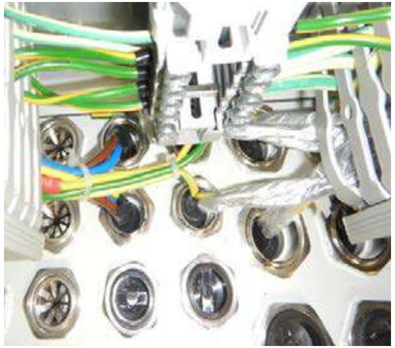
❑ Exposed cables

❑ Waveguides

❑ Honeycomb / wire mesh / netting

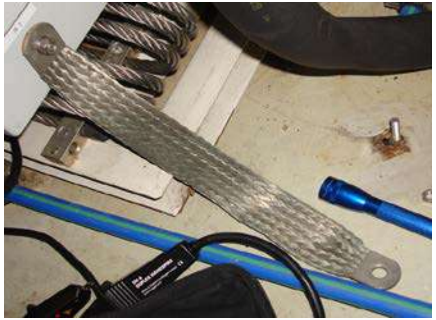
EMC Verification

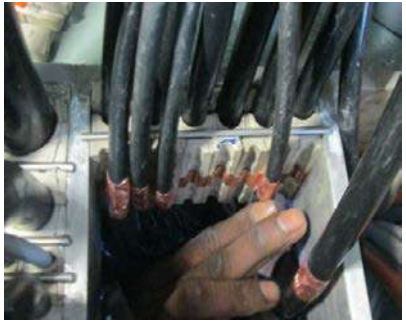
During building phase



Proper Conservation

Proper work methods





Earthing check
R < 2.5 mΩ or 10 mΩ

Proper materials

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EMC Verification

During
HAT
FAT
or
SAT

Is this new?

No!!!

this is

‘EMC engineering’

Although Lloyd’s Register, EU call this Risk-Based EMC

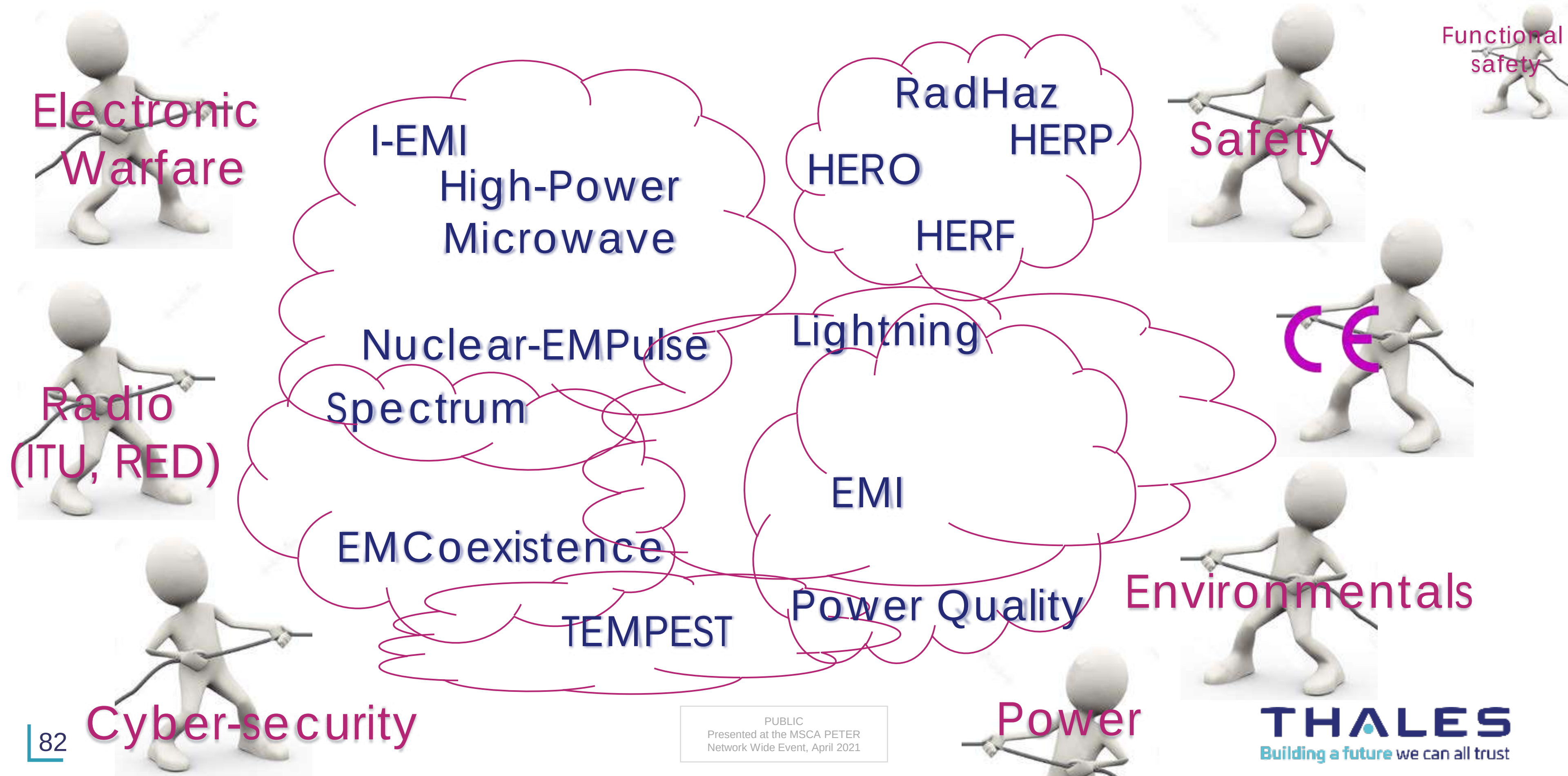
Why this (PETER) research activity??

Why this (PETER) research activity??

Because it is extremely difficult to transfer from the 'simple' rule-based approach to a 'risk-based' approach

We need new methodology, new implementation, and we have to apply it everywhere

EMC = Electro-Magnetic Compatibility = EM Complexity ?



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EMC

In large industrial entities we see many stakeholders with different opinions

- Cyber-Security: TEMPEST is part of Cyber
- Environmentals: EMI, lightning, PQ is part of Environmentals (like mechanical and climatological effects)
- Safety: EMI and Radiation Hazards (and lightning and PQ) are part of Safety (in the Guide on EMCD: *EMC is **not** part of Safety related directives*)
- Electronic Warfare: I-EMI, HPM, N-EMP are part of EW
- Analog front end: EM Coexistence, Spectrum and EMI are part of radio
- Etc. etc. etc.

EMC

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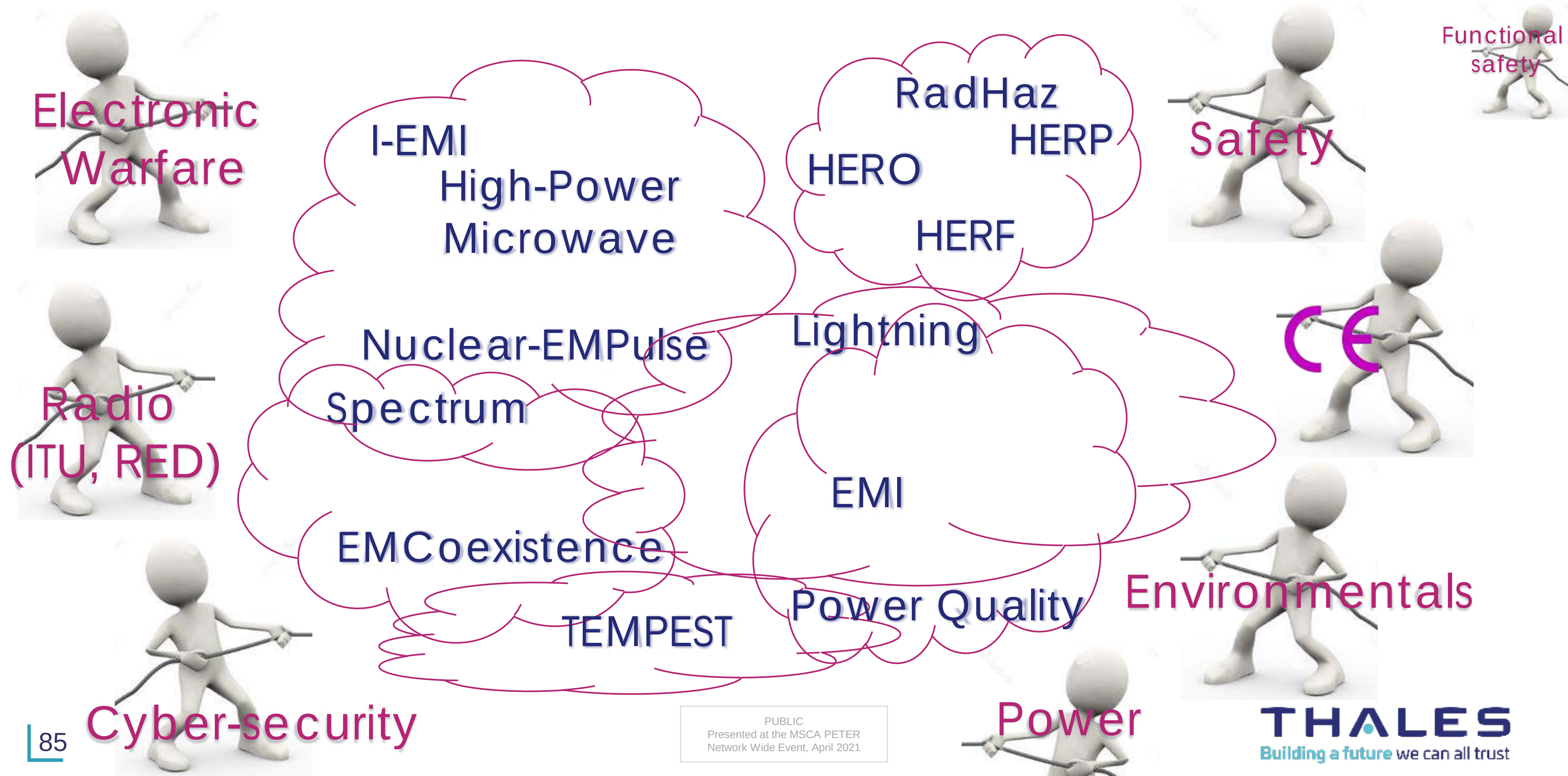
- Etc. etc. etc.

- EMC specialists:

EMC = Electro-Magnetic Compatibility = EM Complexity ?



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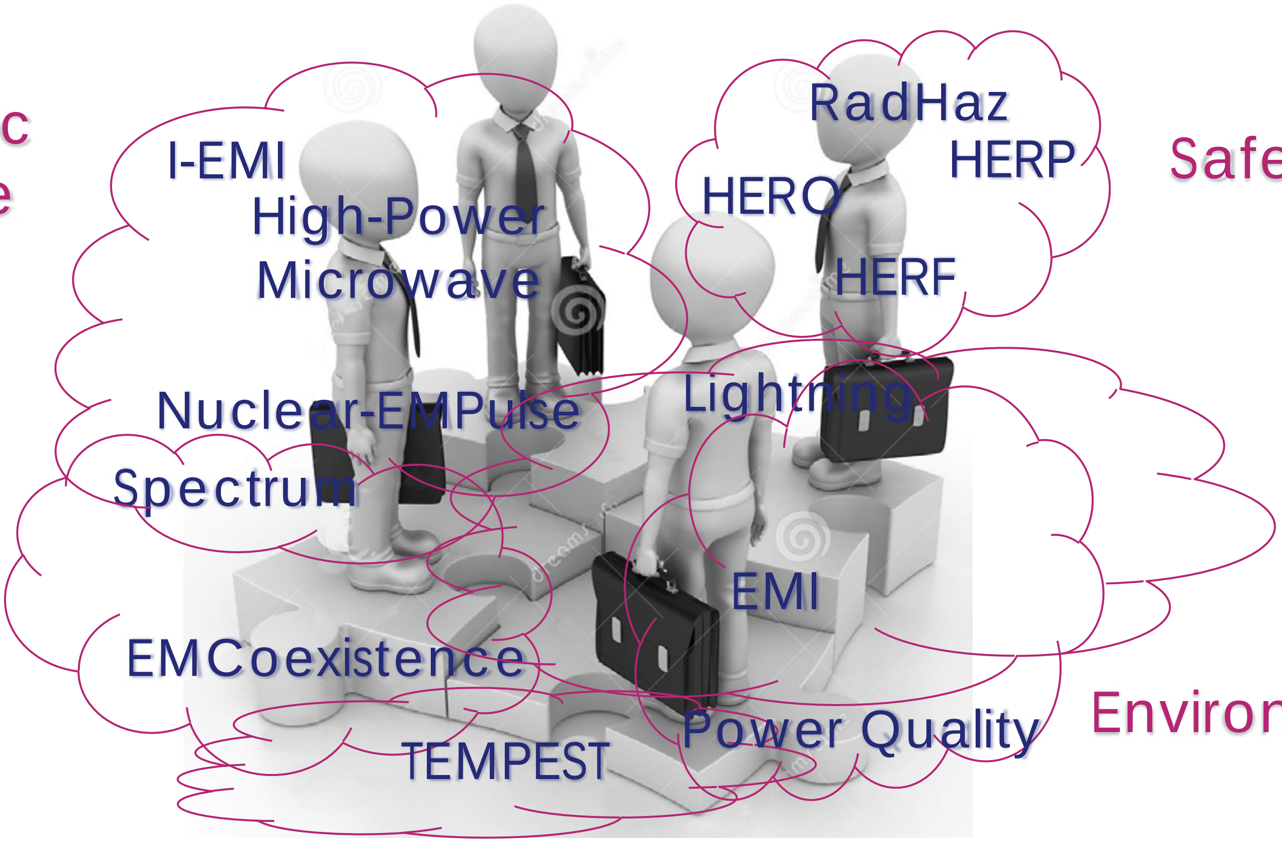
EMC = Electro-Magnetic Compatibility (dealing with EEE (E3))

Electronic Warfare

Safety



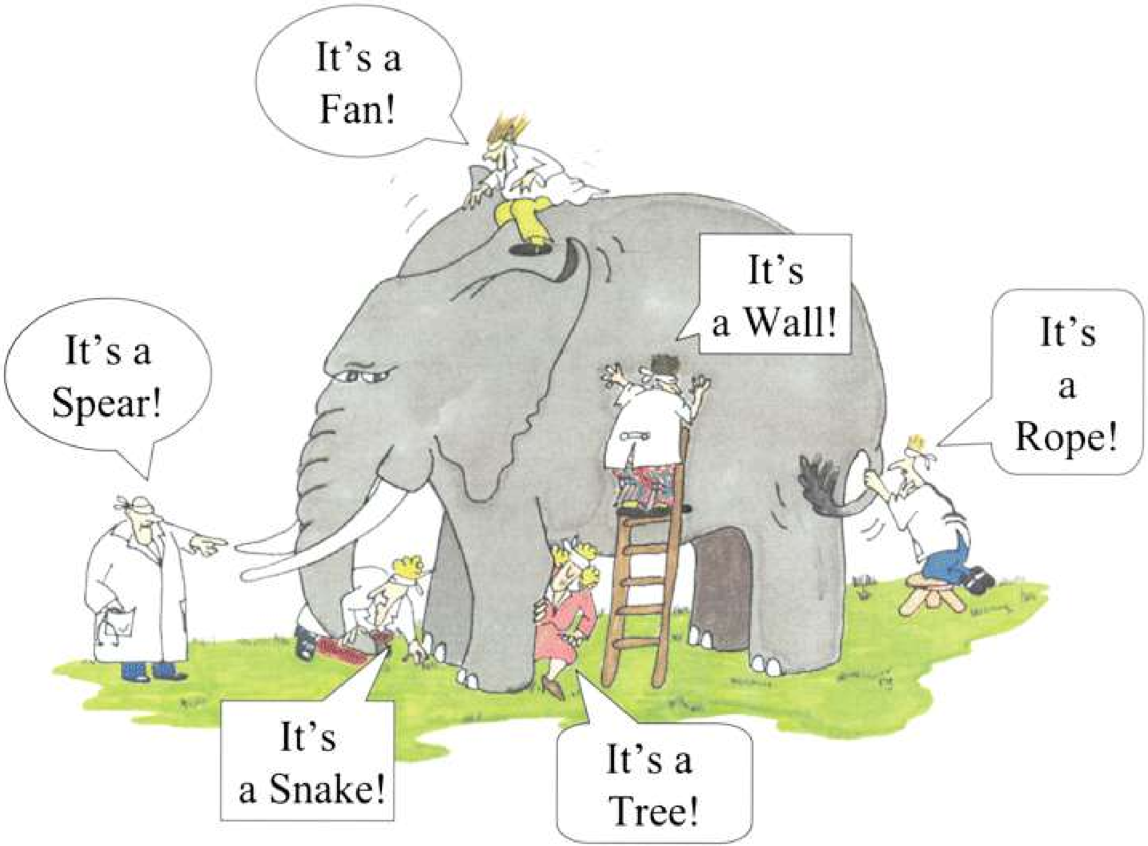
Radio (ITU, RED)

Environmentals

Cyber-security

Power

Observations, opinions, boundaries



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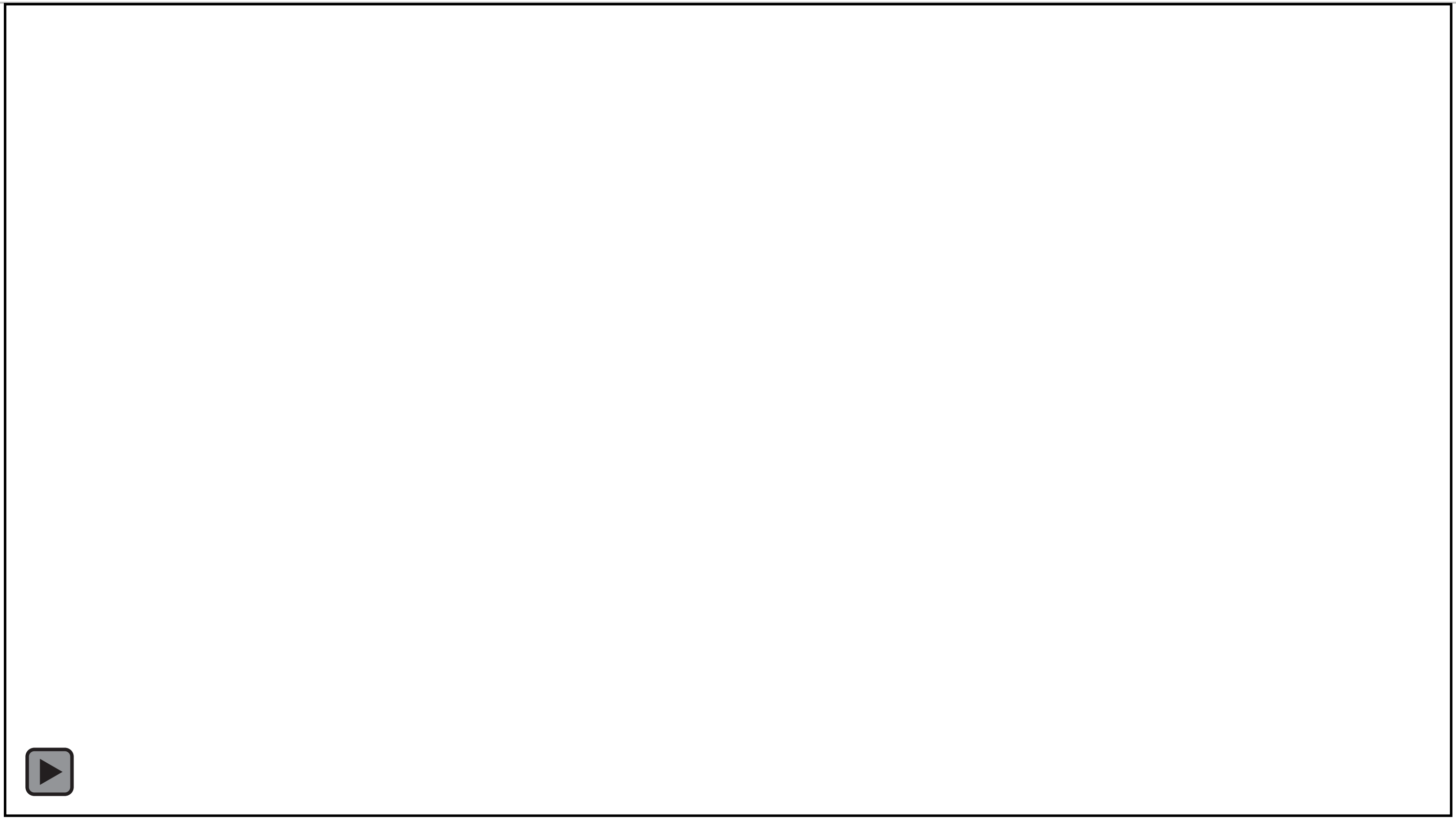
Risk-Based EMC
versus
EM Risk Management
(managing EMC risks)?

Risk-based

Risk management, SIL-2



https://www.boredpanda.com/3d-pedestrian-crossing-island/?utm_source=linkedin&utm_medium=social&utm_campaign=organic

Risk management, SIL 4

Conclusion

- Rule-based (applying harmonised standards) is nice for single EMI issues and simple equipment in basic environments
- For complex systems EMC, the risk-based approach is the most cost-effective and most efficient approach
- According to the EC Blue Guide and the new Guide for the EMC Directive the risk-based approach becomes the standard
- But: Risk-based EMC is just proper EMC engineering:
  - EMC Management (what, when, who)
  - EMC Control (risk management)
  - EMC Implementation (how)
  - EMC Verification (check)

References

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- Frank Leferink; Jan-Kees van der Ven; Hans Bergsma; Bart van Leersum, Risk based EMC for complex systems, 2017 XXXIInd General Assembly and Scientific Symposium of the International Union of Radio Science (URSI GASS), Montreal, 19-26 August 2017, Pages: 1 – 4, DOI: 10.23919/URSIGASS.2017.8105016
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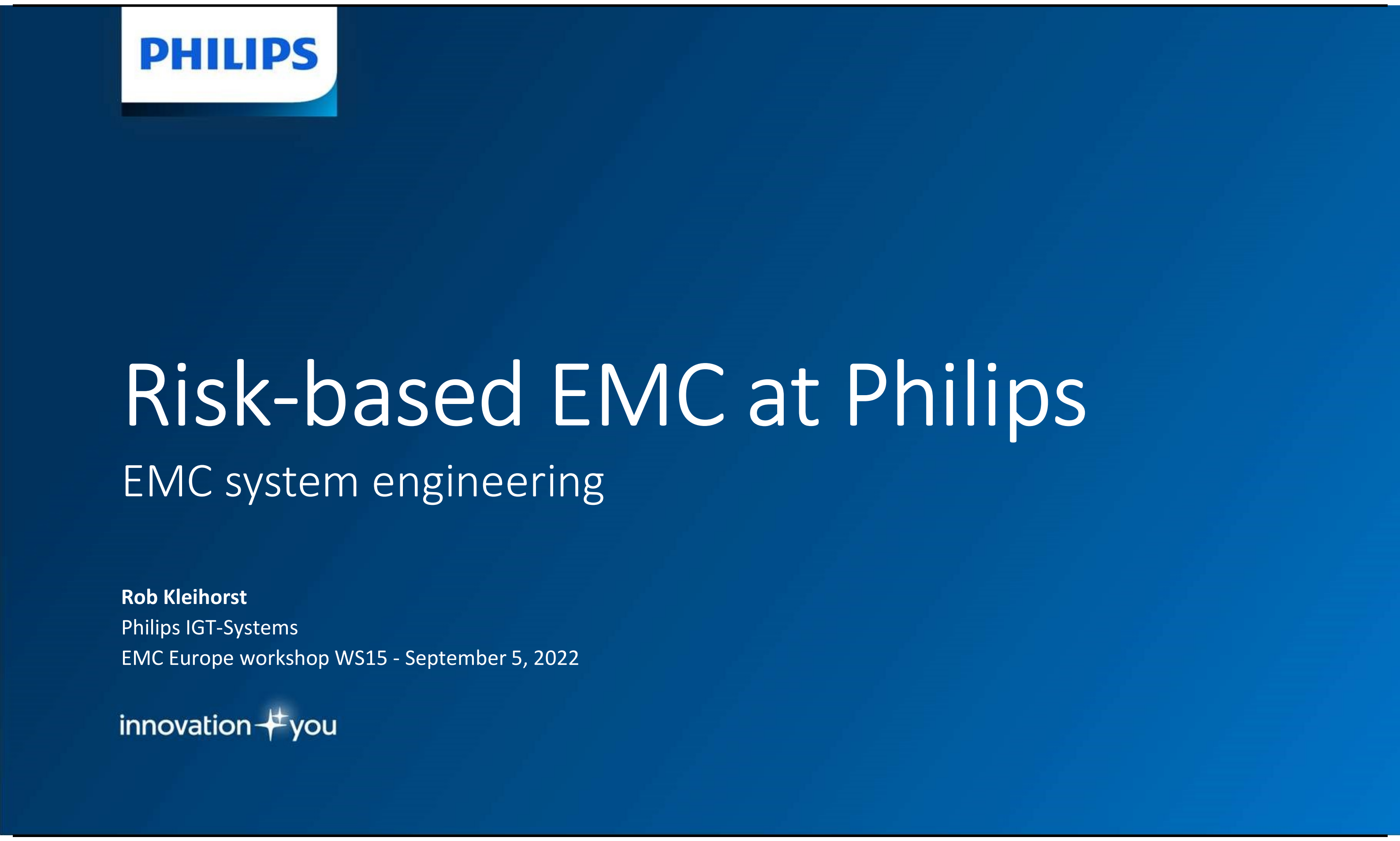


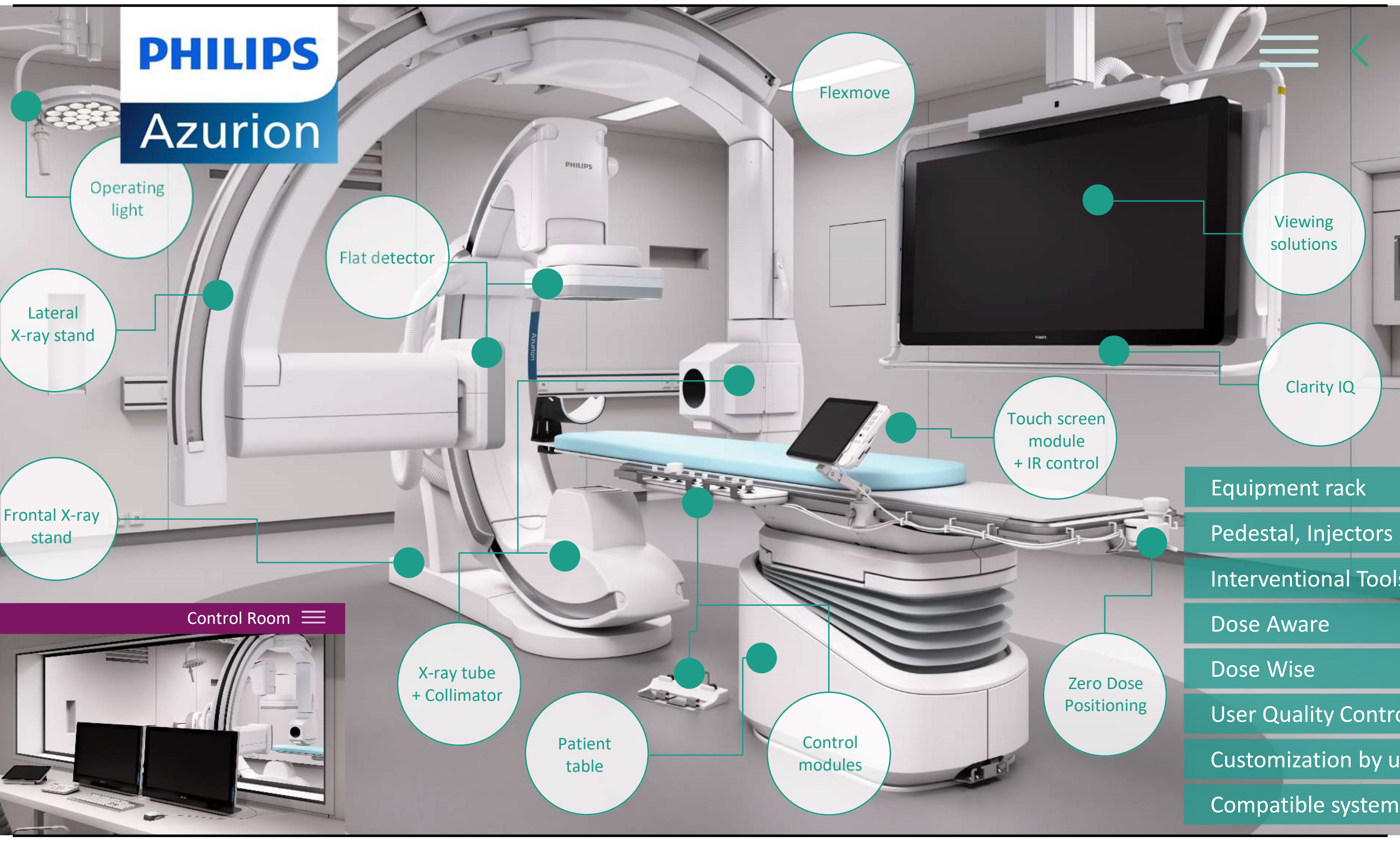
Primary and Secondary Audience

- Primary Audience: Industry professionals and researchers who are interested in an introduction to the risk-based approach on EMC in Europe.
- Secondary Audience: Researchers and industry professionals who are interested in getting introduced to the PETER and ETERNITY networks and their ongoing research.

The recent European Blue Guide [1] (regarding the implementation of EU product rules) has stipulated a risk-based approach (rather than the conventional, rule-based approach) mandatory for the EMC compliance of any new piece of electronic equipment with applicable EU Directives – including the LVD and the EMCD [2], [3]. Many manufacturers in the industry as well as the users of electronic systems may not be familiarized with this novel risk-based EMC approach to the full extent, as there is a lack of understanding and no clearly prescribed risk-assessment methodologies available yet. Particularly, the small and medium scale enterprises (SMEs), may need assistance to adapt to this major shift in approach.
In this workshop, we will present the EMC risk-based approach, emphasizing its contrast to the traditional rule-based EMC approach. We will focus on two examples of implementation of risk-based EMC approach in both military and medical contexts. The workshop will also address an example of systematic analysis of EMI Risks.
There is not only a need for formalization, but also for trained specialists having the capability to deal with the complexity of systems, and all the stakeholders (individuals and institutions) involved. We will introduce two large European networks, **ETERNITY** - **European Training Network on Electromagnetic Risks in**

research and education network on Electromagnetic Risk management that are currently training 29 Early-Stage Researchers focusing on the development and implementation of risk-based EMC methodologies [4], [5].

- Risk-based EMC (military application example) – Frank Leferink
- Systematic Analysis of EMI Risks – Prof. Dr.-Ing. Frank Sabath
- EMC Risk-based at Philips Medical Systems – Rob Kleihorst
- Presentation of the European Training Network PETER – Davy Pissoort
- Presentation of the European Training Network ETERNITY – Anne Roc'h



Azurion has been designed to help make efficient use of time with:

- Instant Parallel Working. Interventional team members can work in parallel at flexible work spots without interrupting each other. This can lead to high throughput and fast exam turnover
- Flexible work spots, like FlexVision Pro and touch screen module Pro allow you to access and control multimodality information from any work spot, which helps improve efficiency and reduce delays
- ProcedureCards. With one click you can select exam presets to accelerate and standardize preparation
- FlexMove is a ceiling mounted option that allows they X-Ray system to be easily positioned where needed and parked out of the way to free up working space
- The operating table (ORT) interface helps you to seamlessly perform open and minimally invasive procedures in a single room
- ProcedureCards that include hospital specific documents to streamline and standardize system operation and reduce preparation errors
- Table side control of all relevant applications, which can help reduce the need to move in and out of the sterile area during a procedure
- ClarityIQ provides significantly lower dose across clinical areas, patients and operators. It has been clinically proven in 18 peer-reviewed comparative studies per clinical area and 3840 patients to date.
- Zero Dose Positioning that allows you to navigate to your new region of interest without using fluoroscopy
- An unique user experience. Information stands out from the distinctive black background and highlights help you easily locate active applications. The system

- Tablet control at table side further simplifies operation: drag and drop apps, select, zoom and pan with your fingertips
- Digital user guides can be accessed with one-click for on-the-spot assistance
- The controls are designed for easy cleaning to meet stringent sterility requirements.

Clinical procedures become more complex

- Dependent on more medical and non-medical devices
- Higher level of integration of devices
- Increased amount of specialized clinical staff

EM environments are becoming less predictable

- Increased use of different electric and electronic devices
- Increased use of intended emitters and sensitive receivers
- Increasing use of frequency spectrum and bandwidth (not only for the clinical procedure purpose)

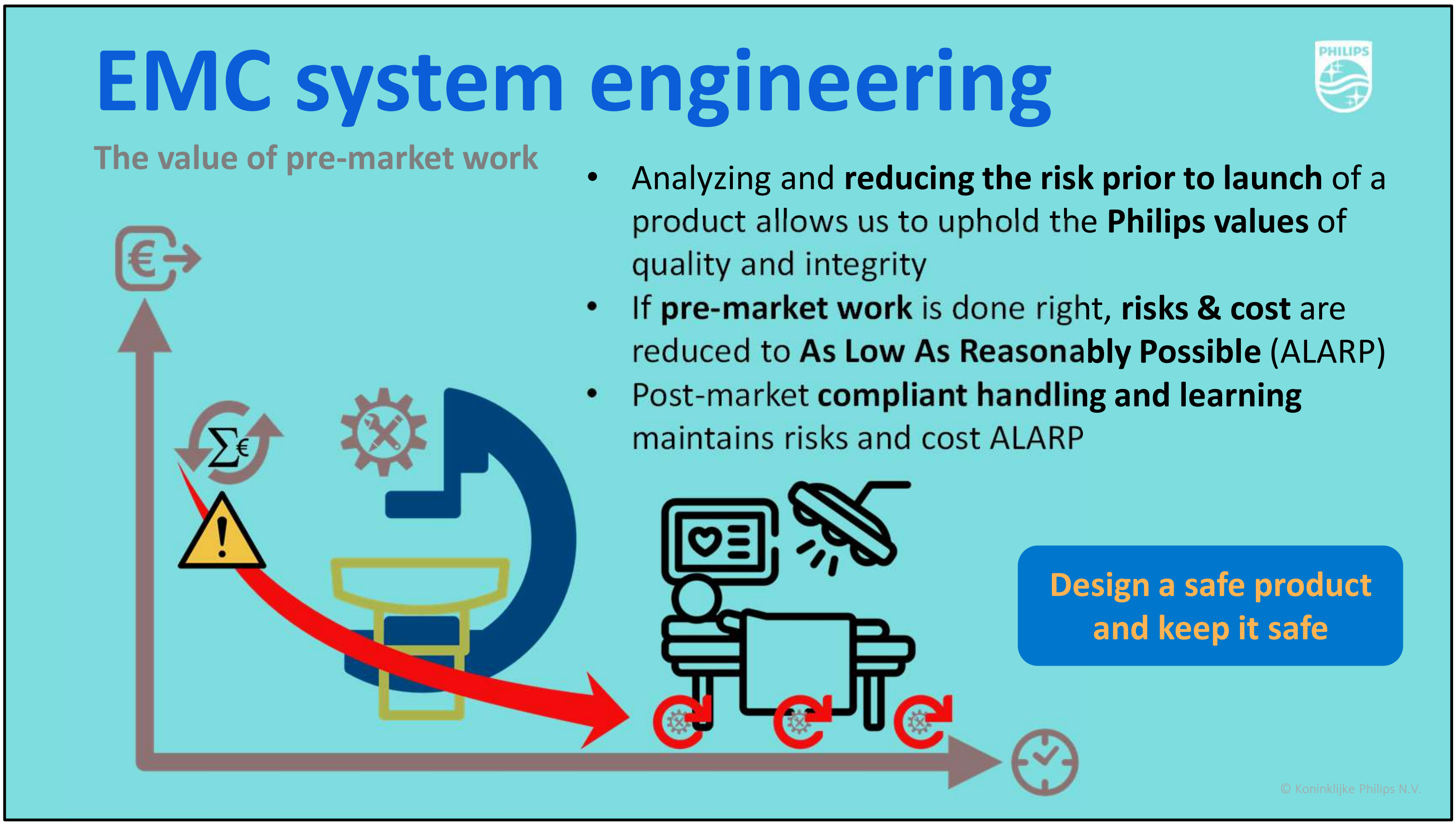
Managing EMI risks is getting increasingly complex

- Risk management in healthcare environments is safety critical
- Sensitive low-power life sustaining equipment and high-power equipment is used in proximity of each other
- Equipment, cabling and people are not static during a clinical procedure
- Predicting concreate equipment setup and use scenarios in clinical practice becomes an impossible task

Required mitigations

- Multi-domain system level expertise required (clinical, regulatory, safety, electromagnetics, electronics, power, ..)
- Structural risk-based requirements development during medical device design

- Risk-based compliance testing (from standardized to tailored test procedures (tailored to show absence of unacceptable EMI risks iso task based standardized testing against harmonized standards (IEC 61000-4-x series).



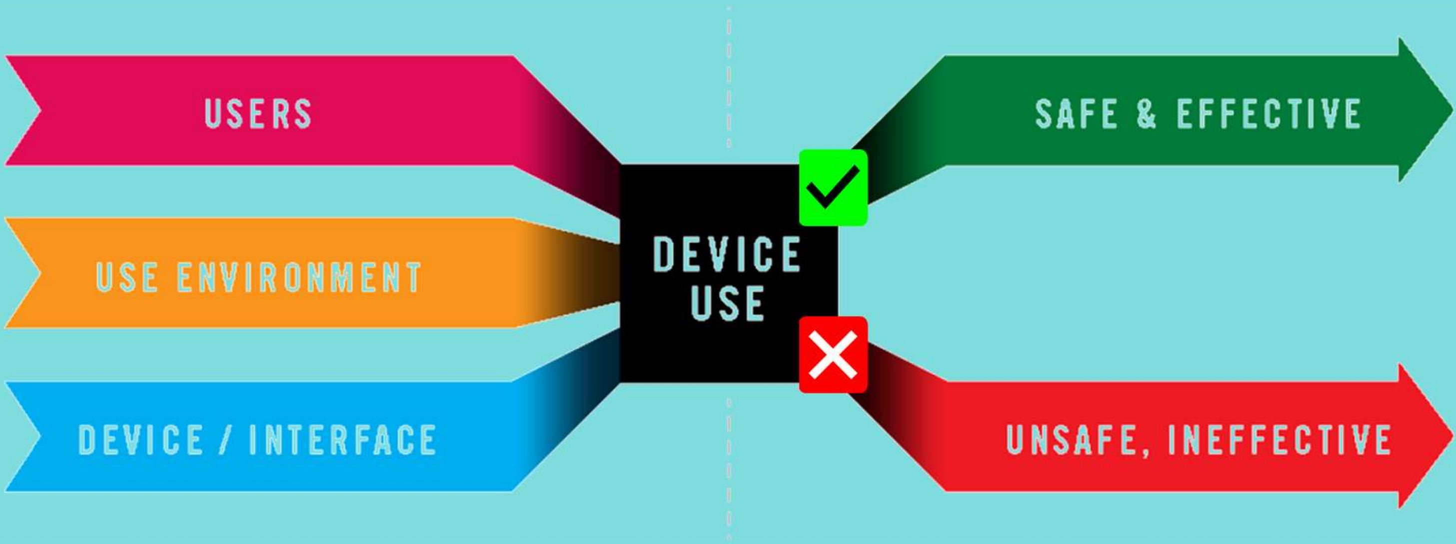
Analyzing and reducing the risk prior to the launch of a product allows us to uphold the Philips values of quality and integrity
If pre-market work is done right, risks are reduced to as low as reasonably possible.

- Passing all regulatory prescribed EMC tests does not imply a product is safe or functional.
- Focus on ensuring EMC and not (just) compliance
- Immunity is the bigger concern although emissions generally gets the focus
- Don’t misuse excempts, they are there to benefit technological and medical advances in the interest of humanity, not for the ease or financial gain for manufacturers.
- The future EMC engineers have the responsibility to guard system-of-systems level safety and coexistence.
- Functional safety and systems architecture should be an inclusive domain of system level EMC engineers including SW, HW, system behavior, intended use, usability and human situational responses. The latter one does include insight in situational responses during the design of the system.
- **EMC can only be verified at system level with the system placed in its intended use environment.** Results from the past (on component or unit level) give no guaranty for the ‘future’.
- EMC engineers should be trained in hazard based safety engineering, which is

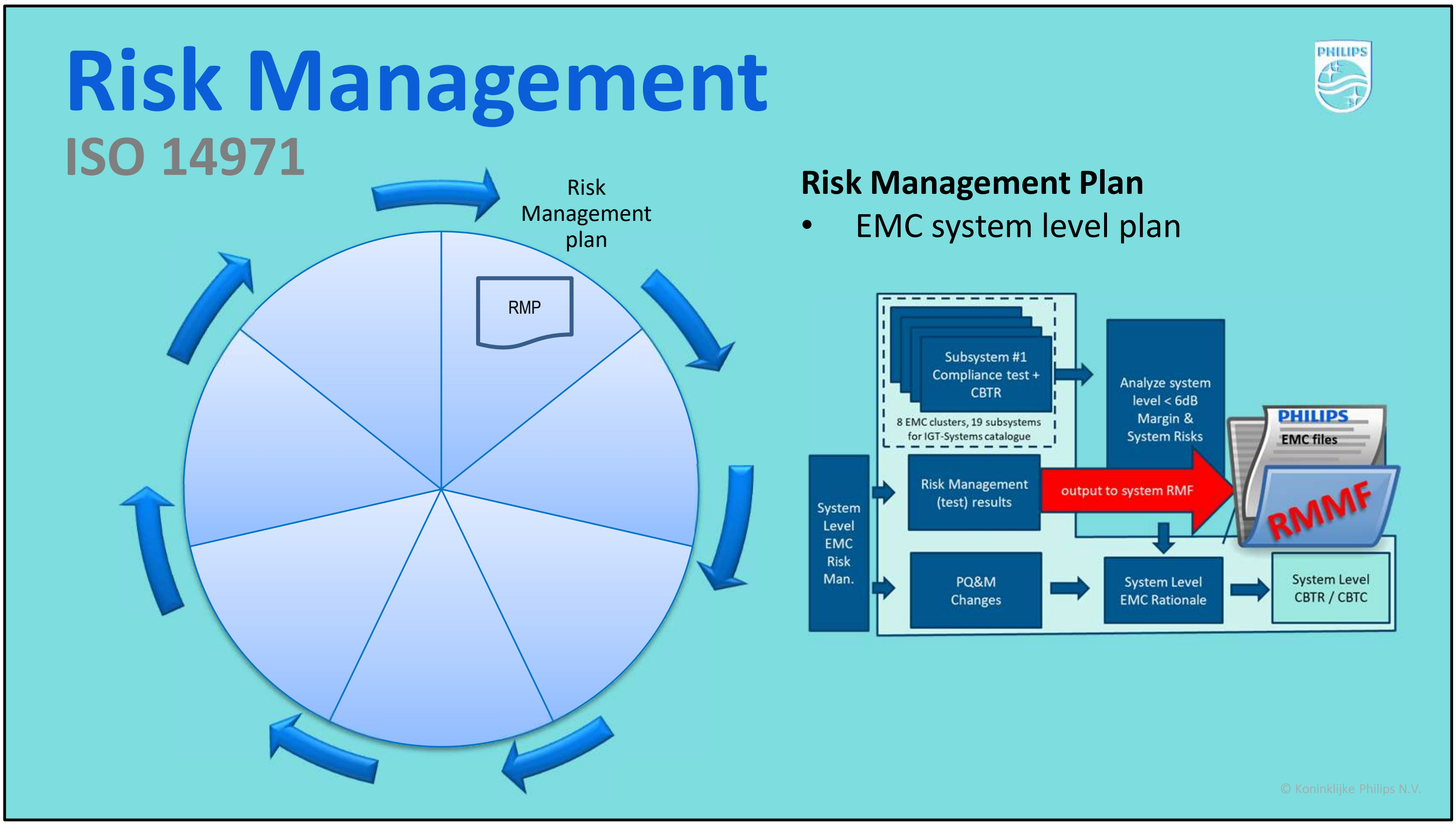
the combination of functional safety with risk management. SW architecture and design starts to play an increasing role in functional safety (detection of abnormal situations, putting systems in a safe situation based on the actual context and providing proper user notifications to minimize risk of harm and maximize operational productivity.

- Experience is key in EMC systems engineering. Models and simulations may help in some aspects, but reality is still way too complex for our state-of-the-art tools. Even if simulations are technically feasible, it requires experience to provide proper inputs and sensible interpretation of results. Simulations remain required for designing complex functionality. For EMC learning electromagnetics and simulations speed-up gaining experience.
- Design for EMC to a large extend facilitates reliability.

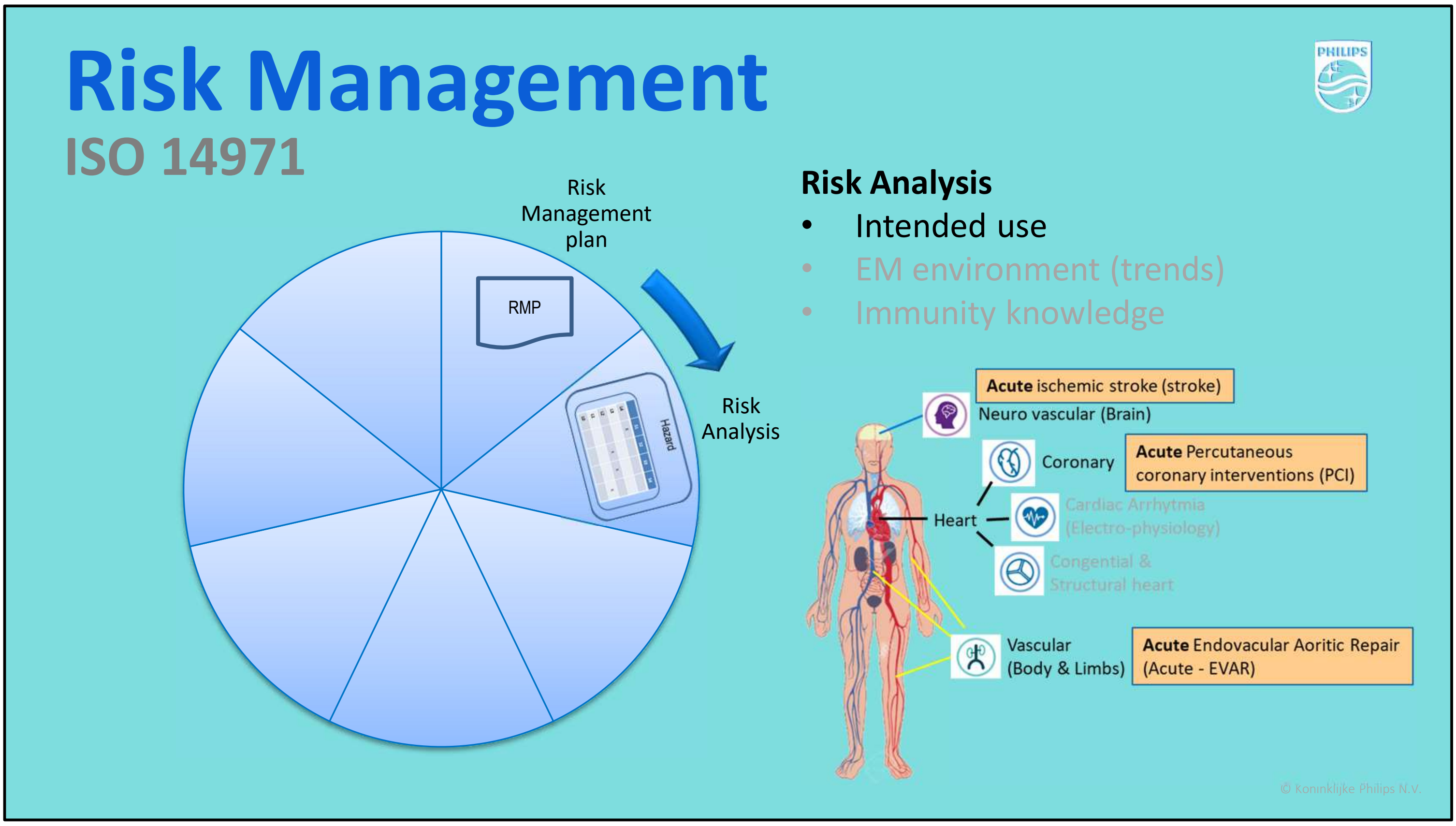
Intended Use
In the medical device environment(s)



Previous slides have given some examples and arguments why EMC risk management involves analysis of users, use environment and devices/interfaces to understand device usage in order to judge if from an EM perspective the device (including its accompanying documentation) can be installed and used safe & effective along its expected service life. The medical EMC standard requires risk management and documentation of objective evidence of how a manufacturer came to its judgement.

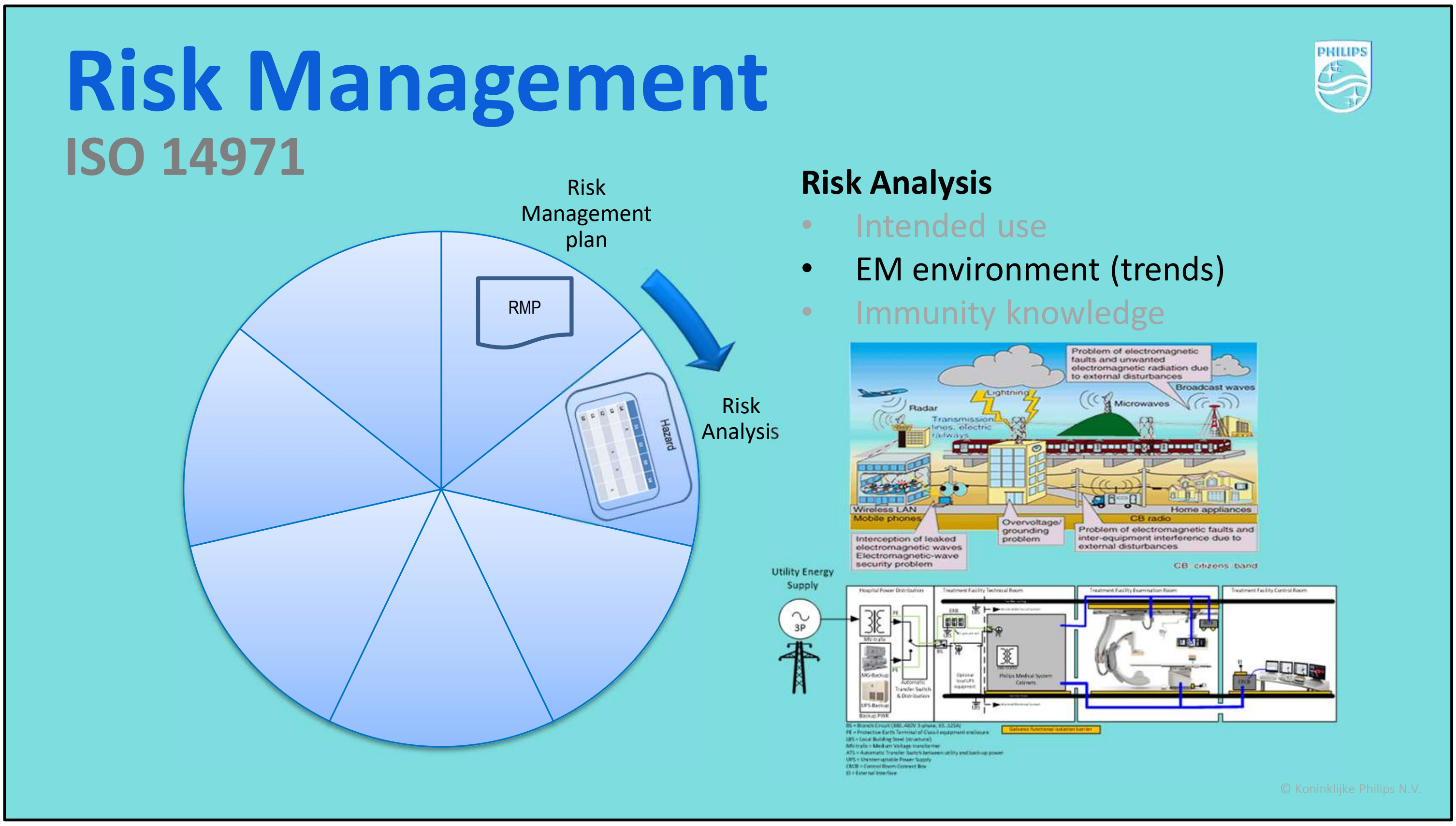


Risk management plan:
a) the scope of the planned risk management activities;
b) assignment of responsibilities and authorities;
c) requirements for review of risk management activities;
d) criteria for risk acceptability, based on the manufacturer's policy for determining acceptable risk;
e) a method to evaluate the overall residual risk, and criteria for acceptability of the overall residual risk;
f) activities for verification of the implementation and effectiveness of risk control measures; and
g) activities related to collection and review of relevant production and post-production information.



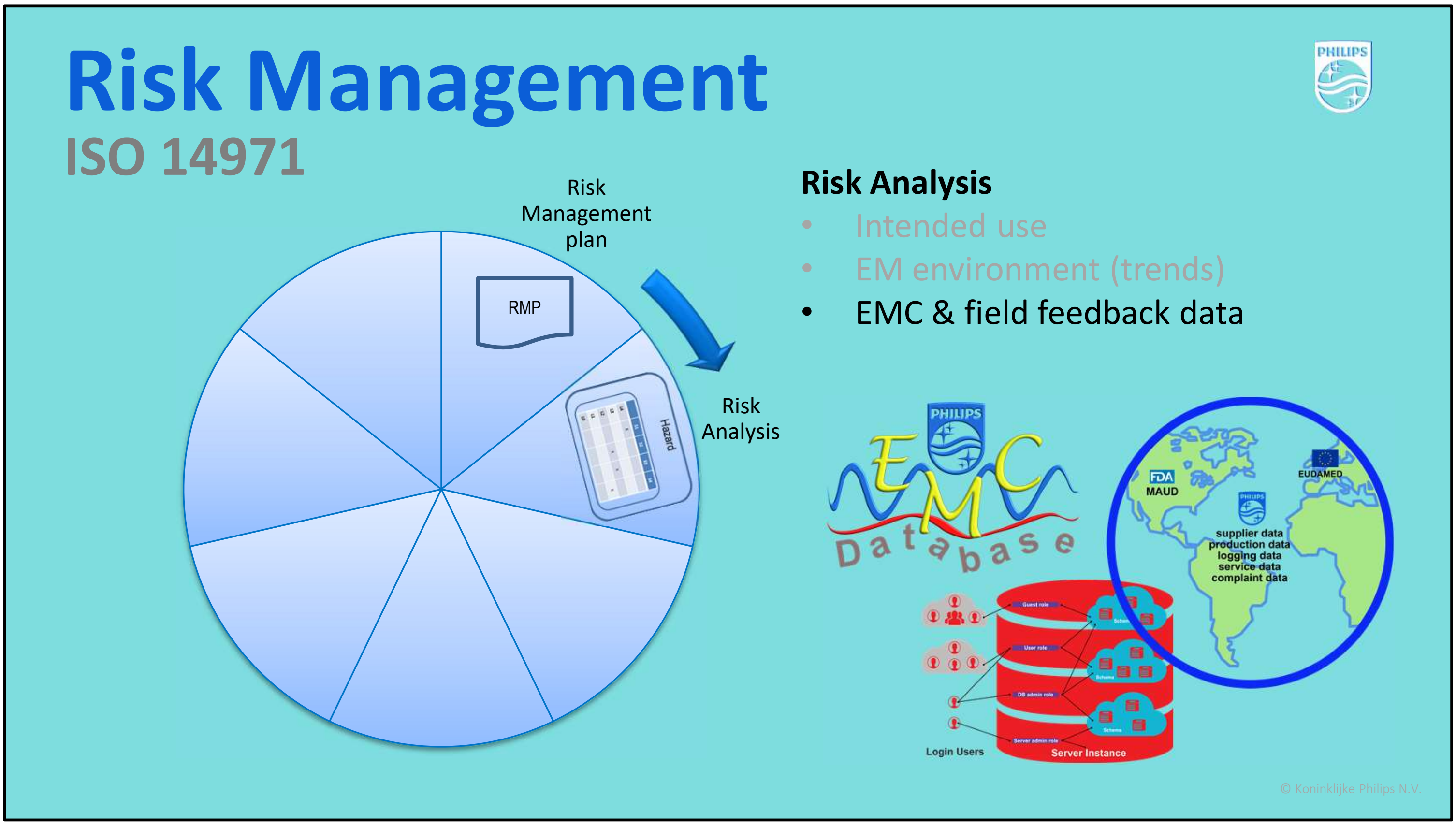
- Hazards
- Hazardous Situations
- Initial risk profiles

Start with the intended use, which are the clinical procedure areas. Especially the clinical areas that are interactive and acute involve higher risks because degradation, interruption or unavailability can result in harm to the patient.



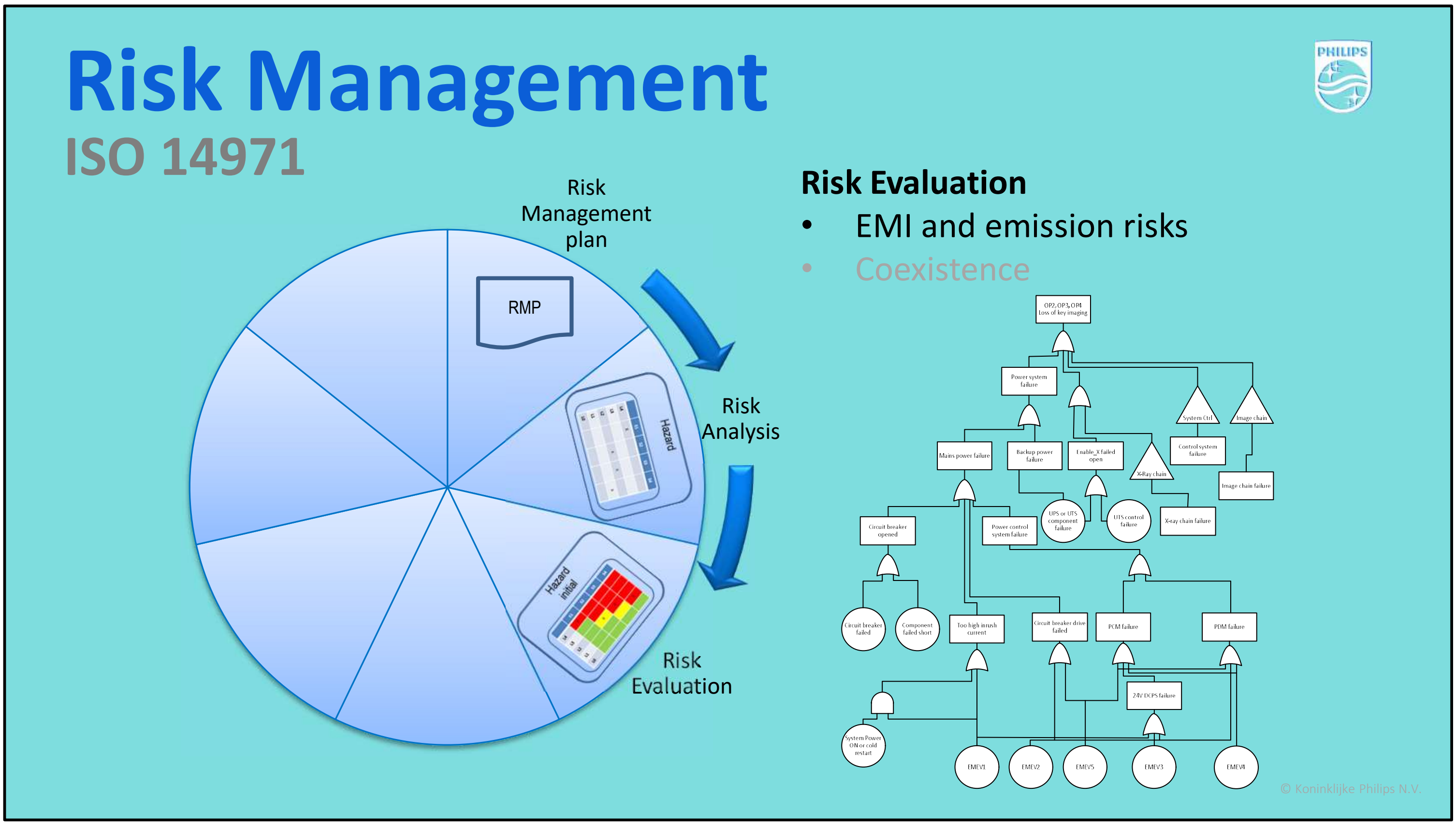
- Hazards
- Hazardous Situations
- Initial risk profiles

When analysing the EM environment, this analysis should include the whole environment going way outside the hospital. For conducted phenomena this must also include the electrical supply infrastructure of the treatment facility including how it is connected to the utility supply.



- Hazards
- Hazardous Situations
- Initial risk profiles

Using external and internal knowledge and feedback is essential for proper risk analysis. The system-of-systems that contribute to the EM environment and thus the risks are way too complex to design first-time right and capture all knowledge in-house.

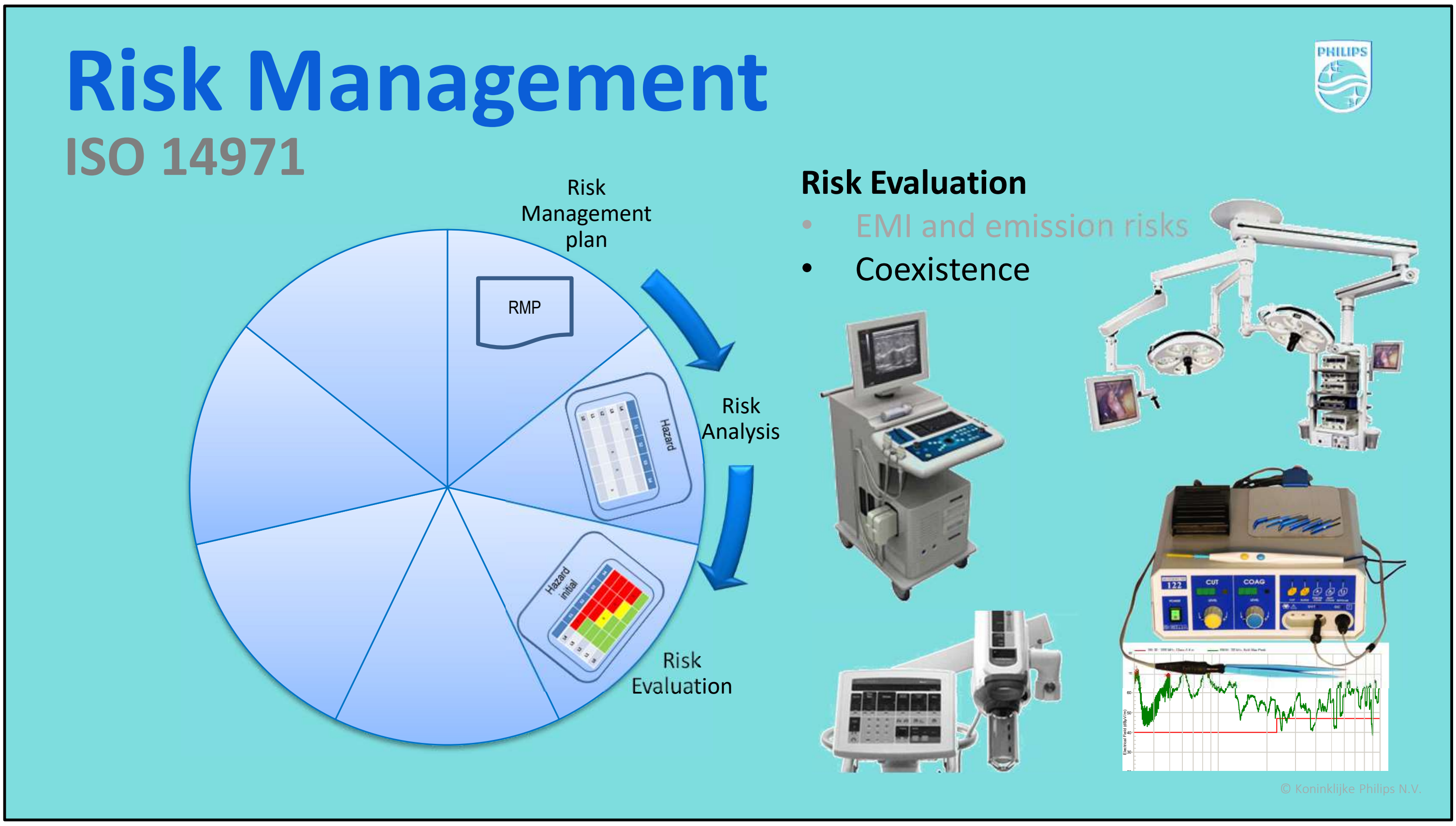


- Compare initial risk profiles with risk acceptance criteria.
- Are risk control measures required?

At this stage, risks are made quantitative by estimations. Don't try to be too accurate…you can't and it provides a wrong sense of precision.

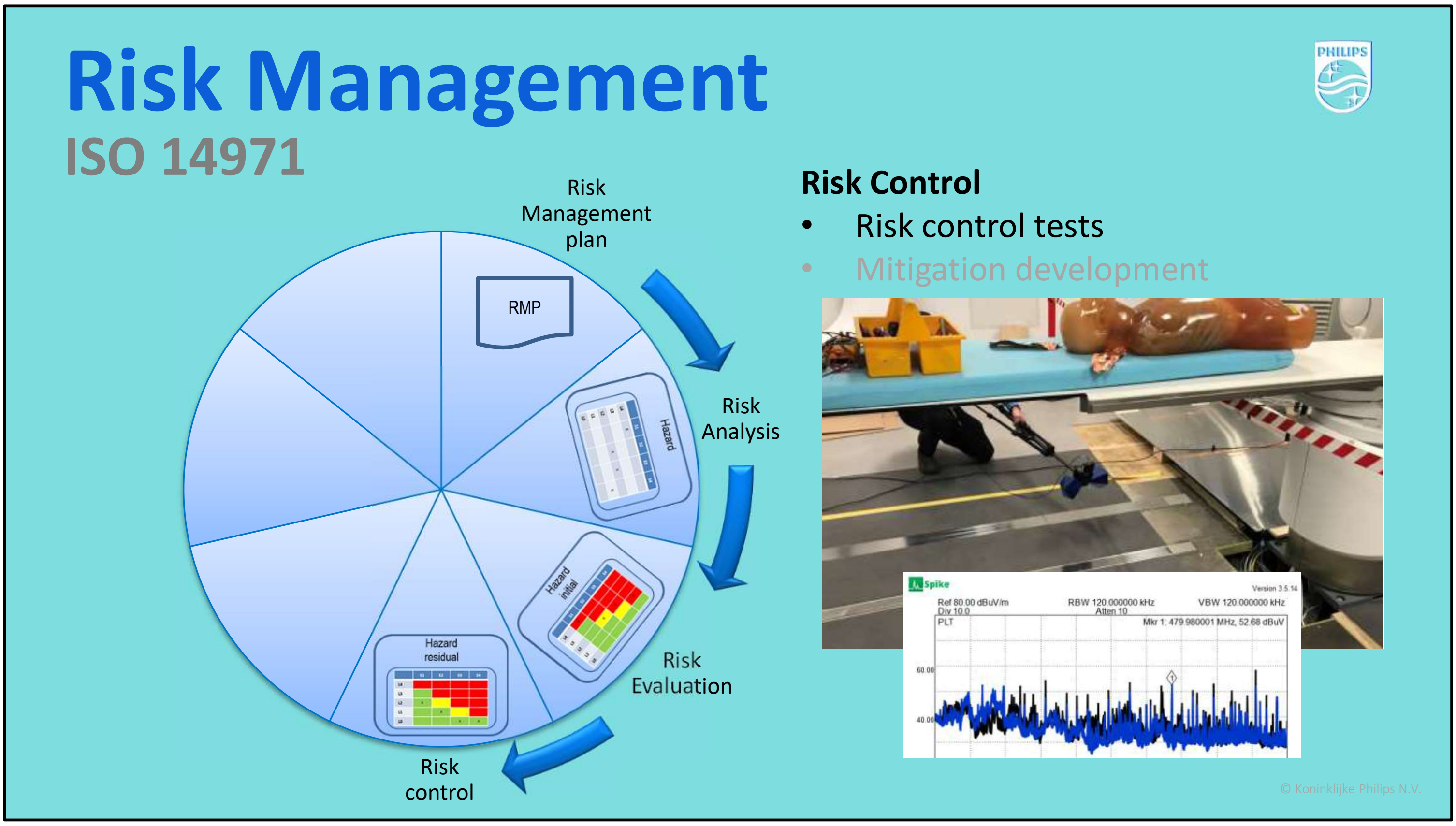
How to estimate?

- Split up in small parts
- Estimate each part
- Think in order of magnitudes
  (once per 1000, 100, 10 examination or for each examination?)
- Estimate worst case situation
- Start with extreme estimations (max and min) and reduce range until everybody agrees that range is not extreme anymore
- Have a look at Fermi Estimations (order-of-magnitude or back-of-the-envelope calculations)
  ==> breaking a big problem into appropriate sub-problems



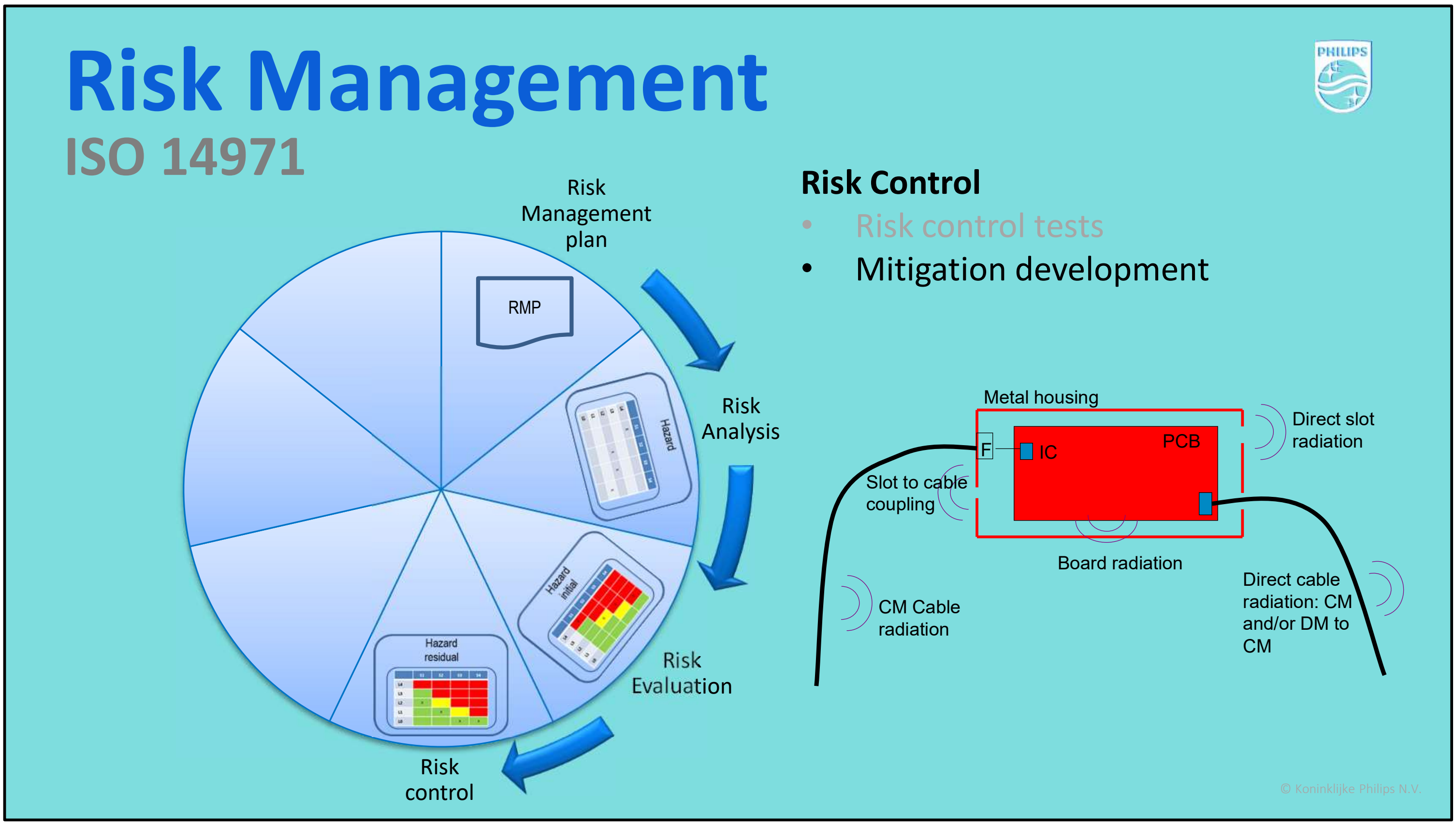
- Compare initial risk profiles with risk acceptance criteria.
- Are risk control measures required?

Philips equipment has to coexist and work together with equipment from other vendors. For some equipment, mainly the ones with functional integration, there are known interfaces and compatibility analysis available. For others we'll have to rely on boundaries established by medical device standards and regulations.



- Risk control options
- Select and implement risk control measures
- Determine if safety risk is reduced as far as possible
- Verify implementation of risk control measures

Where insufficient input is available to properly estimate the a risk, lab or in-situ risk control tests are executed and reported to either show acceptability of the risk or to quantify it and define risk control measures to ensure the risks remain acceptable.

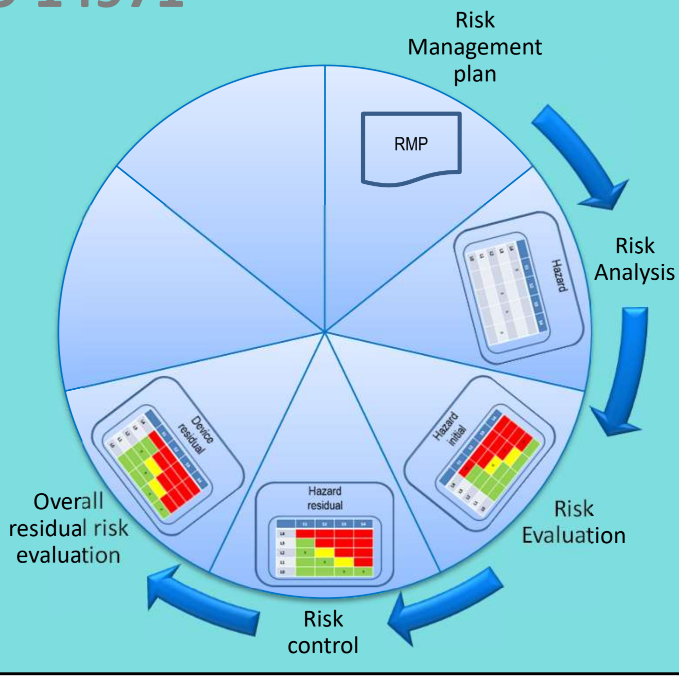


- Risk control options
- Select and implement risk control measures
- Determine if safety risk is reduced as far as possible
- Verify implementation of risk control measures

Risk control measures primarily need to be found in intrinsic safe designs, only if those are not reasonably feasible the lesser measures of training and informing should be used. Mitigations are typically needed on unit enclosure level rather than on system level. The closer the mitigation to the root cause of the found weakness, the more affective the mitigation typically is.

Risk Management

ISO 14971

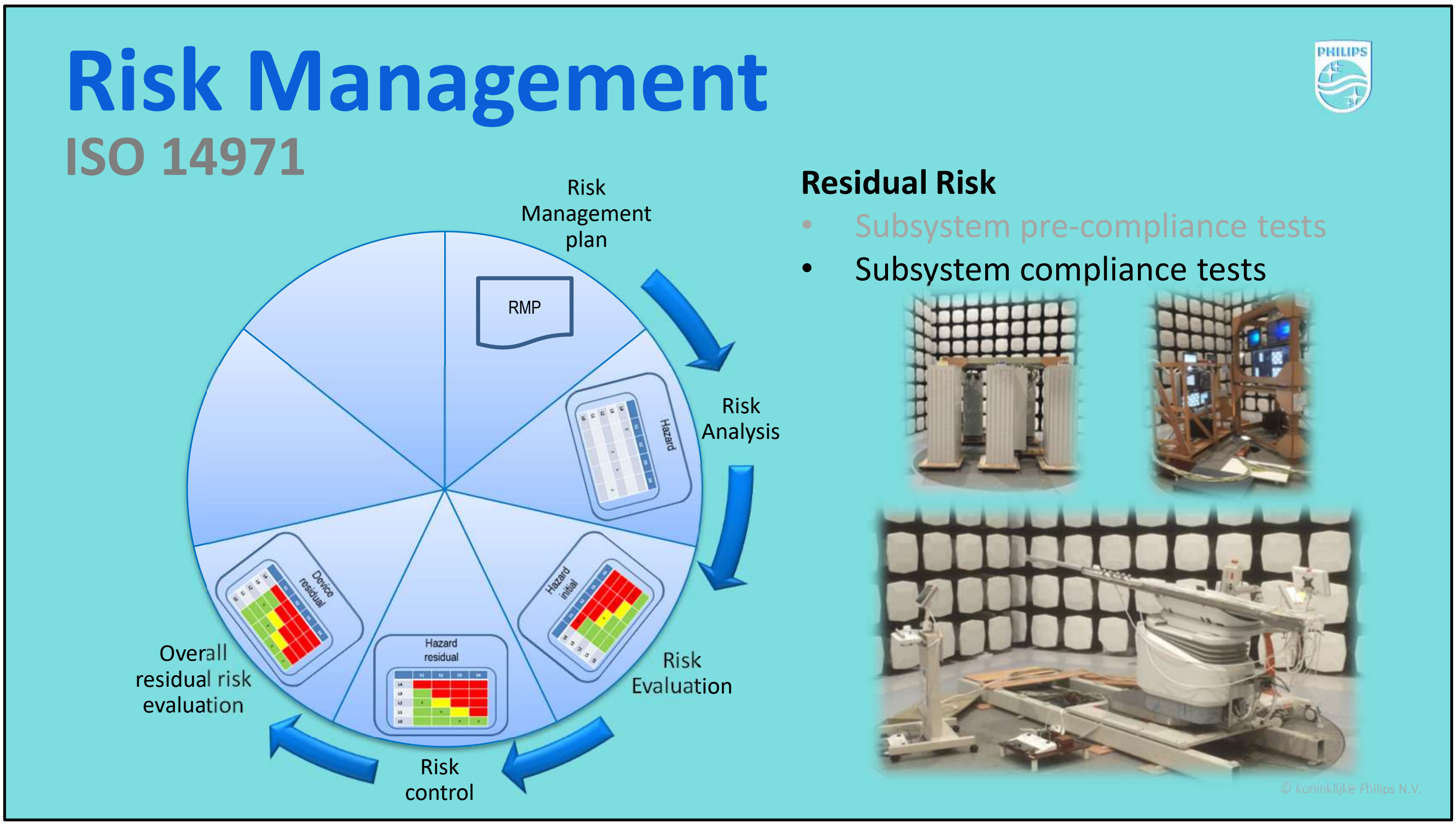


Residual Risk

- Subsystem pre-compliance tests
- Subsystem compliance tests

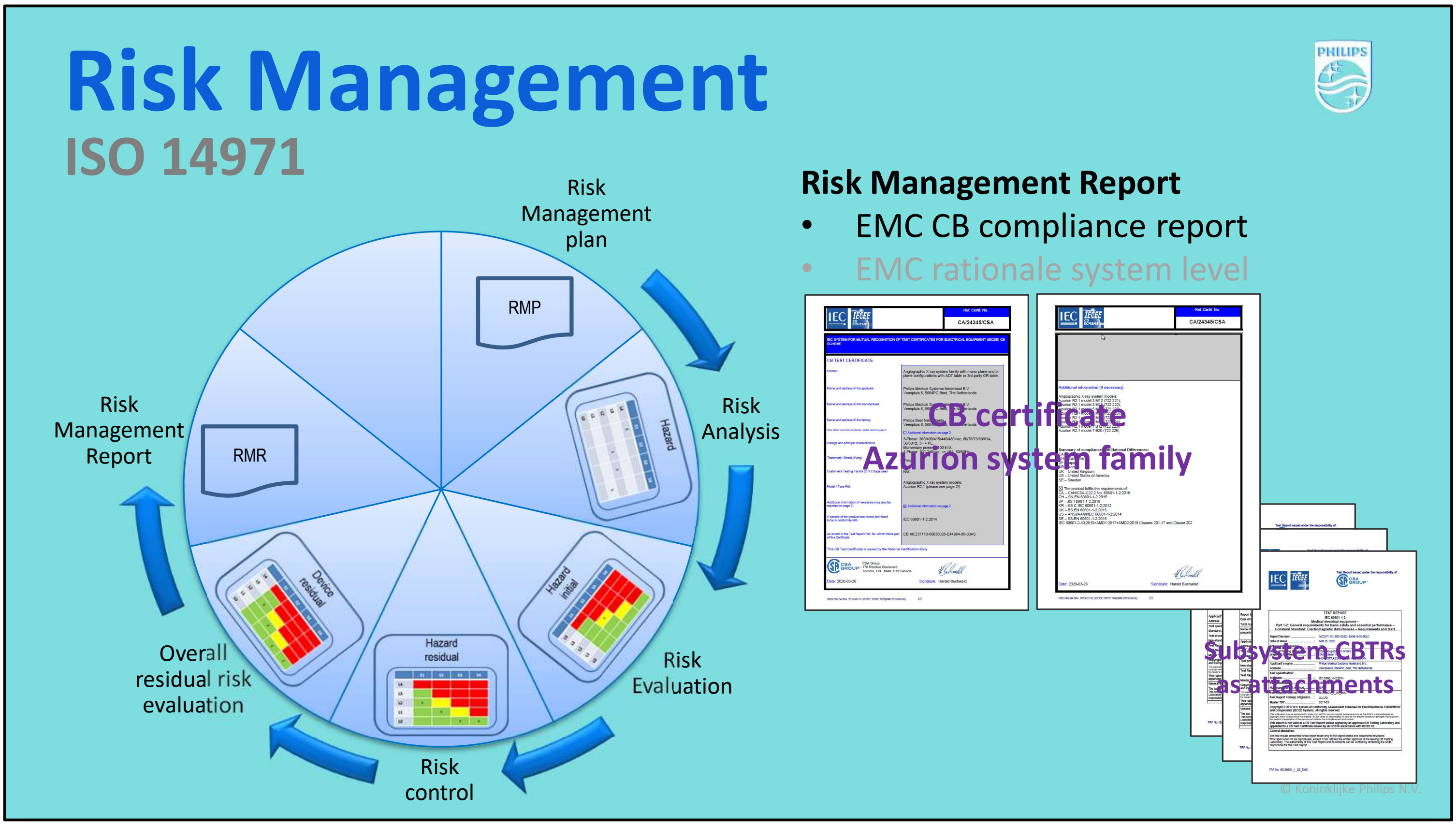
- Determine residual risk profile of the medical device
- Compare with risk acceptability criteria
- If required, make a "Benefit Risk Determination"

Based on system thinking and EM analysis, the Azurion medical device has been partitioned into clusters of functionality that are physically separable from the rest of the system, such that they can be representatively functionally tested controlled by a system simulator on their physical interfaces (this physical simulator is called Auxiliary Equipment in EMC testing). For a system family, each cluster has 1 or more physical subsystems that can be representatively and reproducibly tested in a lab environment. Before going into the compliance lab, the subsystems are prepared and tested in a pre-compliance test environment (e.g. Faraday tent or Faraday Test Bay).



- Determine residual risk profile of the medical device
- Compare with risk acceptability criteria
- If required, make a "Benefit Risk Determination"

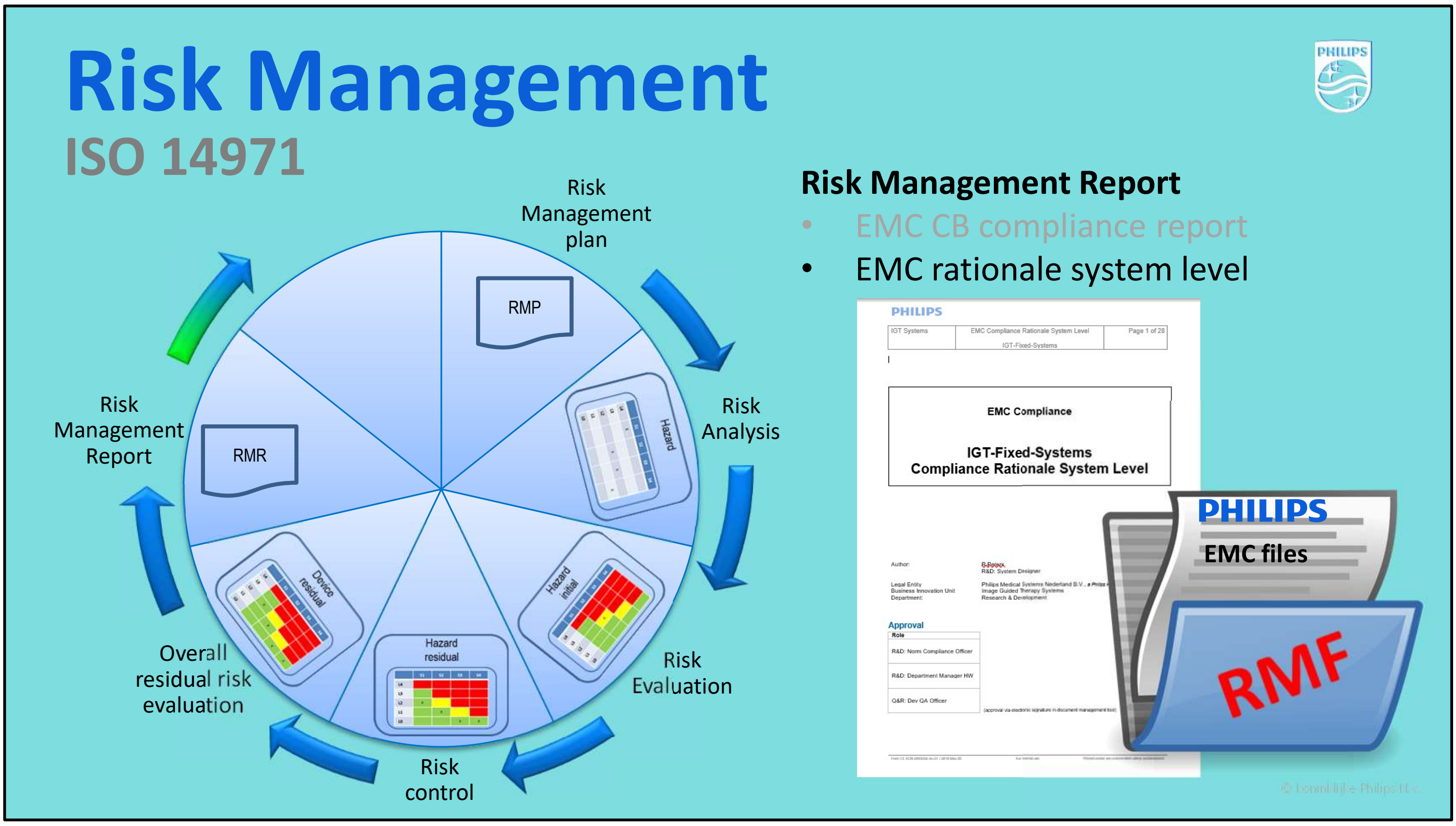
Final compliance testing, against via risk management defined performance criteria and test levels, is done in an accredited compliance lab semi-anechoic chamber (SAC) under representative functional conditions of the medical device. All observations are documented, analyzed and judged for acceptability (both potential safety and functional related observations).



Review of the risk management process:

- Implementation of the risk management plan
- Is residual risk profile of the medical device acceptable
- Are methods / procedures in place to obtain relevant production and post production information

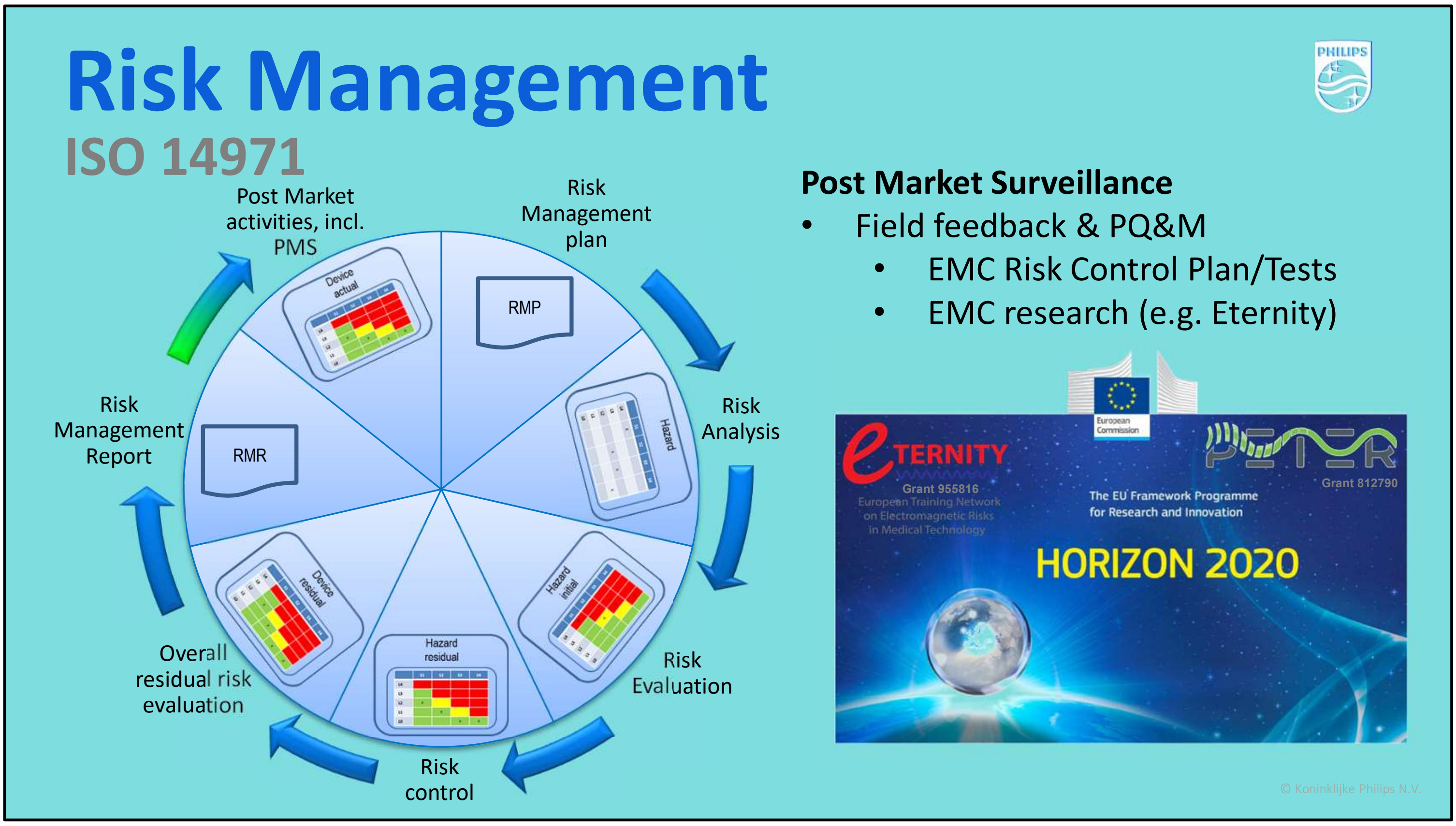
Impartial review and archiving of the compliance test results against the applicable medical EMC standards is done by an impartial CB laboratory under responsibility of a National Certification Body (NCB).



Review of the risk management process:

- Implementation of the risk management plan
- Is residual risk profile of the medical device acceptable
- Are methods / procedures in place to obtain relevant production and post production information

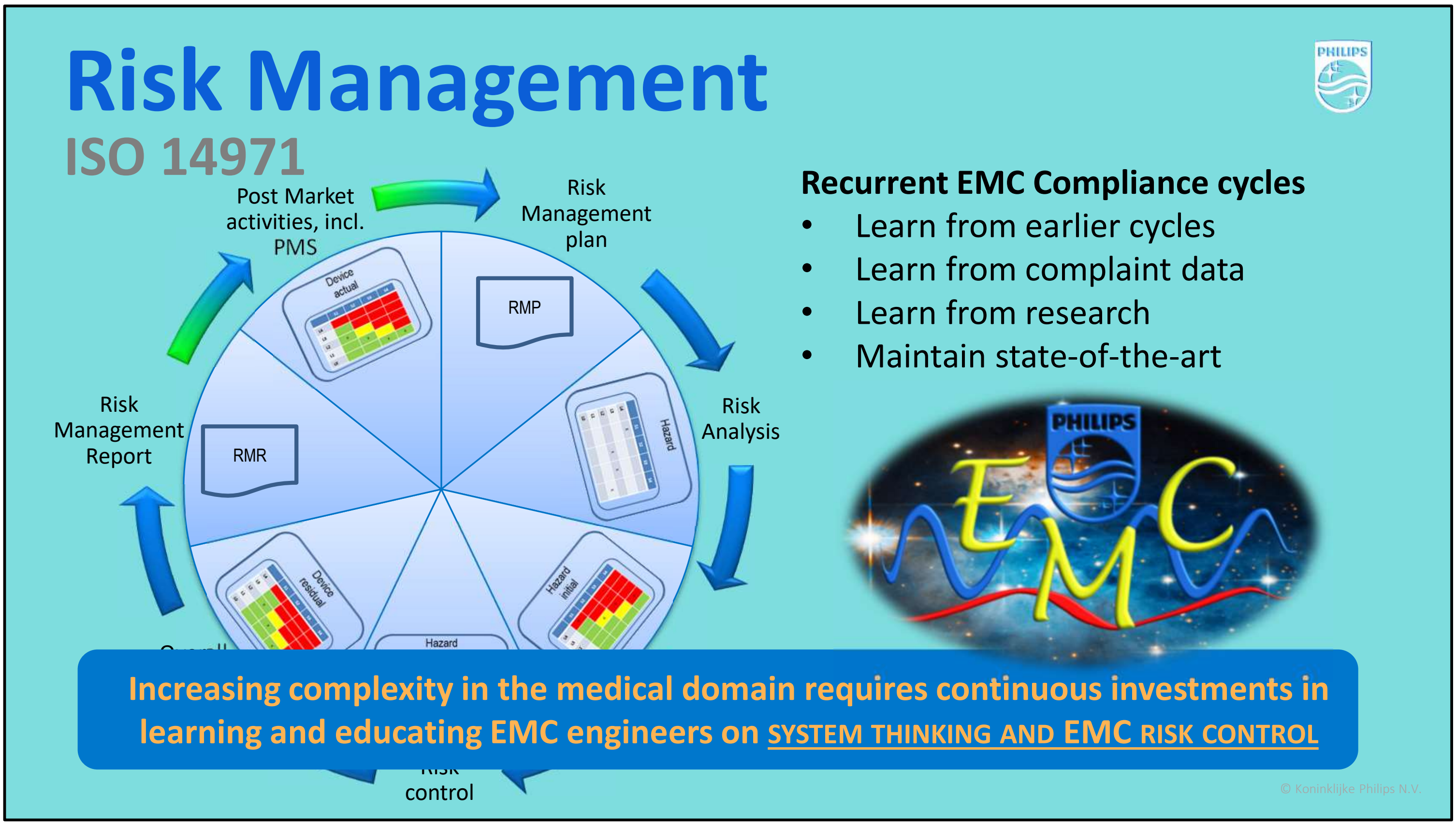
The EMC Risk Management File is completed with the Compliance Rationale System Level document after CB reporting and integrated into the system level RMF for final submission to an NCB for impartial review and the allowance to affix the NCB mark to the medical device product.
All processes and submitted documentation is finally reviewed by a medical device Notified Body and/or local regulators before a medical device is allowed to be placed on the market.



Review of the risk management process:

- Implementation of the risk management plan
- Is residual risk profile of the medical device acceptable
- Are methods / procedures in place to obtain relevant production and post production information

Ones a product is on the market, the EMC risk control activities continue for Product Quality and Maintenance changes that may be triggered by customer feedback or other new insights gained from R&D activities.



This cycle of risk management continues until the product is no longer in active production, after which the cycle still continues in reduced form without the compliance activities to maintain the installed base safe until the end of its service life. This includes keeping track of the EM-environment in which the medical device is used for over 15 years that may induce risks, not envisioned until the end of active development of the device. Typically such developments result in changing regulatory requirements upon the responsible organization (i.e. user of the medical device).

Remember that SYSTEM THINKING and EMC RISK CONTROL are the mitigations against the ever increasing complexity of keeping medical devices EMC compliant and thus safe.

Thank you….

PHILIPS

Pan-European Training, research and education network on ElectroMagnetic Risk management.

This project has received funding from the European Union's EU Framework Programme for Research and Innovation Horizon 2020 under Grant Agreement No. 812.790.

EMC Europe 2022

Risk-based EMC implementation with examples

1

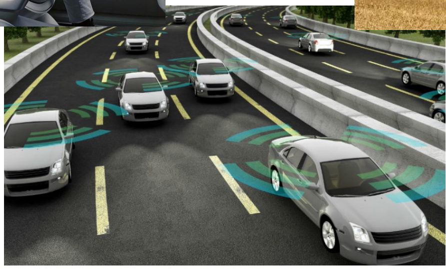
This project has received funding from the European Union's EU Framework Programme for Research and Innovation Horizon 2020 under Grant Agreement No. 812.790

2

Electronic Applications of the Very Near Future

Autonomous Vehicles



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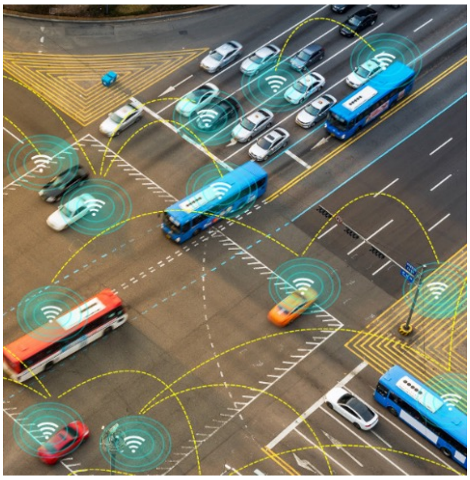
3

Electronic Applications of the Very Near Future

Vehicle-to-X Communication



- Car-to-car
- Car-to-infrastructure
- Car-to-pedestrian
- Etc.

- Robust wireless communication (5G) is key element!

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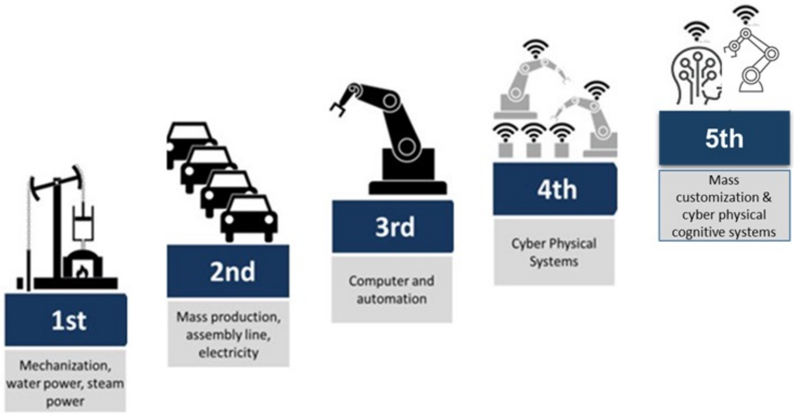
4

Electronic Applications of the Very Near Future

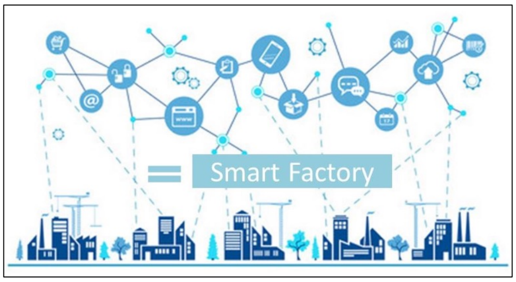
Industry 5.0 and Human/Robot Collaboration



Source: https://furniturkonline.com/2018/08/06/ready-for-industry-5-0/

Electronic Applications of the Very Near Future

Industry 5.0 and Human/Robot Collaboration



- EMC-point-of-view:
  - More and more electronics in and around machines, robots, cobots, autonomis vehicles,…
  - More wireless applications (mobile phones, RFID, M2M communication, 5G,…) very close to safety-critical circuits

Electronic Applications of the Very Near Future

Medical & Healthcare

Image (c) 2010 Intuitive Surgical, Inc.

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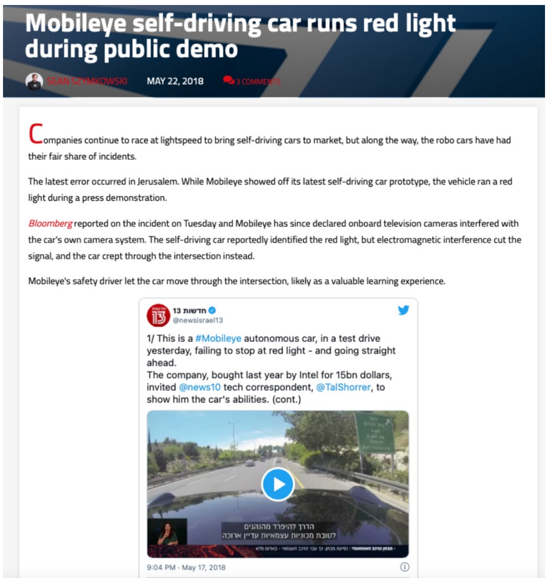
Safety-Critical EMI Incidents Do Happen…



Mobileye self-driving car runs red light during public demo

SEAN SZYMKOWSKI MAY 22, 2018 3 COMMENTS

Companies continue to race at lightspeed to bring self-driving cars to market, but along the way, the robo cars have had their fair share of incidents.

The latest error occurred in Jerusalem. While Mobileye showed off its latest self-driving car prototype, the vehicle ran a red light during a press demonstration.

Bloomberg reported on the incident on Tuesday and Mobileye has since declared onboard television cameras interfered with the car's own camera system. The self-driving car reportedly identified the red light, but electromagnetic interference cut the signal, and the car crept through the intersection instead.

Mobileye's safety driver let the car move through the intersection, likely as a valuable learning experience.

חדשות 13
@newsisrael13

1/ This is a #Mobileye autonomous car, in a test drive yesterday, failing to stop at red light - and going straight ahead.
The company, bought last year by Intel for 15bn dollars, invited @news10 tech correspondent, @TalShorrer, to show him the car's abilities. (cont.)

הדרך להיפרד מהנהגים
לטובת מכוניות עצמאיות עדיין ארוכה

9:04 PM · May 17, 2018

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Technology

Why Intel's Mobileye Blew a Red Light While Showing Off Its Ride

The incident, an embarrassment to the dominant manufacturer of driver assistance systems, shows how fraught the race to fully autonomous cars will be

By Max Chafkin
21 May 2018, 21:07 CEST

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Technology

Why Intel's Mobileye Blew a Red Light While Showing Off Its Ride

The incident, an embarrassment to the dominant manufacturer of driver assistance systems, shows how fraught the race to fully autonomous cars will be

By Max Chafkin
21 May 2018, 21:07 CEST

"It was a very unique situation," he said, referring to the camera crew. "We'd never anticipated something like this." Shashua said Mobileye was also modifying the hardware designed to shield the car's computers from electromagnetic interference in order to prevent similar incidents in the future. Mobileye's Jerusalem fleet has continued to operate and the company hasn't received any complaints from automakers, Shashua said.

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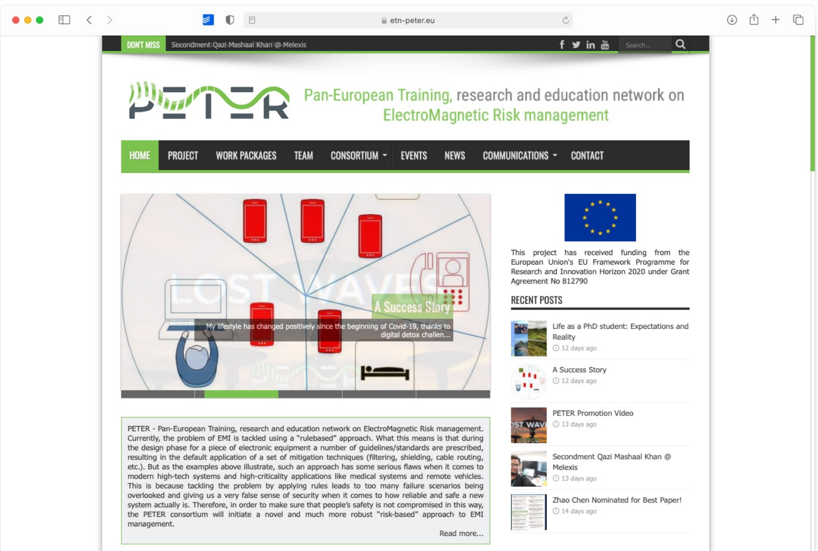
PETER: From "Rule-Based" to "Risk-Based"



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PETER: From "Rule-Based" to "Risk-Based"

- Currently, the problem of EMI is tackled using a "rule-based" approach:
  - During design a number of guidelines/standards are prescribed
  - Default application of a set of mitigation techniques (filtering, shielding, cable routing, etc.)
- However, this rule-based has serious flaws:
  - Too many failure scenarios are being overlooked
  - No certainties when it comes to knowing whether these mitigation strategies, or rules, are really sufficient
  - Standards always lag behind technological developments and are based on economic and technical compromises
  - EMC standards only cover one EMI disturbance at a time, meaning that simultaneous EMI effects are not addressed
  - EMI is a "whole system" property with many of the effects resulting from environmental factors like ageing, vibration, and temperature

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PETER: From "Rule-Based" to "Risk-Based"

- What is needed is a truly interdisciplinary – but also revolutionary – approach to this very serious problem
- Implementation of a "Risk-Based" approach bringing together expertise from 4 key areas: EMC, reliability engineering, functional safety, and risk management
- The PETER project will consider the complete system over its whole lifecycle, i.e., from the earliest concept to the final decommissioning
- Involves 3 main steps: hazard-and-risk analysis, risk reduction, verification and validation

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PETER's Main Goal

"Train 15 early-stage researchers (ESRs) in topics related to the development of high-technology systems that maintain reliability and safety over their full life-cycle, despite these systems being subjected to severe and complex EMI threats"

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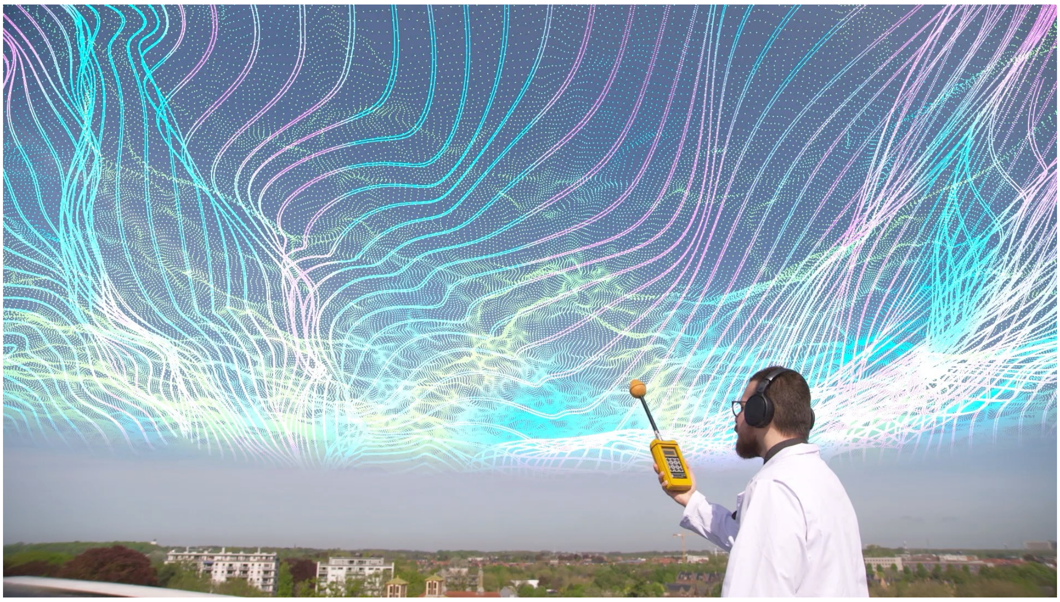

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PETER Consortium

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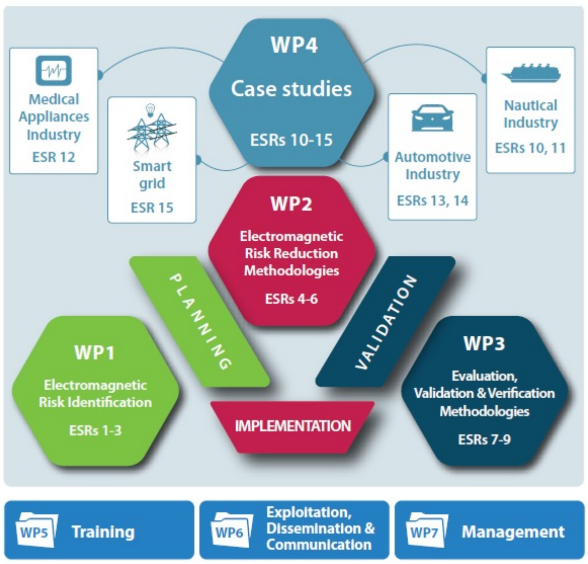
PETER Work-Package Structure



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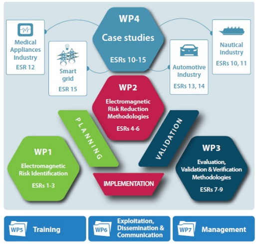
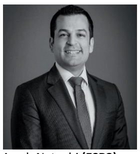
PETER Early-Stage Researchers



- WP1 - Electromagnetic Risk Identification

ESR 1 — **Project: Statistical Electromagnetic Risk Analysis of Large and Complex Systems, Development of Theoretical Description of Risk Assessment Methodologies.**

Samikshya Ghosalkar (ESR1)
Leibniz University Hannover
Main supervisor: Dr.-Ing. Prof. Heyno Garbe



Arash Nateghi **(ESR2)**
WIS
Main supervisor: Dr Martin Schaarschmidt

ESR 2 — **Project: Statistical Electromagnetic Risk Analysis of Large and Complex Systems, Experimental Analysis and Model Verification.**

ESR 3 — **Project: Risk-Based Automotive Electromagnetic Engineering Approach aligned with the ISO26262 Functional Safety Approach.**

Lokesh Devaraj **(ESR3)**
HORIBA MIRA LIMITED
Main supervisor: Dr Alastair Ruddle

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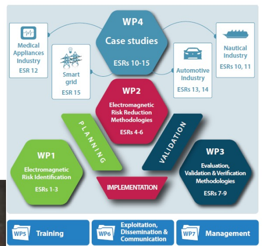
PETER Early-Stage Researchers



- WP2 - Electromagnetic Risk-Reduction Methodologies

ESR 4 — **Project: Risk-Based EMI-Aware Design of Complex Systems.**

Mumpy Das **(ESR4)**
University of Twente
Main supervisor: Prof. Dr. Ir. Ing F.B.J. Leferink

Hasan Habib **(ESR5)**
KU Leuven
Main supervisor: Prof. D Pissoort.

ESR 5 — **Project: IEC 61508 Techniques & Measures for EMI Risk Reduction, Hardware-based Techniques & Measures.**

ESR 6 — **Project: IEC 61508 Techniques & Measures for EMI Risk Reduction, Software-based Techniques & Measures.**

Pejman Memar **(ESR6)**
KU Leuven
Main supervisor: Prof. dr. ing. Jeroen Boydens

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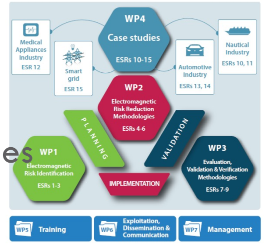
PETER Early-Stage Researchers



- WP3 - Evaluation, Validation and Verification Methodologies

ESR7 **Project: Evaluation of Electromagnetic Hazards due to Environmental Stresses, Obsolescence and/or Ageing, Evaluation at the IC Level.**

Qazi Mashaal Khan **(ESR7)**
ESEO
Main supervisor: Dr Richard Perdriau

Oskari Leppäaho **(ESR8)**
Valeo, France
Main supervisor: Priscila Fernandez-Lopez

ESR8 **Project: Evaluation of Electromagnetic Hazards due to Environmental Stresses, Obsolescence and/or Ageing, Evaluation at the System Level**

ESR9 **Project: Statistical Verification and Validation of Immunity and Enclosure Shielding Effectiveness – Risk of Susceptibility**

Arunkumar Hunasanahalli Venkateshaiah **(ESR9)**
University of York
Main supervisor: Dr John Dawson

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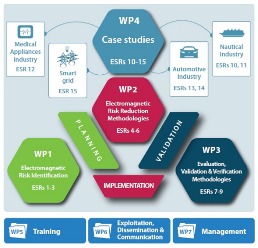
PETER Early-Stage Researchers



- WP4 - Application Case Studies

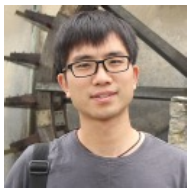
ESR10 **Project: From Rule-Based Standards to Risk-Based, Cost-Effective, Up-to-Date, Maritime EMC Standards**

Nancy Omollo **(ESR10)**
RH Marine
Main supervisor: Jan-Kees van der Ven

Mohammad Tishehzan **(ESR11)**
University of York
Main supervisor: Dr Mark Nicholson, Dr John F. Dawson

ESR11 **Project: Modelling and Reasoning about EMI Interactions in Autonomous and Complex Vessels**

ESR12 **Project: EMI-Resilient Medical Display Systems for Surgical-, Diagnostic Imaging- and Modality Applications**



Zhao CHEN **(ESR12)**
Barco
Main supervisor: Ronny Deseine

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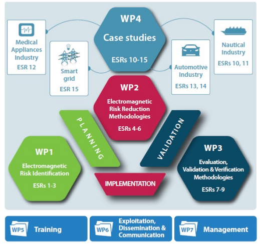
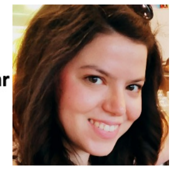
PETER Early-Stage Researchers



- WP4 - Application Case Studies

ESR13

Project: EMI Risk assessment applied to the next generation vehicular communication devices



Vasiliki Gkatsi (ESR13)
University of Twente
Main supervisor: Prof.dr.ir.ing. F.B.J. Leferink

Akram Ramezani (ESR14)
Melexis
Main supervisor: Dr Hugo Pues

ESR14

Project: Risk-Based EMI-Aware Design of an Automotive Integrated Circuit

ESR15

Project: EMI Risk Management on the scale of the Smart Grid as a network of systems

Fernando Ribeiro Arduini (ESR15)
Fraunhofer INT
Main supervisor: Dr Michael Suhrke

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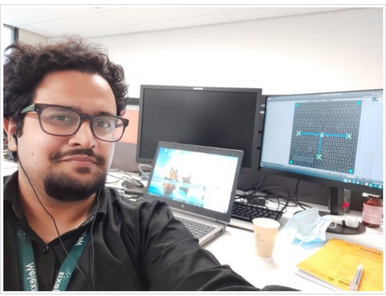
Active Collaboration through Secondments!

Secondment Qazi Mashaal Khan @ Melexis

Qazi Mashaal Khan, ESR 7 (ESEO), executed his physical secondment at Melexis Technologies (Tessenderlo, Belgium).

He worked together with their local EMC team for two months, from 31st May to 30th July 2021. His work's main objective was to characterize a custom-designed Printed Circuit Board (PCB) with Transmission Line Pulse (TLP) & Direct Power Injection (DPI) testing using the state-of-the-art facilities at Melexis. In parallel, he investigated the effect of packaging, S-parameters, and Electrostatic discharge (ESD) protection structures on the performance of a test chip designed in 180 nm SOI (Silicon-on-Insulator) technology. This secondment lead to a fruitful research collaboration between Melexis and ESEO!



Secondment during the Pandemic

As the pandemic heavily disturbed many things around the globe that we found obvious in the past, it also completely turned my secondment plans.

Originally, I had planned a stay at ESEO in Angers (France) for my secondment. I had even booked an apartment and train tickets for the trip, but due to increased coronavirus-restrictions shortly before my departure, we could not do anything other than shift it to an online version. At that moment, I was a bit sad about missing a good opportunity to live in another country and to understand their work environment. However, an online working collaboration also turned out to be a unique and educational experience.

My work revolves around the design of EMI detectors. Such a detector aims to generate a warning when excessive electromagnetic noice disturbs data transmitted through a wired communication channel. So far, I had studied this with simulations. The initial simulations were performed using a simplified mathematical model written in Python. Afterwards, Monte-Carlo based full-wave simulations were used to verify the results in real-like environment. These results have shown that the EMI detector works in most cases, and these results were presented at EMC Europe 2020 and ET 2020. Of course, a physical validation of these sensors is crucial to be sure that indeed they work. And that is the aim of my secondment!

Professor Richard Perdriau and Professor Mohammed Ramdani, both from ESEO were/are my main hosts, during my secondment. For smooth progress of work, meetings were scheduled every Monday for two months using Teams. Both of my supervisors are quite experienced in the design and development electronic PCBA 's. The primary objective of my secondment was defined in close collaboration with my main supervisors at KU Leuven, Professor Davy Pissoort and Dr. Tim Claeys. It was decided to develop an actual EMI detector on a printed circuit board (PCB) and validate it using a small stripline set-up, which was already available out my own campus.

Before developing the EMI detector for a wired channel, the wired channel is to be developed. An FPGA was chosen to set up a wired digital channel. We had two options for the EMI detector design. At the one hand, we could decide to use only analogue blocks. At the other hand, we could decide to convert data from analogue to digital form using ADC and then process it using FPGA, which is already present in the channel itself. Although I designed a basic PCB in the past, this proposed design was quite complex, and I had no idea how to deal with it.

My Virtual Secondment and Teleworking

Teleworking and virtual secondments as adapted by MSCA-ETN PETER project, has enabled secondment activities for continued work progress.

Generally, according to the PETER Project, secondments are supposed to take place in a different institution than the host institution. However, since the start of the pandemic, most of these secondment have not been possible to be carried out physically. Like most companies and universities where teleworking is encouraged due to covid 19 restrictions, Secondments have also become a virtual thing.

Having a secondment during the time of pandemic is not as similar as having a normal secondment. It however still provides the greatest opportunity to have the experience of doing measurements and interacting with people who are more experienced in carrying out those measurements.

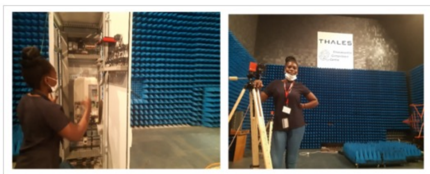


Figure 1: A photo taken while doing measurements in the anechoic chamber at Thales Netherlands, during the secondment.

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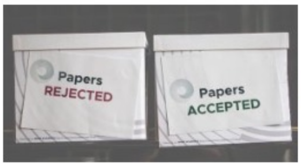
Active Dissemination

PETER ESR papers accepted at IEEE SIPI + EMC Europe 2021



This year, several PETER ESRs have papers accepted at IEEE SIPI + EMC Europe 2021! Congrats to these ESRs:

Read More »

PETER Special Session "Risk-based EMC"

We are very excited to share that our submission of the PETER Special Session "Risk-based EMC" was accepted at the 2021 Joint IEEE International Symposium on Electromagnetic Compatibility, Signal & Power Integrity, and EMC Europe conference. Please, find more information about the conference here: EMCS Symposiums . More information about the Special Session coming soon!

Read More »

PETER Special Session at ESREL 2021

esRel 19 / 23 Sept. 2021 ANGERS .FR European Safety and Reliability Conference

We are Permalink to PETER Special Session at ESREL 2 on "Electromagnetic Risk Management" for ESREL 2021 (http://esrel2021.org) has been accepted. This special session will concentrate on the management of risks that are of electromagnetic origin and have an effect on either the system safety or reliability.

Read More »

The PETER YouTube Channel is Live!

PETER @ YouTube

With the first video posted, the PETER YouTube channel is now Live!

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Innovative Training Network (ITN) ETERNITY - Intro

05/09/2022

Dr. Ir. Anne Roc'h

Electrical Engineering

ETERNITY

EINDHOVEN UNIVERSITY OF TECHNOLOGY

ITN ETERNITY
-
Project Introduction

Project duration: 1st March 2021- 1st March 2025

ETERNITY

European Training Network
on Electromagnetic Risks
in Medical Technology

ITN ETERNITY- Project Introduction

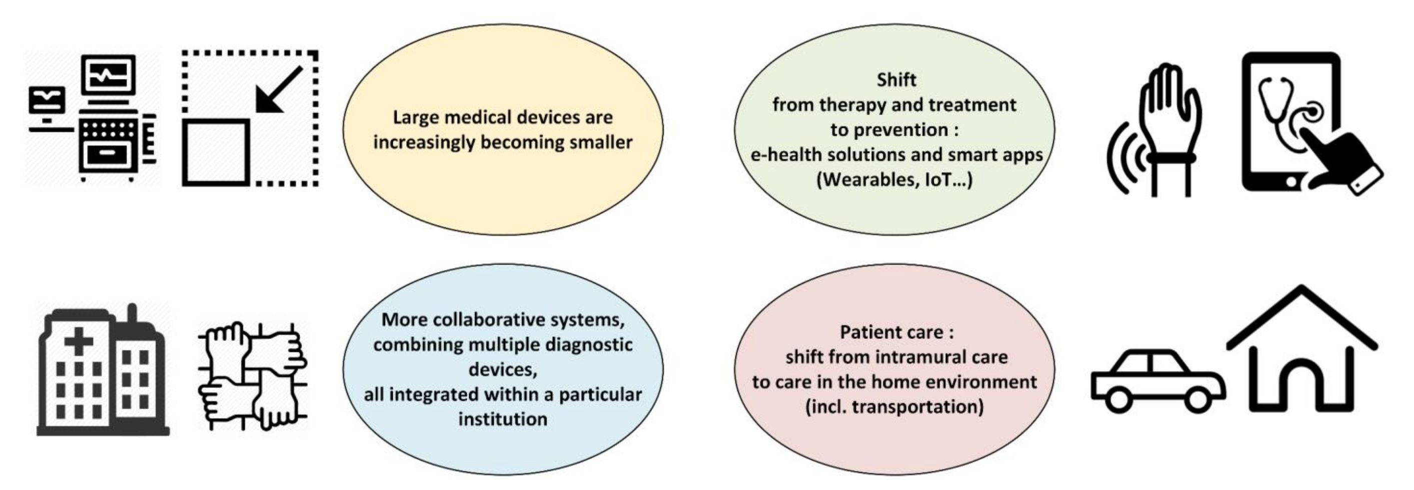
This project has received funding from the European Union's EU Framework Programme for Research and Innovation Horizon 2020 under Grant Agreement No. 955.816.

ETERNITY Main's Goal

*"Each of the 14 Early-Stage Researchers (ESRs) will be trained to work in multi-disciplinary and multi-cultural teams, with a new mindset tuned towards the **inclusion of the EMC risk-based approach into innovative design methods**. For this inclusion to occur, each ESR will develop through their research the missing dedicated tools and techniques and apply them to a representative set of medical devices under development."*

Some context : the (European) MedTech

- One of Europe's most diverse and innovative high-tech sectors : 500 000+ jobs in Europe, 15BEuro in positive trade balance, 95% are Small and Medium enterprises (SMEs),
- First sector in patent application in Europe (7%), close collaboration with patient and an average lifecycle of only 18-24 months,
- EMC Risk-based approach: a lack of understanding and no clearly prescribed risk-assessment methodology in place for a major shift in approach.



ETERNITY - Inclusion of the EMI Risk-Based Approach in MedTech design

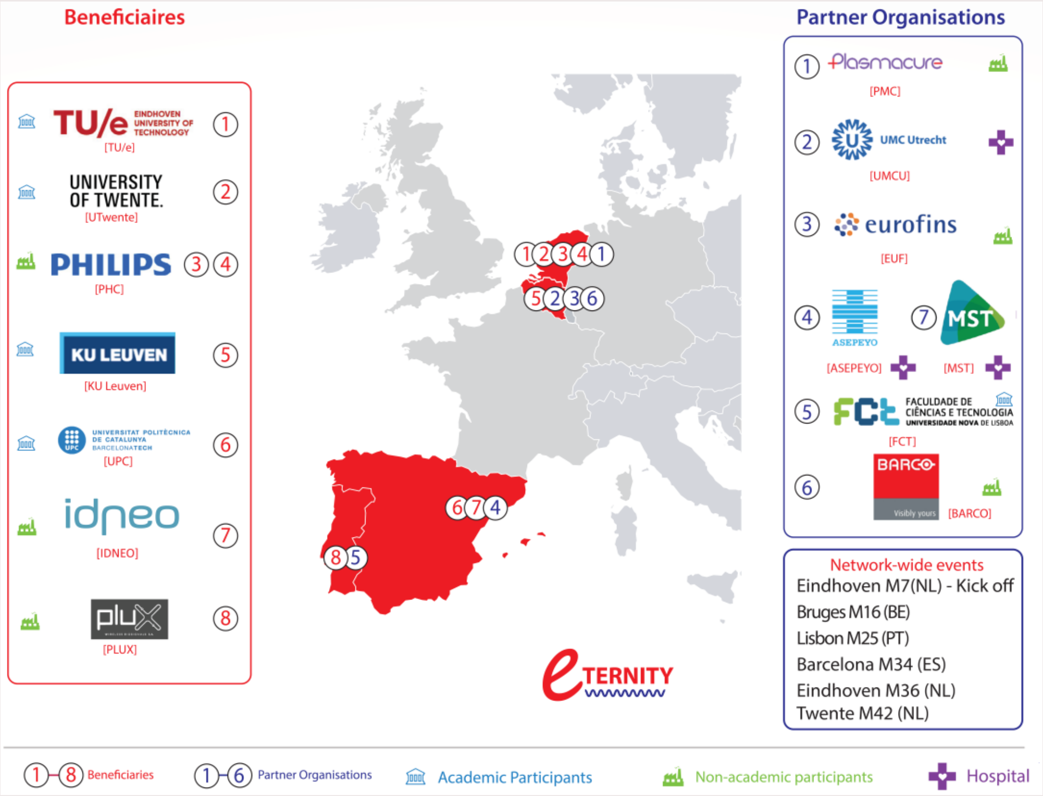
A Rule-based approach (the conventional approach) no longer suffice:

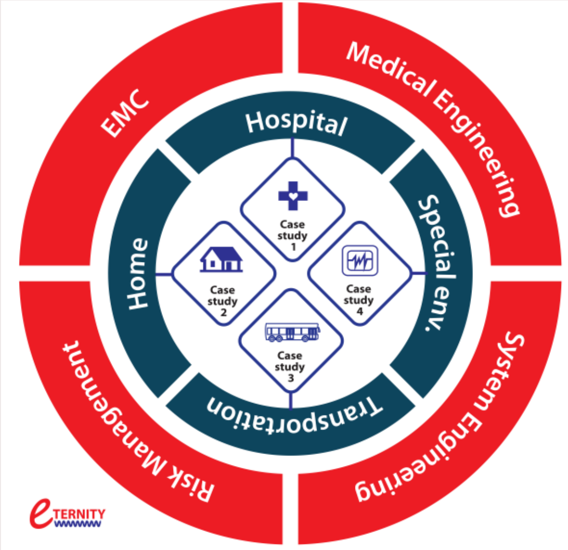
- Standards lagging behind
- High innovation rates
- More complex scenario of use
- More environments
- More wearables and IoT… (wireless communication)

Need for a risk-based approach

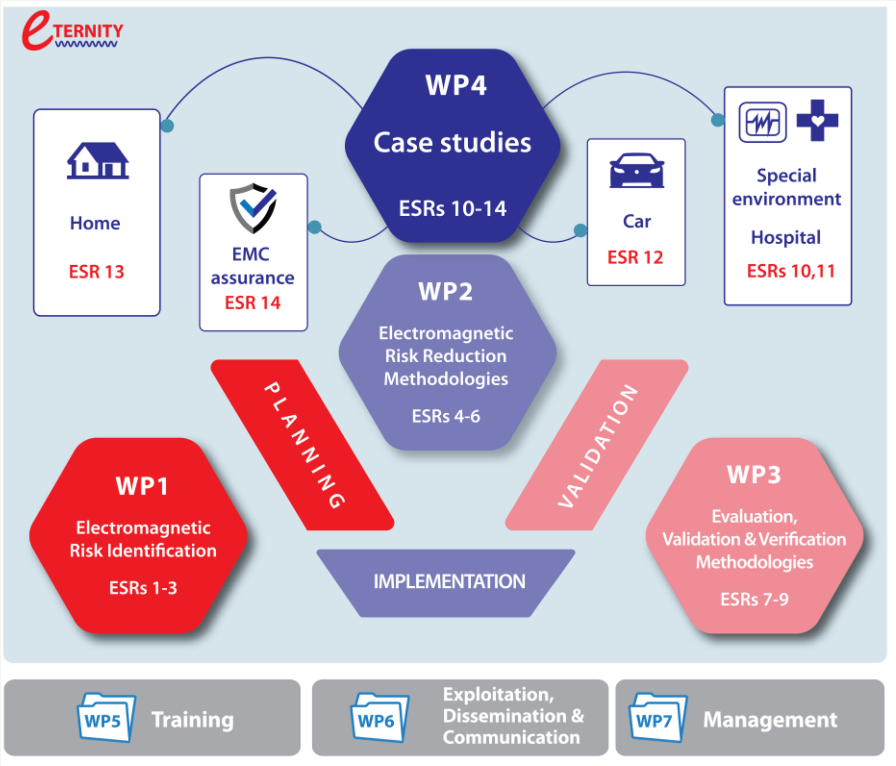
- European law demands it
- Standards lagging technological development
- Need for more flexibility in innovation (focus on (EMI) specific challenges rather than "following strict rules")

ETERNITY Consortium





ETERNITY: Work Package Structure



ETERNITY TU/e

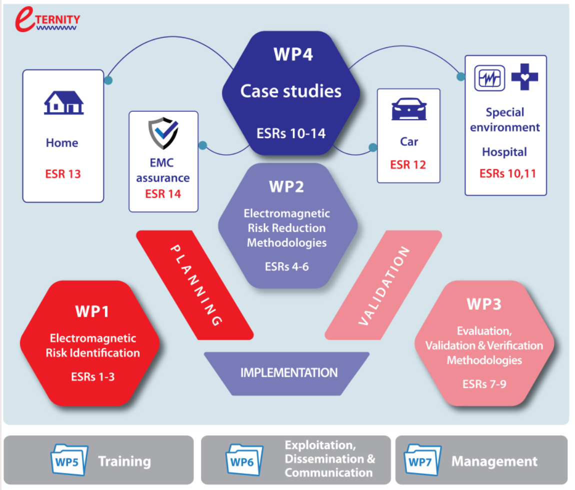
ETERNITY: Early-Stage Researchers

WP1: ElectroMagnetic Risk Identification

ESR1: Marc Kopf
EMI Footprint of Medical Devices
Main supervisor: dr. ir. Anne Roc'h
Eindhoven University of Technology (TU/e) - NL

ESR2: Ukiwo Anya
Characterization of Medical EM environments for new Digital Communication Systems (DCS)
Main supervisor: Prof. Mireya Fernández
UPC - ES

ESR3: Miriam González Atienza
Application of System Thinking and System Safety to EMI Risk Assessment of Medical Applications
Main supervisor: Prof. Davy Pissoort
KU Leuven - Be



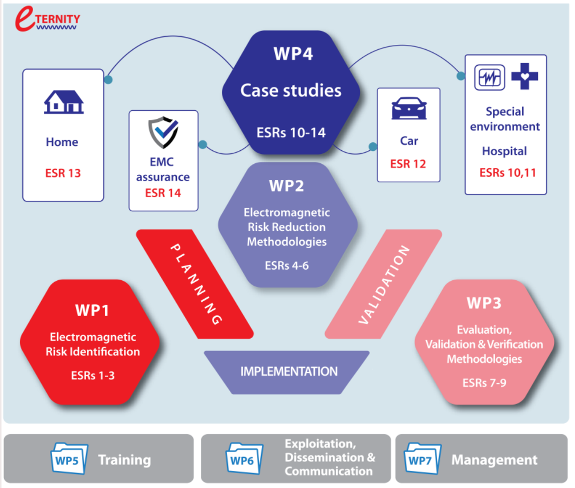
ETERNITY: Early-Stage Researchers

WP2: ElectroMagnetic Risk Reduction Methodologies

ESR4: Ridvan Aba
Risk-Based EMI-Aware Design of Complex System
Main supervisor: Prof. Frank Leferink
University of Twente - NL

ESR5: Asif Ali
Optimal Digital Communication Systems (DCS) in EM noisy Medical Environments
Main supervisor: Prof. Mireya Fernández
UPC – Barcelona - ES

ESR6: Mohammad Kameli
EMI Resilient Sensor and Communication Networks for Complex Medical Systems-of-Systems
Main supervisor: Prof. Davy Pissoort
KU Leuven - BE



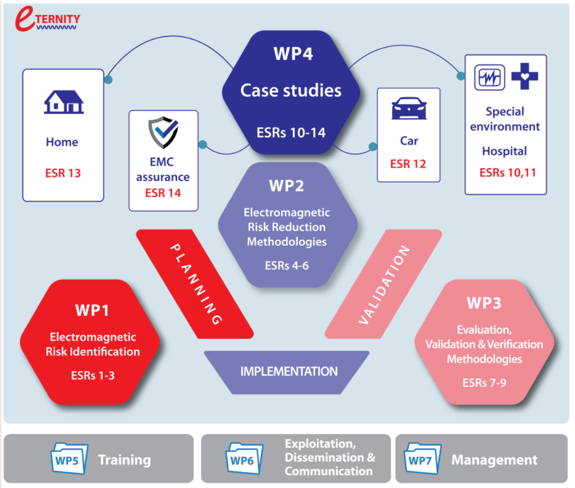
ETERNITY: Early-Stage Researchers

WP3: Evaluation, Validation &Verification Methodologies

ESR7: Sebastian Salas Laurens
Behavioral EMI Risk-based testing of Medical Devices
Main supervisor: dr. ir. Anne Roc'h
Eindhoven University of Technology (TU/e) - NL

ESR8: Nathalia Batista
Improvement of DCS Immunity Tests to Include Complex EM disturbances
Main supervisor: Prof. Ferran Silva
UPC – Barcelona - ES

ESR9: Xinting Xue
Development of EMI Sensors
Main supervisor: Prof. Davy Pissoort
KU Leuven - BE



ETERNITY: Early-Stage Researchers

WP4: Case Studies

ESR10: Simòn Rendòn Vélez
Risk-Management in Collaborative Medical System Development
Main supervisor: dr. ir. Mark van Helvoort
Philips Medical (+ University of Twente) - NL

ESR11: Nandun Senevirathna
Evidence of Quantitative correlation(s) between Different Test Environments
Main supervisor: ir. Rob Kleihorst
Philips Medical (+ TU/e, Eindhoven) - NL

ESR12: Geon George Bastian
EMI from connected, autonomous and electrical vehicles on Driver Monitoring Systems
Main supervisor: Dr. Jordi Vila-Planas
IDNEO (+ UPC – Barcelona) - ES

ESR13: Tiago Nunes
EMI in Medical Device Innovation Process - from design to production
Main supervisor: Hugo Gamboa
PLUX (+ FCT – Lisboa) - PT

ESR14: Vikas Ashok Ghatge
Towards Standardized EMC Assurance Case Patterns for the Certification of Medical Equipment
Main sup.: Prof. Davy Pissoort - KU Leuven - BE

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Thank you for your attention