Another EMC resource
from EMC Standards

The New EU Directives which came into force in 2016

Helping you solve your EMC problems

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By Keith Armstrong

New in 2016

The new EU Directives which came into force in 2016

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New in 2016

Contents

- The New Legislative Framework (NLF)
- The new EMC Directive, 2014/30/EU
- The new LV Directive, 2014/35/EU
- Two new Medical Device Regulations, replacing:
  93/42/EEC Medical Devices
  90/385/EEC Active Implantable Devices
  98/79/EC In-Vitro Diagnostics Directive
- The Radio Equipment Directive, RED, 2014/53/EU
- The other new Directives, not detailed here

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New in 2016

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The New Legislative Framework

The problems it addresses and its changes to the Single EU Market

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New in 2016

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The kinds of problems that gave rise to the NLF

- **It has proven to be very difficult to ensure that only CE-compliant products are sold on the EU market…**
  - **it seems that the various EC Directives were not worded in a way that made it easy to enforce them, especially…**
    - **when Distributors sell products they bought in the EU but which carry no identification of manufacturer or importer…**
    - **and when major on-line companies refuse to take any legal responsibility for compliance of products they "supply"… (arguing that they simply put suppliers in contact with customers, and it is up to them to sort it all out, i.e. the on-line customer is the legal EU Importer)**

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New in 2016

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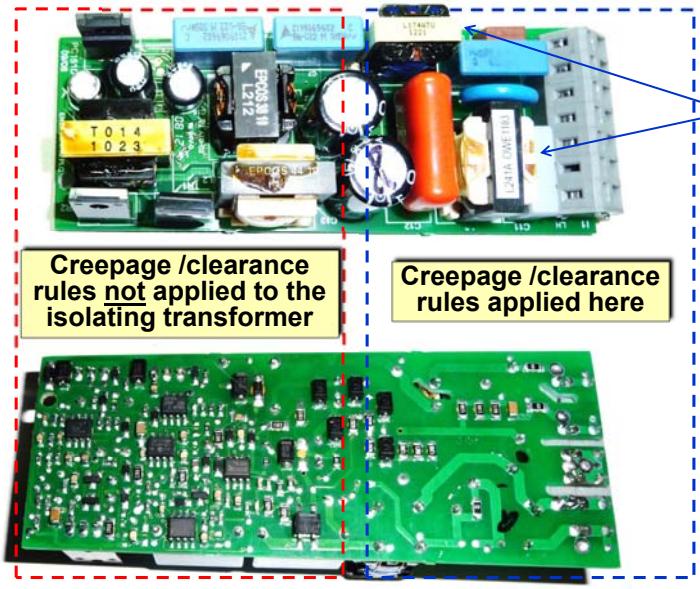
I see a lot of cheap battery-chargers and other mains-power converters with no creepage and clearance rules applied between input and output



This lighting controller is labelled:

"SUITABLE FOR CLASS I AND CLASS II APPLICATIONS"

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New in 2016

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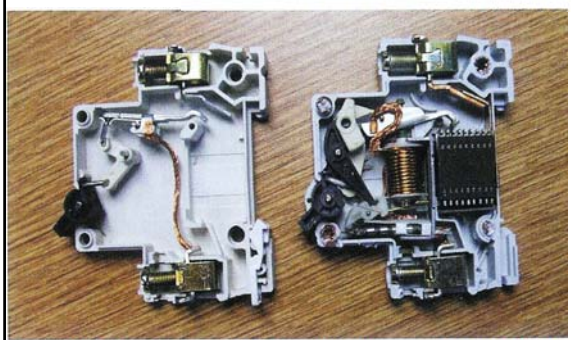
Examples of counterfeit circuit breakers



Counterfeit and genuine circuit breakers – the difference is potentially fatal

Source: Beama Counterfeit Working Group

This distributor in China displays row upon row of Miniature Circuit Breakers (MCBs). All of them are counterfeit, illegal and highly dangerous

The most obvious difference between the real and the fake was its weight, but these days they add small pieces of metal or concrete so they weigh the same

"This distributor in China displays row upon row of Miniature Circuit Breakers (MCBs). All of them are counterfeit, illegal and highly dangerous."

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New in 2016

Australia has similar problems

Remember this news story from June 2014?

The Telegraph

CCC

Woman in Australia killed by cheap phone charger

Australian authorities investigate after woman in her 20s found electrocuted

USB chargers seized by NSW Fair Trading from a Campsie store Photo: NSW Fair Trading

By AFP

6:25AM BST 27 Jun 2014

Australian authorities issued a warning about cheap, non-compliant USB-style chargers after a young woman died from apparent electrocution while using a laptop and possibly a smart phone.

New in 2016

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Can you tell which i-Phone charger is the counterfeit?

(From Ken Shirriff, 27 Oct 2012)

Apple's price $29

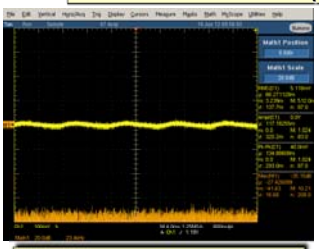
Sold on eBay for $2 as: 'Original Genuine Apple charger'

By Keith Armstrong

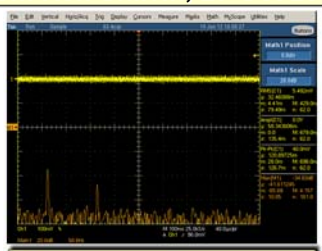
New in 2

The counterfeit i-Phone charger doesn't work as well…

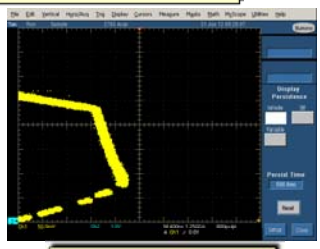
(From Ken Shirriff, 27 Oct 2012)



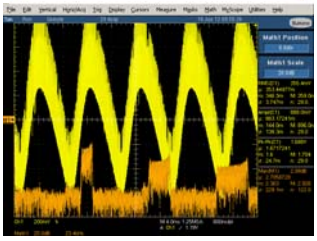
DC noise for 4ms

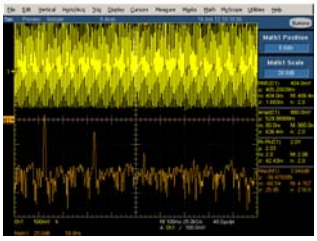


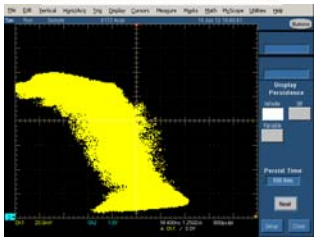
DC noise for 100ms



V/I load curve







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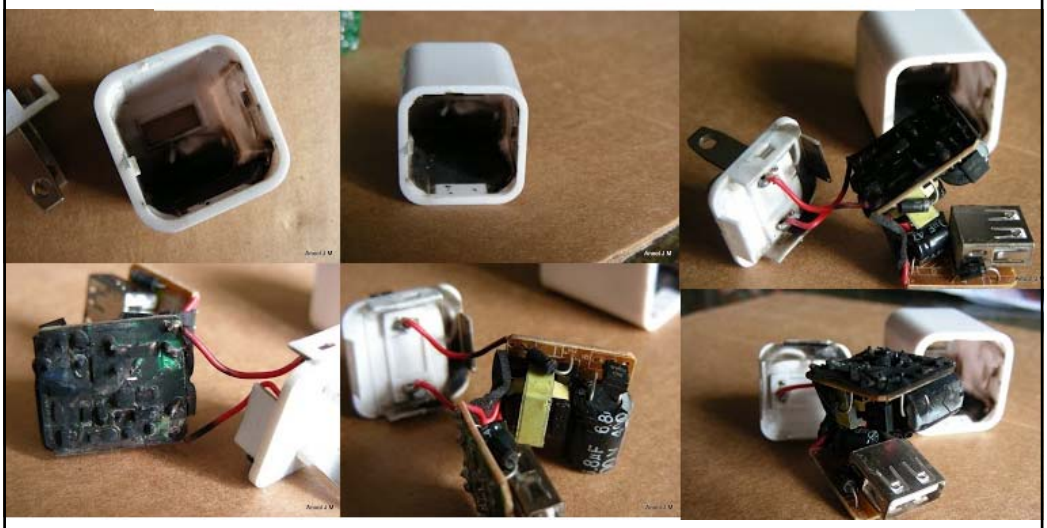
New in 2016

And it could catch on fire, like this one did…

(from Anool Mahidharia, 8 Aug 2011)



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By Keith Armstrong

New in 2016

And of course the Christmas 2015 hoverboard fires

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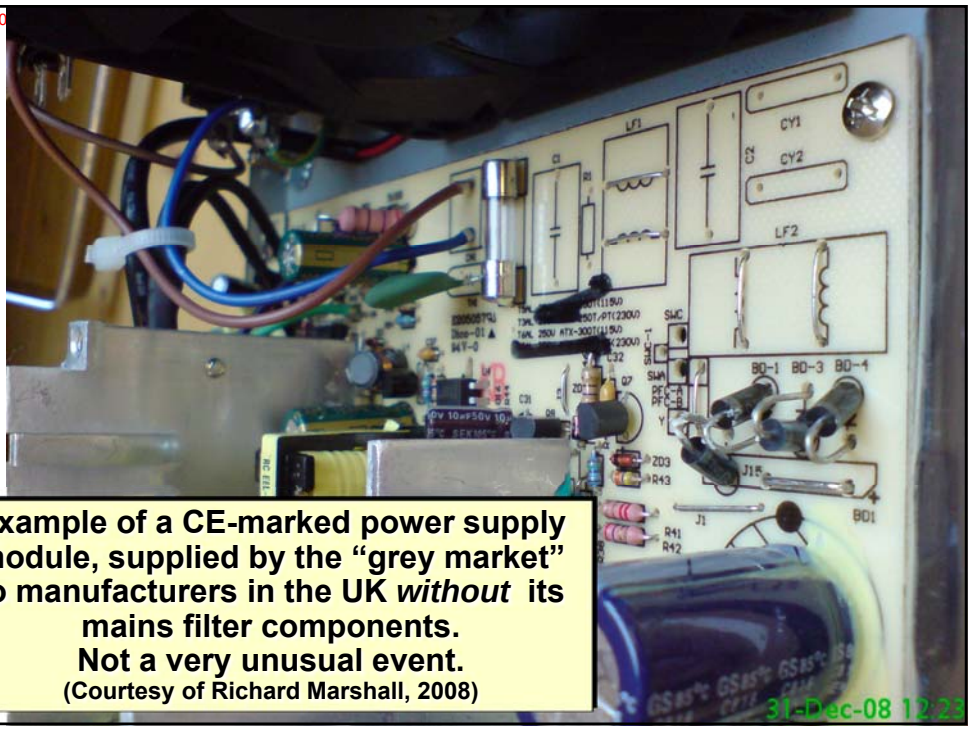
New in 20



Example of a CE-marked power supply module, supplied by the "grey market" to manufacturers in the UK *without* its mains filter components.
Not a very unusual event.
(Courtesy of Richard Marshall, 2008)

By Keith Armstrong

New in 2016

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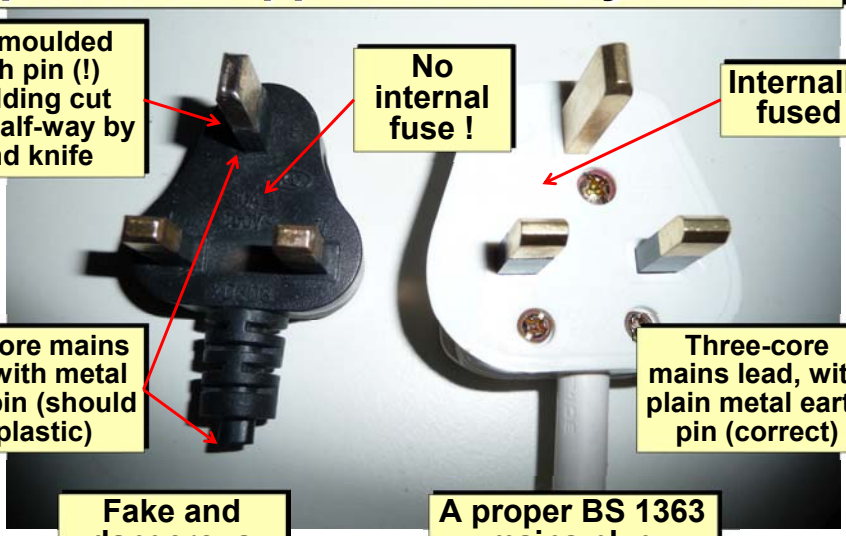
Example of fake UK mains plug on product supplied via eBay in 2015



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New in 2016

The PIP Scandal

Industrial-grade silicone was used by French manufacturer Poly Implant Prothèse (PIP) to make breast implants

The apparent inability of EU Medical Notified Bodies to do *anything* about it – or prevent similar problems from occurring in future – caused the European Commission to suffer huge embarrassment in the media

https://en.wikipedia.org/wiki/Poly_Implant_Proth%C3%A8se

BBC NEWS

Q&A: PIP breast implants health scare

10 December 2013 | Health

French breast implants caused a health scare across Europe and South America last year.

A UK report in June 2012 found the PIP implants, made from unauthorised silicone filler, had double the rupture rate of other implants.

The boss of the French company which distributed defective breast implants around the world has since been sentenced to four years in prison for fraud.

And a German firm responsible for granting European safety certificates for the implants has been ordered by a French court to pay compensation to hundreds of women.

New in 2016

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The New Legislative Framework, NLF

- The NLF was adopted by the EC on 9 July 2008 and published in the OJEU on 13 August 2008…
  - the first major change to the EU's Single Market that created the CE Marking, designed to help the internal EU market work better, by…
    - improving market surveillance rules
    - stronger, clearer rules for conformity assessment bodies
    - clarifying 'CE marking' to enhance its credibility
    - protect CE marking as a trade mark to help authorities and competitors take legal action against abuse
    - creating a 'template' of legal measures for use in Directives to bring them up-to-date with the EU's NLF

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New in 2016

CCC

NLF texts published in the OJEU:

- Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision 3052/95/EC (directly applicable)
- Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing EEC Regulation 339/93 (directly applicable)
- Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC

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New in 2016

Decision 768/2008 does not apply directly: it provides a template for 'NLF-ing' EU Directives including the following, *which all came into force on 20th April 2016 !*

- Electromagnetic Compatibility, 2014/30/EU (*replaced* 2004/108/EC)
- Low Voltage, LVD, 2014/35/EU (*replaced* 2006/95/EEC)
- Civil Explosives, 2014/28/EU (*replaced* 93/15/EEC)
- Simple Pressure Vessels, SPV, 2014/29/EU (*replaced* 2009/105/EC)
- Measuring Instruments, 2014/32/EU (*replaced* 2004/22/EC)
- Lifts, 2014/33/EU (*replaced* 95/16/EC)
- Explosive Atmospheres, ATEX, 2014/34/EU (*replaced* 94/9/EC)
- Non-Automatic Weighing Instruments, NAWI, 2014/31/EU (*replaced* 2009/23/EEC)
- *Toy Directive, 2009/48/EC, is already NLF'd and already fully in force (replaced 88/378/EEC)*
- *RoHS Directive, 2011/65/EU, a CE-marking NLF'd directive, applied on 22 July 2014 for some things, later for others (replaced 2002/95/EC)*

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New in 2016

Some more 'NLF'd' EU Directives

- Radio Equipment 2014/53/EU replaced R&TTE 1999/5/EC on 13 July 2016, with a transition period to 12 July 2017 *only for certain products not previously covered by the R&TTED* *see later*
- Pressure Equipment 2014/68/EU *replaced* 97/23/EC on 19 July 2016
- Marine Equipment 2014/90/EU replaced 96/98/EC on 18 Sept. 2016
- Medical Devices *and* Active Implantable Devices Directives 93/42/EEC and 90/385/EEC will *both* be replaced by a single NLF' Regulation probably between 2017 and 2021
- In-Vitro Diagnostics Directive 98/79/EC will also be replaced by an NLF'd Regulation probably between 2017 and 2021
- Personal Protective Equipment. There is a proposal to replace 89/686/EC (mod'd 2004), but no dates yet

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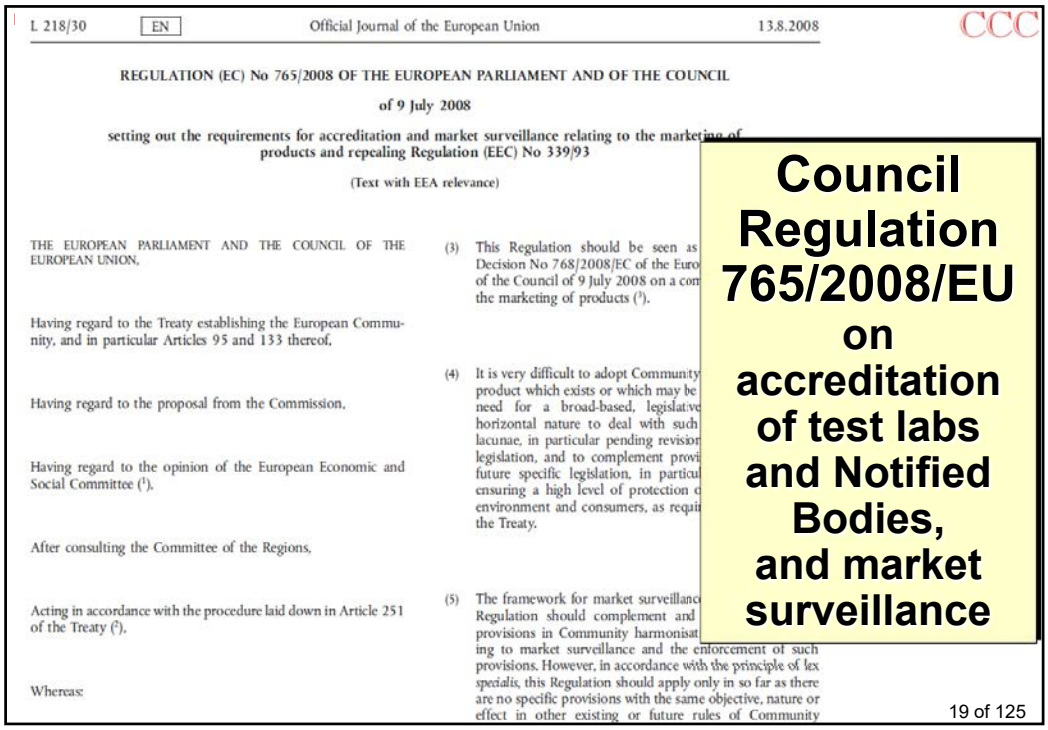
L 218/30 EN Official Journal of the European Union 13.8.2008
REGULATION (EC) No 765/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 9 July 2008
setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93
(Text with EEA relevance)
THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,
Having regard to the Treaty establishing the European Community, and in particular Articles 95 and 133 thereof,
Having regard to the proposal from the Commission,
Having regard to the opinion of the European Economic and Social Committee
After consulting the Committee of the Regions,
Acting in accordance with the procedure laid down in Article 251 of the Treaty
Whereas:
(3) This Regulation should be seen as
(4) It is very difficult to adopt Community
(5) The framework for market surveillanc
Council Regulation 765/2008/EU on accreditation of test labs and Notified Bodies, and market surveillance
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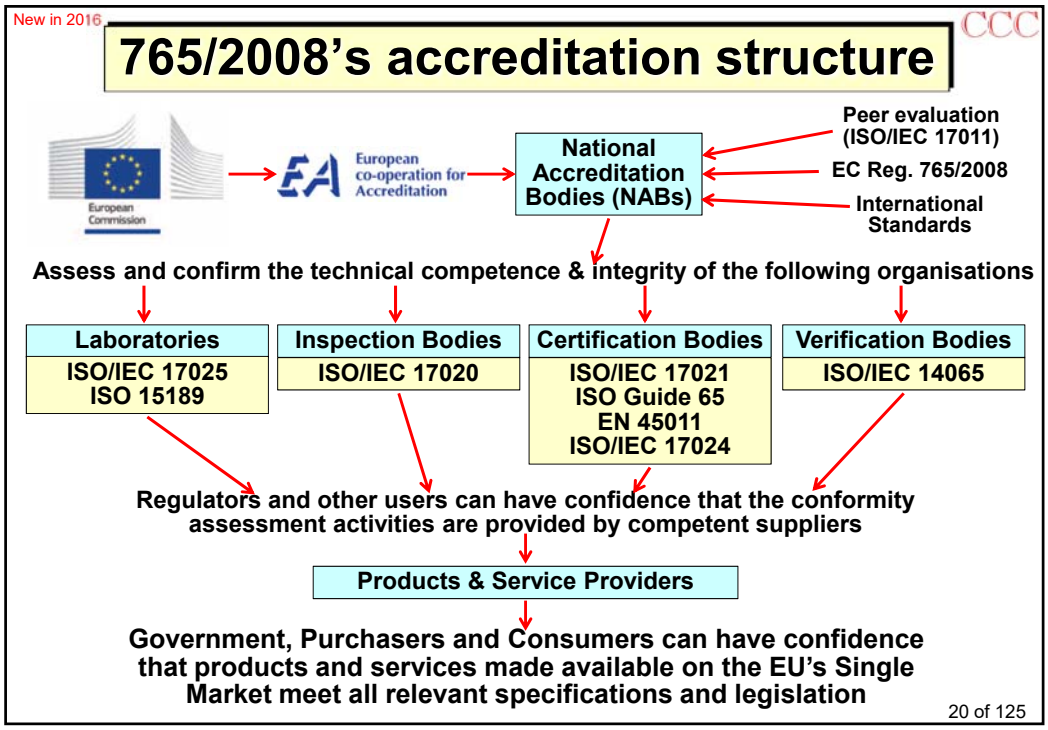
New in 2016
765/2008's accreditation structure
European Commission
European co-operation for Accreditation
National Accreditation Bodies (NABs)
Peer evaluation (ISO/IEC 17011)
EC Reg. 765/2008
International Standards
Assess and confirm the technical competence & integrity of the following organisations
Laboratories
ISO/IEC 17025
ISO 15189
Inspection Bodies
ISO/IEC 17020
Certification Bodies
ISO/IEC 17021
ISO Guide 65
EN 45011
ISO/IEC 17024
Verification Bodies
ISO/IEC 14065
Regulators and other users can have confidence that the conformity assessment activities are provided by competent suppliers
Products & Service Providers
Government, Purchasers and Consumers can have confidence that products and services made available on the EU's Single Market meet all relevant specifications and legislation
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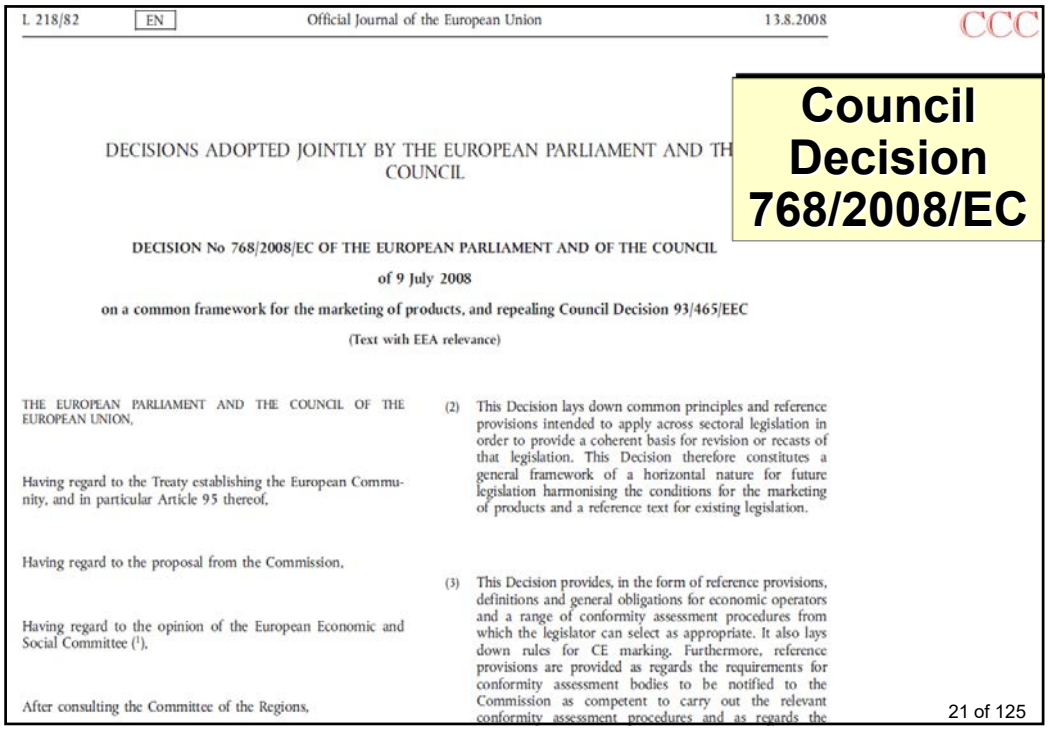

L 218/82 EN Official Journal of the European Union 13.8.2008

CCC

Council Decision 768/2008/EC

DECISIONS ADOPTED JOINTLY BY THE EUROPEAN PARLIAMENT AND TH COUNCIL

DECISION No 768/2008/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 9 July 2008

on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee (1),

After consulting the Committee of the Regions,

(2) This Decision lays down common principles and reference provisions intended to apply across sectoral legislation in order to provide a coherent basis for revision or recasts of that legislation. This Decision therefore constitutes a general framework of a horizontal nature for future legislation harmonising the conditions for the marketing of products and a reference text for existing legislation.

(3) This Decision provides, in the form of reference provisions, definitions and general obligations for economic operators and a range of conformity assessment procedures from which the legislator can select as appropriate. It also lays down rules for CE marking. Furthermore, reference provisions are provided as regards the requirements for conformity assessment bodies to be notified to the Commission as competent to carry out the relevant conformity assessment procedures and as regards the

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New in 201

CCC

768/2008 requires *all economic operators* in a product's *supply chain*…

- to share the responsibility for its compliance when it is *made available* on the EU's Single Market
- *economic operators* is an NLF term, meaning manufacturers, authorised representatives, agents, distributors, importers, etc. in a product's *supply chain* (including distance selling, and selling through electronic means)
- *made available* is an NLF term meaning when an individual unit of a product is available on the EU Market for distribution, hire, consumption or use, whether in return for payment or free of charge…
  - and the NLF term *placed on the market* means *first made available* on the EU Market

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New in 2016

Summary of actions required to comply with the new "NLF'd" Directives:

Manufacturers must ensure that any product they make available on the EU market: (1)

It is important to be aware that in all these Directives and Regulations, the word "product" means an individual commercial item / unit of manufacture — *not a Product Type!*

A. Is designed, manufactured and assessed so as to *individually* conform to all applicable EU Directives

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New in 2016

Manufacturers must ensure that any product they make available on the EU market: (2)

B. Has Technical Documentation which demonstrates compliance, and…

- **makes it possible to assess the product's conformity to the relevant requirements…**
- **includes an adequate analysis and assessment of the risk(s)…** ***(covered in my course: "Safe design of electrical equipment")***
- **is kept updated and available for 10 years after the product was last made available on the EU market**
- **must contain at least the following…** ***(see next 4 slides)***

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New in 2016

B. The new "Risk Assessment" requirement in the NLF

CCC

- The Risks concerned only relate to the Essential Requirements of the relevant Directive, e.g.…
  - EMCD: risks are EMI-related (emissions cause interference, or immunity isn't sufficient for correct functioning, *but no safety risks covered by EMCD*)
  - LVD: risks are safety-related (electrical and non-electrical hazards to humans, domestic animals and/or property)
  - RED: risks are radio related & safety related (SAR!) & EMC related, plus other issues.
  - Toy Directive: risks are related to harming children
- Administrative non-compliance is not a risk (in this context)

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New in 2016

B. The minimum contents of the Technical Documentation (1)

CCC

- A general description of the product, including…
  - (i) photographs or illustrations showing external features, markings, and internal layouts…
  - (ii) versions of software or firmware which can affect the compliance with a Directive's Essential Requirements…
  - (iii) user information and installation instructions
- Conceptual design, manufacturing drawings, and the schemes of components, sub-assemblies, circuits, and other relevant similar elements

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New in 2016

B. The minimum contents of the Technical Documentation (2)

CCC

- Descriptions and explanations necessary for the understanding of those drawings and schemes…
  - and understanding the operation of the product
- A copy of the *single* EU Declaration of Conformity (DoC) *for all relevant Directives* *see later*
- The results of design calculations made, examinations carried out, and other relevant similar activities
- Test reports (whether generated internally or externally)

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New in 2016

B. The minimum contents of the Technical Documentation (3)

CCC

- A list of the harmonised standards applied in full or in part…
  - the references of which have been published in the Official Journal of the European Union (OJEU)…
  - where harmonised standards were partly applied, specify the parts which were applied…
  - where relevant harmonised standards or parts of them were not applied, descriptions of the solutions adopted to meet the relevant Essential Requirements…
  - including a list of any other relevant technical specifications applied

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New in 2016

B. Additional Technical Documentation requirements that can apply

- The minimum requirements in the previous slides…
  - are for the "Internal Production Control" conformity assessment procedure (the simplest one, which doesn't require any involvement by a Notified Body)
  - other conformity assessment procedures *will* have additional requirements to this minimum list…
  - and certain Directives might as well (e.g. RED)…
  - so always read the relevant Directive carefully, to make sure everything required is in the Technical Documentation

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New in 2016

Manufacturers must ensure that any product they make available on the EU market: (3)

C. Has its compliance continually maintained in manufacture…

– e.g. by a Quality Control Procedure that contains the necessary mission statements, procedures, and work instructions to maintain compliance with the Technical Documentation for each/every relevant Directive…

– 3rd-party assessment bodies (UL, TUV, SGS, ETL-SEMKO, Intertek, etc.) will be pleased to help

D. Has a single DoC for all EU Directives *(see next!)*

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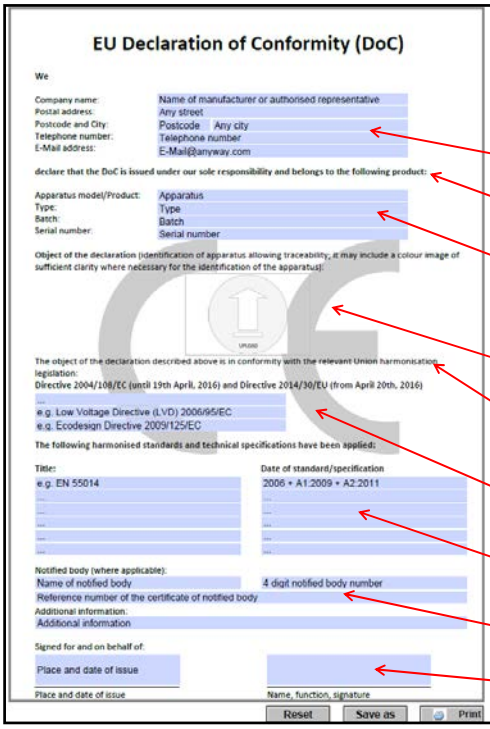

D. Details of the single DoC for all Directives

- Name, address, phone, email for manufacturer or authorised rep.
- 'Sole authority' declaration
- Product name, type, batch(es), serial number(s)
- Information allowing identification and traceability. A colour image of the product is suggested.
- Compliance statement
- List <u>all relevant Directives</u>
- List <u>all Standards</u> "applied"
- Notified Body details (if applicable)
- Name, function, signature, place, date

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New in 2016

D. More details of the single DoC for all Directives

- **Products' DoCs must be continuously updated…**
  - and must be translated into the language or languages required by the Member States on whose markets the product is placed or made available
- **The version on the previous slide was recommended by the EMC ADCO on 4 Jan 2016** (the EC EMC Working Group on Administrative Co-operation)…
  - and can be downloaded from the "Guidance" section of: http://ec.europa.eu/growth/sectors/electrical-engineering/emc-directive/#t_0_1
    - as a "fillable PDF form", which can be reused any number of times to generate new DoCs for products

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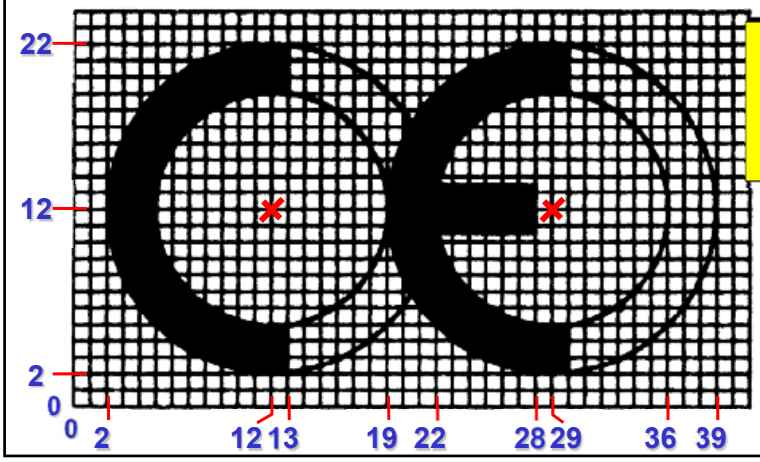
New in 2016

CCC

Manufacturers must ensure that any product they make available on the EU market: (4)

E. Has the CE marking affixed, now specified by Reg. 765/2008/EU, but unchanged



Only the solid shapes should be used
(the rest are to help construct them)

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New in 2016

CCC

Manufacturers must ensure that any product they make available on the EU market: (5)

F. Has a type, batch or serial number affixed, allowing identification of the product, *plus*…

– it's manufacturer's name, trade name or trademark, and a single <u>postal</u> address where he, or his Appointed Agent, may be contacted…

– without misleading anyone about who is the manufacturer…

– all indelibly marked on the product itself…

– or, if that is *not possible…*
for reasonable technical or economic conditions <u>only</u>…
marked on the packaging instead…

– or *(last resort)* on other documents accompanying the product

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New in 201

F. Examples of markings

(courtesy of Jan Coenraads, jan.coenraads.brynyago.com, from his presentation to the RED Compliance Association, March 2016)

OK

NOT OK!
No address at all

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New in 2016

Manufacturers must ensure that any product they make available on the EU market: (6)

G. Is accompanied by user / operating instructions…

– *and* by complete safety information…

– in a language that is easily understood by consumers and other end-users…

– in the Member State in which the product is to be made available on the EU's markets

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New in 2016

F. and G. Both the new LVD (2014/35/EU) and the RED (2014/53/EU) add more requirements than 768/2008:

- They both require the contact details marked on the product to be in a language easily understood by end-users and Market Surveillance Authorities
- And they both require the user instructions and safety information, as well as any labelling, to be clear, understandable and intelligible…
  - *but these seem like common sense to me anyway, so I recommend they are done whichever Directives apply*

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New in 2016

Authorised Representatives must have a written mandate that *at least* requires them to:

H. Act on the manufacturer's behalf regarding all communications with Market Surveillance and National Authorities…

– but this mandate cannot make them responsible for a product's design, manufacture, assessment or the creation of its Technical Documentation

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New in 2016

Importers and Distributors must ensure, *for each product they intend to make available on the EU market*:

I. That its manufacturer has carried out all conformity assessments, created the Technical Documentation, and provided each product with…

– a single DoC for all Directives, and CE marking;

– type, batch or serial number;

– manufacturer's name, trade name or trademark;

– manufacturer's single postal address for contact;

– clear/understandable operating instructions and safety information in a language that is easily understood by consumers and other end-users in the Member State in which the product is to be made available on the EU's markets

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New in 2016

Importers and Distributors must also (1)

J. Mark ***their*** name, trade name or trademark, and single postal address for contact…

– on the product, or *if not possible only for reasonable technical or economic conditions*, on the packaging…

– or, *in the last resort*, on other documents accompanying the product…

– without misleading anyone about who is the actual manufacturer, agent, importer, etc.

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New in 2016

Importers and Distributors must also: (2)

K. **Ensure that any storage or transport they are responsible for…**

– does not jeopardise any products' compliance with any relevant EU Directives…

- **the mechanical shocks and vibrations, and air pressure fluctuations during transportation can fracture enclosures and cause components and connections to come loose…**
- **and the thermal cycling of hot days and cold nights in storage, not to mention possible condensation, can affect the integrity of a product**

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New in 2016

Importers and Distributors must also: (3)

L. **Be ready to provide any product's documentation to Market Surveillance and National Authorities…**

– for up to 10 years after the last instance of the product was made available on the EU market…

– in a language easily understood by the Authorities in that Member State…

– so, given the time it can take to get documents translated – I recommend that all these documents are translated into all relevant languages before making any product available on the EU market

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New in 2016

CCC

Any/all Economic Operators: (1)

M. **Must, for traceability reasons, identify to Market Surveillance Authorities (on their request)…**

– any economic operator who has supplied them with products…

– and/or any economic operator they have supplied products to…

– for up to 10 years after the supply…

– so I recommend keeping all invoices and other purchase/sale/loan etc. documents for at least 10 years

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New in 2016

CCC

Any/all Economic Operators: (2)

N. **Who consider / have reason to believe that a product is not in conformity with a Directive…**

– should not make it available on the EU market…

– recalling it if necessary…

– until it is brought into conformity

O. **Must immediately inform their national authorities if a product presents a risk…**

– EMI risk, radio-spectrum risk, EMF risk, safety risk, etc…

– at least giving details of the non-compliance, and any corrective measures taken

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New in 2016

CCC

Any Economic Operators: (3)

P. **…who modify any products…**

– or even simply market any products (manufactured by someone else) under their own names (i.e. "re-badge" them)…

– effectively *becomes their manufacturers* under EU law…

– automatically taking on *all* of the manufacturer's legal responsibilities for it, under *all* EU Directives…

– so must do *everything* covered by points A – G in the earlier slides

45 of 125

New in 2016

CCC

Any/all Economic Operators: (4)

Q. **Have direct legal rights under 768/2008/EU…**

– which they can enforce through national courts…

– against both national authorities…

– and against other Economic Operators…

– for not respecting the requirements of 768/2008

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New in 2016

CCC

Some important points for any/all Economic Operators

- If a product is non-compliant and requires corrective action, or presents a risk…
  - any/all of the Economic Operators in its supply chain can be held liable in law…
  - e.g. for damages…
  - *so I recommend that all economic operators in a supply chain keep each other well-informed…*
  - *of any/all non-conformities, risks, complaints, corrective actions, etc., that they know of…*
  - *as soon as they know about them*

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New in 2016

CCC

Some useful references on the NLF

- Download Regulation 764/2008:
  http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:218:0021:0029:en:PDF
- Download Regulation 765/2008:
  http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:218:0030:0047:en:PDF
- Download Decision 768/2008:
  http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:218:0082:0128:en:PDF
- Some useful documents:

  http://ec.europa.eu/growth/single-market/goods/new-legislative-framework/index_en.htm

  http://www.european-accreditation.org/brochure/a-briefing-for-european-commission-officials

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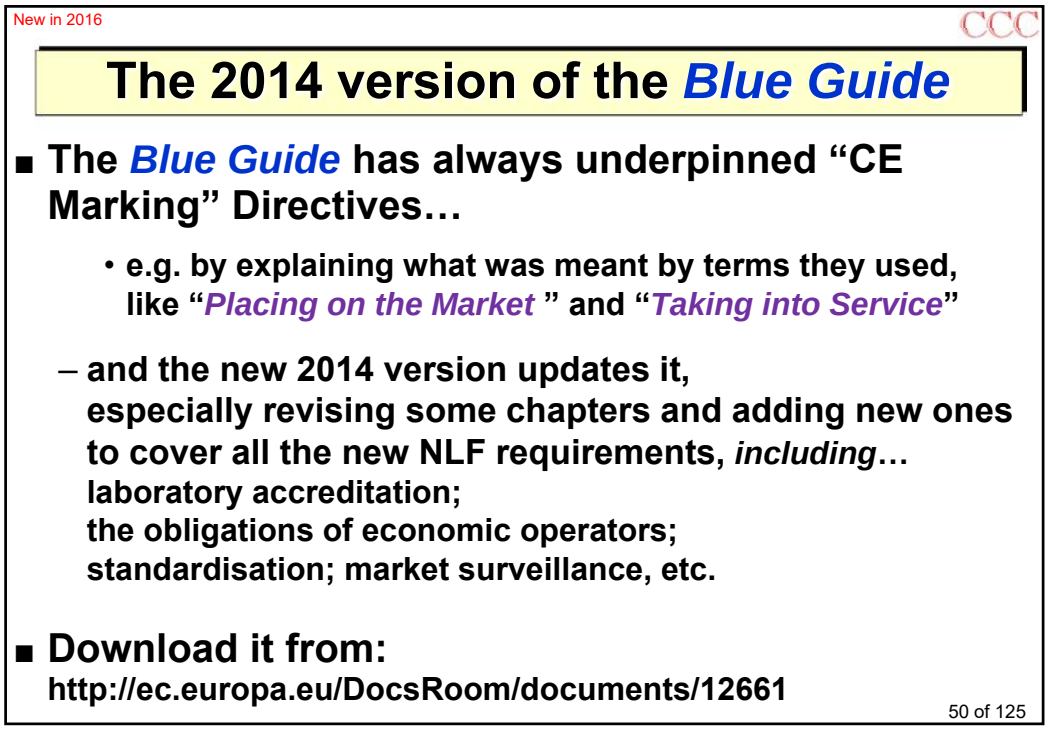
By Keith Armstrong



By Keith Armstrong

New in 2016

CCC

The NEW EMC Directive 2014/30/EU

replaced 2004/108/EC on 20 April 2016

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New in 2016

29.3.2014 EN Official Journal of the European Union L 96/79

DIRECTIVE 2014/30/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 26 February 2014

on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (recast)

(Text with EEA relevance)

The new EMCD 2014/30/EU

Every *individual item* made available on the EU Market on/after 20 April 2016 must declare compliance to this, regardless of how long the same products have been supplied in/to the EU!

(1) A number of amendments are to be made to Directive 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/ apply across sectoral legislation in order to provide a coherent basis for revision or recasts of that legislation. Directive 2004/108/EC should be adapted to that Decision.

(4) Member States should be responsible for ensuring that radiocommunications, including radio broadcast reception and the amateur radio service operating in accordance with International Telecommunication Union (ITU) radio regulations, electrical supply networks and telecommunications networks, as well as equipment connected thereto, are protected against electromagnetic disturbance.

(5) Provisions of national law ensuring protection against electromagnetic disturbance need to be harmonised in order to guarantee the free movement of electrical and electronic apparatus without lowering justified levels of protection in the Member States.

(6) This Directive covers products which are new to the Union market when they are placed on the market; that is to say they are either new products made by a manufacturer established in the Union or products, whether new or second-hand, imported from a third country.

New in 2016

NLF-related changes in 2014/30/EU

- A lot of NLF definitions added
- Text now includes: “placed on the market”; “made available on the market”, and “first taken into service”
- New Chapter: “Obligations of Economic Operators” covers all the requirements of 768/2008
- New Chapter: “Notification of Conformity Assessment Bodies” covers all the requirements of 765/2008
- New Article: “Procedure for dealing with apparatus presenting a risk at national level”, plus Technical Documentation must now include a Risk Assessment…
  - these are non-safety-related EMI risks only

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New in 2016

Other changes in 2014/30/EU…

- In Annex I, “Protection Requirements” are now called “General Requirements”…
- Added to the list of exemptions…
  - “(e) custom built evaluation kits destined for professionals to be used solely at research and development facilities for such purposes”
- Some rewording of the text, presumably to improve its legal status…
  - but without any actual change in meaning, as far as I can determine or have heard mentioned by others

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New in 2016

CCC

Beware!

Some products which used to Declare Conformity to the EMCD *will have to* declare to the Radio Equipment Directive (RED) *instead*

- **Under the R&TTE directive (1999/5/EC)…**
  - **if a product incorporated a radio module which was itself compliant to 1999/5/EC, and installed according to its manufacturer's instructions…**
  - **the overall product could be declared in conformity with the EMCD…**
  - **BUT THIS MIGHT NOT BE THE CASE FROM 12 July 2017! Such products may now have to comply with the RED (2014/53/EU) instead** *see the slides on the RED, later*

55 of 125

New in 2016

CCC

Some useful references on the EMCD

- **List of harmonised EMCD standards published in the OJEU:**
  http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/electromagnetic-compatibility/index_en.htm
- **Download 2014/30/EU:**
  http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014L0030
- **Fillable PDF template for the "single DoC":**
  http://ec.europa.eu/growth/sectors/electrical-engineering/emc-directive/index_en.htm#t_0_1
- **Some articles:**

  www.conformance.co.uk/adirectives/doku.php?id=emc

  www.tuv-sud.co.uk/uploads/images/1405607074361087990248/changes-to-the-electromagnetic-compatibility-emc-directive.pdf

  www.cemarkingassociation.co.uk/new-emc-directive-what-are-the-changes

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By Keith Armstrong

New in 2016

CCC

The NEW Low Voltage Directive (LVD) 2014/35/EU

replaced 2006/95/EC on 20 April 2016

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New in 2016

29.3.2014 EN Official Journal of the European Union L 96/357

DIRECTIVE 2014/35/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 26 February 2014

on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits

(recast)

(EEA relevance)

The new LVD, 2014/35/EU

Every *individual item* made available on the EU Market on/after 20 April 2016 must declare compliance to this, regardless of how long the same products have been supplied in/to the EU!

framework for the marketing of products (5) lays down common principles and reference provisions intended to apply across sectoral legislation in order to provide a coherent basis for revision or recasts of that legislation. Directive 2006/95/EC should therefore be adapted to that Decision.

(4) This Directive covers electrical equipment designed for use within certain voltage limits which is new to the Union market when it is placed on the market; that is to say it is either new electrical equipment made by a manufacturer established in the Union or electrical equipment, whether new or second-hand, imported from a third country.

(5) This Directive should apply to all forms of supply, including distance selling.

(6) Economic operators should be responsible for the compliance of electrical equipment with this Directive, in relation to their respective roles in the supply chain, so as to ensure a high level of protection of public interests, such as health and safety of persons, of domestic animals and property, and to guarantee fair competition on the Union market.

Whereas:

(1) A number of amendments are to be made to Directive 2006/95/EC of the European Parliament and of the Council of 12 December 2006 on the harmonisation

New in 2016

CCC

But beware!

Some products which used to Declare Conformity to the LVD *will have to* Declare to the Radio Equipment Directive (RED) *instead*

- **Under the R&TTE directive (1999/5/EC)…**
  - **if a product incorporated a radio module which was itself compliant to 1999/5/EC, and installed according to its manufacturer's instructions…**
  - **the overall product could be declared in conformity with the LVD…**
  - **BUT THIS MAY NO LONGER BE THE CASE!**
    Such products may now have to comply with the RED (2014/53/EU) instead *see the slides on the RED, later*

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New in 2016

CCC

NLF changes between 2006/95 and 2014/35/EU

- **NLF definitions added on "Economic Operators"**
- **Text now includes: "placed on the market"; "made available on the market", and "first taken into service"**
- **New Chapter: "Obligations of Economic Operators" covers all the requirements of 768/2008/EU**
- **New Chapter on "Market Surveillance…"…**
  - **which includes an Article on: "Compliant electrical equipment which presents a risk"…**
    - **because a Safety Risk Assessment is now a requirement , and must be included in the Technical Documentation**

60 of 125

New in 2016

CCC

Other changes in 2014/35/EU (1)

- Added to the list of exemptions…
  - "Custom built evaluation kits destined for professionals to be used solely at research and development facilities"
- The Manufacturer or Authorised Representative is no longer required to be in the EU
- The last two digits of the year in which the CE marking was affixed is no longer required !!!

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New in 2016

CCC

Other changes in 2014/35/EU (2)

- Annex 1 now lists the LVD's Essential Legal Requirements, which it calls the "Principal Elements of the Safety Objectives"
- Point 1: "General conditions" (1)…

(a) the essential characteristics, the recognition and observance of which will ensure that electrical equipment will be used safely and in applications for which it was made, shall be marked on the electrical equipment, or, if this is not possible, on an accompanying document;

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New in 2016

CCC

Annex 1, Point 1: "General conditions" (2)

(b) the electrical equipment, together with its component parts, shall be made in such a way as to ensure that it can be safely and properly assembled and connected;

(c) the electrical equipment shall be so designed and manufactured as to ensure that protection against the hazards set out in points 2 and 3 is assured, providing that the equipment is used in applications for which it was made and is adequately maintained.

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New in 2016

CCC

Annex 1, Point 2: "Protection against hazards arising from the electrical equipment" (1)

Measures of a technical nature shall be laid down in accordance with point 1, in order to ensure that:

(a) persons and domestic animals are adequately protected against the danger of physical injury or other harm which might be caused by direct or indirect contact;

(b) temperatures, arcs or radiation which would cause a danger, are not produced;

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New in 2016

CCC

Annex 1, Point 2: "Protection against hazards arising from the electrical equipment" (2)

(c) persons, domestic animals and property are adequately protected against non-electrical dangers caused by the electrical equipment which are revealed by experience;

(d) the insulation is suitable for foreseeable conditions.

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New in 2016

CCC

Annex 1, Point 3: "Protection against hazards which may be caused by external influences on the electrical equipment" (1)

Technical measures shall be laid down in accordance with point 1, in order to ensure that the electrical equipment:

(a) meets the expected mechanical requirements in such a way that persons, domestic animals and property are not endangered;

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New in 2016

CCC

Annex 1, Point 3: Protection against hazards which may be caused by external influences on the electrical equipment (2)

(b) is resistant to non-mechanical influences in expected environmental conditions, in such a way that persons, domestic animals and property are not endangered;

(c) does not endanger persons, domestic animals and property in foreseeable conditions of overload.

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New in 2016

CCC

Some useful references on the LVD

- **List of harmonised LVD standards published in the OJEU:**
  http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/low-voltage/index_en.htm
- **Download 2014/35/EU from:**
  http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2014.096.01.0357.01.ENG
- **Some articles:**

  http://ec.europa.eu/DocsRoom/documents/13141/attachments/1/translations/en/renditions/native

  www.cemarkingassociation.co.uk/new-low-voltage-directive-what-are-the-changes/

  www.conformance.co.uk/adirectives/doku.php?id=lowvoltage

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New in 2016

CCC

Two new Medical Device Regulations replacing:

93/42/EEC Medical Devices *and* 90/385/EEC Active Implantable Devices

98/79/EC In-Vitro Diagnostics Directive

Replacement dates: 2017-21 ??

Nobody knows!

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CCC

Council of the European Union

Brussels, 11 June 2015
(OR. en)

9769/15

This document includes the text of the proposed Regulation on both Medical and Active Implantable Devices

Interinstitutional File:
2012/0266 (COD)

PHARM 26
SAN 176
MI 391
COMPET 304
CODEC 858

NOTE

From:	Presidency
To:	Council
No. prev. doc.:	9238/15 PHARM 22 SAN 155 MI 347 COMPET 259 [illegible]
No. Cion doc.:	14493/12 PHARM 71 SAN 215 MI 597 COMPET 600 CODEC 2305 + COR 1
Subject:	Proposal for a Regulation of the European Parliament and of the Council on **medical devices** and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009

Delegations will find in the Annex to this document a consolidated text for the Articles of the proposed Regulation mentioned above prepared by the Latvian Presidency with a view to the meeting of the Council (EPSCO) on 19 June 2015.

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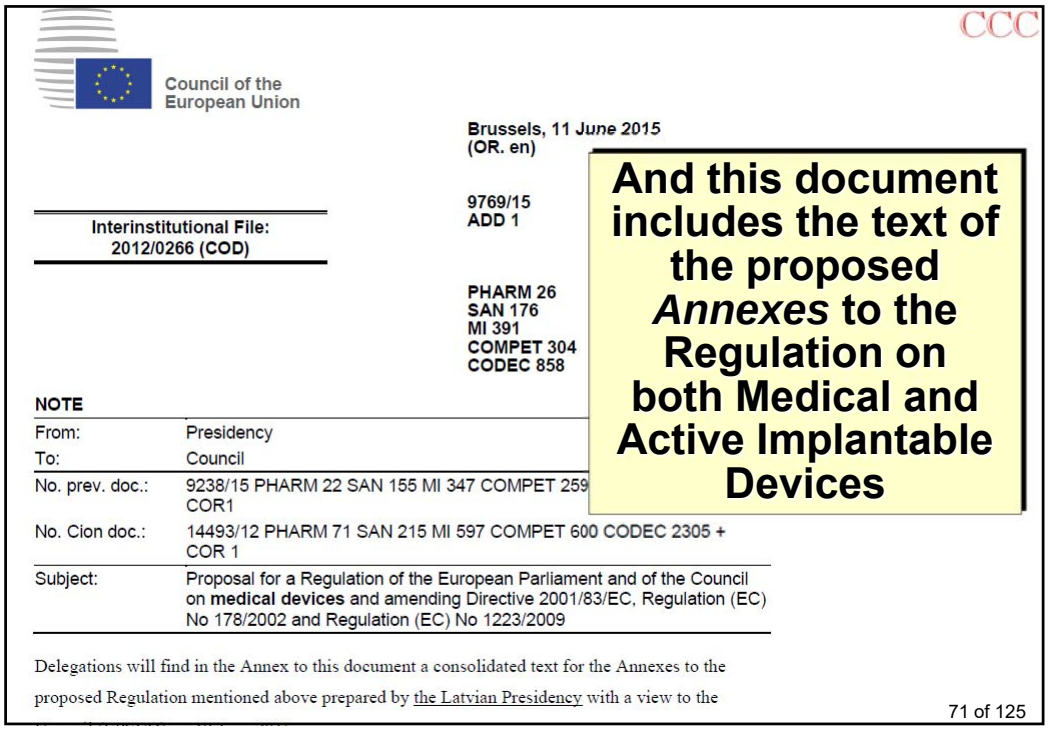

CCC

Council of the European Union

Brussels, 11 June 2015
(OR. en)

Interinstitutional File:
2012/0266 (COD)

9769/15
ADD 1

PHARM 26
SAN 176
MI 391
COMPET 304
CODEC 858

And this document includes the text of the proposed *Annexes* to the Regulation on both Medical and Active Implantable Devices

NOTE

From:	Presidency
To:	Council
No. prev. doc.:	9238/15 PHARM 22 SAN 155 MI 347 COMPET 259 COR1
No. Cion doc.:	14493/12 PHARM 71 SAN 215 MI 597 COMPET 600 CODEC 2305 + COR 1
Subject:	Proposal for a Regulation of the European Parliament and of the Council on **medical devices** and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009

Delegations will find in the Annex to this document a consolidated text for the Annexes to the proposed Regulation mentioned above prepared by the Latvian Presidency with a view to the

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New in 2016

CCC

11 June 2015 proposal for a Regulation on medical (inc. Active Implantable) devices

- **After a number of safety and enforcement problems, leading up to the PIP breast implant scandal…**
  - **the Commission argued that Medical Directives had been inconsistently implemented in Member States, affecting both patient safety and the internal market…**
  - **so the Commission have proposed to implement the NLF – *and much more* – as a Medical Device Regulation…**
  - **because Regulations are *directly enforceable* in Member States…**
    - **unlike the current regime based on Directives**

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New in 2016

CCC

The 11 June 2015 proposal for a Regulation includes the following… (1)

(from: https://medtechengine.com/article/new-eu-medical-device-regulations by Matthew Orman, 10 February 2016

- Greater transparency for patients – in particular those taking part in clinical trials
- Manufacturers / importers must register themselves and devices they place on the EU market in a central database – the European databank on medical devices (Eudamed)
- Manufacturers must fit their products with a unique device identification to ensure traceability (and detect counterfeits)
- New rules for the reprocessing of single-use medical devices to make them suitable for further use

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New in 2016

CCC

11 June 2015 proposal for a Regulation includes… (2)

- Reinforced rules governing clinical evaluation throughout the life of the device, including the introduction of the concept of a 'sponsor'…
  - as well as a new requirement for manufacturers to have a 'qualified person' responsible for regulatory compliance
- The creation of an EU portal where manufacturers would have to report serious incidents and any corrective actions they have taken to reduce the risk of recurrence
- Extension of the scope of medical device regulation to cosmetic/aesthetic devices (e.g. contact lenses or fat-removal devices), as well as 'ingested products'

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New in 2016

11 June 2015 proposal for a Regulation includes… (3)

CCC

- A post-market surveillance system detailing manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market
  - these include annual periodic safety update reports (PSURs), a step which brings medical devices into line with pharmaceutical reporting requirements
- A tightening of the rules for the designation of notified bodies, the monitoring of their assessment activities by national competent authorities and cooperation between competent authorities…
  - these new rules also give Notified Bodies the right and duty to do spot checks during *unannounced* factory inspections

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New in 2016

11 June 2015 proposal for a Regulation includes… (4)

CCC

- The introduction of a new expert group (the Medical Device Coordination Group)…
  - which will have the power to review and comment on Notified Body assessments of high-risk medical devices…
    - *before the device is put on the EU market*
- Download the 11 June 2015 proposals:
  - www.consilium.europa.eu/en/policies/new-rules-medical-in-vitro-diagnostic-devices/
  - http://data.consilium.europa.eu/doc/document/ST-9769-2015-INIT/en/pdf
  - http://data.consilium.europa.eu/doc/document/ST-9769-2015-ADD-1/en/pdf
  - www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+REPORT+A7-2013-0324+0+DOC+XML+V0//EN

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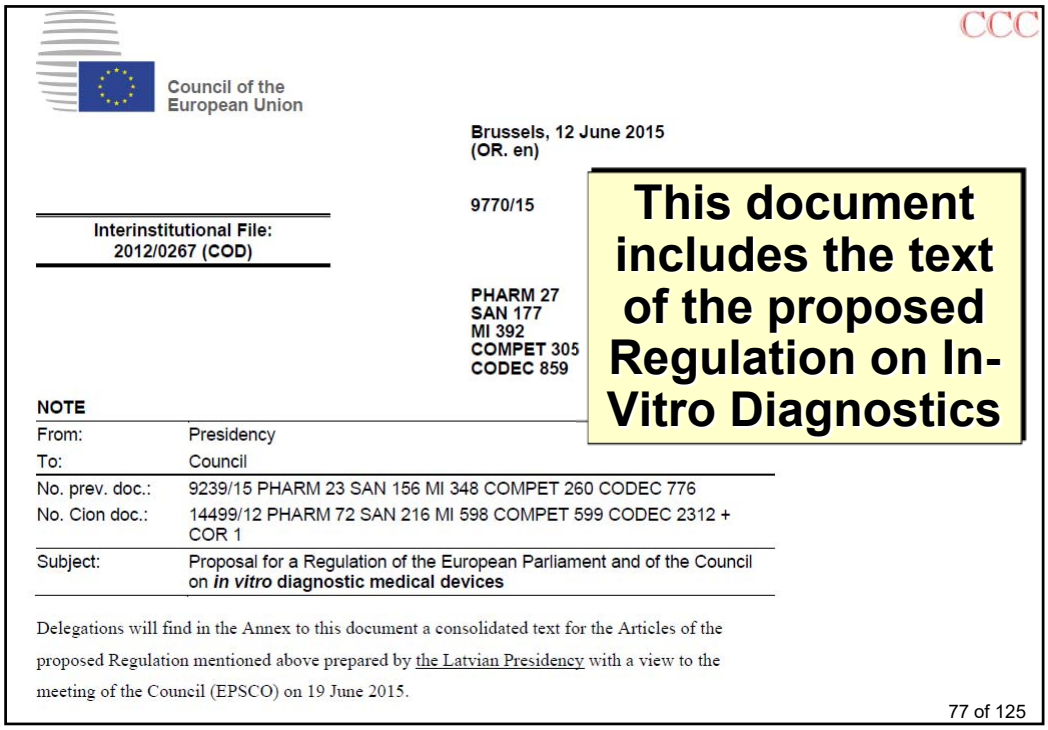

CCC

Council of the European Union

Brussels, 12 June 2015
(OR. en)

9770/15

Interinstitutional File:
2012/0267 (COD)

PHARM 27
SAN 177
MI 392
COMPET 305
CODEC 859

This document includes the text of the proposed Regulation on In-Vitro Diagnostics

NOTE

From:	Presidency
To:	Council
No. prev. doc.:	9239/15 PHARM 23 SAN 156 MI 348 COMPET 260 CODEC 776
No. Cion doc.:	14499/12 PHARM 72 SAN 216 MI 598 COMPET 599 CODEC 2312 + COR 1
Subject:	Proposal for a Regulation of the European Parliament and of the Council on ***in vitro*** **diagnostic medical devices**

Delegations will find in the Annex to this document a consolidated text for the Articles of the proposed Regulation mentioned above prepared by the Latvian Presidency with a view to the meeting of the Council (EPSCO) on 19 June 2015.

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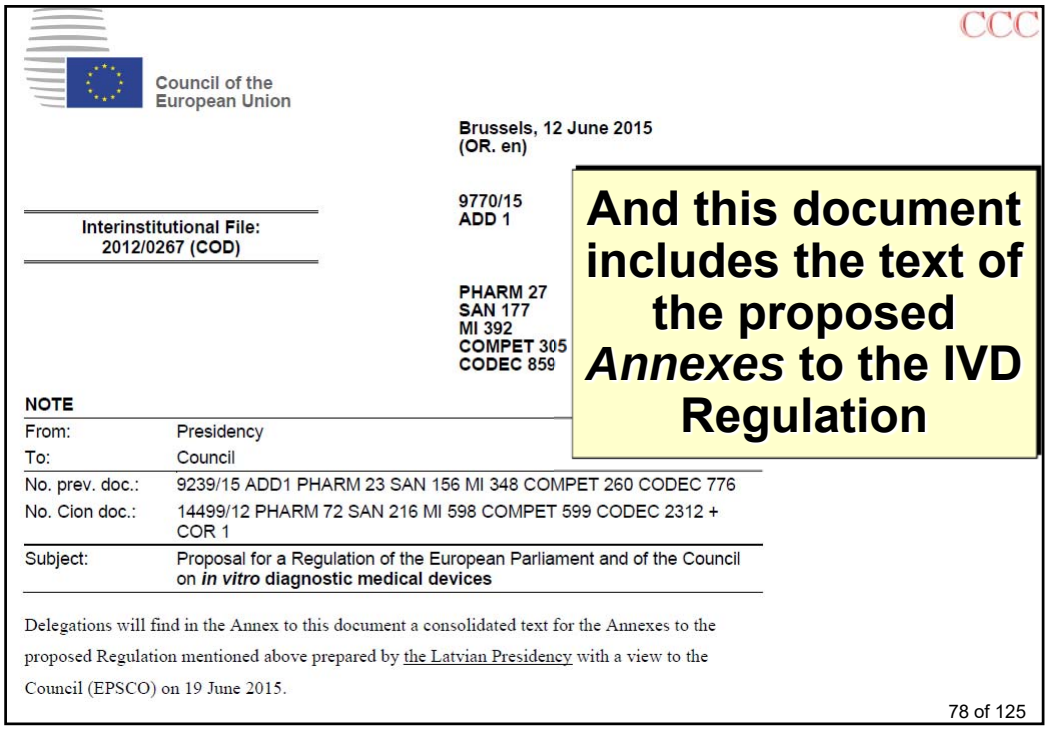

CCC

Council of the European Union

Brussels, 12 June 2015
(OR. en)

9770/15
ADD 1

Interinstitutional File:
2012/0267 (COD)

PHARM 27
SAN 177
MI 392
COMPET 305
CODEC 859

And this document includes the text of the proposed *Annexes* to the IVD Regulation

NOTE

From:	Presidency
To:	Council
No. prev. doc.:	9239/15 ADD1 PHARM 23 SAN 156 MI 348 COMPET 260 CODEC 776
No. Cion doc.:	14499/12 PHARM 72 SAN 216 MI 598 COMPET 599 CODEC 2312 + COR 1
Subject:	Proposal for a Regulation of the European Parliament and of the Council on ***in vitro*** **diagnostic medical devices**

Delegations will find in the Annex to this document a consolidated text for the Annexes to the proposed Regulation mentioned above prepared by the Latvian Presidency with a view to the Council (EPSCO) on 19 June 2015.

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New in 2016

12 June 2015 proposal for EU Regulation on IVD's includes… (1)

from Lloyds Register:
www.lrqa.co.uk/standards-and-schemes/IVD/new-regulation.aspx

- New conformity requirements…
  - a new 'risk-rule' classification system based on the Global Harmonization Task Force (GHTF) rules…
  - seven classification rules leading to four risk classes, A-D (lowest-highest), and only Class A can be self-certified (but not under all circumstances)…
  - about 80% of IVDs are currently self-declared, but the new Regulation means about 80% will have to use a Notified Body for conformity assessment

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New in 2016

June 2015 proposal for EU Regulation on IVDs includes… (2)

- Clarified and expanded Scope will cover…
  - tests providing information about the predisposition to a medical condition or disease…
  - tests providing information to predict treatment response or reactions…
  - medical software which is explicitly mentioned in the definition of an IVD…
  - devices manufactured and used within a health institution

80 of 125

New in 2016

June 2015 proposal for EU Regulation on IVDs includes… (3)

CCC

- Manufacturers will have to have at least one person accountable for Regulatory compliance…
  - who must have expert knowledge in the field of IVDs
- Manufacturers must fit their devices with a Unique Device Identification (UDI)…
  - that makes it possible to access certain information about it
  - and high-risk devices must have a publicly-available summary of safety and performance with key elements of the supporting clinical data

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New in 2016

June 2015 proposal for EU Regulation on IVDs includes… (4)

CCC

- A Performance Evaluation Report is required…
  - that demonstrates conformity to the general safety and performance requirements…
    - proportionate to the Risk Class
- The Commission plans to set up an electronic vigilance system…
  - to collate and process reports on serious incidents, field safety corrective notices/actions and periodic reports…
    - and manufacturers of Class C & D IVDs will have to report all incidents that affect their risk/benefit analyses

82 of 125

New in 2016

June 2015 proposal for EU Regulation on IVDs includes… (5)

- **Notified Bodies will have a stronger role…**
  - **including the right (and duty) to carry our unannounced factory inspections, and to test IVDs…**
    - **and will have to rotate their IVD assessment personnel at regular intervals**
- **Download the IVD Regulation proposals…**

www.consilium.europa.eu/en/policies/new-rules-medical-in-vitro-diagnostic-devices/

http://data.consilium.europa.eu/doc/document/ST-9770-2015-INIT/en/pdf

http://data.consilium.europa.eu/doc/document/ST-9770-2015-ADD-1/en/pdf

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New in 201

Beware!

Some products which currently Declare Conformity to a Medical Device Directive *might have to* declare to the Radio Equipment Directive (RED) *instead*

- **Under the R&TTE directive (1999/5/EC), if a Medical Device incorporated a radio module which was itself compliant to 1999/5/EC, and installed according to its manufacturer's instructions…**
  - **the overall product could be declared in compliance with the relevant Medical Device Directive…**
  - **BUT THIS MAY NO LONGER BE THE CASE!**
    Such devices might now have to comply with the RED (2014/53/EU) instead (at least, until the new Medical Device and IVD Regulations are in force) *see the slides on the RED, later*

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By Keith Armstrong

New in 2016

CCC

The new Radio Equipment Directive, 'RED', 2014/53/EU

Replaced the R&TTE Directive (1999/5/EC) on 13 June 2016

– however, it is not a simple 'handover': see the following slides

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CCC

DIRECTIVE 2014/53/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 16 April 2014

on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the Economic and Social Committee (1),

Acting in accordance with the ordinary legislative procedure (2),

Whereas:

(1) Directive 1999/5/EC of the European Parliament and of the Council (3) has been substantially amended several times. Since further amendments are to be made, it should be replaced in the interests of clarity.

(2) Regulation (EC) No 765/2008 of the European Parliament and of the Council (4) lays down rules on the accreditation of conformity assessment bodies, provides a framework for the market surveillance of products and for controls on products from third countries, and lays down the general principles of the CE marking.

The new Radio Equipment Directive: RED 2014/53/EU

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New in 2016

RED is totally new

- Unlike all the other EU Directives replaced with "NLF" ones…
  - RED is a new Directive…
    - not simply an update of the R&TTE Directive 1999/5/EC
- It covers…
  - "Radio Equipment" and "Radiodetection"…
  - all frequencies: DC to 3,000GHz (3THz)…
  - with no lower limit on supply voltage (unlike the LVD)

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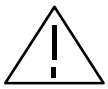
New in 2016

Unlike R&TTED, RED *does not* require:

- "Prior Notification" of Member States…
  - because of 672/2002/EC & 2007/344/EC, Member States now use EFIS to communicate their spectrum use decisions (EFIS = ECO Frequency Information System, www.efis.dk)...
  - RE manufacturers wishing to use non-harmonised radio spectrum must search EFIS to discover what frequencies are available, and what conditions / restrictions apply, in the Member States they want to sell products in
- The "Alert" symbol 
- CE mark to be in the user / instruction manual
- Specific provisions for "essential radio test suites"

88 of 125

New in 2016

The RED defines "Radio Equipment" like this…

CCC

- 'Radio equipment' means an electrical or electronic product, which intentionally emits and/or receives radio waves for the purpose of radio communication and/or radiodetermination, or an electrical or electronic product which must be completed with an accessory, such as an antenna, so as to intentionally emit or receive radio waves for the purpose of radio communication and/or radiodetermination.
- 'Radio communication' means communication by means of radio waves.

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New in 2016

And the RED defines "Radiodetermination" like this:

CCC

- 'Radiodetermination' means the determination of the position, velocity and/or other characteristics of an object, or obtaining of information relating to those parameters, by means of the propagation properties of radio waves.
- 'Radio waves' means electromagnetic waves of frequencies lower than 3 000 GHz, propagated in space without artificial guide;

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New in 2

RED does not apply to the following types of radio equipment (RE)….

- Used *exclusively* for public security, defence, state security, or the economic well-being of the state
- Kits assembled; RE modified; RE constructed, *by* radio amateurs *for the use of* radio amateurs
- Marine equipment (in the scope of 96/98/EC, soon 2014/90/EU)
- Airborne products, parts and appliances (as regulated under Article 3 of EC Regulation 216/2008)
- Custom built kits solely for Research and Development
- Equipment using RF other purposes (e.g. RF heating, diathermy, medical imagery, wireless power transfer, etc.)

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New in 2016

NLF-related items in the RED

- NLF definitions included
- Chapter II: "Obligations of Economic Operators" covers all the requirements of 768/2008
- Chapter IV: "Notification of Conformity Assessment Bodies" covers all the requirements of 765/2008
- Risk Analysis and Assessment required, and must be included in the Technical Documentation…
  - this is a radio Directive and has EMI and safety risks, as well as risks caused by radio functions not working
- "Single DoC" requirements as 768/2008 *(but see later!)*
- Text includes "placed on the market"; "made available on the market", and "first taken into service"

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New in 2016

Individual product items currently declared compliant to R&TTED, and WILL be covered by RED…

- Made available on EU Market *before* 13 June 2016…
  - they must continue to declare conformity to the R&TTED
- When made available on EU Market *between* 13 June 2016 and 12 June 2017…
  - they can choose to declare conformity to R&TTED *or* RED
- When made available on Market *after* 12 June 2017…
  - they must declare compliance to RED

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New in 2016

Individual product items currently declared compliant to R&TTED, but NOW covered by EMC / LVD…

- Examples of telephone terminal equipment (TTE) to which this applies, includes…

  Landline telephones ("POTs")
  Fax machines
  Telephone answering machines
  Ethernet routers and switches
  Set-top boxes (cabled TV distribution systems)
  LAN internet access gateways
  Telephone exchanges

  – *as long as they have no embedded radio functions!*

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New in 2016

Individual product items currently declared compliant to R&TTED, but NOW covered by EMC / LVD… (2)

- Must be declared compliant to the new EMCD (2014/30/EU)…
  - and – if powered from 50-1000Vac rms, or 75-1500Vdc – also declared compliant to the new LVD (2014/35/EU)…
  - from 13 June 2016…
  - *i.e. no transition period!*

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New in 2016

Individual product items currently declared compliant to EMCD and/or LVD, but NOW covered by the RED… (1)

- including, for e.g.:
  stand-alone radio receivers (not controlled by a network)
  including broadcast receivers and scanners
  transmitters and receivers which operate < 9kHz
  radio determination equipment
  stud finders < 9kHz; railway applications 500Hz – 2kHz
  animal fences 1kHz – 9kHz; metal detectors 3kHz – 20kHz;
  electronic article surveillance (EAS) 10Hz – 1kHz…
  ANYTHING with an embedded radio (wireless) function!!!
  - ?? There seems to be some debate about DVB-C receivers…
  - ?? It is often said that Wireless Power Transfer is not covered by the RED – *but most WPT uses radiodetermination!*

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New in 2016

CCC

Individual product items currently declared compliant to EMCD and/or LVD, but NOW covered by the RED… (2)

- Came under the RED from 13 June 2016…
  - with a transition period of 1 year until 12 June 2017 where they can choose to declare compliance to EMC/LVD or RED…
    - *BUT:* if still declaring compliance to EMC/LVD after 20 April 2016 – must declare to the NEW EMC (2014/30/EU) and/or NEW LVD (2014/35/EU)
  - but in any case, after 12 June 2017, must all be placed on the EU Market with a DoC to the RED…
    - more on this very contentious subject at the end !

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New in 2016

CCC

Keep aware of any national restrictions

- EU Member States might add legal requirements *beyond those in the RED*…
  - e.g. for efficient/effective use of their radio spectrum…
    - avoidance of harmful interference (e.g. to emergency services, military, etc.)…
    - avoidance of electromagnetic disturbances…
    - public health…
  - these might require, for example…
    - children's mobile phones meeting lower SAR levels…
    - special user licenses for certain types of RE

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New in 2016

The RED requires… (1)

- **CE marking on *both* the product *and* its packaging and the products' CE mark *can be less than 5mm high!***
- **Mobile phones to use a common charger (but what type of charger is not yet agreed)**
- **Testing of an RE product for compliance to RED's Essential Requirements to be performed *at the expense of the manufacturer or importer*…**
  - **if requested by a Market Surveillance Authority (MSA)…**
  - **within a time period specified by that MSA...**
  - **by a test laboratory specified by that MSA**

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New in 2016

The RED requires… (2)

- **Each individual product to be accompanied by a full copy of its (up-to-date!) DoC…**
  - ***or,* by this specific text of a simplified DoC, which allows people to download the full *up-to-date* DOC version:**

"Hereby, *[Name of manufacturer]* **declares that the radio equipment type** *[designation of type of RE]* **is in compliance with Directive 2014/53/EU.**
The full text of the EU DoC is available at the following internet address: *[URL or email address]*"

  - **either DoC must use the language(s) required by the Member State where the RE is made available on the EU Market…**
  - **authorised translations for the *simplified* DoC can be found in the appropriate language versions of the RED**

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New in 2016

The RED requires… (3)

CCC

- An instruction manual and safety information which…
  - describes the accessories & components, including software, which allow the RE product to operate as intended…
  - and all such instructions and safety information, as well as any labelling, must be clear, understandable and intelligible
  - for transmitters: the frequency band(s) used, and the maximum RF transmitted power in each band…
  - identify any Member States or geographical areas, where the RE *must not be used, and* warn the user about any restrictions in use or requirements for authorisation before use that might apply in certain Member States…
    - this information must be repeated on the packaging

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New in 2016

The RED requires… (4)

CCC

- Where the Risk Analysis shows that the health and safety of end-users requires it…
  - manufacturers must carry out sample testing (most likely of human exposure to EMF, electromagnetic fields)…
  - investigate and keep a register of non-conforming RE, and any recalled RE…
  - keep other Economic Operators in the supply chains for the affected RE products informed of these activities and their results

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New in 2016

Article 3.1: Essential Requirements (1)

Radio equipment shall be constructed so as to ensure:

(a) the protection of health and safety of persons and of domestic animals and the protection of property, including the objectives with respect to safety requirements set out in Directive 2014/35/EU, but with no voltage limit applying;

(b) an adequate level of electromagnetic compatibility as set out in Directive 2014/30/EU.

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New in 2016

Article 3.1: Essential Requirements (2)

- **Note that 3.1 uses the ERs from the new EMCD and new LVD…**
  - **so these ERs have to be applied as intended in the EMCD and LVD…**
  - **but the Declaration of Conformity has to be to the RED *alone…***
    - **and *must not mention* the EMCD or the LVD**

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New in 2016

CCC

Article 3.2: Some additional ERs

Radio equipment shall be so constructed that it both effectively uses and supports the efficient use of radio spectrum in order to avoid harmful interference.

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New in 2016

CCC

Article 3.3: some more ERs, which can be invoked as necessary via "Delegated Acts" in the future (1)

- Radio equipment within certain categories or classes shall be so constructed that it complies with the following essential requirements:
- (a) radio equipment interworks with accessories, in particular with common chargers;
- (b) radio equipment interworks via networks with other radio equipment;
- (c) radio equipment can be connected to interfaces of the appropriate type throughout the Union;

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New in 2016

CCC

Article 3.3: some more ERs, which can be invoked via "Delegated Acts" (2)

- (d) radio equipment does not harm the network or its functioning nor misuse network resources, thereby causing an unacceptable degradation of service;
- (e) radio equipment incorporates safeguards to ensure that the personal data and privacy of the user and of the subscriber are protected;
- (f) radio equipment supports certain features ensuring protection from fraud;
- (g) radio equipment supports certain features ensuring access to emergency services;

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New in 2016

CCC

Article 3.3: some more ERs, which can be invoked via "Delegated Acts" (3)

- (h) radio equipment supports certain features in order to facilitate its use by users with a disability;
- (i)radio equipment supports certain features in order to ensure that software can only be loaded into the radio equipment where the compliance of the combination of the radio equipment and software has been demonstrated.

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New in 2016

CCC

New harmonised standards are awaited on:

- Receiver performance
- Common chargers
- Access to Galileo
- Software-Defined Radio (SDR)…
  - an SDR subgroup aims to provide the Commission with guidance on RED Articles 4.1 and 4.2, and on the Essential Requirements in RED Article 3.3, by Dec. 2016

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New in 2016

CCC

Proposal for pictogram on packaging

- To help communicate any restrictions or authorisation requirements (if there are any) to users…
  - e.g. the following *proposals…*
    (courtesy of Jan Coenraads, jan.coenraads.brynyago.com, from his presentation to the RED Compliance Association, March 2016)

'Restrictions in IT, CH, FR, AT, FI, GB, PL, DE and PT'

'Restrictions in:

IT	CH	FR
AT	FI	GB
PL	DE	PT

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New in 2016

Possible Product Registration scheme

- If *by 12 June 2018* the Commission decides that RED compliance is too poor…
  - it can set up a product registration scheme…
  - which would require a Registration Number to be affixed to the RE
- This scheme is already in the RED…
  - but most of its rules are yet to be decided by the Commission…
  - and we don't yet know if it will ever be implemented

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New in 2016

Three Routes to complying with RED's Essential Requirements (ERs)

1. Manufacturer can show that a product meets the ERs *without any Notified Body involvement*, by…
   - using internal / external testing facilities to "apply" all relevant Harmonized Standards…
   - providing the manufacturer has Quality Control in place that ensures continuing compliance of all production
2. "EU-type examination" (using a Notified Body)
3. "Conformity based on full quality assurance" (using a Notified Body)

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New in 2016

Beware!

Some products which used to Declare Conformity to the EMCD and/or LVD *will have to* Declare to the RED *instead*

- **Most say that *mere presence* of a radio function means the RED applies instead of EMCD or LVD…**
  - **even, for example, a Machine Tool – if it has a WiFi module affixed (e.g. to join the Industrial IoT)…**
  - **but products can only be declared compliant with RED using harmonised standards listed under RED…**
  - ***and there aren't enough RED standards listed!***
  - **e.g. Machine Tools are covered by EN 50370 under the EMCD, but have no equivalent standard published under RED**

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New in 2016

Here's the list of relevant standards originally listed under EMCD and LVD, which are already listed under RED, at 11 March 2016

- **EMC standards:**

EN 50561-1	PLC
EN 55022 & 55024	ITE
EN 55032	Multimedia
EN 61000-3-2, 3, 11, 12	Mains harmonics, flicker, etc.
EN 61000-6-1, 2, 3, 4	Generics: immunity & emissions

- **LVD standards:**

EN 60065	Audio, video, etc.
EN 60825-1, 2, 4, 12	Lasers, fibre-optics, etc.
EN 60730-1	Automatic household controls
EN 60950-1, -22, -23	ITE
EN 62368-1	Audio, video, etc.

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New in 2016

CCC

RED conformity for 'combined equipment' * (1)

* 'combined equipment' is the RED term for what we get when we add a wireless module (e.g. Bluetooth) to a non-wireless product

- We only have *draft* guidance on how it can comply with RED's requirements in Articles 3.1b and 3.2…
  - ETSI EN 301 489-1, "EMC for radio equipment and services, common technical requirements", especially its Annex C…
  - ETSI TR 102 070-1, "Guide to the application of harmonized standards to multi-radio and combined radio and non-radio equipment; Part 1: EMC"…
  - *draft* ETSI EG 203 367, "Guide on applying harmonized standards covering Articles 3.1b and 3.2 to multi-radio and combined radio and non-radio equipment"

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New in 2016

CCC

RED conformity for 'combined equipment' (2)

- The *draft* guidance on complying with RED Articles 3.1b (EMC) and 3.2 (Radio Spectrum) seems sensible…
  - basically saying that the harmonised standards that have been listed in the OJ under the EMCD…
    - i.e. the ones applied before 13 July 2016 to declare the whole combined equipment in conformity with the EMCD…
  - will *still be* the standards to be applied to the non-radio part from 13 July 2017 when the whole combined equipment has to declare conformity to RED instead
- The radio part of the 'combined equipment' (e.g. a WiFi, Bluetooth, GSM, 3G, etc., wireless module) will still have to comply with harmonised standards listed under RED, of course

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New in 2016

RED conformity for 'combined equipment' (3)

- The get-out that allows EMCD-listed standards to be used, instead of RED-listed EMC standards…
  - is that the DoC to the RED must list ETSI EG 203 367 and/or ETSI EN 301 489-1…
    - which are EMC standards listed in the OJ *under the RED*
- These RED-listed EMC standards specify that the original EMCD-listed standards shall be applied…
  - but those original EMCD-listed standards will only appear in the Technical Documentation…
  - not in the DoC!

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New in 2016

RED conformity for 'combined equipment' (4)

- This *seems* like a way to get around the fact that only RED-listed standards can go on a RED DoC…
  - however, both ETSI EG 203 367 and ETSI EN 301 489-1 also deal with the complex EMC and spectrum issues that can arise when creating 'combined equipment'
- Easiest EMC compliance with RED is when a <u>single</u> wireless module is installed *fully in accordance with its manufacturers instructions…*
  - it very quickly gets more complex and costly when there are two or more wireless modules; and/or any wireless installation instructions aren't fully applied; and/or one or more wireless modules are modified in some way

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New in 2016

RED conformity for "combined equipment" (5)

- I won't go through all the gory details here…
  - it's easy to obtain, read and apply the relevant ETSI standards (when they are published)…
    - especially because they are free to download from the ETSI website! (*I wish all other standards were free too!)*
- But this is just for the RED's Articles 3.1b and 3.2
  - we can only hope that a similar approach will be taken for the safety requirements in RED Article 3.1a…
  - which the non-radio parts of our 'combined equipment' used to cover by complying with LVD-listed standards

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New in 2016

Some useful RED references

- Download the RED, 2014/53/EU…
  http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOL_2014_153_R_0002&from=EN
- List of harmonised standards…
  http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/rtte/index_en.htm
- Orgalime comments to the draft Guide for the application of the Radio Equipment Directive (RED), 29 June 2015,
  www.orgalime.org/sites/default/files/position-papers/Orgalime%20comments%20RED%20Guide%20-%202015-06-29.pdf
- "Harmonised Standards and Radio Equipment Directive", Michael Sharpe, CEPT Workshop on European Spectrum Management and Numbering: 4 June 2014,
  www.cept.org/files/1051/.../2-2-ETSI%20presentation-M.Sharpev2.ppt

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New in 2016

CCC

Don't forget the other newly 'NLF'd' directives which have come into force

I'm not going to go into detail on these, here

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New in 2016

CCC

Don't forget the other NLF'd directives that were not covered by the earlier slides:

- Civil Explosives Directive 2014/28/EU, replacing 93/15/EEC
- Simple Pressure Vessels Directive (SPVD) 2014/29/EU, replacing 2009/105/EC
- Non-Automatic Weighing Instruments (NAWI) 2014/31/EU, replacing 2009/23/EEC
- Measuring Instruments Directive (MID) 2014/32/EU, replacing 2004/22/EC
- Lifts Directive 2014/33/EU, replacing 95/16/EC
- Explosive Atmospheres (ATEX) Directive 2014/34/EU, replacing 94/9/EC
- *Note that the Toy Directive, 2009-48-EC, is already NLF'd (replaced 88-378-EEC)*
- *Note that the RoHS Directive, 2011/65/EU, a CE-marking NLF'd directive, applied on 22 July 2014 for some things, later for others (replaced 2002/95/EC)*

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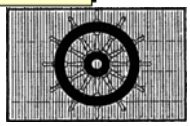
New in 2016

Some other NLF'd directives
that were not covered by the earlier slides:



- Pressure Equipment Directive (PED) 2014/68/EU, *replaced 97/23/EC on 19 July 2016*
- Marine Equipment Directive 2014/90/EU (Wheelmarking, not CE marking) *replaced 96/98/EC on 18 September 2016*
- Medical Devices *and* Active Implantable Devices Directives 93/42/EEC and 90/385/EEC will *both* be replaced by a single NLF' Regulation *probably between 2017 and 2021*
- In-Vitro Diagnostics Directive 98/79/EC will also be replaced by an NLF'd Regulation *probably between 2017 and 2021*
- Personal Protective Equipment, 89/686/EC has a proposal "COM/2014/0186 final - 2014/0108 (COD)" but I can't find anything more on it
- I understand the Machinery Directive, 2006/42/EC, is: "Being reviewed but no proposals yet although 2006/42/EC already includes the main elements of 768/2008/EC"…
  - from: www.element14.com/community/servlet/JiveServlet/previewBody/51606-102-1-264610/CE%20Mark%20-%20Machinery.pdf

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New in 201

Beware!
Some products which currently Declare Conformity to any other Directive *might have to* Declare to the Radio Equipment Directive (RED) *instead*

- Under the R&TTE directive (1999/5/EC)…
  - if a product incorporated a radio module which was itself compliant to 1999/5/EC, and installed according to its manufacturer's instructions…
  - the overall product could still be declared in compliance with its relevant Directive…
  - **BUT THIS MAY NO LONGER BE THE CASE!**
    Such devices might now have to comply with the RED (2014/53/EU) instead *see the slides on the RED, earlier*

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By Keith Armstrong

New in 2016

CCC

The new EU Directives which came into force in 2016

the end

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