

# How to really comply with the EMC Directive: from rules-based over risk-based to EM resilience

Prof. D. Pissoot

EMC Seminar: Back 2 Basics

KU Leuven Bruges Campus



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## EU Acknowledgement



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

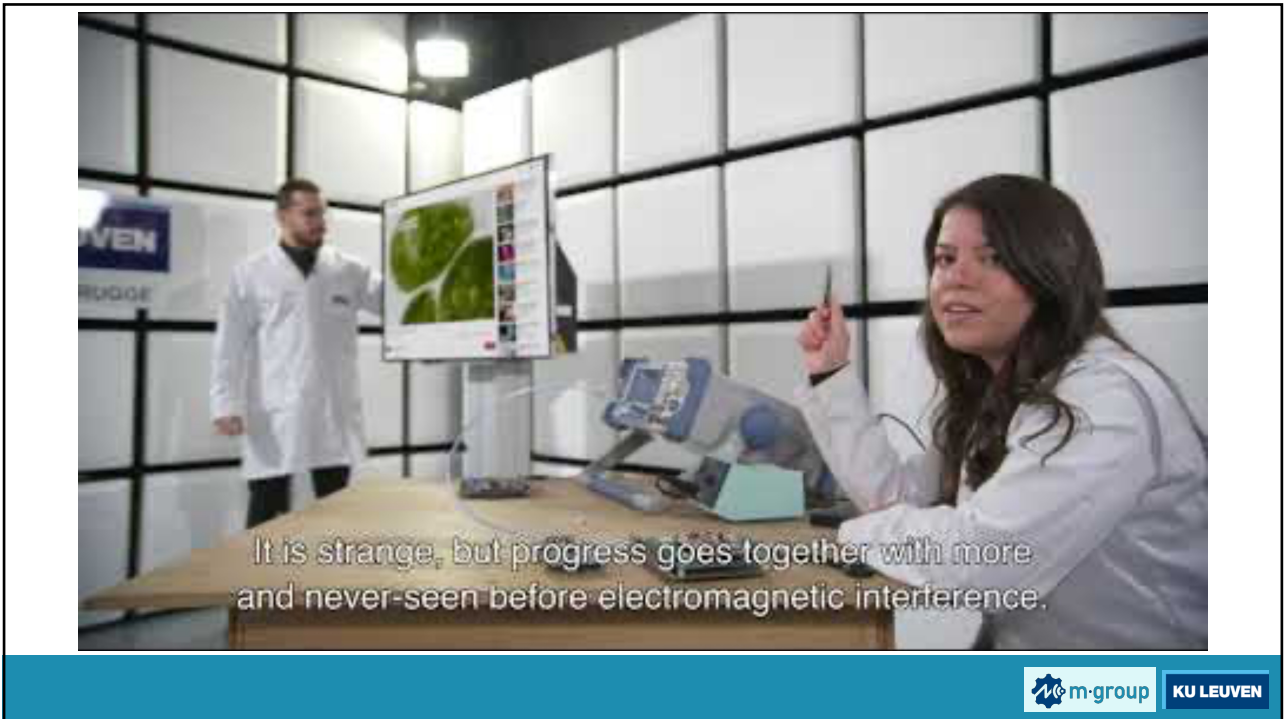
This project has received funding from the European Union's EU Framework Programme for Research and Innovation Horizon 2020 under Grant Agreement **No. 812790**



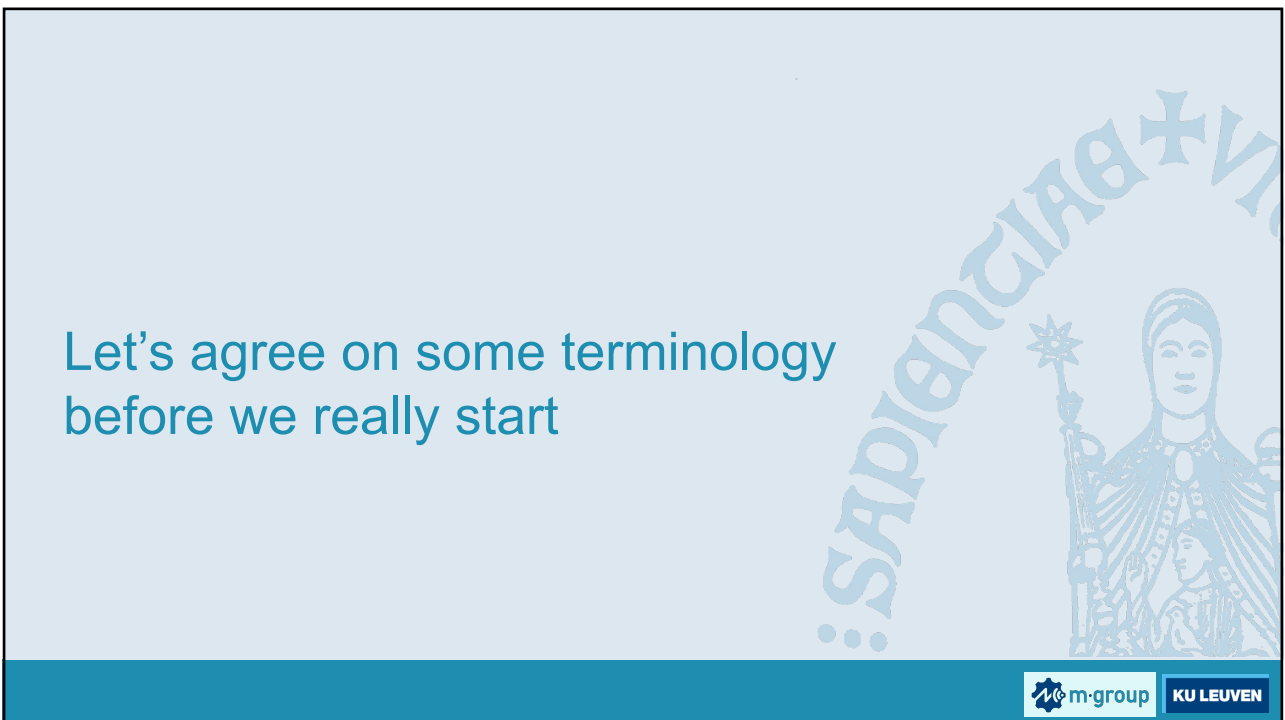
European Training Network on Electromagnetic Risks in Medical Technology

This project has received funding from the European Union's EU Framework Programme for Research and Innovation Horizon 2020 under Grant Agreement **No. 955816**

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Electromagnetic environment =  
totality of electromagnetic phenomena  
existing at a given location

Electromagnetic disturbance =  
electromagnetic phenomenon that can  
degrade the performance of a device,  
equipment or system, or adversely  
affect living or inert matter

Electromagnetic interference =  
degradation in the performance of  
equipment or transmission channel or  
a system caused by an  
electromagnetic disturbance

*“The reason why something happens”*

**Cause**

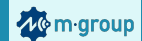
EM Disturbance

EM Interference

**Effect**

*“What happens because of the cause”*

Rules-based EMC approach?



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The “Rules-Based” approach actually relates to

**C E**



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## CE Marking?

- CE marking is a process that applies to a wide variety of products and one which manufacturers located in the EU or importers of goods into the EU must complete
- "CE" originated as an abbreviation of "Conformité Européenne"
- The CE mark is affixed to the product as the final stage of this process and is effectively a statement from the manufacturer (or importer) that the process has been successfully completed and that the product meets the essential requirements of all relevant EU regulations
- The CE marking is a symbol of free marketability in the EEA



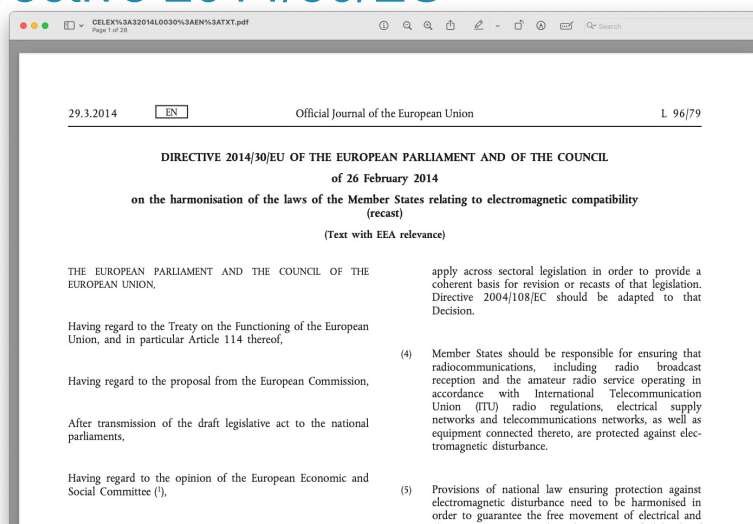
## Global and New Approach

- What is new and global approach in Europe?
  - "New": full responsibility by the manufacturer or legal representative
  - "Global": recognised by all countries from EEA (European Economic Area)
- How to prove conformity with European "rules":
  - Self-declaration
    - Technical documentation (incl. manual)
    - Declaration of Conformity (DoC)
    - CE marking

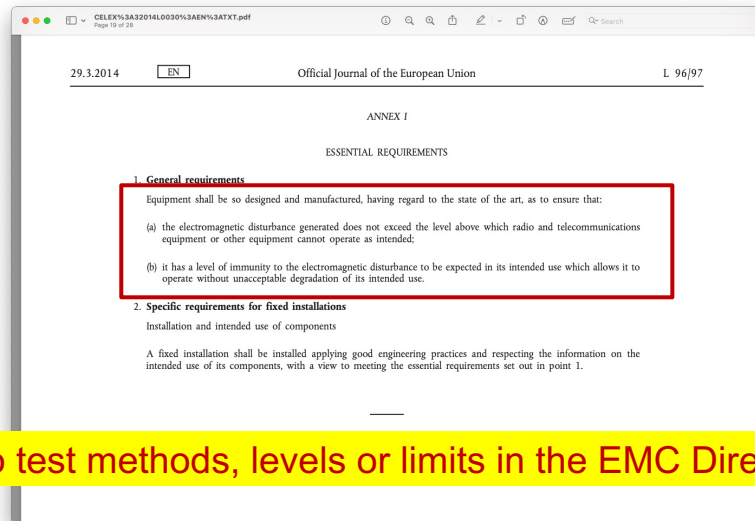
## Directives and Regulations

- It all starts from **Directives** or **Regulations**
  - Have the legal status of a law at European level and are approved by the European Parliament
  - A Directive to be transposed in a national law, a Regulation immediately applies from EU level
  - Typical examples we are dealing with:
    - Medical Device Directive (93/42/EEC) / Medical Device Regulation (2017/745)
    - EMC Directive (2014/30/EU)
    - Radio Equipment Directive (2014/53/EU)
    - Low Voltage Directive (2014/35/EU)
    - Product Liability Directive (1999/34/EC)
- Only describe **essential requirements** that have to be complied with

## EMC Directive 2014/30/EU



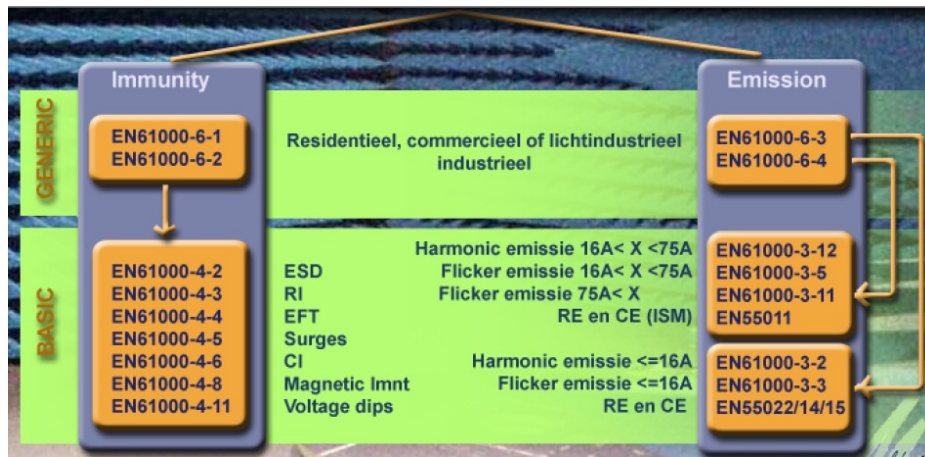
## Essential Requirements in the EMC Directive...



## And what about standards?

- What is a **standard**?
  - Describes limits and/or measurement methods
- What is a **harmonised standard**?
  - They have the technical requirements to comply with the essential requirements of the directive
  - Published in the OJEU
  - To be transposed into National set of standards
  - Give **presumption of conformity**
    - *but what does this actually mean?*

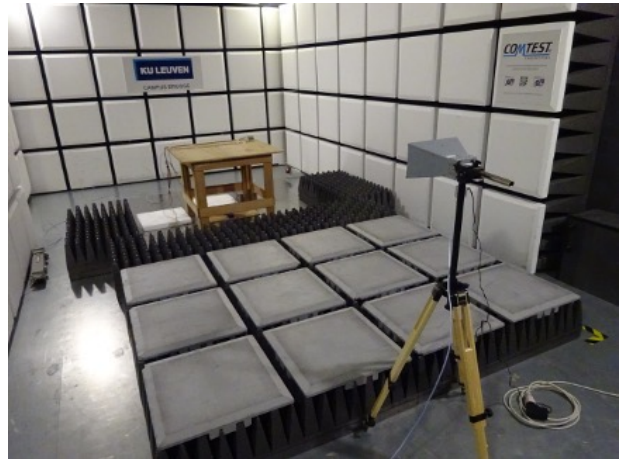
## Some Well-Known EMC Standards



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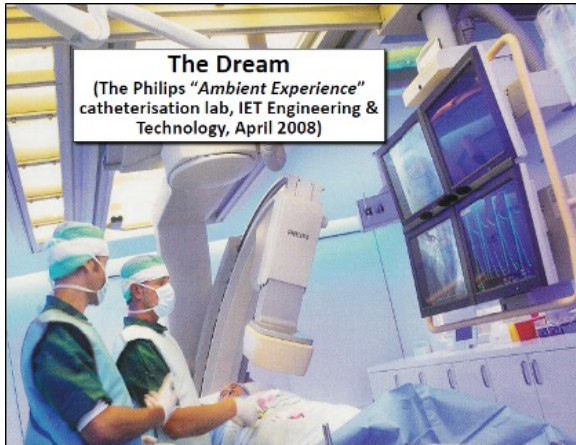
(Harmonized) standards

And a lot of testing...

Does the rules-based approach solve all issues in practice?

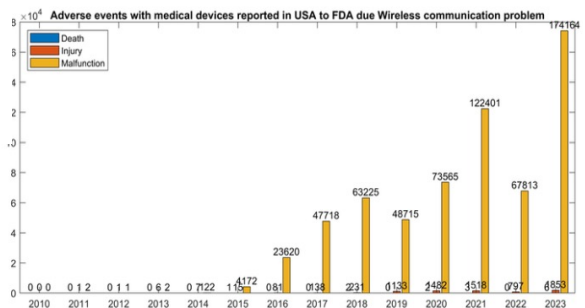
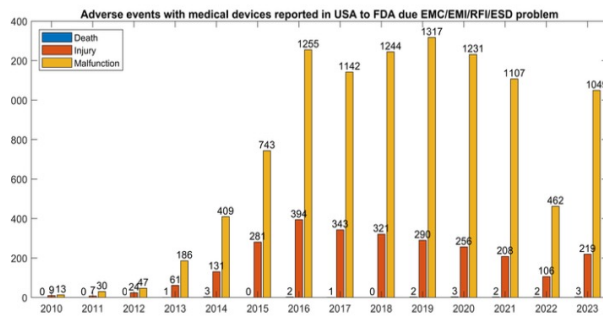


# Dream vs Reality



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# Medical Devices Failures due to EMI



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### Mobileye self-driving car runs red light during public demo

SEAN RYAN/KOWSKI 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.

13 חדשות @news13

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

5.9K views 0:00 / 0:35

9:04 PM · May 17, 2018

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הדרך להיפרד מהנהגים  
לטובת מכוניות עצמאיות עדיין ארוכה

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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

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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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2015 IEEE 5th International Conference on Consumer Electronics Berlin (ICCE-Berlin)

## Electromagnetic Interference: a Radiant Future!

Frank Leférink  
University of Twente, Enschede, The Netherlands, and  
THALES, Hengelo, The Netherlands

**Abstract**—Although Electromagnetic Interference and Electromagnetic Compatibility are well established domains, the introduction of new technologies results in new challenges. Changes in both measurement techniques, and technological trends resulting in new types of interference are described. These are the Smart Grid and conducted interference, generally below 150 kHz, while the use of the radio spectrum pose challenges at high frequencies.

### I. INTRODUCTION

Electromagnetic interference (EMI) was a subject for specialist only, and large industries employed EMI specialists, or hired EMI consultants, to make sure that equipment fulfilled contractual or legal EMC (electromagnetic compatibility) requirements. Most activities were often carried out by older experienced engineers during the testing phase. If equipment failed during the EMC test costly retrofits or redesigns, causing delay in time-to-market, were needed. This post-design approach is changing rapidly, supported by many young engineers educated at universities where EMC is a mandatory part in the curriculum. Post-design analysis and testing is changing towards concurrent EMC analysis and design, using modern EMI modelling and simulation tools and new test techniques.

Will this solve all EMI issues? No. Every introduction of a new technology will bring novel EMI challenges. For example, the use of mobile phones in cars with air bag systems caused exploding airbags. Pacemakers should not be near to strong electromagnetic fields. Power line telecommunication is causing electronic light switches to operate at most strange moments day and night, 4G mobile base stations are interfering

whole volume of the chamber. An object will be illuminated with the same amount of energy from every direction, or reverse, any energy emitted by an object from whatever angle, will be measured. This is much faster, and better reproducible than tests in a semi-anechoic chamber.

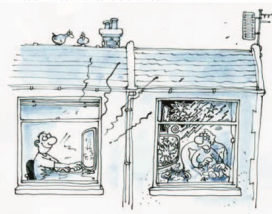


Fig. 1: Classic interference case, from neighbor to your aerial [1]. Cartoon by Rupert Bealey


Another major step forward is the use of time-domain EMI meters, or so-called real-time spectrum analysers. By sampling a large part of the frequency band at once using fast fourier transform processors, the measurement time for EMI measurements is reduced drastically.

A third innovation is near-field scanning. By using highly sensitive electric and magnetic field sensors combined with

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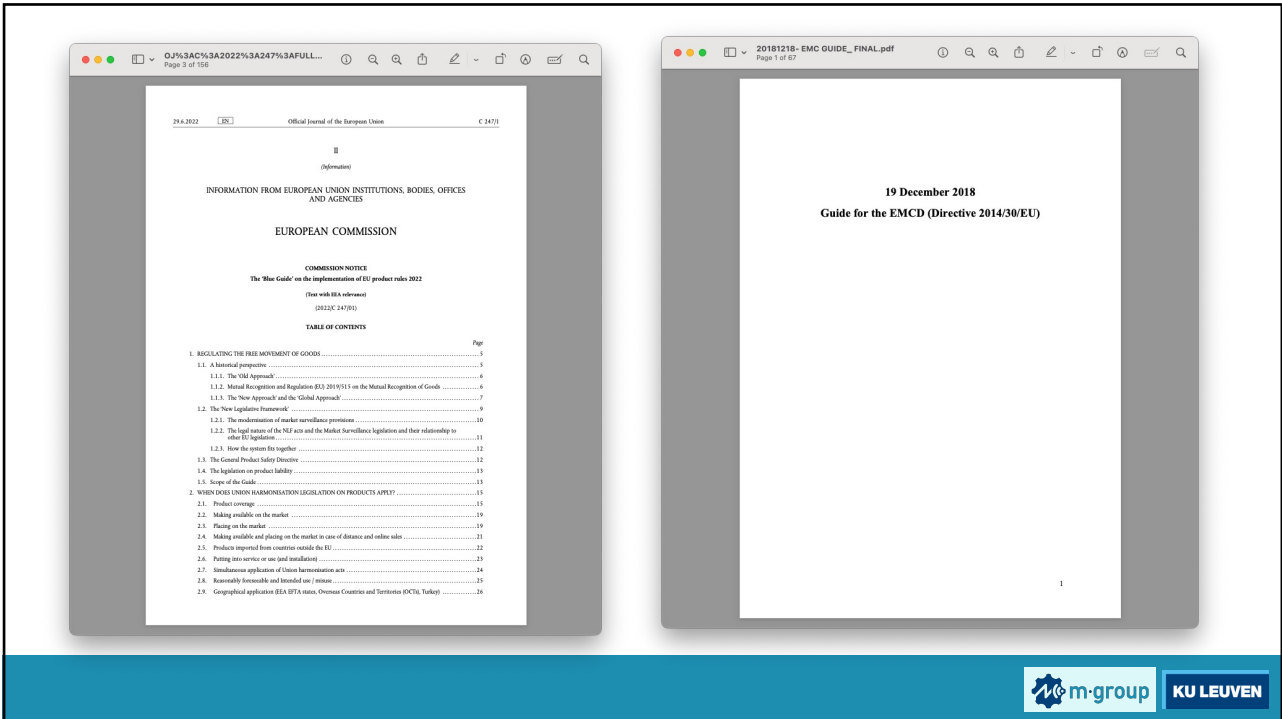
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# Risk-based EMC approach?

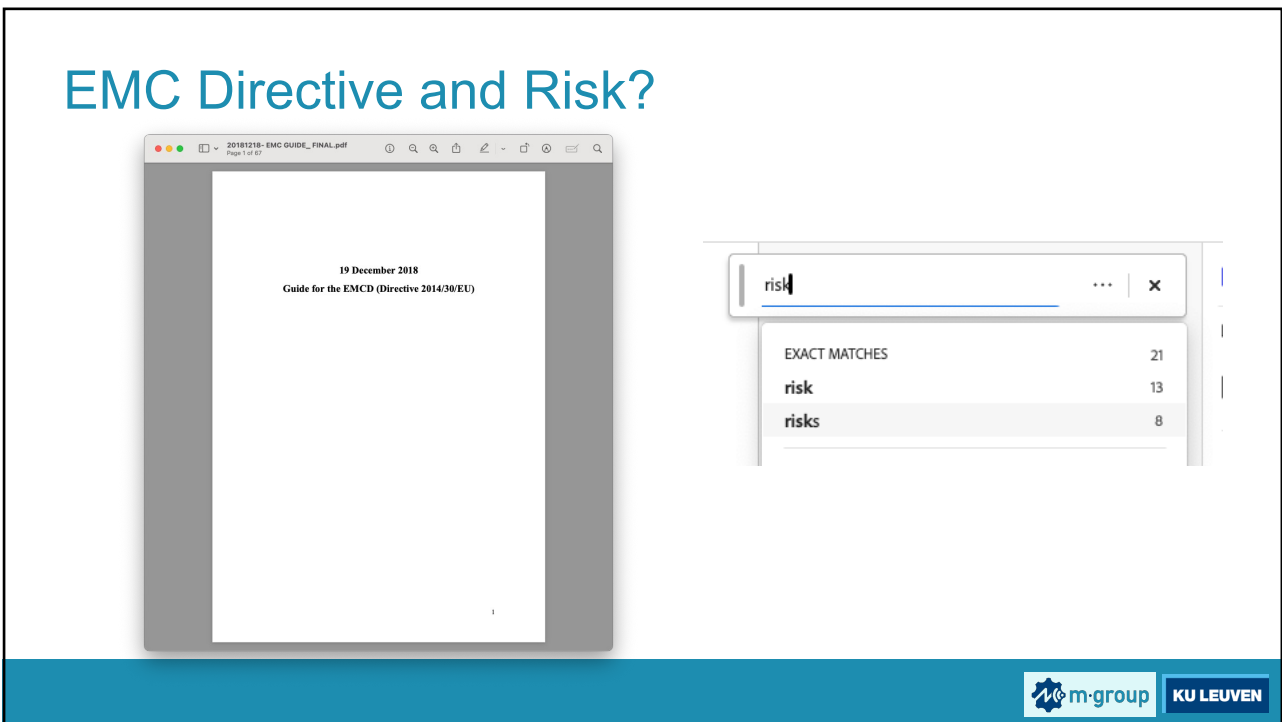


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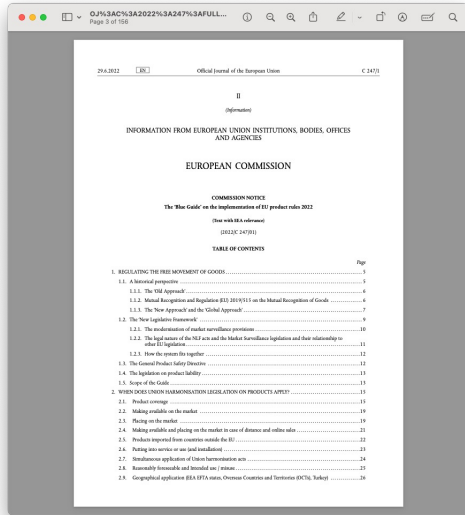


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# EMC Directive and Risk?



## 4.2 Risk analyses and risk assessment

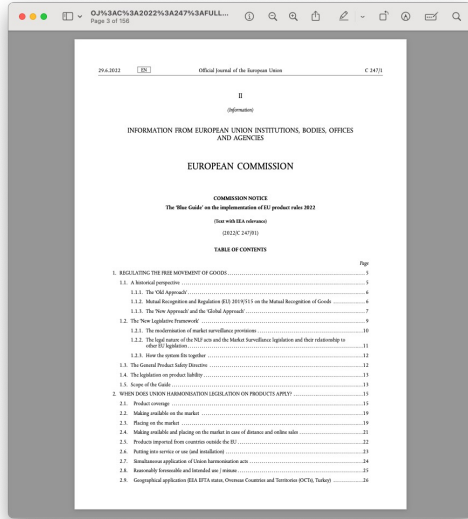
The conformity assessment procedures for apparatus require the manufacturer to establish technical documentation. This documentation shall make it possible to assess the conformity of the apparatus to the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). In 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".

# EMC Directive and Risk?

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# Are harmonized standards sufficient?

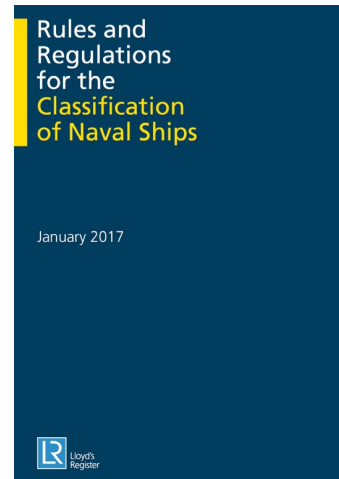


Harmonised standards never replace legally binding essential requirements. A technical specification given in a harmonised standard is not an alternative to a relevant essential or other legal requirement but only a possible technical means to comply with it. In risk related harmonisation legislation this means in particular that manufacturers always, even when using harmonised standards the references of which are published in the OJEU, remain fully responsible for assessing all the risks of their product in order to determine which essential (or other) requirements are relevant. After this assessment a manufacturer may then choose to apply technical specifications given in harmonised standards the references of which are published in the OJEU to implement 'risk reduction measures' (189) which are specified by harmonised standards. In risk related harmonisation legislation harmonised standards the references of which are published in the OJEU most commonly provide certain means to reduce or remove risks while manufacturers remain fully responsible for risk assessment to identify relevant risks and to identify relevant essential requirements in order to select suitable harmonised standards the references of which are published in the OJEU or other specifications.

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## So, we need a risk-based EMC approach!



## Risk-Based Approach

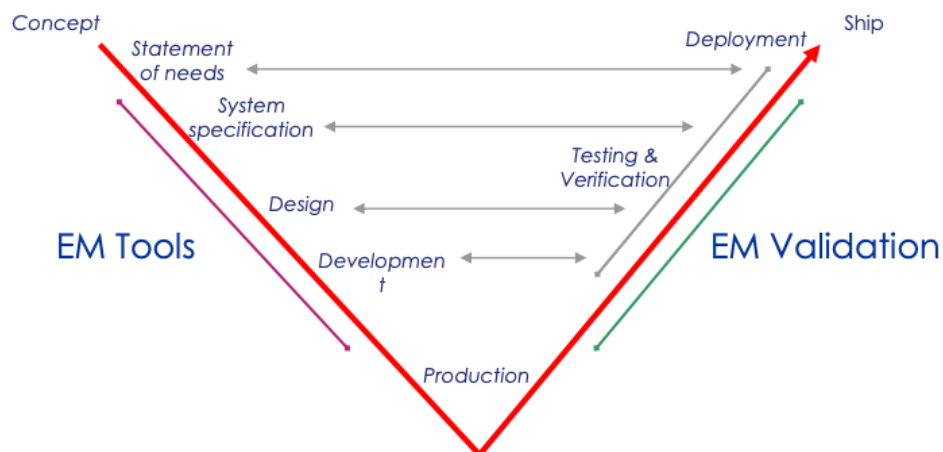
- Follows a thorough **systems-engineering approach**
- Assessment of:
  - the expected actual EM environment
  - immunity and emission characteristics of equipment
- Then: Implement necessary measures (incl. non-technical)
- Some parts/equipment will be hardened more, some others less compared to the “rule-based EMC-approach”

# Risk-Based Approach

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



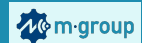
# Risk-Based Approach



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.



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Does the risk-based approach solve all issues in practice?



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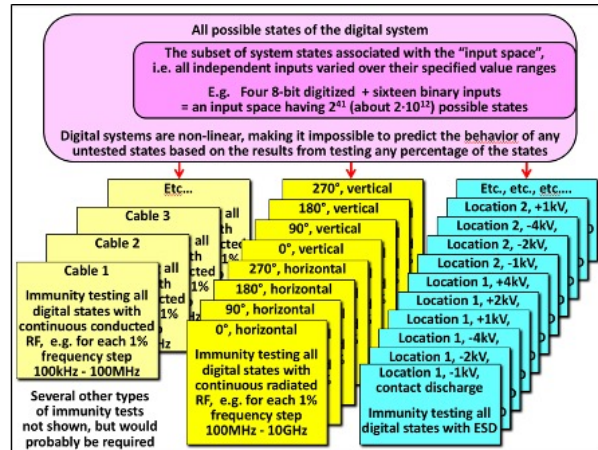
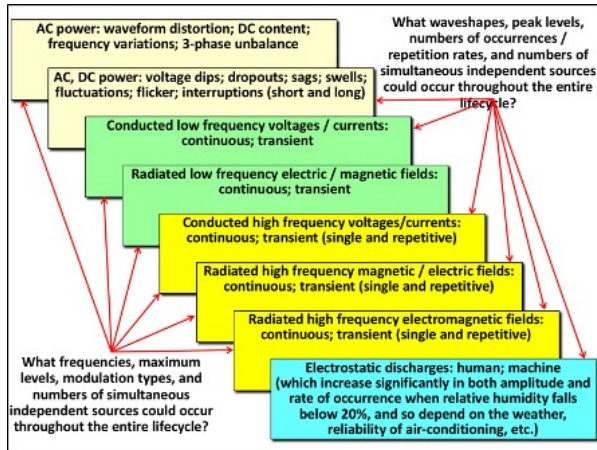
## Risk-based approach

- Follows a thorough **systems-engineering approach**
  - Assessment of:
    - the expected actual EM environment
    - immunity and emission characteristics of equipment
  - Then: implement necessary measures (incl. non-technical)
  - Some parts/equipment will be hardened more, some others less compared to the “rule-based EMC-approach”
- This is the “weak” point**

## An Uncertain Future...

- As Niels Bohr once said: *“Prediction is very difficult, especially if it’s about the future”*
- We simply do not know what new technologies will be introduced within the next decade
- All we do know is that they will generate multitude forms of EMI, both radiated and conducted, quasi-continuous as well as transient

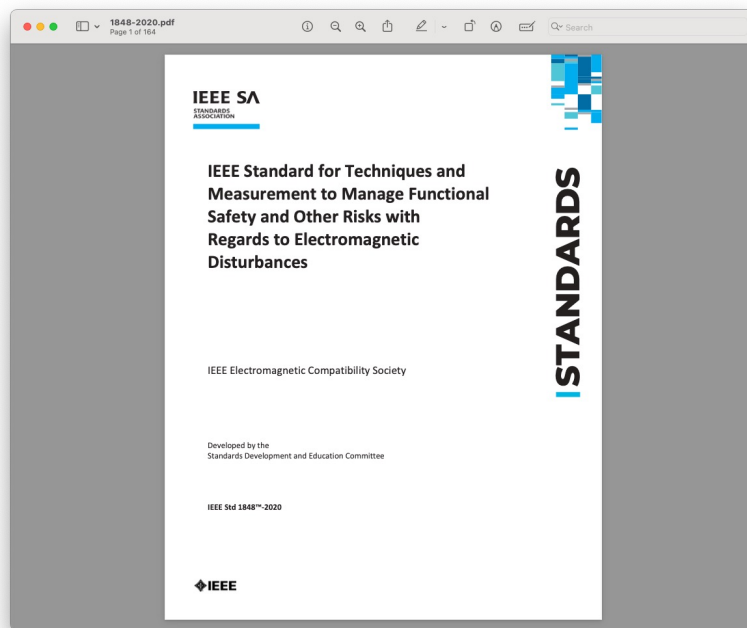
# The exploding testplan...



# Electromagnetic resilience?



## IEEE 1848



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## 1. Overview

This IEEE Standard provides guidance on the assessment and application of techniques and measures that can reduce the risks associated with the interfering effects of electromagnetic disturbances on digital electronic systems, especially safety- or mission-related systems.

When competently selected and applied, a set of such techniques and measures can provide the part of the evidence relevant to EMI required for justifying functional safety decisions and for compliance with functional safety standards (including all applicable parts of IEC 61508 Ed.2:2010 or functional safety standards that are based on IEC 61508; see the partial list in Annex C).

They can also provide part of the evidence relevant to EMI for medical/healthcare systems for which risks are managed in accordance with ISO 14971:2007 [B11].<sup>2</sup>

This standard supports the adoption of adequate electromagnetic resilience engineering practices throughout the functional safety lifecycle by offering further guidance and practical advice on the application of risk management activities, including the techniques and measures set out in IEC 61000-1-2:2016.

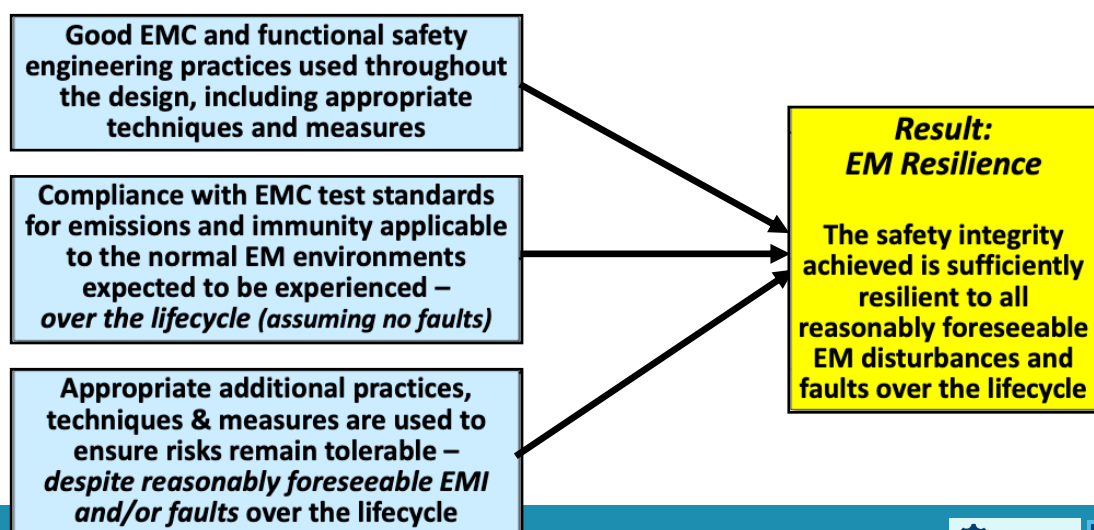
While it is primarily intended to be used by those who have responsibilities for functional safety, the methodologies, techniques, and measures it describes can also be used for the reduction of other kinds of risks in any systems that employ electronic technology, such as security risks and non-safety-related risks (for example, risks to the operation of commercial IT systems). However, this standard does not address the risks to human health that can be caused by electromagnetic fields (EMF); HERF (Hazards of Electromagnetic Radiation to Fuel); or HERO (Hazards of Electromagnetic Radiation to Ordnance).

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“A system is resilient if it can adjust its functioning prior to, during, or following events (changes, disturbances, and opportunities), and thereby sustain required operations under both expected and unexpected conditions.”

–Erik Hollnagel, author of the book “Resilience Engineering”

## IEEE 1848's EM Resilience Approach



## Think of EM Resilience like this

- Application of Risk-Based EMC ensures (in a cost-effective way) that most EM disturbances don't cause actual EMI
- But extreme, unusual, unforeseen EM disturbances and/or degradations in EM mitigations mean that EMI can still occur during the full lifetime
- EM Resilience means additional techniques & measures to:
  - Detect EMI-induced errors, malfunctions, or faults in signals, data, control,...
  - Correct these errors so that operation continues safely-enough, perhaps with some functional degradation
  - Or switch the system into a safe / minimum risk state

So for me...



Risk-Based EMC

EM Resilience



Table 1—Checklist of electromagnetic resilience techniques and measures (continued)

Overview of the electromagnetic resilience techniques and measures applied to the Safety Function: .....		Importance (see 4.7)				Ref's in this Standard	How applied for this Safety Function? Add all relevant document links, comments, references, etc.
		SIL1	SIL2	SIL3	SIL4		
<b>Time-based error detection/correction in buses and interfaces to detect transient failures</b> Combine with error checking codes to protect the sequence numbers or time codes.		R	R	HR	HR	A.3.12 A.3.11 & A.3.13	
<b>Error detection and error correction for variable memory (e.g. RAM).</b> Detecting failures during addressing, writing, storing and reading data in memory.	<b>Memory testing</b> Before and/or during operation to detect memory-system-specific errors.	R	R	HR	HR	A.3.13.1	
	<b>One-bit redundancy</b> To detect some changes in the content of a memory location, bus or I/O register.	R	R	R	R	A.3.13.2	
	Block replication with inversion to detect all bit failures Using diverse types of memory can improve the effectiveness of this technique.	HR	HR	HR	HR	A.3.13.3 A.3.3	
	Memory boundary protection	R	R	HR	HR	A.3.13.4	
<b>Error detection/correction in ROM, RAM, buses and interfaces</b> Detects/corrects one or more bit failures in a word.		R	R	HR	HR	A.3.14	
<b>Error detection for logic and data processing units</b>	<b>Self-test supported by hardware</b> (one-channel)	HR	HR	HR	HR	A.3.15.1	
	<b>Coded processing</b> (one-channel)	R	R	R	R	A.3.15.2	
	<b>Reciprocal comparison by software</b> Two or more electromagnetically diverse processing units exchange data (results, intermediate results, and test data) and cross-check at defined 'restore points' from which system operation could be continued in the event of a fault.	HR	HR	HR	HR	A.3.15.3	
	<b>Self-test by software during operation</b>	R	R	HR	HR	A.3.15.4	

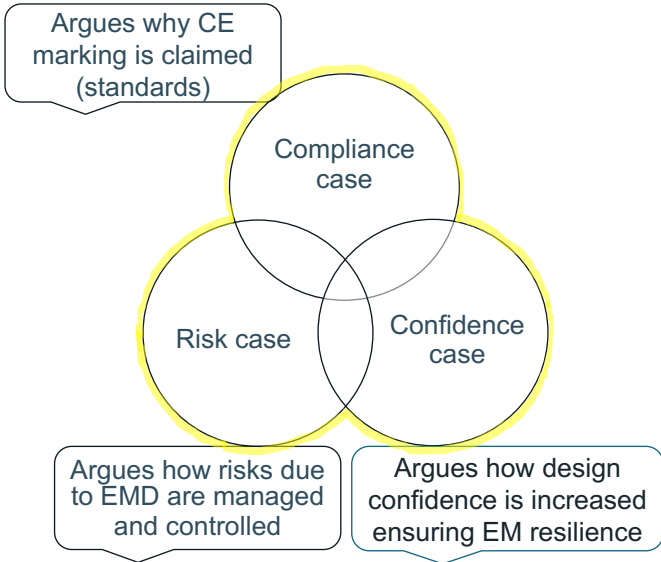
## Example: Diverse Redundancy

- A commonly used technique in a safety-related system is hardware redundancy
- This means using different parallel channels to send the same data or perform the same operation
- At the end, a majority voter will decide on the final outcome
- However, EMI will likely affect all redundant channels in the same way and, hence, the majority voter will make the “wrong” decision
- So, we need electromagnetically diverse redundant systems...

# Summary



## Unified EMC assurance case



Thank you!  
Comments or Questions?



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