



Godkendelse af medicinsk udstyr med radio

Jakob Steensen

Notified Body EMC DIR2014/30/EU & RE DIR2014/53/EU

National Certification Body, IECEE CB Scheme

Vice President, Business Unit Executive

Product Compliance – FORCE Technology



EU's direktiv-rammeverk

New Legislative Framework

- Specificerer de overordnede rammer for EU-direktiverne
- Regler om markedsovervågning for at forhindre farlige produkter (for mennesker eller miljø)
- Specificerer reglerne for akkreditering af godkendelsesorganer (såsom NB's)
- Forklarer betydningen af CE-mærket
- Gør det lettere at udvide med fremtidig lovgivning ved at sætte rammer herfor

NLF består af:

- [Regulation \(EC\) 765/2008](#) : Krav til akkreditering og markedsovervågning
- [Decision 768/2008](#) : Fælles platform for regler om markedsføring af produkter i EU
- [Regulation \(EC\) 764/2008](#) : Procedurer vedrørende individuelle (nationale) tekniske bestemmelser

EU's direktiv-rammeverk



New Legislative Framework dækker 22 direktiver og forordninger, bl.a.:

- Restriction of Hazardous Substances in Electrical and Electronic Equipment - Directive 2011/65/EU
- Electromagnetic Compatibility - Directive 2014/30/EU
- Measuring Instruments - Directive 2014/32/EU
- Radio equipment - Directive 2014/53/EU
- Low Voltage - Directive 2014/35/EU
- Medical devices - Regulation (EU) 2017/745
- In vitro diagnostic medical devices - Regulation (EU) 2017/746

Essential requirements

RED – DIR2014/53/EU

RED har i al væsentlighed tre essentielle krav:

- Artikel 3.1.a: (...) *sikkerhed for personer, husdyr og ejendom (inklusive målene fastsat i Lavspændingsdirektivet, dog uden nedre spændingsgrænse).*
- Artikel 3.1.b: *Et tilstrækkeligt niveau af elektromagnetisk kompatibilitet som fastsat i EMC-direktivet.*
- Artikel 3.2: *Effektiv anvendelse af frekvensbåndet og understøttelse af en effektiv anvendelse af radiofrekvenser, således at skadelig interferens undgås.*

MDR – REGL (EU) 2017/745

MDR har mange ER's, men der er sammenfald på EMC og electrical safety:

- Req 18.5 & 18.6 / Annex I, 14.2(b): EMC emission & immunitet.
- General safety: Beskrevet mange steder i regulativet, indbefatter bl.a. elsikkerhed.

Essential requirements

Synergier mellem funktionskriterier?

Essential Requirement	RED	MDD/MDR
Elsikkerhed	EN 62368-1	EN/IEC 60601-1
EMC	ETSI EN 301 489-x	EN/IEC 60601-1-2
Radioparametre	ETSI EN 300 328	N/A

Hvad med emission?

Opstiller funktionelle krav til (hele) apparatet

Hvilke EMC tests skal udføres?
Ved hvilke niveauer?

Opstiller udelukkende krav til funktion af risk-relaterede kliniske funktioner og til basal sikkerhed

Andre EMC tests?
Andre testniveauer?

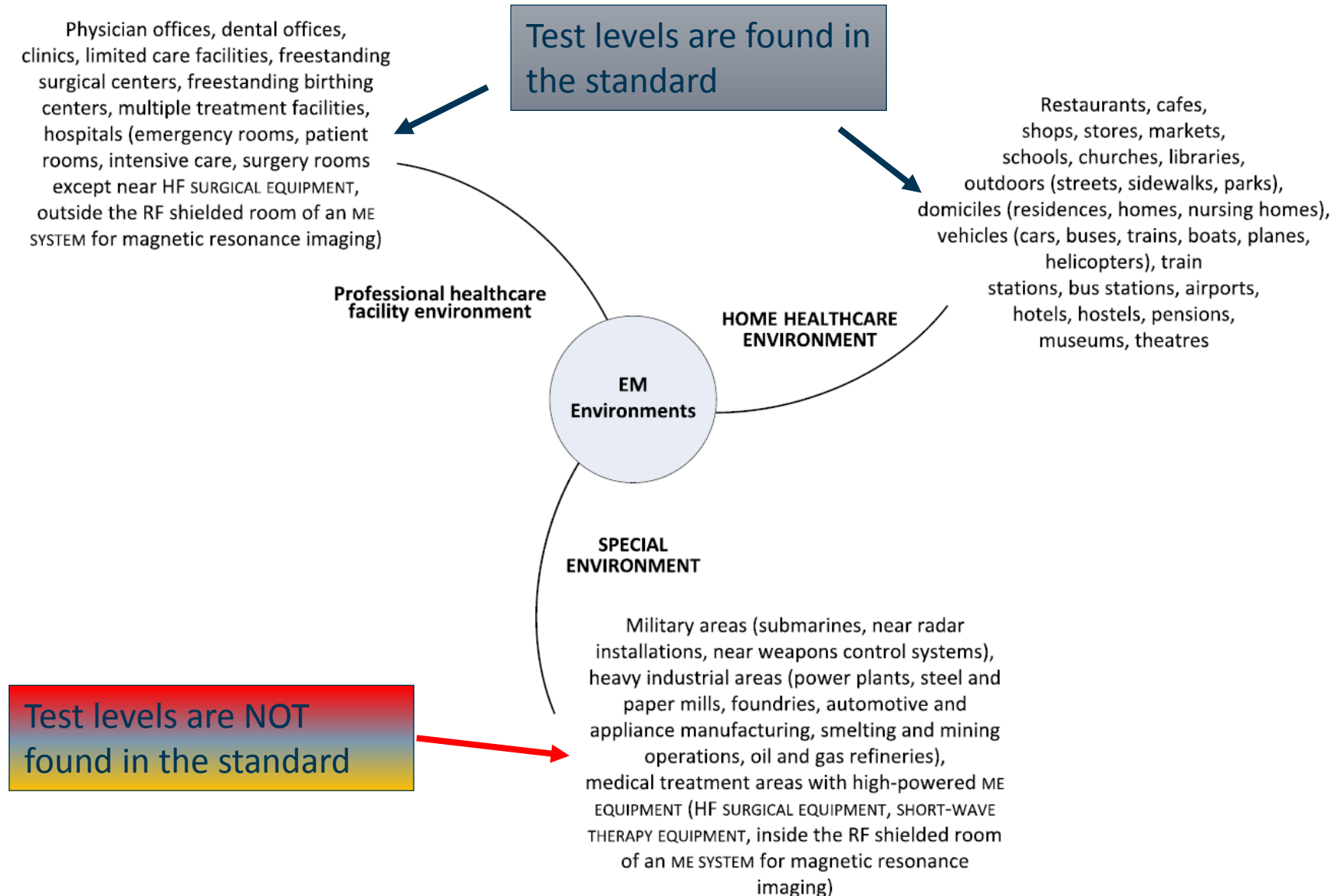
Performancekriterier

MDR vs. RED -> to forskellige verdener

MDR	RED
Essential Performance (Risk of hazards – Risk Management File)	Transient phenomena Sendedel, modtagedel, øvrige funktioner
Basic Safety (Risk of hazards – Risk Management File)	Continuous phenomena Sendedel, modtagedel, øvrige funktioner
Other functionality (Fabrikantens egne, frivillige funktionskrav)	A, B, C..? Måske er der en produktstandard involveret
Risk of non-compliance Fabrikantens analyse af, om de øvelser, der er udført, er tilstrækkelige til at opfylde hensigten med samtlige essentielle krav	

Brugsmiljø

IEC 60601-1-2, 4th ed: testniveauer og grænseværdier



Brugsmiljø

IEC 60601-1-2, 4th ed: Fastlæggelse for special environments

The situations that could justify new IMMUNITY TEST LEVELS or an increase or decrease in the existing IMMUNITY TEST LEVELS are as follows:

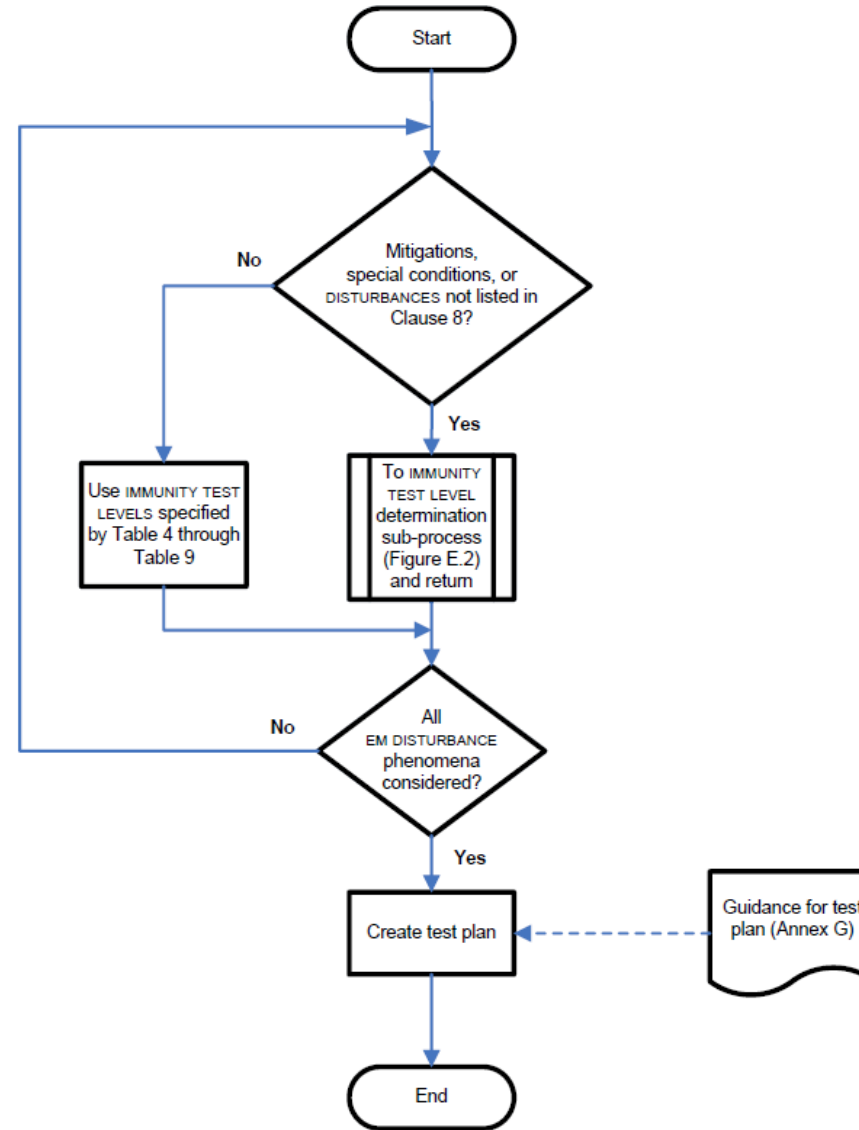
- a) mitigations that might reduce exposure to EM DISTURBANCE levels resulting from the phenomena listed in Clause 8;
- b) special conditions, due to INTENDED USE or SPECIAL ENVIRONMENTS, where one or more of the EM phenomena listed in Clause 8 are expected to have lower EM DISTURBANCE levels;
- c) special conditions, due to INTENDED USE or SPECIAL ENVIRONMENTS, where one or more of the EM phenomena listed in Clause 8 are expected to have higher EM DISTURBANCE levels (e.g. shorter minimum separation distances for RF wireless equipment);
- d) the presence of an EM DISTURBANCE from an EM phenomenon which is not listed in Clause 8.

Clause 8 is the clause
with all the EMC tests



Brugsmiljø

IEC 60601-1-2, 4th ed:
Fastlæggelse for special
environments

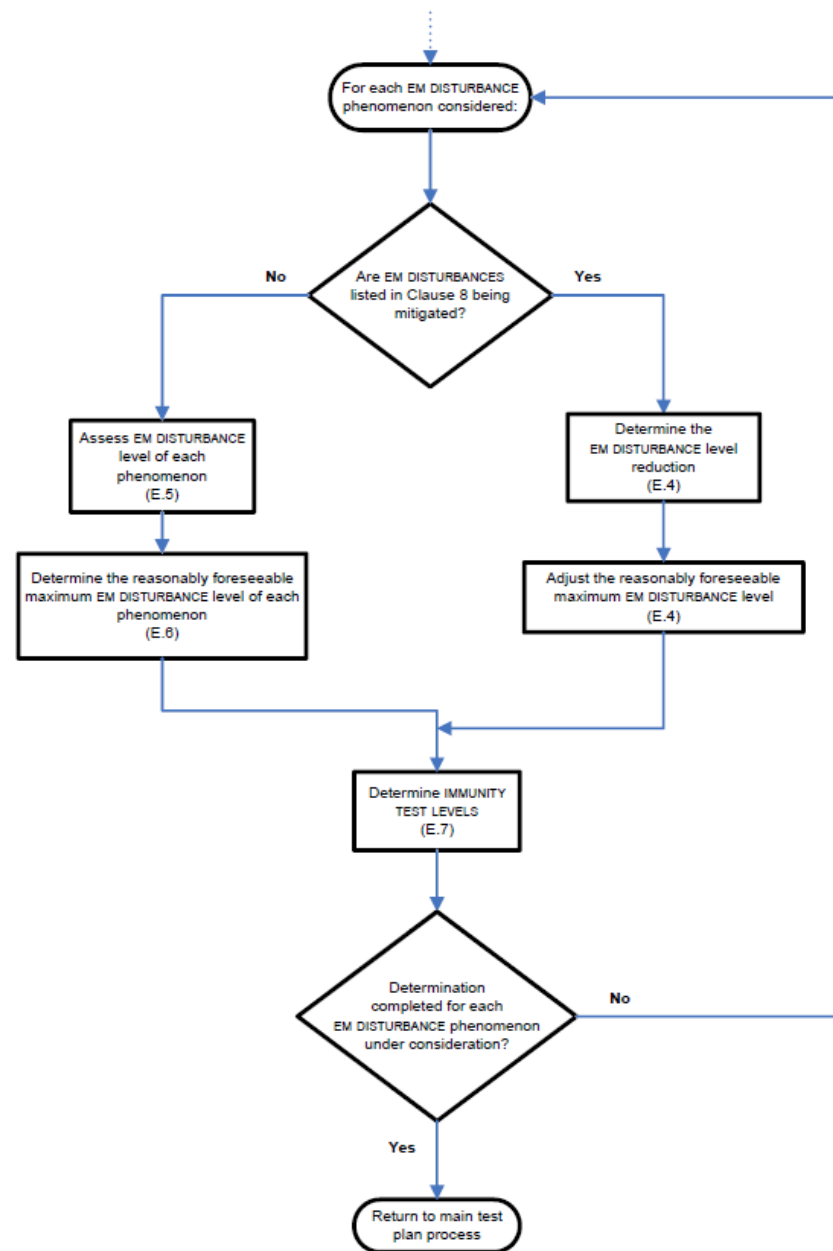


IEC 0644/14

Figure E.1 – Test plan development flow when SPECIAL ENVIRONMENTS are known

Brugsmiljø

IEC 60601-1-2, 4th ed:
Fastlæggelse for special
environments



IEC 0045/14

Figure E.2 – Sub-process for determination of IMMUNITY TEST LEVELS FOR SPECIAL ENVIRONMENTS

EMC risk management

IEC 60601-1-2, 4th ed - 2014

- **4.1 RISK MANAGEMENT PROCESS for ME EQUIPMENT and ME SYSTEMS**

RISKS resulting from reasonably foreseeable ELECTROMAGNETIC DISTURBANCES shall be taken into account in the RISK MANAGEMENT PROCESS.

NOTE 1 Annex F provides additional guidance on taking ELECTROMAGNETIC DISTURBANCES into account in the RISK MANAGEMENT PROCESS.

NOTE 2 This collateral standard requires the MANUFACTURER to perform a number of activities with regard to EM DISTURBANCES during the design and realization of their ME EQUIPMENT or ME SYSTEM, and to document them in the RISK MANAGEMENT FILE. However, EMC test laboratories cannot be expected to perform or document these activities.

Compliance is checked by verifying the presence of the corresponding entries in the RISK MANAGEMENT FILE.

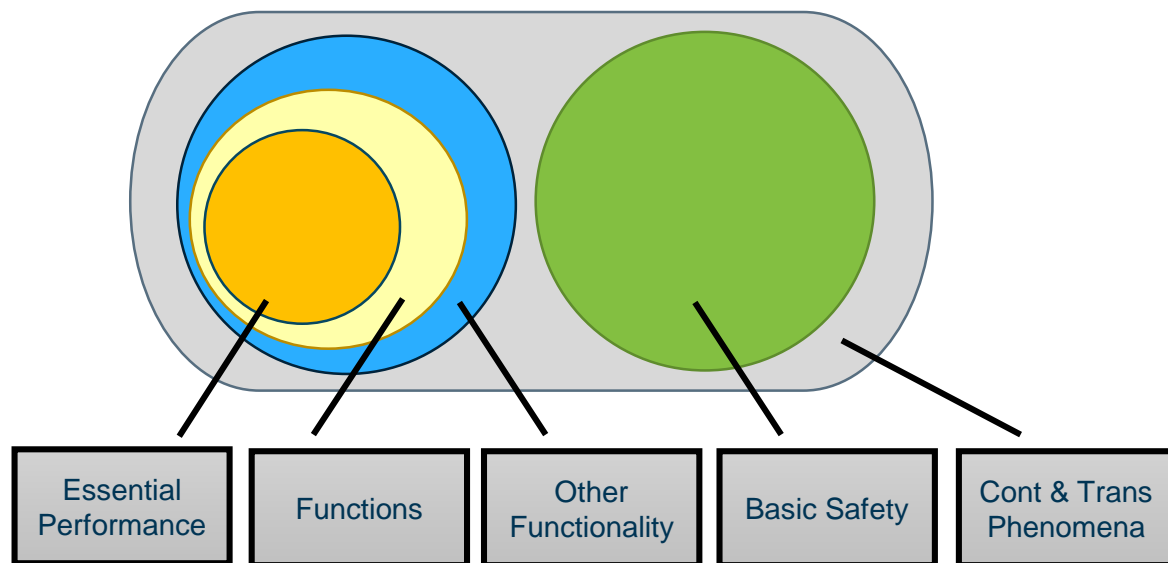
Tests, levels, limits, and performance criteria as per the Risk Management File (unlike -1-2, 3rd ed).

Check that correct environment is used in the RMF & IFU!

Medical devices med radio

- Er der radio i produktet, så kommer performance criteria TP, CP, A, B og C som begreber i spil igen for ALLE FUNCTIONS (EMC-standarderne for radio-devices skelner ikke mellem de radiorelaterede funktioner og de øvrige funktioner).
- 3.10 * EXCLUSION BAND
Frequency band for intentional receivers of RF electromagnetic energy that extends from -5% to $+5\%$ of the frequency, or frequency band, of reception for frequencies of reception greater than or equal to 80 MHz and from -10% to $+10\%$ of the frequency, or frequency band, of reception for frequencies of reception less than 80 MHz
NOTE Other definitions of this term are sometimes used for other purposes in national radio regulations.
- ME EQUIPMENT and ME SYSTEMS that include radio equipment
ME EQUIPMENT and ME SYSTEMS that include radio equipment and have been tested and found to comply with applicable national radio regulations are exempt from testing to CISPR ELECTROMAGNETIC DISTURBANCE requirements, provided the EMISSIONS limits of the applicable national radio regulations are less than or equal to the corresponding applicable CISPR ELECTROMAGNETIC DISTURBANCE limits.
ME EQUIPMENT and ME SYSTEMS that include RF transmitters are exempt from the EMISSIONS requirements of this collateral standard in the dedicated transmission band of the transmitter. Otherwise, and for ME EQUIPMENT and ME SYSTEMS intended only for countries with no national radio regulations, the EMISSIONS requirements of this collateral standard shall apply.

Tilbage til performance kriterier...



Essential Performance: Den delmængde af funktionalitet, hvor det er behæftet med uacceptabel klinisk risiko, såfremt funktionaliteten udebliver eller degraderes.

Functions: De funktioner, der skal til for at udføre den tiltænkte anvendelse (Intended Use), men ikke andre funktioner.

Other functionality: De funktioner, som det medicinske udstyr har, og som hverken er Essential Performance eller Functions, men som ønskes monitoreret under test.

Basic Safety: De ting, der *ikke* må ske, før det er behæftet med uacceptabel risiko (bryder i brand, starter af sig selv...). Dertil basale ting, såsom at elektrisk isolering skal være i orden.

Cont & Trans Phenomena: Begreber for påtrykningsfænomener. Det skal defineres for begge fænomeners indvirkning på al funktion, hvad der må ske og ikke ske under test, dette indenfor definitionsrammerne for CP og TP, som anført i ETSI-standarderne.

Hvorfor teste EMC?

... hvis der ikke er nogen performancekriterier..?



Further information at forcetechnology.com

