



Risk Assessments –
as required by the EMC and
Radio Equipment Directives

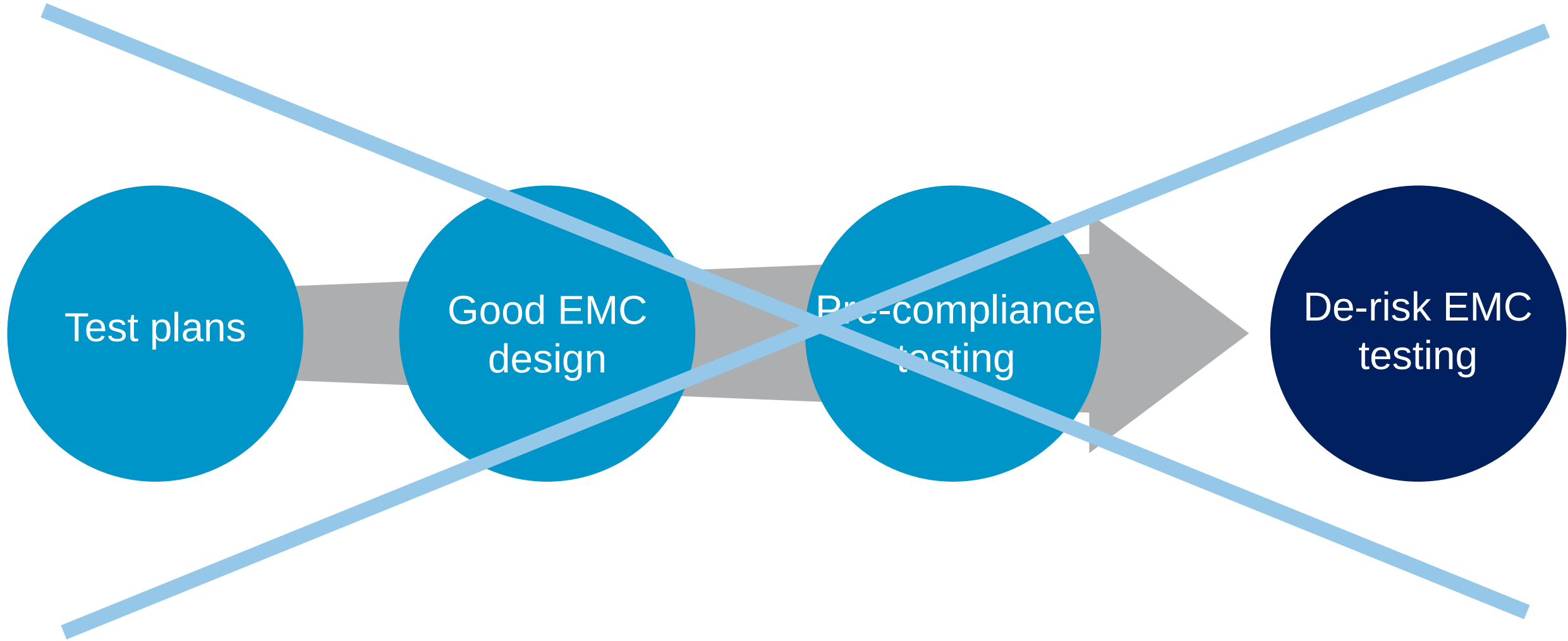
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Element Materials Technology

Agenda

- 
- Why current legislation requires Risk Assessments
 - Standards, Directives, and where risk lies
 - How to identify essential requirements
 - Examples of risks for EMC and Radio Risk Assessments
 - When to begin your Risk Assessment
 - 5 Steps of Risk Assessment
 - Examples of documentation

Reducing risk



Risk Assessment is now a mandatory requirement

NLF introduced concept of Risk

DECISION No 768/2008/EC

‘The documentation shall make it possible to assess the product's conformity to the relevant requirements, and shall include an adequate analysis and assessment of the risk(s)’

Analysis and assessment of risk in the technical documentation

L 96/98	EN	Official Journal of the European Union	29.3.2014
ANNEX II			
MODULE A: INTERNAL PRODUCTION CONTROL			
1. Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3, 4 and 5 of this Annex, and ensures and declares on his sole responsibility that the apparatus concerned satisfy the requirements of this Directive that apply to it.			
2. Electromagnetic compatibility assessment The manufacturer shall perform an electromagnetic compatibility assessment of the apparatus, on the basis of the relevant phenomena, with a view to meeting the essential requirements set out in point 1 of Annex I. The electromagnetic compatibility assessment shall take into account all normal intended operating conditions. Where the apparatus is capable of taking different configurations, the electromagnetic compatibility assessment shall confirm whether the apparatus meets the essential requirements set out in point 1 of Annex I in all the possible configurations identified by the manufacturer as representative of its intended use.			
3. Technical documentation The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the apparatus conformity to the relevant requirements, and shall include an adequate analysis and assessment of the risk(s).			

22.5.2014	EN	Official Journal of the European Union	L 153/97
ANNEX III			
CONFORMITY ASSESSMENT MODULES B AND C			
EU-TYPE EXAMINATION AND CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL			
When reference is made to this Annex, the conformity assessment procedure shall follow Modules B (EU-type examination) and C (Conformity to type based on internal production control) of this Annex.			
Module B			
EU-type examination			
1. EU-type examination is the part of a conformity assessment procedure in which a notified body examines the technical design of the radio equipment and verifies and attests that the technical design of the radio equipment meets the essential requirements set out in Article 3.			
2. EU-type examination shall be carried out by assessment of the adequacy of the technical design of the radio equipment through examination of the technical documentation and supporting evidence referred to in point 3, without examination of a specimen (design type).			
3. The manufacturer shall lodge an application for EU-type examination with a single notified body of his choice. The application shall include: (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well; (b) a written declaration that the same application has not been lodged with any other notified body; (c) the technical documentation. The technical documentation shall make it possible to assess the radio equipment's conformity with the applicable requirements of this Directive and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the radio equipment. The technical documentation shall contain, wherever applicable, the elements set out in Annex V;			

**The [technical] documentation shall....
include an adequate analysis and
assessment of the risk(s)**

Why has 'risk' been introduced into CE Marking?



BBC Your account News Sport Weather Shop Earth Travel M

NEWS

Home Video World US & Canada **UK** Business Tech Science Magazine En

UK England N. Ireland Scotland Wales Politics

Ministers 'must act on faulty white goods fire risk'

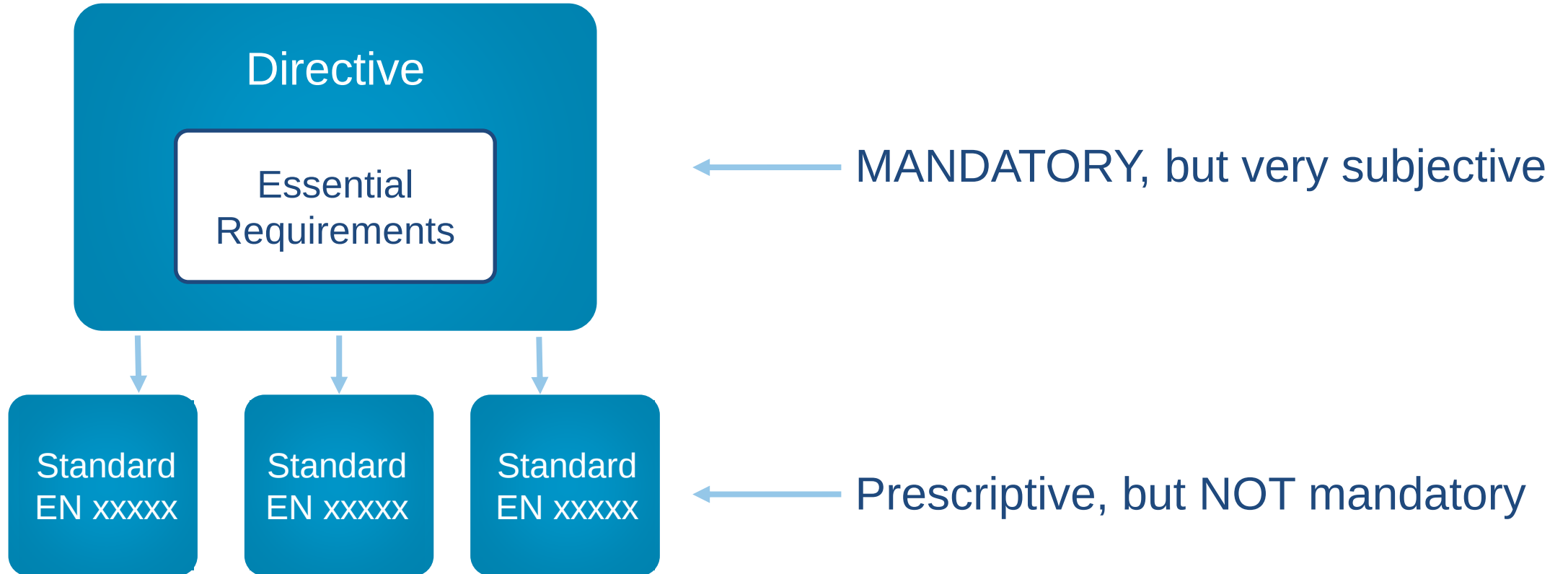
21 August 2017 | UK

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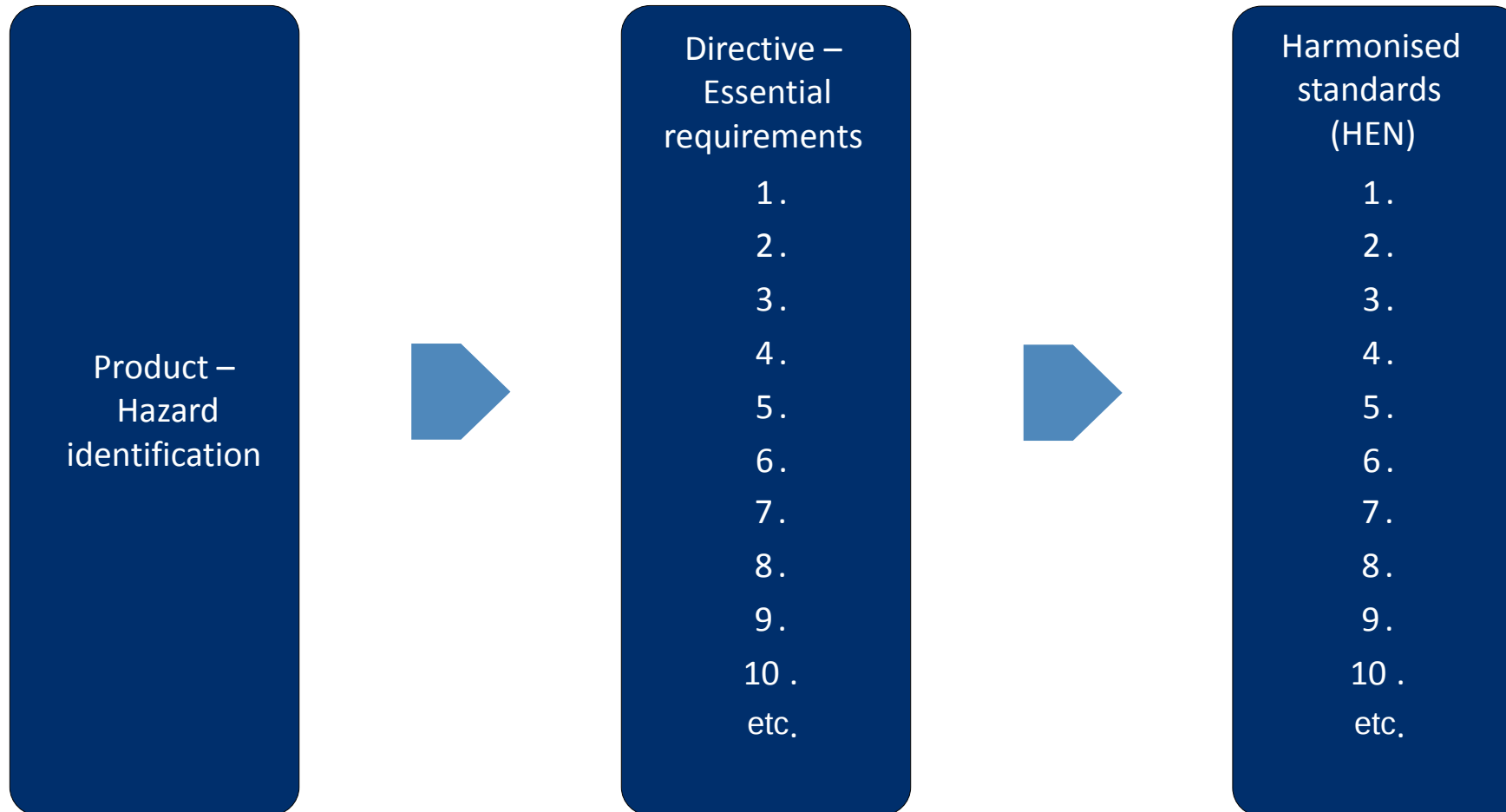


More people will die from fires started by faulty white goods if ministers do not act to implement recommendations, the London Fire Brigade, the city's mayor, and safety groups have warned.

Directives vs Standards



Relationship between Standards and Directives



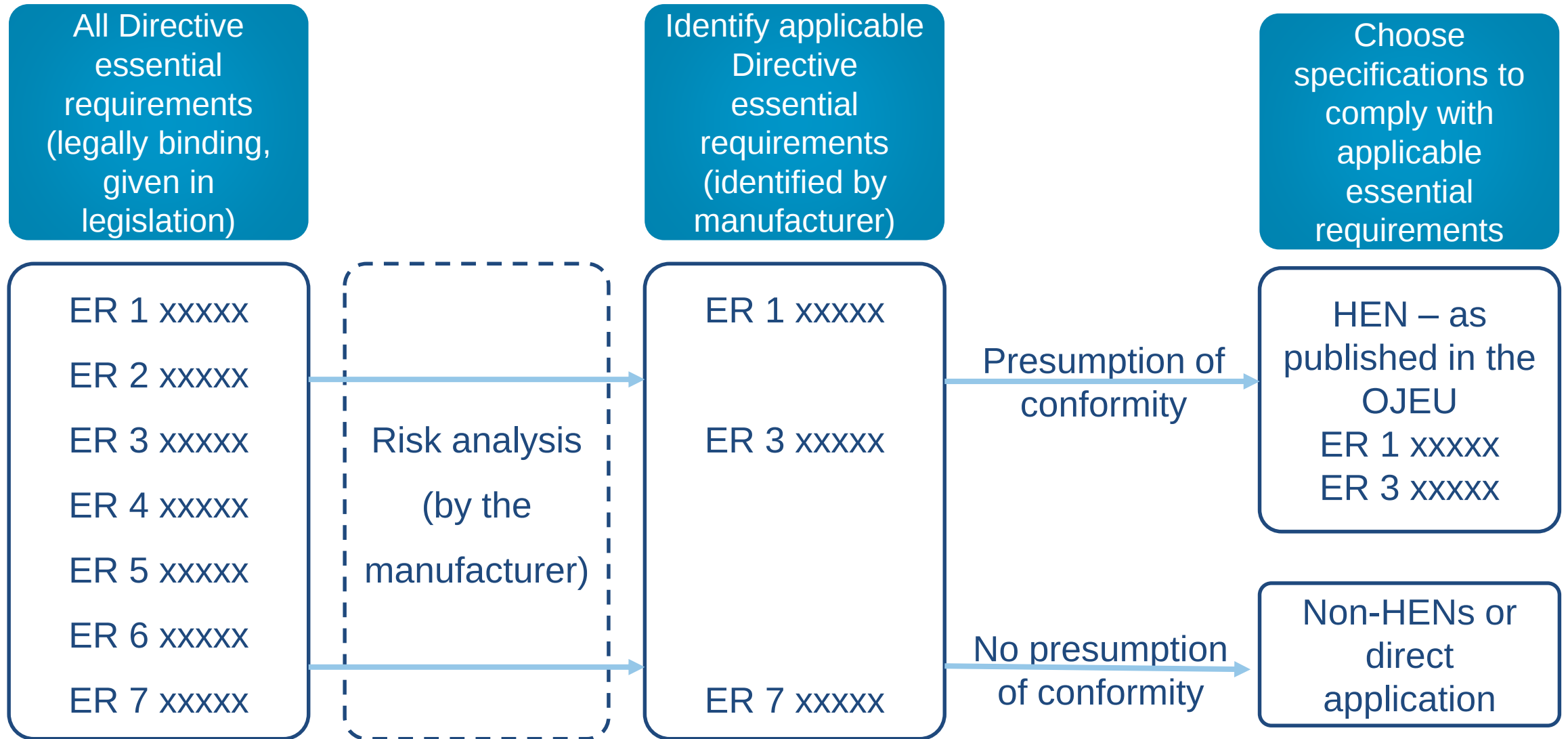
Guidance from the Blue Guide – Essential requirements

Essential requirements must be applied as a function of the hazard inherent to a given product.

Therefore, manufacturers have to carry out a risk analysis to first identify all possible risks that the product may pose and determine the essential requirements applicable to the product.

This analysis has to be documented and included in the technical documentation.

Identifying relevant essential requirements and specifications



Essential requirements addressed in Standards Annex ZZ/ZA

Essential requirements of Directive 2014/30/EU	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
Annex I. 1(a) – (electromagnetic disturbances)	4 Limits of disturbances.	Only with regard to electromagnetic disturbances from 30 MHz to 1 GHz. All requirements apply.
	6.3 Evaluation (general)	Presumption of conformity is not conferred using statistical analysis.
Annex I. 1(b) – (electromagnetic immunity)	5 Immunity requirements Table 1 – Immunity requirements	

An annex in each harmonised standard identifies which essential requirements are met by each clause

Blue Guide - relationship between Standards and Directives

Harmonised standards never replace legally binding essential requirements. A harmonised standard is not an alternative to a relevant essential requirement but only a possible technical means to comply with it.

Thus...a manufacturer always remains fully responsible for assessing all the risks of his product in order to determine which essential requirements are applicable – even when using harmonised standards.

After this assessment, a manufacturer may then choose to apply specifications given in harmonised standards to implement ‘risk reduction measures’ which are specified by harmonised standards (or other specifications)

Using harmonised standards – do I still need a Risk Assessment?

Even where the manufacturer uses a Harmonised Standard (where published in the OJEU) to satisfy essential requirements, **the Risk Assessment has to be carried out** and he must check whether the Harmonised Standard covers all risks of the product.

Because...it cannot be assumed that...the product in question [does not] introduce other risks not considered in the Harmonised Standard.

In addition, the manufacturer needs to document the assessment of how he is addressing the risks identified...

Example: Is risk fully considered by the EMC Standards?

Risk is incorporated into Standards when they are written

– really?

Example: Is risk fully considered by the EMC Standards?

**For equipment in series production, there shall be 80 % confidence that at least 80 % of manufactured items comply with the limits given
– unlawful?**

...equipment is made available on the market and/or put into service only if it complies with this Directive...

**The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured apparatus with the technical documentation...
and with the essential requirements**

Notified Bodies cannot ignore gaps in standards

**Notified Bodies are aware of the current situation for EMC performance
below 150 kHz and above 1 GHz**

**NBs cannot ignore gaps in standards –
they will need evidence that the risk assessment has been adequately performed**

For EMC performance above 1GHz, RED standards can be helpful –
e.g. Immunity limits up to 6 GHz from EN 301 489-1

This standards shortfall is relevant for most products, particularly due to 5 GHz WiFi apparatus
being commonly encountered in many operating environments (up to 40 GHz is being considered)

Some standards available under the EMC directive 2014/30/EU do have limits
and test levels available above 1 GHz, up to 6 GHz, or even 18 GHz
(e.g. EN 55032, EN 55035, EN 55011, IEC 61000-6-X series).

3 types of CE Directive

SAFETY

Low Voltage

Machinery

ATEX

PERFORMANCE

EMC

Measuring
Instruments

ENVIRONMENTAL

ErP

RoSH

No guidance on Risk for EMC and Radio - yet

SAFETY

CENELEC
Guide 32:2014

EN ISO
14971:2012

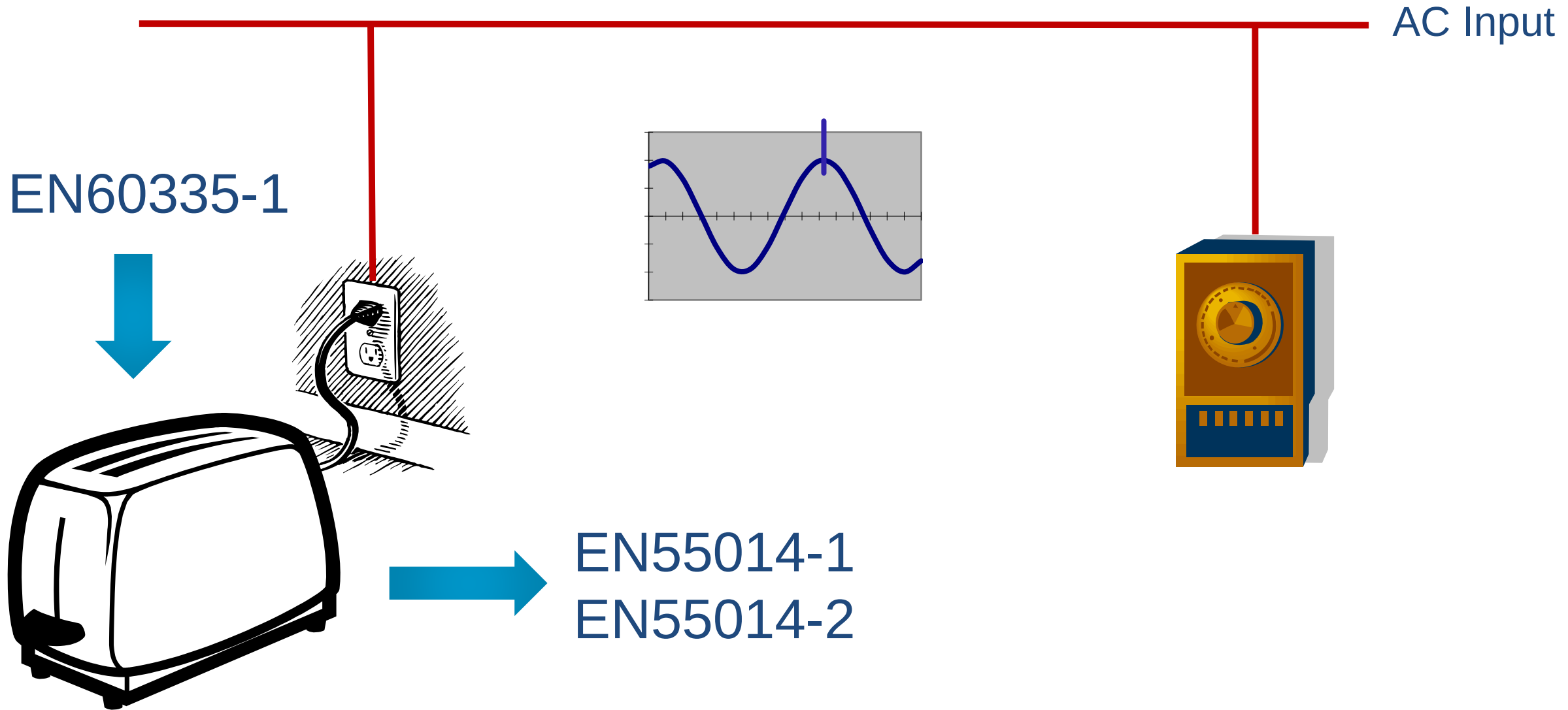
EN ISO
12100:2010

PERFORMANCE

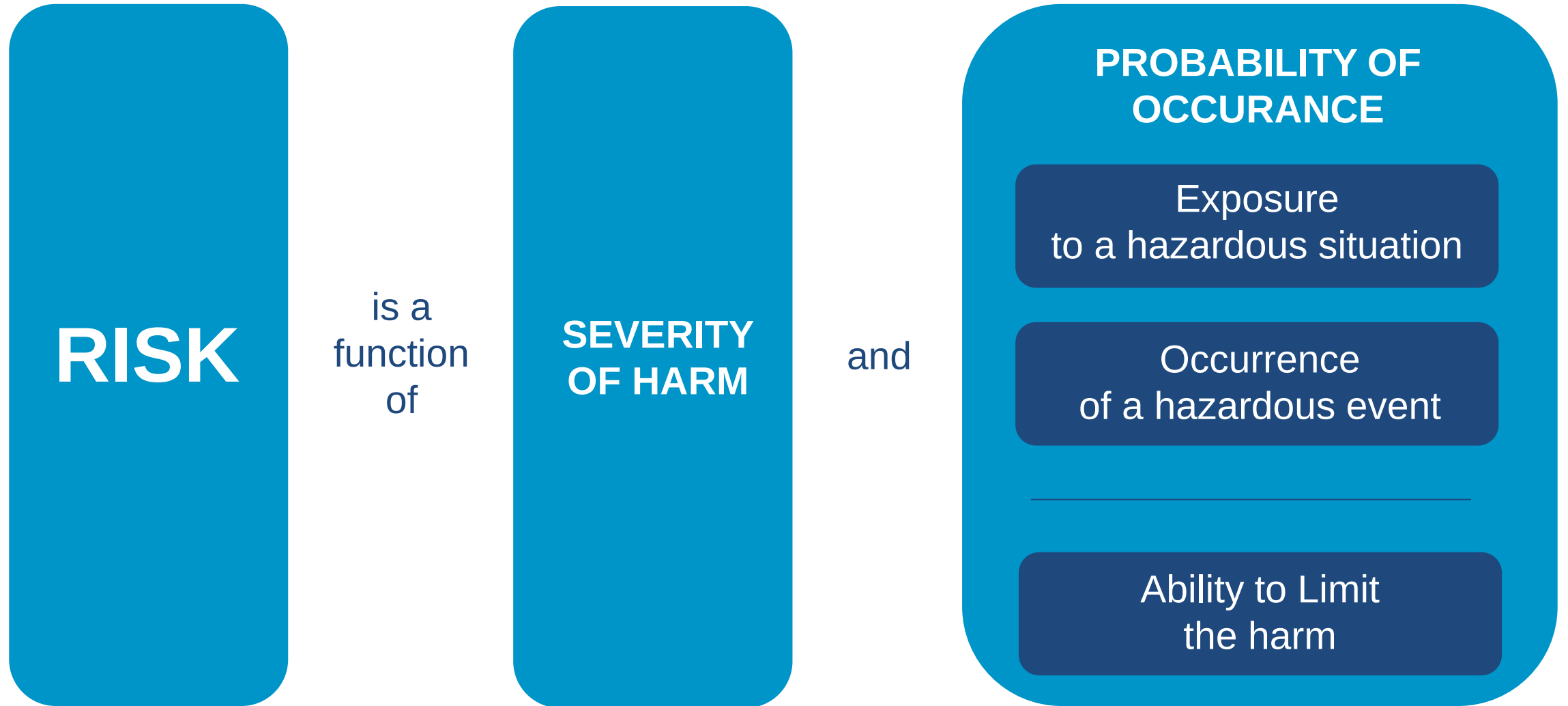
EMC
Draft TGN 17(017)

Radio
?

Example 1 – EMC requirements in a safety standard



What is risk in regards to safety?



What is risk in regards to EMC?

RISK

is a
function
of

**SEVERITY
OF
NON-
COMPLIANCE**

and

**PROBABILITY
OF
OCCURANCE**

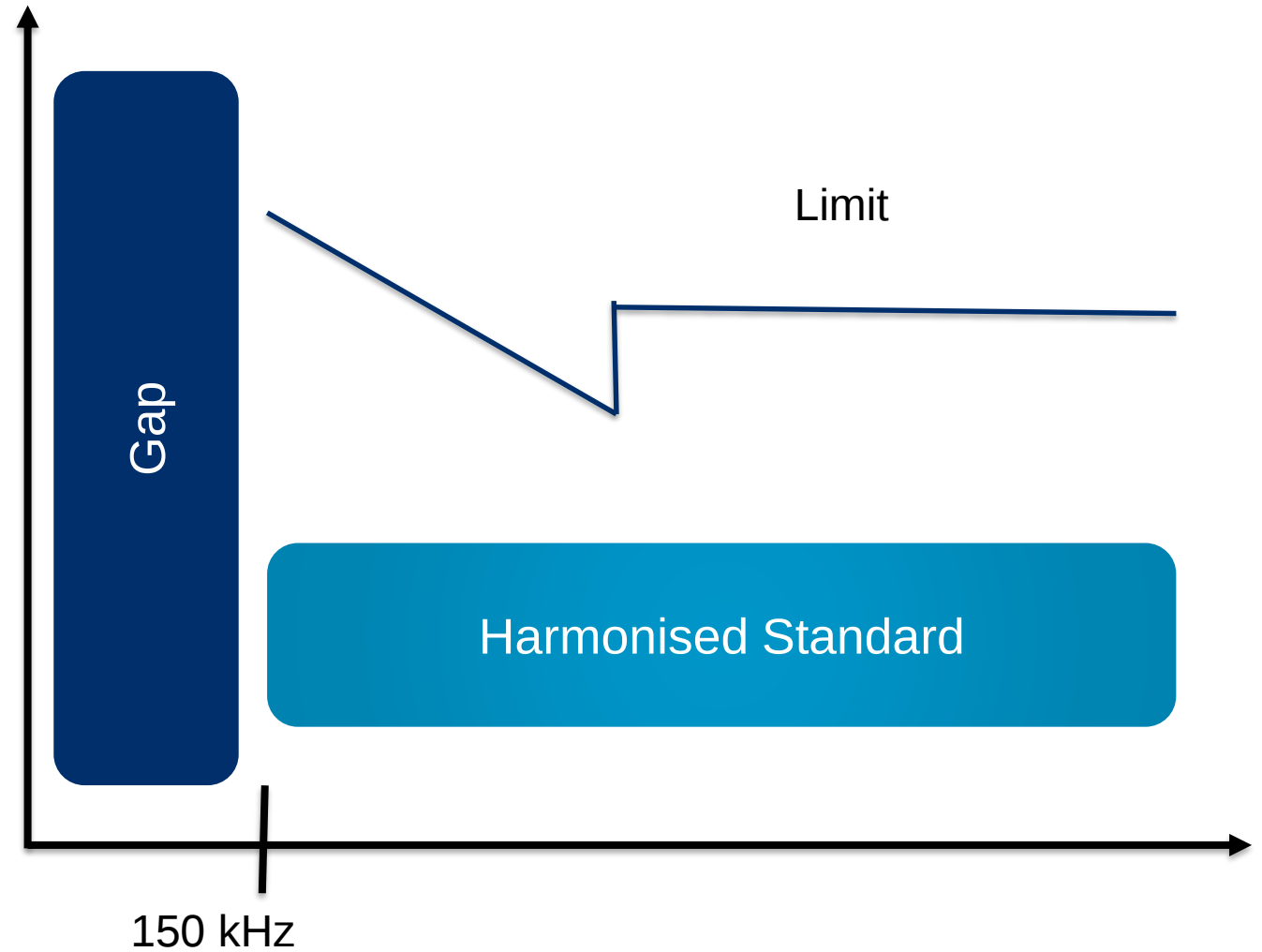
Human exposure to EM fields – Safety not EMC



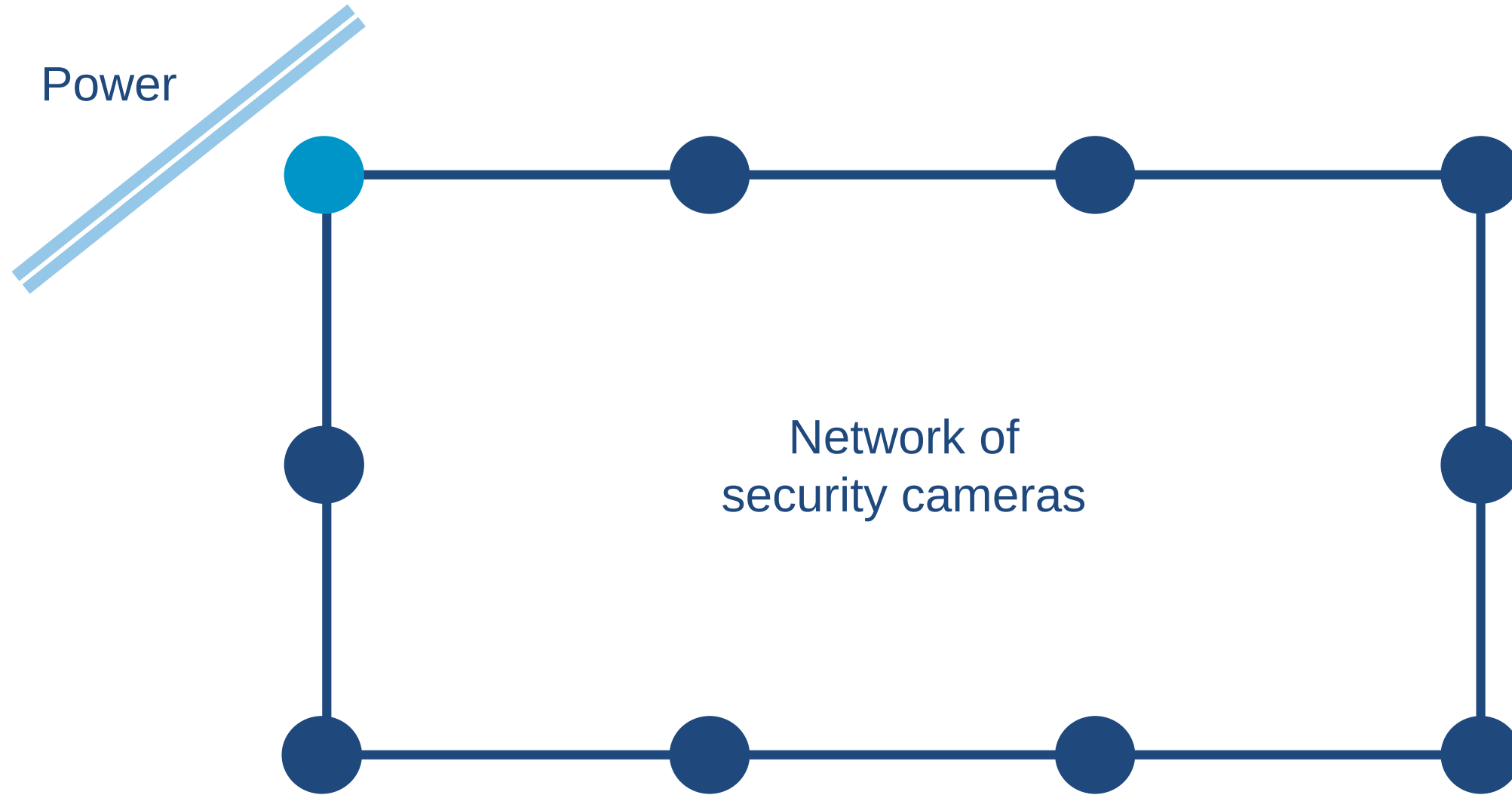
Example 2 – Standards not covering the full frequency range



125 kHz



Example 3 – Inadequate consideration of installation restrictions



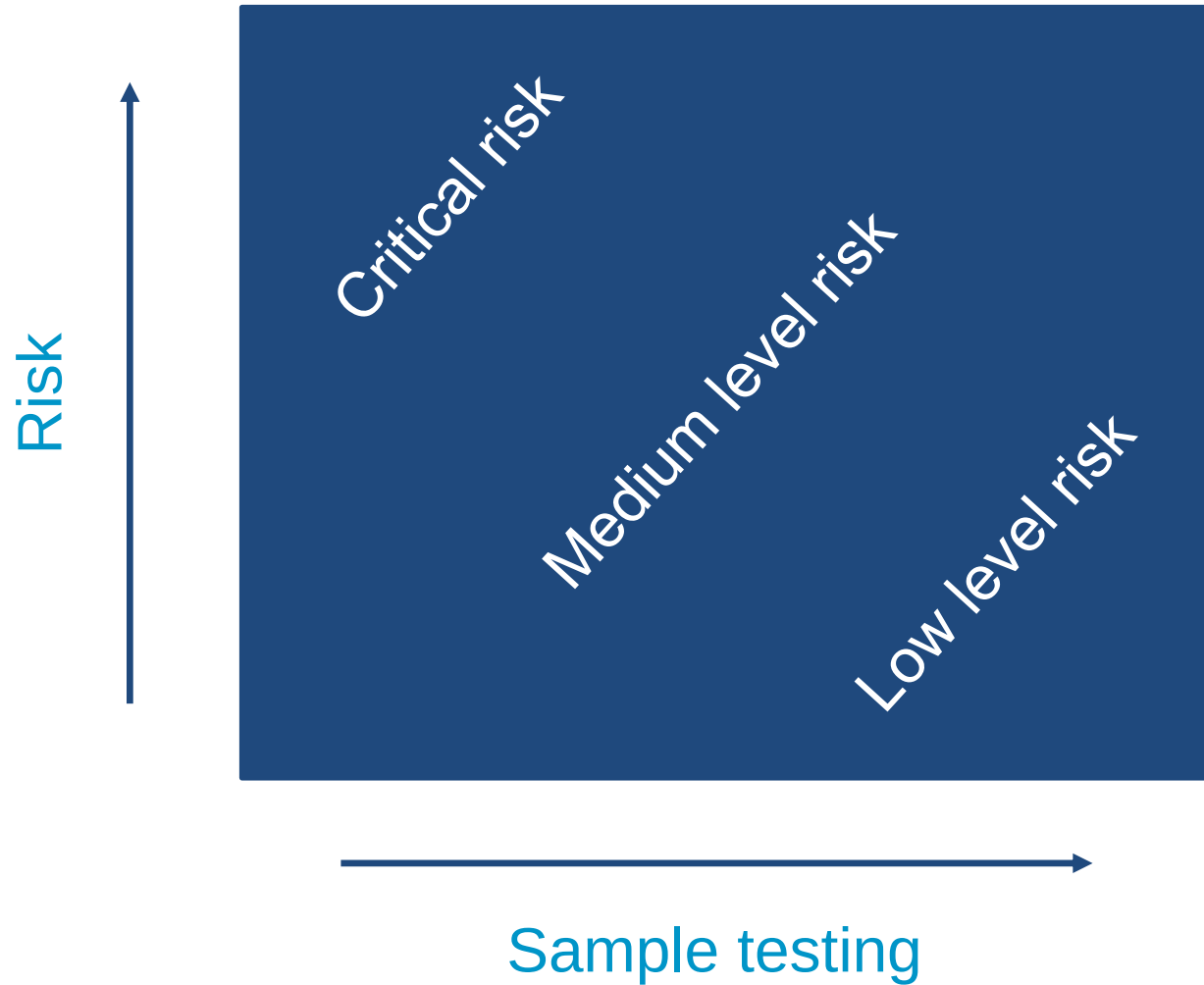
Example 4 – Harsh EM environment



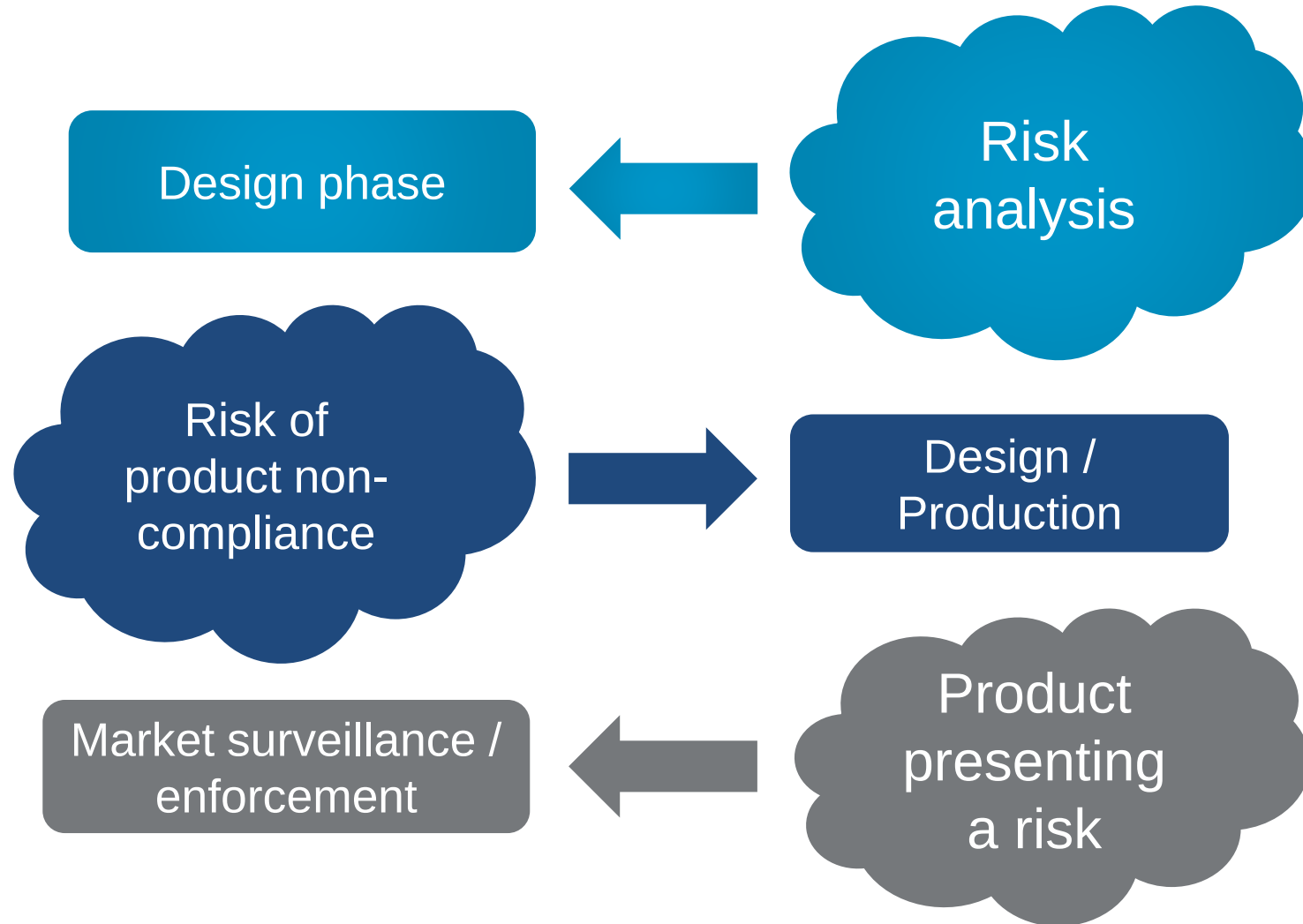
Example 5 – Knowing the intended environment



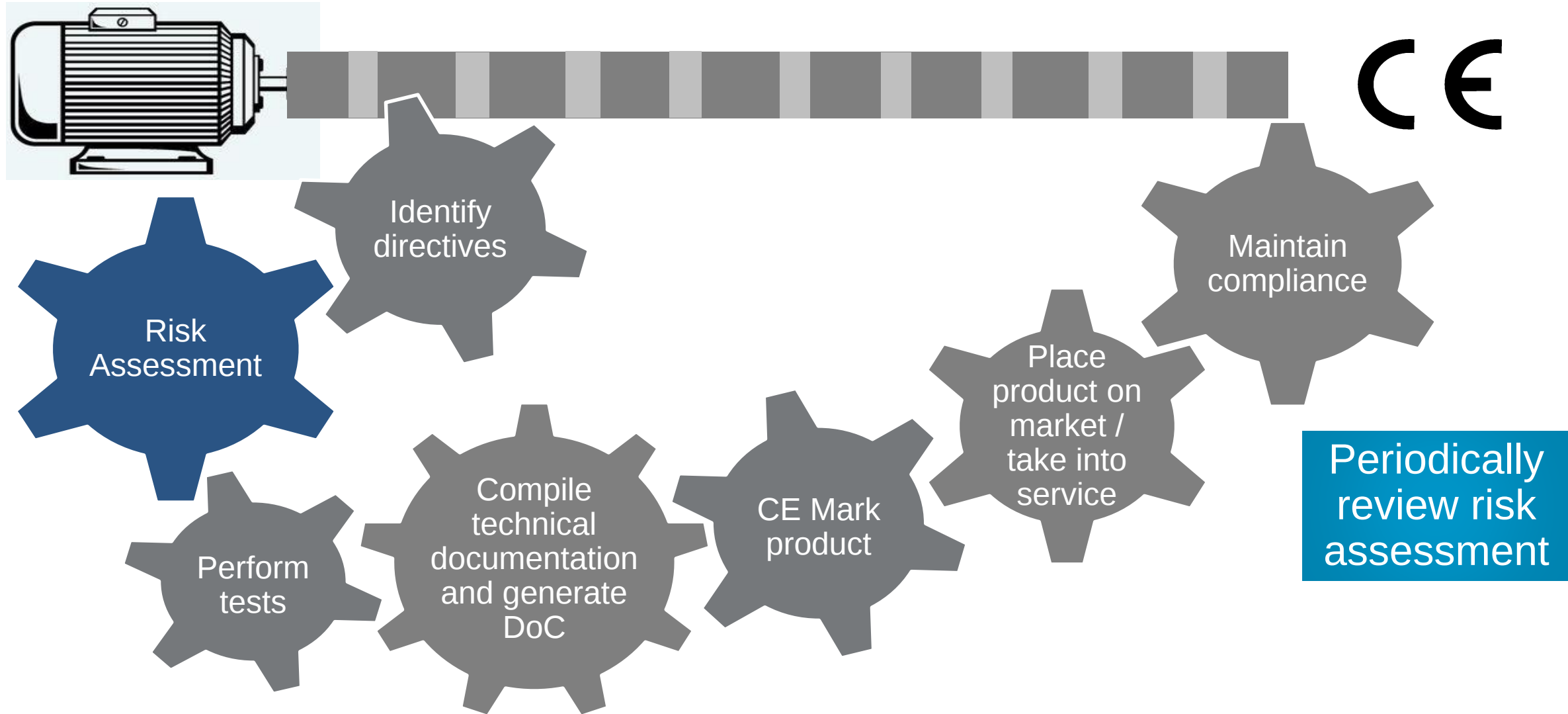
The importance of maintaining ongoing compliance



Three phases of risk to be aware of



When do you do your risk assessment?



Risk Assessment is a tool to determine standards and requirements



Risk Assessment protects consumers AND manufacturers



Example 6 - Products presenting a risk



Risk Assessment methodologies

PHA
Preliminary Hazard
Analysis

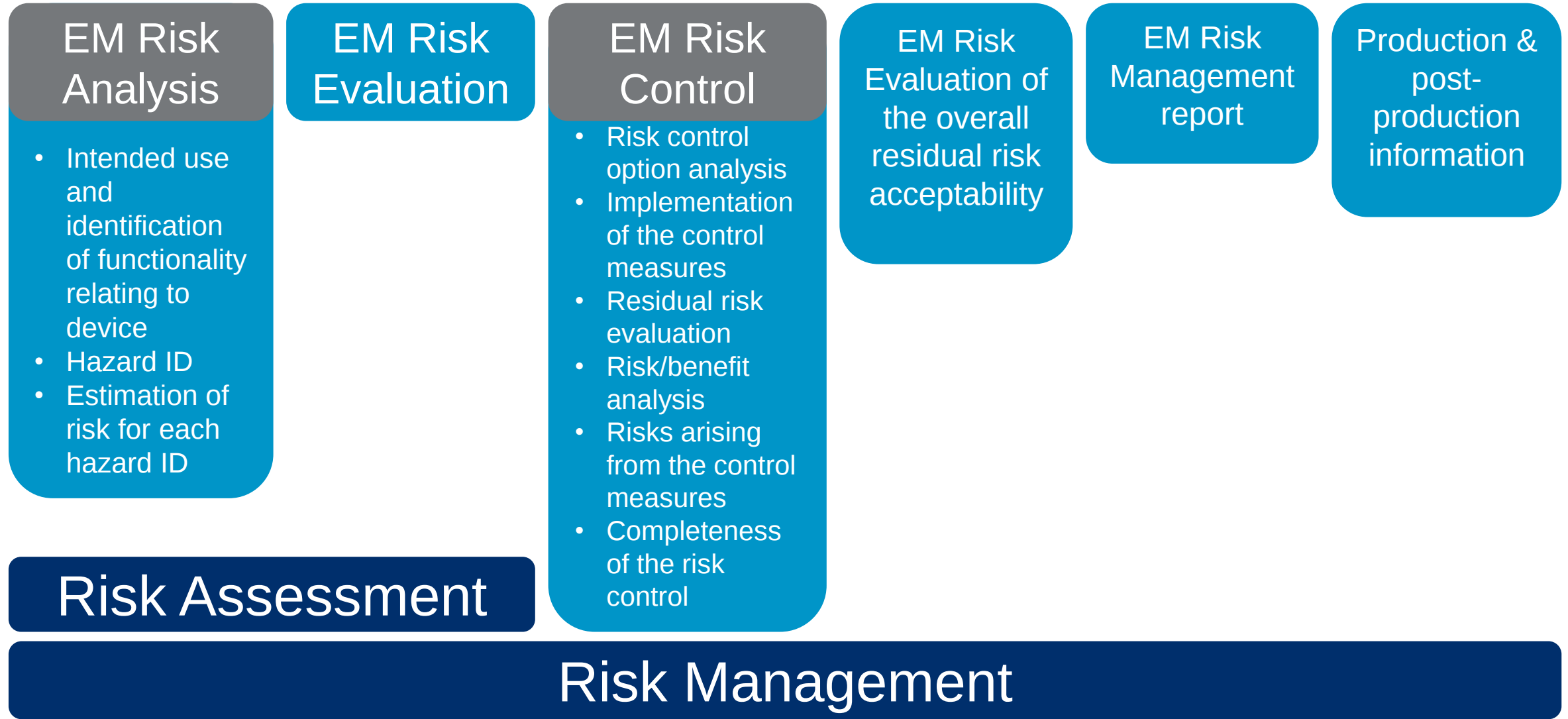
HAZOP
Hazard and Operability
Study

FMEA
Failure Mode and
Effects Analysis

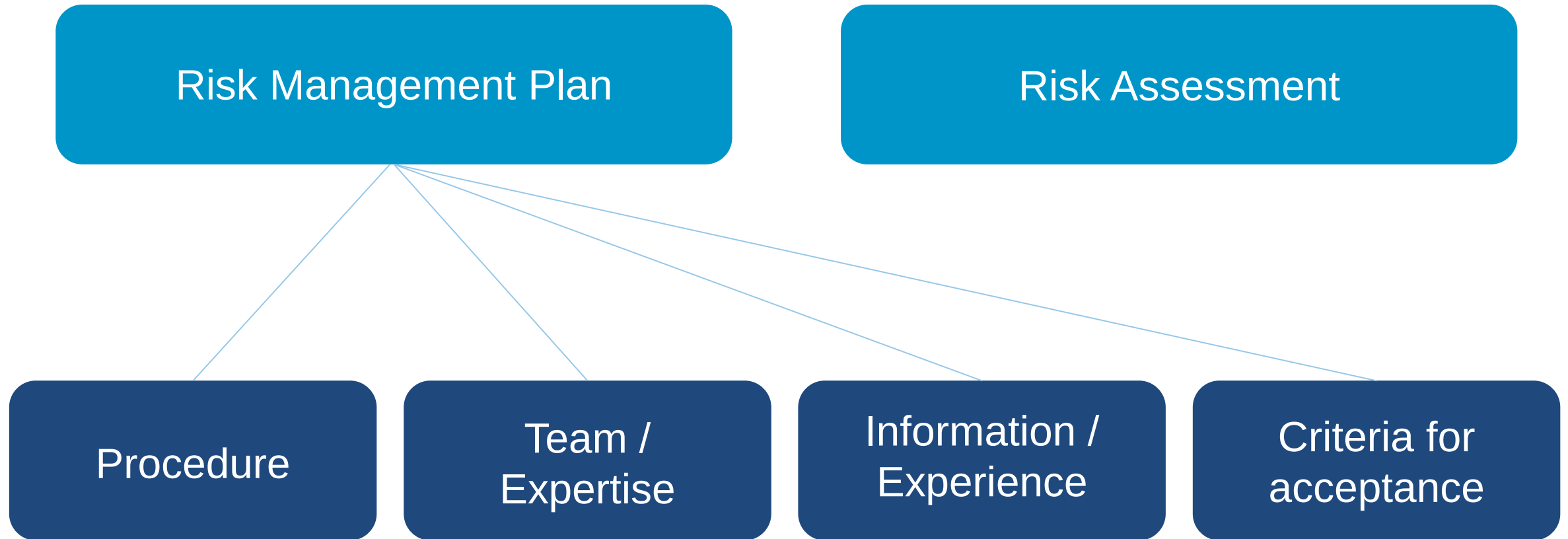
FTA
Fault Tree Analysis

HACCP
Hazard Analysis and
Critical Control Point

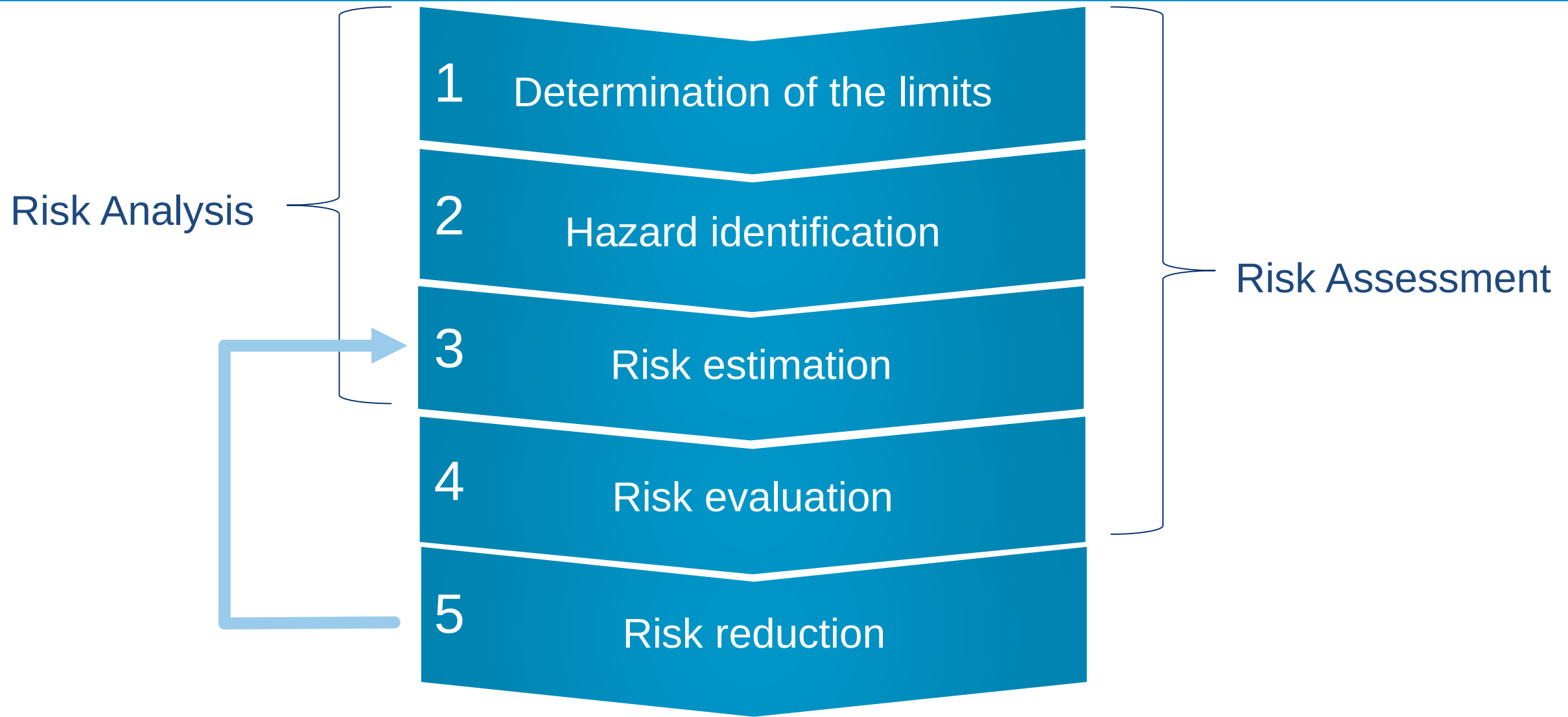
Risk Assessment is a part of Risk Management



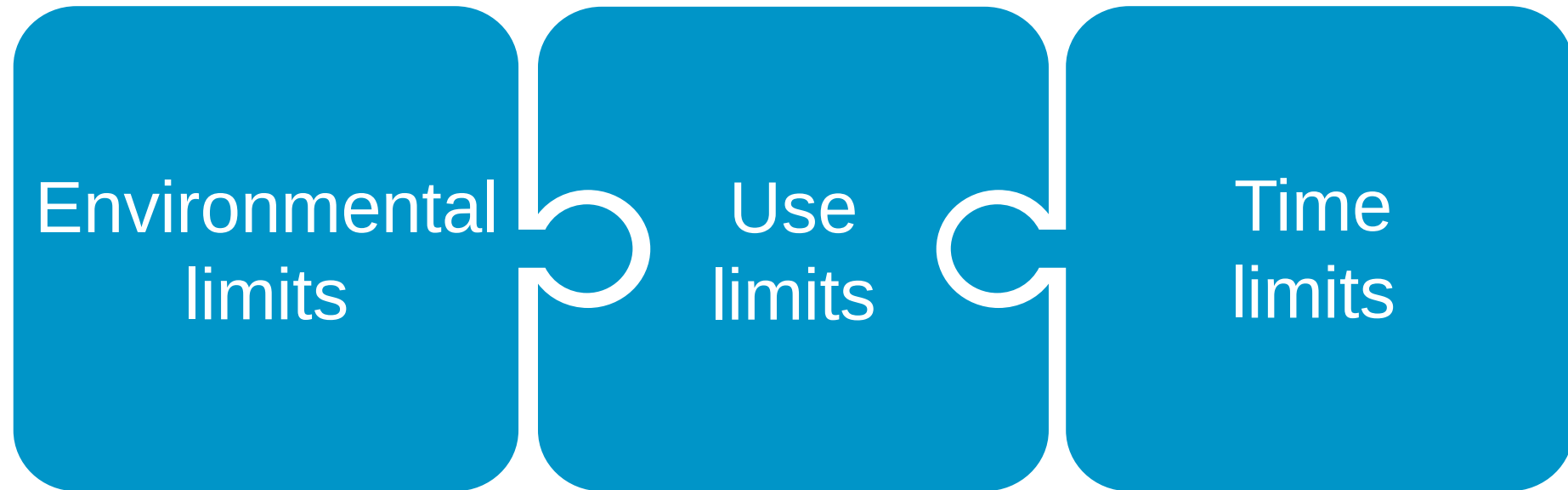
Components of a Risk Management File



Risk Assessment - 5 Steps



1. Determination of the limits



2. Hazard identification - hazard types

Restricted
scope of
(generic)
standards

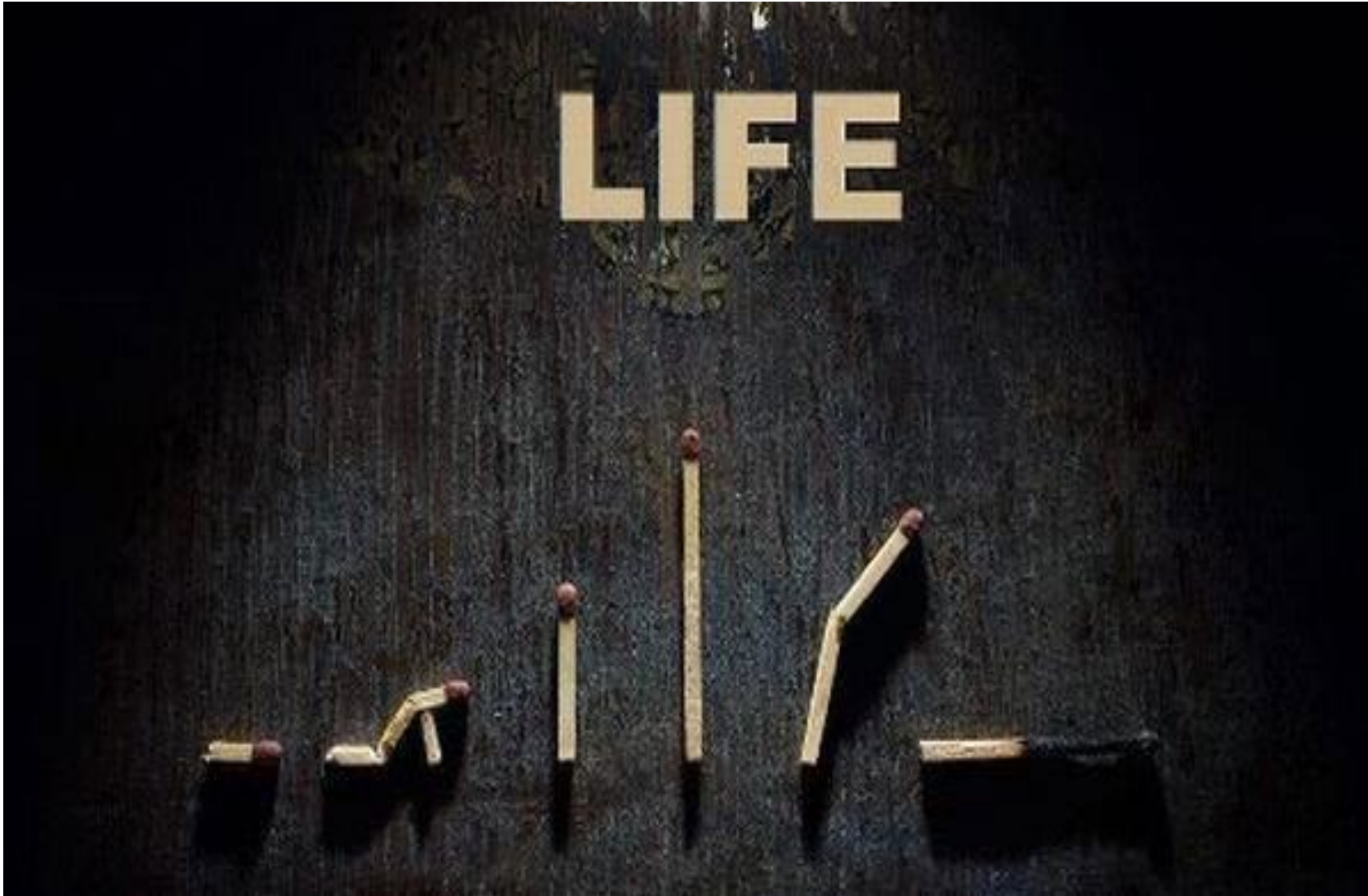
Simultaneous
disturbances

Standards out
of date

Lifecycle /
ageing

Environment

2. Hazards throughout the life of the product



3. Risk estimation

		SEVERITY		
		LOW	MEDIUM	HIGH
PROBABILITY	LOW	NEGLIGIBLE	LOW	MEDIUM
	MEDIUM	LOW	MEDIUM	HIGH
	HIGH	MEDIUM	HIGH	EXTREME

3. Risk estimation

SEVERITY	
0	Conformity
1	Non-Conformity
2	Occasional/intermittent minor change of state
4	Occasional/intermittent major change of state
6	Permanent minor change of state
10	Permanent major change of state
15	Damage to components/product resulting in permanent failure

PROBABILITY	
0.1	Almost impossible
1	Highly unlikely
1.5	Unlikely
2	Possible
5	Even chance
8	Probable
10	Likely
15	Certain

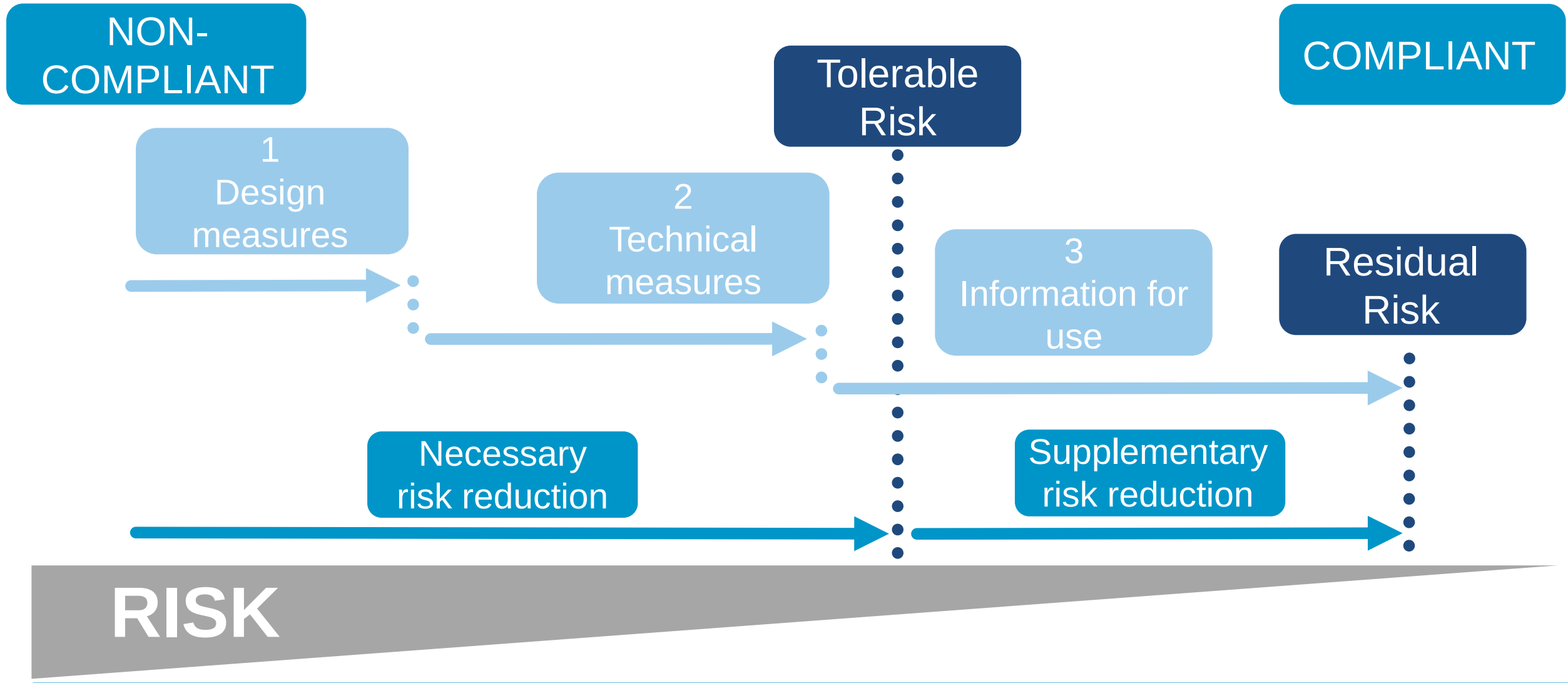
TOTAL RISK	
< 1	Negligible
1-1.5	Low, significant
2	Medium
5-8	High
10-15	Unacceptable

4. Risk evaluation

TOTAL DEGREE OF RISK

IS THE RISK ACCEPTABLE?

5. Principles of risk reduction



Risk Assessment documentation

HAZARD		RISK (Who, What, Where, How)	EXISTING CONTROL MEASURES	RISK ESTIMATION			ADDITIONAL CONTROL MEASURES	RESIDUAL RISK			INFORMATION TO SUPPLY
				P	S	R		P	S	R	
EMC / Radio	Electromagnetic phenomena	Malfunction of equipment (inaccuracy and/or failure of display) when adjacent RFID (125 kHz) device operates	EMC testing to harmonised standards	2	1	2	Additional EMC (radiated immunity) testing at 125 kHz	0.1	1	0.1	Information in user manual regarding the intended use and environment and warnings of possible degradation of performance

Example Assessment

Essential Requirements	Risk			Measures applied to prevent the risk becoming effective		Evidence and comments	
	Source of risk	When it occurs	Possible effect	Description of the measure applied	Proof of effectiveness of measure	Technical documentation	Comments
Annex I, 1(a) - Emissions	Equipment generates internal frequencies > 1 GHz	Normal operation	Interference to other equipment	Apply additional testing to cover the higher frequency	Test data provided up to and including the upper frequency	Test report XYZ1-EMC	Pass result
Annex I, 1(a) - Emissions	Equipment generates internal frequencies < 150 kHz	Normal operation	Interference with LF radio devices	Apply the additional testing to cover the lower frequency	Test data provided down to and including the lower frequency	Test report XYZ1-EMC	Pass result
Annex I, 1(a) - Emissions	Long cables that run close to other equipment	Normal operation	Unwanted emissions from these cables	Apply additional testing to standard EN xxxxx:yyyy to cover cable testing	Test data provided for all cables	Test report XYZ1-EMC	Pass result
Annex I, 1(b) - immunity	Equipment is used in industrial and domestic environment	Use in industrial locations	Microprocessor errors	Apply standard EN xxxxx:yyyy to cover industrial locations	Test data provided	Test report XYZ2-EMC	Pass result
Annex I, 1(b) - immunity	Vehicular transients	Can be used in cars and trucks	Functional interruption	Apply standard EN xxxxx:yyyy to cover vehicle transients	Test data provided	Test report XYZ3-EMC	Pass result
Annex I, 1(b) - immunity	Close proximity of wireless devices	When mobile phones used near equipment	Screen interference	Advise customer not to place mobile phone within 600 mm of equipment	Test at 10 V/m at 600 mm. Add warning in manuals	Test report XYZ3-EMC. Manuals	Pass result
Annex I, 1(a) & (b)	Ageing of EM gaskets	After gasket life	Immunity and emission issues	Maintenance instructions to include gasket replacement after 5 years	Add warning in manuals	Manuals	-

The solution?

Application of additional techniques and measures

Good EMC design practices used

Compliance with EMC test standards

Consideration of additional risks -
Life of the product

Ageing

Expected EM environment

Possible disturbances

Multiple disturbances

Result:
Conformity to the
Essential Requirements
of the EMC Directive is
considered

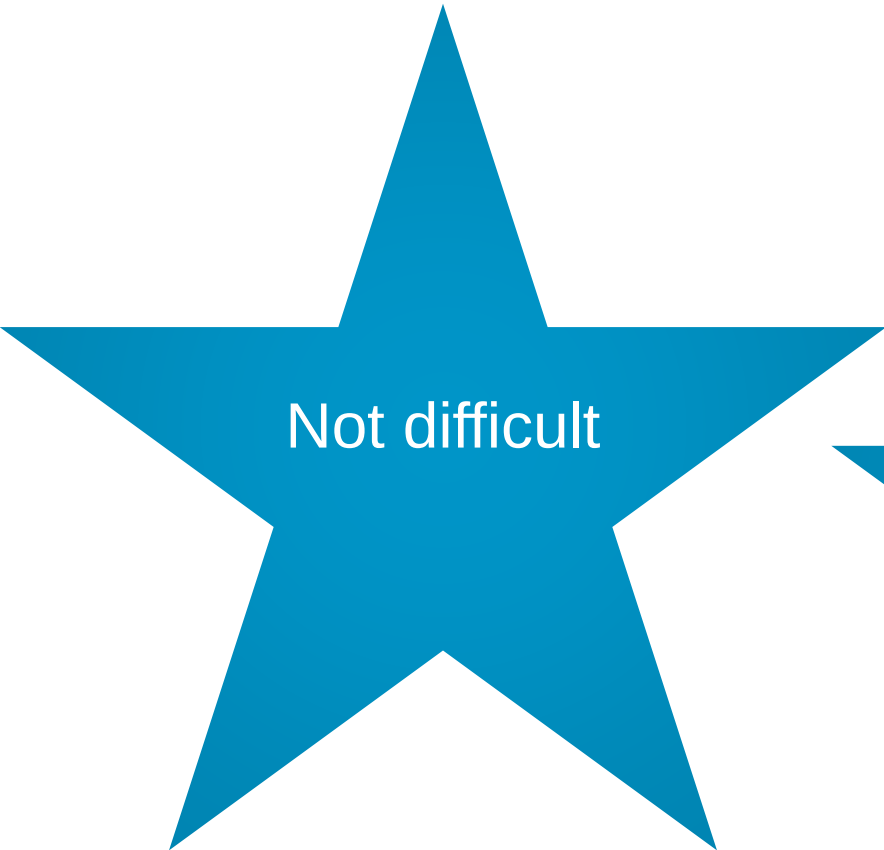
EMC hazards starter checklist

Have you considered...

- All possible locations/environments for use? Are these covered by the standard(s) chosen?
- Is the product likely to be used near equipment other than that typical for the environment?
- Have the installation/operating instructions stated clearly the intended use/limitations?
- Does conformity rely on characteristics that may degrade over time?
- Has the product been tested fully? (frequency range, class of equipment, modes of operation, all ports, etc.)
- Are there technologies within the product likely to cause EM disturbances above the highest frequency of test?
- Are there any other unique factors within the product that should be considered? - e.g. intentional radiators, but not radio communications, which are not covered by ISM frequency bands.

**REDUCE RISK AS FAR AS IS
REASONABLY PRACTICABLE**

Risk Assessment summary



Not difficult



A tool to help
identify
standards



Helps you
ensure
compliance



Thank you

James Daniels

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Element Materials Technology

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