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Regulations, Guidance and Standards

What's it all about?

- Clarity regarding the difference between:
  - Regulations
  - Guidance
  - Standards
- An important issue for the future

You may consider this the boring bit. Stick with me!
An important message & my colleagues will liven things up later!

What is the difference?

- Regulations
  - The Law: a requirement
  - Written in general terms; often little detail
- Guidance
  - More detail: how to achieve the outcome
  - Sometimes called ‘Approved Code of Practice’
- Standards
  - Voluntary
  - ‘State of the art’
  - Detailed process or requirements

Electricity at Work Regulations

An example from Regulation 4 (1)

(1) All **systems** shall at all times be of such construction as to prevent, so far as is reasonably practicable, **danger.**

Note: Definitions in Regulation 2:

- '**System**' includes '**electrical equipment**'
- '**Electrical equipment**' includes plugged-in equipment

That is what the law says!

Electricity at Work Regulations

What does the Guidance say?

- Paragraph 62 regarding Regulation 4(1)
  - The word ‘construction’ in the regulation has a wide application. It may be considered to cover the physical condition and arrangement of the components of a system at any time during its life. It will include aspects such as the design of the system and the equipment comprising that system.

[my emphasis]

Electricity at Work Regulations

An example from Regulation 4 (2)

Very important for Clinical Engineering

(2) As may be necessary to prevent **danger,** all **systems** shall be maintained so as to prevent, so far as is reasonably practicable, such **danger.**

That is what the law says!

Electricity at Work Regulations

What does the Guidance say?

- Paragraph 69 regarding Regulation 4(2)
  - Inspection and, where necessary, testing of equipment is an essential part of any preventive maintenance programme. Practical experience of use may indicate an adjustment to the frequency at which preventive maintenance needs to be carried out. This is a matter for the judgement of the dutyholder, who should seek all the information they need to make this judgement including reference to the equipment manufacturer's guidance. [my emphasis]

Electricity at Work Regulations

What is said about Standards?

- NOTHING in these Regulations
  - Standards are not the law
- A lot of reference in the Guidance; mostly … *should* … or … *can*…

  e.g. “Standards such as BS 7671can provide assistance but, ultimately, compliance with the Regulations is required.”

Electricity at Work Regulations

What is said about Standards?

- However; Guidance paragraph 166 on **Regulation 10 Connections** says:
  … Plugs and sockets for portable equipment must be constructed in accordance with appropriate standards … and British Standards give further guidance on portable equipment.

  [my emphasis]

Do Standards matter? Are they important?

- Standards matter and are important
  - They must be used in the right context
  - Not always the only source of guidance
  - Always read the Introduction and the Scope
  - Always read the informative Annex A
- Consider a new Regulation and its link to Standards

The Medical Devices Regulation

- Regulation to replace MD Directive proposed by the EC in 2012
- Agreed by the EU Council of Ministers in February 2017
- Approved by EU Parliament on 4th April 17
- Will come into force late May or early June
  - EU Regulations immediately become law in Member States
- 3-year transition period from MDD to MDR

What does the MDR require?

- Legal requirements for a new MD set out in Annex 1 - General safety and performance requirements
- Very general e.g. Annex 1,18.7

Devices shall be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks to the patient, user or any other person, both during normal use of the device and in the event of a single fault condition in the device, provided the device is installed and maintained as indicated by the manufacturer.

Where do Standards come in?

- No citation of any specific Standard, but -
- Article 8.1

Devices which are in conformity with the relevant harmonised standards, or the relevant parts of those standards, the references of which have been published in the Official Journal of the European Union, shall be presumed to be in conformity with the requirements of this Regulation covered by those standards or parts thereof.

[my emphasis]

Presumption of conformity

- Applies also to … *other legal requirements, such as relating to quality and risk management* …
- For example:
  - EN 60601-1: Medical electrical equipment
  - Many EN 60601-2-xx: MEE Particular standards
  - EN ISO 13485: Med Devices – QMS for regulatory purposes
  - EN ISO 14971: Med Devices – Application of risk management
- There are different types of Standards

Types of Standards

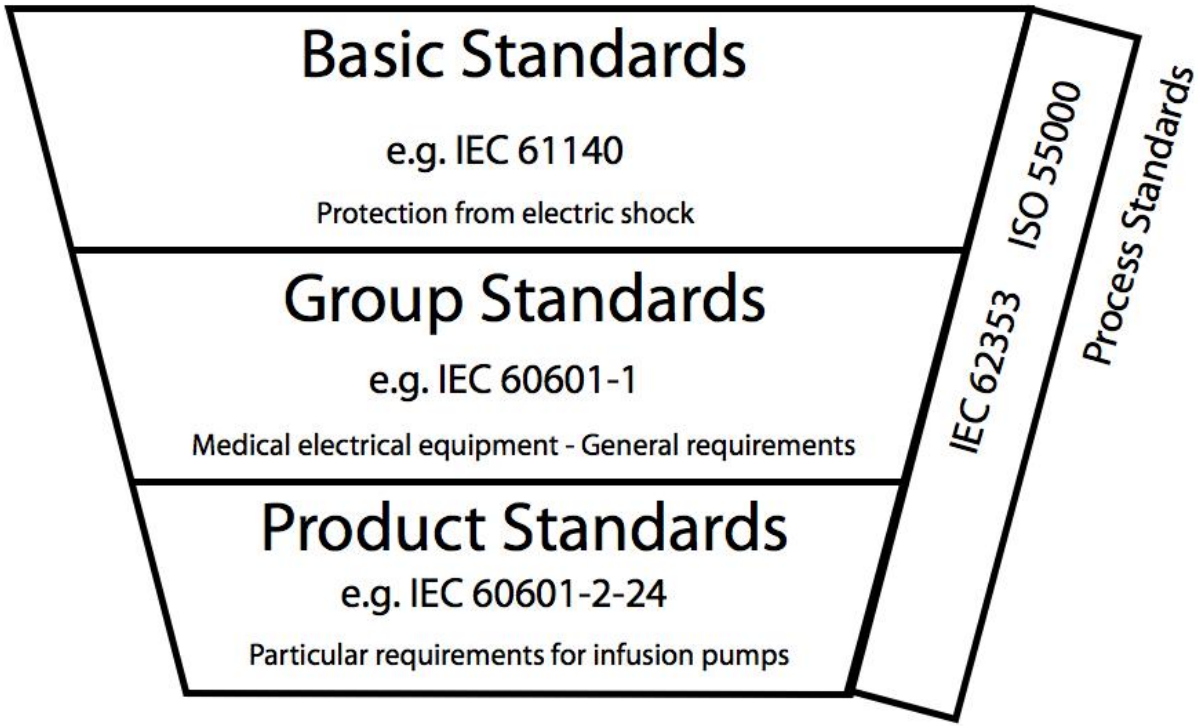

FIGURE 3.2 in Hegarty et al. 2017
Hierarchy of Standards. (Adapted with permission from ISO 16142-1, Medical devices – Recognized essential principles of safety and performance of medical devices – Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards.)

An issue for the future

- The MDD is silent on ‘in-house manufacture and use’ (IHMU)
- The original 2012 EC draft MDR would have made IHMU devices subject to full regulation with 1 exception
  - Stifle innovation
  - Big problem in Rehabilitation Engineering
  - Possible issues if putting together ME systems
- IPEM decided to lobby hard on this
- MHRA changed original position and were very collaborative (External Strategy Group)

In-house Exemption: Article 5.5

With the exception of the relevant *general safety and performance requirements* set out in Annex I, the requirements of this Regulation shall not apply to devices, manufactured and used only within health institutions established in the Union, provided that all of the following conditions are met:

[my emphasis]

Provided that …

1) Devices are not transferred to another legal entity*
2) Manufacture and use occur under appropriate QMSs*
3) Justify not using an available CE marked device*
4) Info is provided on request to CA; MHRA in UK
5) Design and risk management is documented in Technical File*
6) Make publically available a declaration of IHMU
7) Review experience and correct if necessary*

Guidance and Standards

Full circle!

A Regulation with general requirements, but …

- Guidance will be needed
- MHRA are working on it with IPEM input
- … appropriate QMS … points to ISO 9001 or ISO 13485; but which is appropriate?
- Standards represent ‘state of the art’ so need to be used in design and construction

Summary

- A Regulation sets out legal requirements
  - Usually only gives wide and general objectives
- Guidance, especially official guidance
  - Expands on Regulation's requirements
  - Gives wider context
- Standards
  - Often give specific, testable technical requirements or detailed processes
  - If followed, you have a defendable position re. the Regulation

Thank you

- Any questions
- References on the following slide

References

HSE. 2015. *The Electricity at Work Regulations 1989 – Guidance on the Regulations.* London: HSE
ISBN 978 0 7176 6636 2

Medical Devices Regulation 2017 Final text
http://data.consilium.europa.eu/doc/document/PE-14-2017-INIT/en/pdf

Illustration on slide 15 taken from:
Hegarty, Amoore, Blackett, McCarthy and Scott. 2017. *Healthcare Technology Management – A systematic approach*. CRC Press: Abingdon, UK www.htmbook.com

See also Chapter 3 of the above