Medical Device and Health Software

Standards and regulations now and in the future

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Introduction

- I was head of Clinical Engineering in Cardiff till 2009.
- I have been chair of BSI committee CH/62 *Electrical equipment used in medical practice* since 2007.
- Since 2011 I have been chair of IEC SC62A *Common aspects of electrical equipment used in medical practice.*

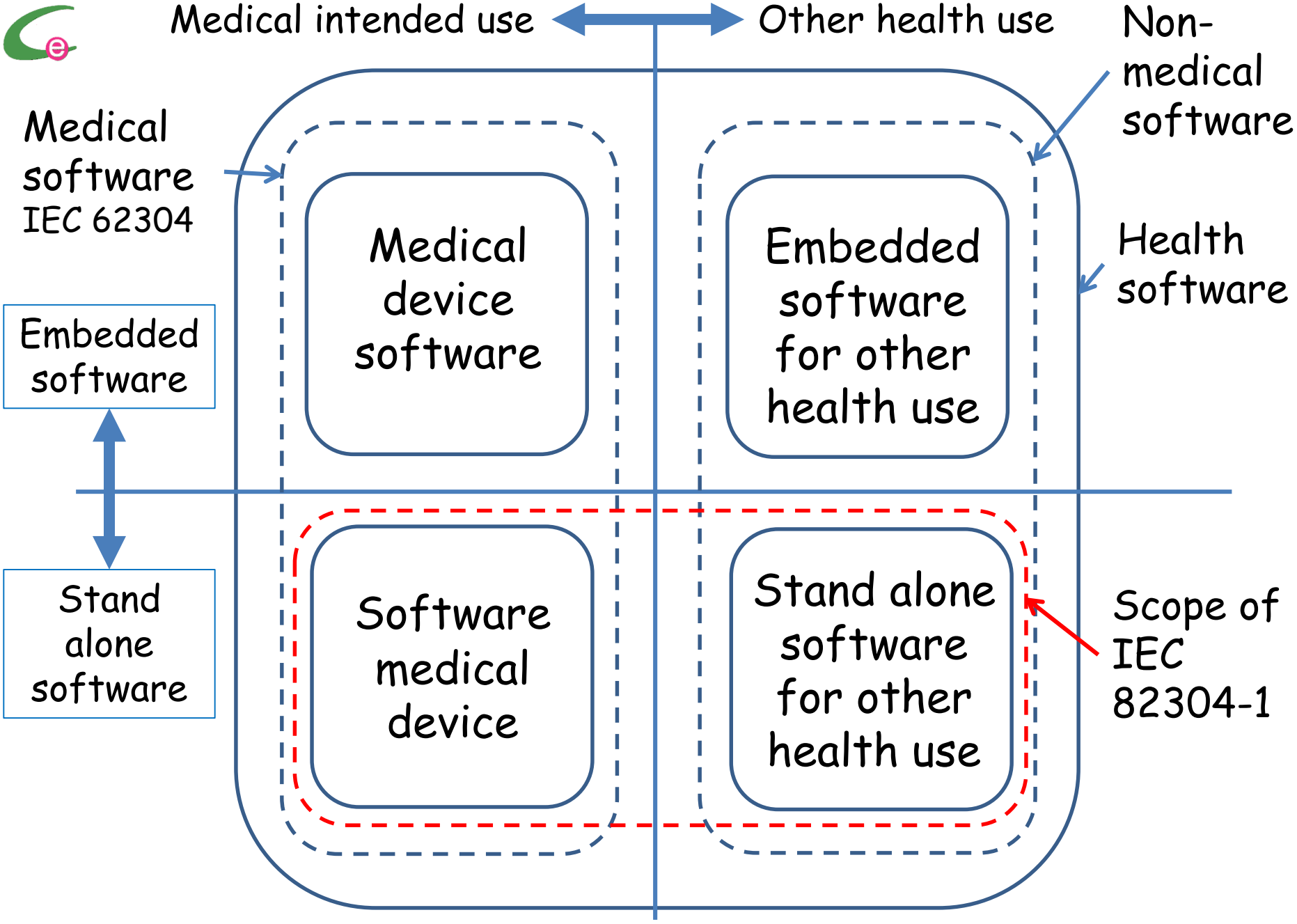
Health software

Software intended to be used specifically for managing, maintaining or improving health of individual persons, or the delivery of care

IEC 82304-1 Draft Ed. 1.0

Health Software – Part 1: General requirements for product safety [at 2nd Committee Draft stage]

Note Most of the relevant standards are the responsibility of JWG7 between IEC SC62A and ISO TC/215 *Health Informatics*


Medical intended use
Other health use
Non-medical software
Medical software
IEC 62304
Medical device software
Embedded software for other health use
Health software
Embedded software
Stand alone software
Software medical device
Stand alone software for other health use
Scope of IEC 82304-1

Medical software

Software intended to be used specifically for incorporation into a physical medical device or intended to be a software medical device

Refer to the full definition of a medical device

BS EN 62304:2006 *Medical device software. Software life-cycle processes*

Medical device software

Software intended to be used specifically for incorporation into a physical medical device

Most medical electrical equipment now includes medical device software therefore

IEC 60601-1 Clause 14 (PEMS) applies

Software medical device

Software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device.

Refer to the definition of a medical device

NOTE All foregoing definitions are taken from either:
Annex A, IEC 82304-1 Ed. 1.0 at 2nd Committee Draft stage;
or
IEC/SC 62A-ISO/TC 215 Joint Working Group 7 Ad Hoc Group interim report 2014;
or
IEC 62304: Draft 2nd Edition 2015.

Standards

Product safety	draft IEC 82304
Lifecycle processes	IEC 62304
	IEC/ISO 12207
guidance	IEC/TR 80002-3
Risk management	ISO 14971
guidance	IEC/TR 80002-1
Quality management	ISO 9001
	ISO 13485
	ISO 90003

Questions

- Who has written software?
- Who has asked themselves the question, "Is this a medical device?"
- Where did you go for the answer?

NOTE: a device that purely has a research purpose is not a medical device

Medical device definition re. software

MEDICAL DEVICE means any …, software, … whether used alone or in combination, … intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes … for the *(medical)* purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- etc.

Regulations in the EU and UK

Medical Devices Directive 93/42/EEC

Updated by Directive 2007/47/EC ++

Put into UK law by Medical Devices Regulations 2002 as amended particularly in 2008 and 2012

Current MHRA guidance

'In-house development and use' of a medical device (MD) is not subject to the UK Regulations

PROVIDED THAT:

You do not envisage commercial exploitation;

BUT,

Sharing with other centres may be 'placing on the market'.

How should we/you proceed?

- You should proceed as if you are going to CE mark your software MD.
- This reduces the risk of things going wrong and gives you a defensive argument if they do.

Step 1, Step 2 and Step 3

1. Establish for certain that it is a MD.
2. Establish which risk category the software MD falls into.
3. Establish which of the Essential Requirements are applicable.

Where do you find the risk categories and the Essential Requirements?

Step 4 and beyond

- Document everything in a Technical File.
- Include your risk management file.
- Keep track and records of development changes.
- Think about the usability of your software for the end user. [IEC 62366]
- Think about what Instructions for Use will be needed. [MDD Annex I]

The future

The EC proposes to change from:

MD Directive to MD Regulations

Many good aspect BUT:-

Article 4

4.4 Devices that are manufactured and used within a single health institution shall be considered as being put into service. ...

Issues

- The Eu Parl have approved that part of the draft, so it won't be rescinded.
- All in-house developed devices would have to be 'conformity assessed'. Very costly for risk Class IIa and above.
- The definition of a MD has changed to include "medical purpose" but difference with "research" not explicit.

Possible solutions

- Add a new sub-clause to allow in-house manufacture and use under certain conditions:-
  - Consider using an available CE marked device
  - Manufacture under a QMS
  - Manufacturing facilities meet ISO 13485
  - Notify Competent Authority (CA) [MHRA]
  - CA can inspect, must publish list, can restrict.

Actions

Co-ordinated lobby from IPEM

- MHRA now appreciate the problem.
- IPEM have provided input / comments and examples.
- Emphasise patient benefit.
- NHS Confederation EU Office on board.
- Relevant MEP has been lobbied

Thank you & watch this space!

However, progress is being made in lobbying

Any questions?

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