Best-practice guidance for the in-house manufacture of medical devices and non-medical devices, including software in both cases, for use within the same health institution

Version Record

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Background

Some types of clinical activity require health institutions to manufacture medical devices for their own use. Such devices are not at present required to comply with full regulatory requirements, because they are not 'placed on the market'.

This guidance document has been developed to provide scientific, engineering, technical, clinical and risk management staff with guidance on the regulatory issues and best-practice involved in the manufacture, management and use of these devices. These recommendations will help to minimise risk and maximise patient safety.

The principles and good practice in this guidance apply equally to the creation of safe and effective non-medical devices within health institutions.

The document will be kept under review by the Engineering Policy and Standards Panel and updated as appropriate.

Key recommendations

See Section 4 for detailed discussion.

1. Determine whether the device under consideration is a medical device.
2. Carry out manufacture of devices under a Quality Management System that has been set up and approved to comply with an external standard such as ISO 9001 or ISO 13485. This will cover among other things:
    1) Control of design and development;
    2) Control of production;
    3) Control of documentation;
    4) Audit, both internal and external;
    5) A designated individual responsible for best-practice compliance. Note: many Clinical Engineering Departments have quality management systems in place with senior staff who have relevant technical knowledge plus an in depth understanding of clinical and

regulatory implications. They are well placed to provide and support an individual to undertake this role (see 4.2.5).

3. In addition to establishing detailed specifications for device function and design, it is vital to determine the essential safety and performance requirements that the item must meet.
4. Undertake a formal risk assessment and risk management process as part of the quality management system.
5. Follow a systematic design and development process.
6. Establish and maintain detailed technical documentation.
7. Undertake appropriate clinical, technical, performance and safety evaluations.
8. Plan for ongoing support of the device.
9. Plan and undertake post deployment surveillance including appropriate clinical follow up.

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Contents

1 Introduction and context

1.1 Aims and scope of this document

The aim of this document is to provide best-practice guidelines for the manufacture of products of any type that are not medicinal products (for which other regulations apply) and are intended to be put into use within health institutions or other relevant organisations.

Fundamentally, it will be about medical devices, a key aspect of which is that the manufacturer intends them to be used for a medical purpose. The full definitions are given in Annex D. However, the principles set out in this document can and should[1] be applied to the manufacture of non-medical devices. Other UK regulations may then apply, and this is dealt with in section 4.1.2.

Most of the general guidance we present below is also applicable to software. However, there are specific issues that relate only to software and this is covered in section 5. Annex A covers issues relevant to medical device and health software and contains a list of further references. This Annex is under further consideration and development, and more detail will be added to future issues of this guidance.

Our aim is to provide guidelines based on best engineering practice that are, in the first instance, largely independent of regulatory requirements for the reasons outlined below. It is our intention to update the document from time to time as the UK regulatory situation becomes clearer.

We hope that this guidance may also encourage healthcare organisations to consider how best to align their approaches to the oversight of in-house medical device manufacturing and use throughout their organisation and assist their understanding and application of relevant legislation.

This document is primarily aimed at engineers, scientists, technical staff and clinicians engaged in activities requiring in-house device development, manufacture and use. It will also be of interest to risk managers and others concerned with clinical and organisational governance and patient safety.

The guidance is written in the context of the situation existing in the UK, but the principles are, in our opinion, universal so could be applicable in other jurisdictions.[2]

1.2 UK Regulatory context

With final exit of the UK from the EU which took place on 31st December 2020 and the postponement of the date of full application of the new *EU Medical Devices Regulation* (EU MDR) (European Parliament and Council, 2017), the EU MDR will not become retained EU law throughout the UK.

The regulations in force up to the end of 2020 regarding the manufacture of medical devices to be placed on the market (based on the *EU Medical Devices Directive* (EU MDD) are in the *UK Medical Devices Regulations 2002 — SI 2002 No 618* (The Medical Devices Regulations, 2002), as amended from time to time since. These have been amended again by the *Medical Devices (Amendment etc.) (EU Exit) Regulations 2020* which came into force on 1st January 2021.

[1] We use the word *should* throughout in the sense of *strongly advise*.

[2] In various places we make reference to formal Standards. For simplicity we refer to them by their international prefix, either ISO or IEC. However the UK British Standards versions, available through BSI, will have the prefix BS EN …

This amendment to the 2002 regulations is complex and no consolidated text is made available. It makes different provisions for Northern Ireland and for England, Wales and Scotland (GB). For GB, it does not alter the existing regulations in respect of there being no explicit regulatory requirements for medical devices that are not placed on the market. For Northern Ireland , under the terms of the Northern Ireland Protocol, the EU MDR, and therefore Articles 5.4 and 5.5 (the so called health institution exemption) will be applicable, in line with the EU's implementation timeline. We have set out these Articles in Annex C below.

We will refer to the updated UK regulations, applicable from the beginning of 2021, as the UK MDR 2002+. Whilst the immediate development of UK regulations regarding medical devices from the start of 2021 is now set out, albeit in a very complicated format, it is highly probable that a new set of medical device regulations will be developed over the next two years. How these will affect medical devices manufactured and used only within the same health institution is not certain at present. Hence the need for best-practice guidelines at this time.

We have expanded in Annex B on the UK regulatory context as it exists from the beginning of 2021 and will keep that Annex up to date as legislation develops.

1.3 In-house manufacture and use of medical devices within the same health institution

One reason for the need for this guidance is that many health institutions have departments that manufacture medical devices but only use them within the same organisation.
Examples in outline from different clinical services would be:

Example 1: A medical device to monitor patient position during Intracranial Pressure (ICP) Monitoring

Body position is known to affect intracranial pressure readings and the only way to record this information was by relying on nursing staff to input the patient's position manually whenever they could throughout the 48 hr recording period. A system was developed to automatically integrate patient position and movement data into the ICP recording, allowing easy identification of ICP pressure events that were related to the patient's movement or posture. The system comprises a three-axis accelerometer that is attached to the patient's clothing via two press stud gel electrodes, and an electronic interface box.

Example 2: Glomerular Filtration Rate (GFR) calculation spreadsheet commonly used in Nuclear Medicine

A GFR audit organised by IPEM in 2013 (55 UK centres responded) estimated that about 15,000 GFR tests are performed each year in the UK and revealed that 78% of centres use a spreadsheet and 81% of centres developed their own software in-house for the purpose of calculating patients' GFR.

Example 3: Custom-made seating for wheelchair users

For the definition of a 'custom-made' medical device, see Annex D.

Some clients of posture and mobility services require custom-made seat devices to be fitted to their wheelchair. The requirement is to enable the patient to be seated appropriately and at the same time not to compromise the stability or safety of the wheelchair. Such seats are custom-made medical devices.

Example 4: Septal Button (a custom-made medical device)

A Maxillo Facial department in a regional burns and plastic surgery hospital manufacture custom-made silicone buttons used to obturate a nasal perforation. These are used to close a perforation (hole) in the nasal septum; a condition referred to as a nasal septal perforation (NSP). Perforations can vary in size from a few millimetres to centimetres in diameter. The button friction fits the defect and has thin flanges to retain the button and allow insertion by the clinician / patient.

Example 5: Orthotic medical devices issued to patients by podiatrists

Podiatrists sometimes supply orthotics such as custom-made insoles, padding and arch supports to relieve arch or heel pain. The orthotic is put into the patient's shoe to realign the foot or take pressure off vulnerable areas of the foot.

We refer to this and similar clinical activity as 'in-house manufacture and use' (IHMU). Such activity is clearly not 'placing the device on the market', to use a concept from both the UK MDR 2002+ (based on the EU MDD) and the EU MDR. Thus neither regulations apply.

The legal issue is whether IHMU is 'putting into service', another defined term in both sets of regulations. The EU MDD and the UK MDR 2002+ for GB are both silent on this situation and the interpretation of 'putting into service' in the UK was and remains that this Directive did not cover such activity (https://www.gov.uk/government/publications/in-house-manufacture-of-medical-devices/in-house-manufacture-of-medical-devices).

The EU MDR clarified this and introduced explicit requirements for IHMU (as set out in Annex C below) which if followed, exempted such devices from full conformity assessment. However, as explained in section 1.2 above, the EU MDR will not be applicable in GB but will still apply in Northern Ireland as part of the Northern Ireland Protocol to the UK-EU exit agreement.

This guidance will provide some examples as to what activity clearly is 'in-house manufacture and use' and some of the less clear situations and will expand on best-practice details.

1.4 Best-practice and state-of-the-art

The aim of this document is, as far as possible, to provide guidance which conforms to best-practice as understood in the UK and which follows relevant standards and regulations

Now that it is clear that EU MDR rules can be applied for placing on the market in UK till June 2023 (see Annex B below) they still have applicability. The UK had significant influence on the content and wording of these and they represent 'state-of-the-art'. We have therefore not ignored EU MDR definitions where they can be appropriately applied.

The best we can do is provide well thought out best-practice guidance for the situation we know about now, and keep that up to date as the UK regulatory regime becomes clear.

2 Health Institutions

2.1 What constitutes a 'health institution'

The words 'health institution' appear twice in the UK MDR 2002 in Part IV dealing with in-vitro diagnostic devices (IVDs); see Regulation 33.(1)(a) and 33.(2)(a). The term is not listed as a defined term, but the context indicates that the applicability of this section, which gives an exemption from the UK

regulations for in-house IVDs, depends on there having been no transfer to another legal entity. There is no similar explicit exemption in Part II which deals with general medical devices.

In the EU MDR, a health institution is defined in Article 2(36) as *… an organisation the primary purpose of which is the care or treatment of patients or the promotion of public health*. The MHRA issued draft guidance on the health institution exemption for public consultation but never finalised it (MHRA, 2018). On 1st January 2021 they issued an updated version for Northern Ireland which states … *This includes hospitals, laboratories, local authorities and public health institutes supporting the health care system and/or addressing patient needs, but who may not treat or care for patients directly e.g. laboratories, local authorities and public health institutes.*

The key characteristic of a health institution is that it is a legal entity. It may be physically located in many places, all under common governance.

Many organisations are clearly health institutions:

- NHS Trusts or Health Boards.
- Private hospitals.

Some are less clear:

- Charitable trusts with a healthcare purpose.
- Non-NHS wheelchair services.
- University laboratories providing a clinical service along side research work, for example clinical gait analysis.

Where there is any doubt authoritative legal advice should be sought.

2.2 Placing on the market.

Again, there are situations were neither set of regulations is clear.

The key factor seems to be whether the responsibility and control of a medical device manufactured in a heath institution (a legal entity) passes out of the control and responsibility of that health institution.

For example, on that basis, if a Clinical Engineering workshop in a hospital in Trust P works with Surgeon A (employed by Trust P) and makes a surgical instrument for their use in a different hospital also in Trust P, there is no 'placing on the market'.

However, suppose Surgeon A is asked to go and perform an operation in a hospital in Trust R and, with the approval of Trust P, takes this surgical instrument with them and returns it, would that be placing on the market? Perhaps not legally, but there are significant governance issues. Furthermore, if something went wrong, the patient would sue Trust R so arguably the control and responsibility have passed from Trust P to Trust R. Legal advice would be required and governance in some Trusts would not allow this scenario.

To continue this narrative, surgical colleagues in Trust R are so impressed with the instrument that they ask for one to be made for them. To do so would be placing on the market and the HIE would not be applicable.

Suppose that the Clinical Engineering department in Trust P agree to pass on to Trust R all the design and manufacturing documentation for them to make one themselves under their own full responsibility and liability, taking account of their own environment and circumstances and following best-practice. That would probably not fall within the regulations because there is no transfer of a medical device but there would need to be an agreement between the Trusts and Trust P would need to ensure they were not carrying any ongoing liability.

A different unclear situation that would need careful consideration would be when staff from two different Trusts, or from a Trust and a university agree to work collaboratively on the development of a medical device for which they do not foresee commercial exploitation. For the health institution exemption to apply, a health institution would have to be leading and taking the responsibility.

If commercial exploitation is foreseen, then different parts of the UK MDR 2002+ or the EU MDR come into play.

2.3 Devices made for a research purpose

A clear part of the definition of a medical device is that its manufacturer must intend it to have a specific medical purpose. Thus, a device made in-house for or in support of a research study that is not itself the subject of the study is not a medical device, provided it is not intended to influence the clinical management of the patients involved in the research study. If it is being used with patients or volunteers, all the usual research ethics requirements including approval of the non-medical device must be complied with. Following this best-practice guide will ensure safety and assist in getting the necessary approvals.

It is important to note that should a subsequent decision be made to use the research device in routine clinical practice, then at that point it has been given a medical purpose and therefore becomes a medical device. These guidelines should be applied, and local governance mechanisms should include consideration of this scenario. Research device should not be allowed to simply drift into routine clinical use.

Also, as stated above if at some point in the research project, commercial exploitation of the device is foreseen then other parts of Regulations become applicable. Clinical evaluation and clinical investigation need to be controlled appropriately (see 4.7.1) in conjunction with ethical approval and MHRA consent.

A particular difficulty that requires careful thought is the status of devices at the 'proof of concept' stage of development, whether or not commercial development is contemplated. Even at this early stage technical documentation should have started.

3 Manufacture

3.1 What constitutes 'manufacture'?

Manufacture in this context is broader than taking raw materials, components or sub-assemblies and bringing them together to make an identifiable 'thing'. Manufacture encompasses medical device design, development and production. In addition to the creation of novel devices it can include modifying a device, repurposing a device, bringing together a number of devices to form a system. Additionally, software that is either embedded in a medical device or that in itself meets the definition of a medical device must be included in 'manufacture'. Furthermore, software used to control or influence a medical device i.e. from another platform, is an 'accessory for a medical device'. Note: an accessory for a medical device (as defined, see Annex D below) is to be treated as a medical device.

For the purpose of this best-practice guide it is sensible to adapt the wording from MHRA guidance issued for Northern Ireland.

Where any of the actions below are not explicit in a commercial medical device manufacturer's intended purpose or instructions for use (IFU), manufacturing a medical device by a health institution could include:

- the putting together of a device from raw materials or component parts,
- the complete rebuilding of an existing device and giving it a new identity,

- making a new device from used devices,
- fully refurbishing a device[3],
- development of software (which might include scripts, compiled code, web pages, spread sheets or apps etc.) that meet the definition of a medical device,
- assigning a medical purpose to a product that is not CE marked as a medical device even if the product is CE marked under a different Directive/Regulation, e.g. the Low Voltage Directive 2014/35/EU. MHRA have provided guidance on off-label use.
- putting together combinations of medical devices and other equipment,
- deviations from the instructions for use (including maintenance instructions) that significantly alter the safety, performance or function of the device, or
- using an existing medical device for a different purpose from that intended by the original manufacturer. This would also be off label use.

In the context of rehabilitation engineering, the Rehabilitation Engineering Services Management Group (RESMaG) have put together a useful document that sets out various scenarios and gives advice to achieve compliance to the EU MDR. https://resmag.org.uk/hie/. It addresses specifically Article 5.5 in the EU MDR, now no longer relevant in full in GB, but the decisions whether a device or activity constitutes in-house manufacturing and use and how to satisfy each EU MDR requirement are helpful.

4 Key aspects of in-house manufacture and use (IHMU) guidance

In developing this guidance, we have drawn up and expanded on nine key aspects that should be considered once you have made a clear and informed decision that your proposed activity is not 'placing on the market'.

These are dealt with in detail in the rest of this section but can be summarised as follows.

1. Determine whether the device under consideration is a medical device.
2. Carry out manufacture of devices under a Quality Management System that has been set up and approved to comply with an external standard such as ISO 9001 or ISO 13485. This will cover among other things:
    1) Control of design and development;
    2) Control of production;
    3) Control of documentation;
    4) Audit, both internal and external;
    5) A designated individual responsible for best-practice compliance. Note: many Clinical Engineering Departments have quality management systems in place with senior staff who have relevant technical knowledge plus an in depth understanding of clinical and regulatory implications. They are well placed to provide and support an individual to undertake this role (see 4.2.5).
3. In addition to establishing detailed specifications for device function and design, it is vital to determine the essential safety and performance requirements that the item must meet.
4. Undertake a formal risk assessment and risk management process as part of the quality management system.
5. Follow a systematic design and development process.
6. Establish and maintain detailed technical documentation.

[3] NOTE: this is a defined term in the EU MDR

7. Undertake appropriate clinical, technical, performance and safety evaluations.
8. Plan for ongoing support of the device.
9. Plan and undertake post deployment surveillance including appropriate clinical follow up.

4.1 Is the device that you are considering manufacturing a 'medical device'?

We have given both the current UK MDR 2002+ definition (based on the MDD but with improved English) and the EU MDR definition in Annex D. The words need to be read carefully and thoughtfully. Two key phrases in the preamble of the EU MDR are, '*intended by the manufacturer …*' and '*… for one or more of the specific medical purposes:*'

At the beginning of your project, as you document the requirements and detailed specification of the device you intend to design and manufacture you should set out clearly your intention and the purpose of the device. A key step at this stage is to be certain that your requirements cannot be met or cannot be met at the appropriate level of performance by a device that is on the market. Cost may be a factor if what you want is, for example, a simple single parameter medical device when that parameter is only available in a costly multi-parameter device. However, the true cost of one-off in-house development can be significant.

Software applications running on non-medical device platforms such as smart phones or PCs can often be difficult to categorise as to whether they are medical devices or not. MHRA have provided a PDF based app to assist in making this decision. https://www.gov.uk/government/publications/medical-devices-software-applications-apps#history. Note that this app references the EU MDD definitions and that the classification of software under the EU MDR are stricter than under the EU MDD. Best-practice is to refer to the stricter classifications.

4.1.1 The device is a medical device

The UK MDR 2002+ are relevant but at present include no requirements for IHMU in GB. See section 1.2 above and Annex B (which we will endeavour to keep up to date) for an explanation of the current regulatory situation. For as long as there are no regulatory rules for IHMU in your jurisdiction, these best-practice guidelines will provide a solid, defendable platform for your development.

4.1.2 The device is not a medical device

Other UK regulations may apply. A comprehensive list of other UK regulations is given on the Health and Safety Executive website here: https://www.hse.gov.uk/work-equipment-machinery/uk-law-design-supply-products.htm

The emphasis of all these regulations is on 'placing on the market' and CE marking of the particular type of non-medical device. The extent to which they apply to IHMU would need careful and thorough examination. All contain appropriate 'essential health and safety requirements', usually in their respective first Annex.

In respect of The Supply of Machinery (Safety) Regulations 2008 the HSE says here https://www.hse.gov.uk/work-equipment-machinery/new-machinery.htm):

In particular, they must be designed and built to meet the relevant essential health and safety requirements listed in Annex 1 of this Directive. This requirement applies to the manufacturers of machinery, even where it is for

their own use. It also applies to those who modify existing machinery to such an extent it must be considered a new machine …

The manufacturer … carries the full responsibility for the safety and conformity of the product. This duty must be met before the product is placed on the market or put into service. …

Users who make machinery for their own use also have the full manufactures' responsibilities for CE marking and compliance with the Supply of Machinery (Safety) Regulations. This must be done before they put the machine into service for the first time.
(our emphasis underlined)

In respect of the Electrical Equipment (Safety) Regulations 2016 it seems that there is not a requirement to CE mark IHMU products. There is no defined term 'put into service' and 'manufacturer' is defined as:

"manufacturer" means any person who—

(a) manufactures electrical equipment, or has electrical equipment designed or manufactured; and

(b) markets that electrical equipment under that person's name or trade mark;

Further guidance is here: https://www.gov.uk/government/publications/electrical-equipment-safety-regulations-2016.

Having no IHMU requirement for electrical equipment seems a bit inconsistent with the general advice here: https://www.hse.gov.uk/work-equipment-machinery/manufacturer.htm

However, going back to our first link, https://www.hse.gov.uk/work-equipment-machinery/uk-law-design-supply-products.htm HSE point out that Section 6 of the Health and Safety at Work etc Act 1974 (HSW Act) applies to articles and substances for use at work where other more specific product safety law does not apply.

For software that is not a medical device, as a minimum, issues such as the General Data Protection Regulations and copyright would need to be considered.

This guidance cannot give definitive legal interpretation of these various regulations; only the courts can do that. However, following best-practice as outlined in these guidelines will substantially minimise the likelihood of adverse events.

From here on this guidance will assume that the product being designed and manufactured is a medical device. However, we suggest the guidance is equally relevant to the best-practice design and manufacture of a non-medical product, taking account of the different essential safety and performance requirements (see section 4.3) and different relevant Standards.

4.2 Have a Quality Management System (QMS) in place

Many departments have put in place formal quality management systems to cover the provision of their services. We believe that the first in the NHS was the MEMO organisation in Bristol in the late 1980s. The adoption of QMS Standards has expanded very considerably since then and includes ISO 9001 in Radiotherapy applications and ISO 9001 or ISO 13485 in Clinical Engineering Departments.

A QMS provides a structured framework that helps to minimise risk, including risks to patients, by ensuring that actions and decisions are considered

and documented and that lessons are learned. It also provides a systematic way to capture organisational actions taken to reduce risk and prevent harm.

ISO 9001 is the internationally recognised standard for quality management systems; it is intentionally generic, to be adoptable by organisations irrespective of their industry sector, products, type of services, or size. The generality of ISO 9001 does however mean that key requirements in specialist sectors are not explicitly captured, and as such some sector-specific QMS standards have evolved, particularly in high risk and highly regulated industries. The international QMS standard for design and manufacture of medical devices is ISO 13485. See Annex F for further historic detail.

4.2.1 Which QMS framework to use

a) If you have no QMS in place and you manufacture or intend to manufacture in-house and put into use medical devices, you should (and perhaps should already have started to) put a QMS in place.

You should use ISO 13485 as your framework. The title of the document makes its purpose clear: *Medical devices. Quality management systems. Requirements for regulatory purposes.*

The Introduction, section 0.1 General says:

This International Standard specifies requirements for a quality management system that can be used by an organization involved in one or more stages of the life-cycle of a medical device, including design and development, production, storage and distribution, installation, servicing and final decommissioning and disposal of medical devices, and design and development, or provision of associated activities (e.g. technical support).

It is therefore clear that an ISO 13485 QMS can be developed to cover all aspects of the work of a Clinical Engineering, Rehabilitation Engineering, Medical Physics, Scientific Computing or Informatics department or a clinical department who are engaged in manufacture of (usually) custom-made devices, for example a Maxillo-facial or Podiatry Department.

b) If you have an ISO 9001 QMS in place and you manufacture or intend to manufacture medical devices in-house and put them into use, you should first check that your QMS scope includes and covers design, development and manufacture. If not, you should first extend the scope and put in place policies and procedures to cover this activity, using aspects taken from ISO 13485.

You may wish to develop and put in place a plan to convert the whole of your QMS to be based on ISO 13485. Many of your existing policies and procedures can readily be moved across into the new system. There is little point, as well as cost and complexity, in running an ISO 13485 system just for design, development and manufacture alongside an ISO 9001 system for service provision, when the former can cover all activities.

4.2.2 Internal QMS management

Both ISO 13485 and ISO 9001 allocate specific responsibilities to *top management*. If you already have a QMS in place, the allocation of these responsibilities will have been decided but if not, you will need to decide at what level in the organization these should be set. Do not go too high up the chain of command because the person concerned needs to be actively involved and have an understanding of the QMS and its operation.

The other requirement is to have a ‘management representative’ though this explicit requirement has gone from ISO 9001:2015. The role is more usually described as *quality manager* or *quality lead* and the basic role description is in ISO 13485 at 5.5.2. The person appointed to this role needs to be appropriately

experienced and qualified. Familiarity with and a thorough understanding of ISO 13485 would be required. Training in internal audit would be necessary and appropriate courses are available.

4.2.3 Certification of your QMS

Internal auditing of your QMS is a requirement of both ISO 9001 and ISO 13485. External auditing and certification of your QMS is good practice and should be considered best-practice for manufacture of higher risk medical devices i.e. above risk Class I as well as medical devices that are in Class I and require sterilization or have a measurement function or are reusable surgical instruments.

Certification of an organisation's QMS by an external auditing body provides independent confirmation that the QMS meets the requirements of the standard that has been adopted. The external auditors should be accredited to certify the particular standard being audited. In the UK, the sole agency for accrediting certification bodies is the UK Accreditation Service (UKAS). For higher risk medical devices placed on the market the certifying body must also be a legally designated Notified Body (NB) (or a UK Approved Body (UKAB) from 1st January 2021) that satisfies prescribed capability and specialist competency requirements.

A list of organisations accredited to certify ISO 13485 quality management systems can be found on the UKAS website at – https://www.ukas.com/browse-accredited-organisations/?org_cat=5565&parent=Certification%20Bodies&type_id=11

Any of these certification bodies may suffice for departments (e.g. Podiatry or Occupational Therapy) that only ever make risk Class I medical devices. A pragmatic but advantageous approach for such departments within a Trust or Health Board would be for them to work together to put in place a single externally certified QMS that covers multiple services. Internal cross auditing would then help share ideas and ways of working across professional boundaries.

However, departments manufacturing medical devices of higher risk classifications should select a certification body that is also a legally designated NB/UKAB and whose designated scope should be appropriate to the types of medical devices being manufactured. Also note that under the EU MDR much of the software meeting the requirements of a medical device has been re-classified from Class I to at least the higher Class IIb.

In the current times of change there may be problems of UKAB availability in the short-term. In the event of a need to develop and put into use higher risk devices and where UKAB input cannot be obtained, then the decision to proceed should be fully risk assessed and approved (or rejected) via the health institution's governance framework. Additionally, in these circumstances, external audit from a Certification Body that is UKAS accredited to audit to ISO 13485 but is not a MHRA approved UKAB would provide additional assurance.

4.2.4 The role of formal accreditation in health care systems

The independent regulator of health and social care in England, the Care Quality Commission (CQC), now uses accreditation schemes that relate to a particular service to inform their inspection activity and enable them to take a proportionate approach. Recognised accreditation schemes such as the Quality Imaging Standard, Medical Laboratories (15189) and Improving Quality in Physiological Services Accreditation Scheme (IQIPS) demonstrate a higher level of inspection and audit through peer assessment of quality and competency. IPEM has worked with BSI to produce a Standard, BS 70000:2017 against which

departments can be formally accredited, and in partnership with UKAS and NHS England has produced a new accreditation scheme for Medical Physics and Clinical Engineering services, known as MPACE. https://www.ukas.com/news/an-introduction-to-mpace/

BS 70000 has the full title *Medical physics, clinical engineering and associated scientific services in healthcare – Requirements for quality, safety and competence*. It is based on BS EN ISO 15189:2012 *Medical laboratories. Requirements for quality and competence*.

BS 70000 is described in its Foreword as an 'accreditation standard' but states that … *Fundamental to accreditation to BS 70000 is the implementation of a formal quality management system equivalent to BS EN ISO 9001.* It gives both ISO 9000 and ISO 13485 as normative reference Standards (i.e. other Standards that will be required to fulfil the requirements of the base Standard). In section 4.3 *Governance and risk management* at 4.3.1b)8) *product development and manufacture* there is a note which states:
NOTE For medical devices development this should be consistent with BS EN ISO 13485 and BS EN ISO 14971. For IT networks incorporating medical devices this should be consistent with BS EN 80001-1.

The decision to seek MPACE accreditation based on BS 70000 will be determined by senior level leadership in medical physics and clinical engineering, but it seems that if design, development and manufacture of medical devices is part of a department's work, ISO 13485 certification will be needed.

4.2.5 Person responsible for best-practice compliance

In a health institution where there are several unconnected departments manufacturing medical devices for internal use (and see 3.1 for what might constitute 'manufacture' – it is quite wide) the health institution should appoint an individual to be responsible for monitoring, advising and reporting at an executive level on best-practice compliance across the organisation.

The MHRA guidance issued for Northern Ireland, where the EU MDR are being statutorily applied, has a paragraph in the Governance section as follows:

Health institutions should appoint the most appropriate competent and senior person(s) with relevant expertise to sign the declaration and take responsibility for regulatory compliance of exempted devices including the supervision and control of manufacturing, and surveillance over the lifetime of the device.

Such a person would need to be appropriately qualified and experienced, and be able to understand and advise on details of the performance, the limitations and the clinical implications of the technology being deployed, as well as the overall regulatory and best-practice requirements. Senior clinical engineers are able to meet these requirements across a wide range of devices and technologies.

As has been noted in 1.2 and explained in more detail in Annex B, although there are at present no specific medical device regulatory requirements for the in-house manufacture and use of any type of manufacture of medical devices in GB, other regulatory or civil law issues may apply which could constitute a risk to the organisation.

Appointment of a suitably qualified and experienced person to take such a role in all jurisdictions would help health institutions to:

a) manage the risks around in-house manufacture and use particularly as the new regulatory framework develops after 1st January 2021,

b) coordinate expertise and compliance monitoring across the organisation, and

c) take the lead for the organisation in working with the MHRA.

4.3 Find out which are the 'essential safety and performance requirements' relevant to the product being designed and manufactured

4.3.1 For medical devices

Two options are available for medical devices:

The UK MDR 2002+ regulations for GB point out to Annex I, the 'Essential Requirements' of the EU MDD for the relevant essential safety and performance requirements.

The more up to date and stricter 'General Safety and Performance Requirements' of the EU MDR are in Annex I of that regulation. These would represent best-practice as being 'state of the art' and are applicable in Northern Ireland . An Excel based app has been developed by the Rehabilitation Engineering Department in Swansea Bay University Health Board. This provides a checklist for the General Safety and Performance Requirements in Annex I of the EU MDR. The app has been made available with a suitable disclaimer under a Creative Commons copyright licence on an open part of the IPEM website. https://www.ipem.ac.uk/ScientificJournalsPublications/FreePublications.aspx

4.3.2 For non-medical products

Consider the points made above in section 4.1.2. Work out which of the various categories your proposed product falls into and find the relevant essential safety and performance requirements which will either be directly in the UK regulation or will be signposted from there to the associated EU Directive or Regulation.

A recent example has been the in-house manufacture of non-medical device personal protective equipment (PPE).

4.4 Risk assessment and risk management

4.4.1 Fundamentals

The fundamentals of risk assessment and risk management are that you should have in your QMS a process which meets the requirement in ISO 13485: 7.1 … *The organization shall document one or more processes for risk management in product realization.*
Records of risk management activities shall be maintained …

Hazard identification, risk assessment and risk management are a feature of all the essential safety and performance requirements in UK legislation that we have looked at. See section 4.1 above.

The risk assessment process requires you to:

- identify possible hazards in general terms;
- identify actual and reasonably foreseeable hazardous situations around those hazards in your particular product;
- consider hazardous situations that might arise from ergonomic factors during the use of the medical or non-medical device;
- quantify or estimate the severity of the harm that those hazardous situations might cause;
- quantify or estimate the likelihood of the occurrence of those hazardous situations;
- decide and set an acceptable level of residual risk for each hazardous situation;

- apply risk reduction measures that will reduce the initial risks to the acceptable level in each case;
- for medical devices in particular, consider the benefit-risk ratio and demonstrate in your risk management file that the benefits of using the medical device outweigh the identified residual risks.

Remember, nothing is 100% safe. Safety is defined as '*freedom from unacceptable risk'* (ISO 14971:2019 subclause 2.26).

The general requirement for management of health and safety at work is to reduce risk to 'as low as reasonably practicable' (ALARP), which allows technical and economic considerations to be made when judging practicability. https://www.hse.gov.uk/managing/theory/alarpglance.htm. The ALARP principle is also introduced in some risk management standards, such as ISO 14971.

You should note however that there is a more exacting requirement under regulations for medical devices; the EU MDD and the EU MDR require risk to be reduced 'as far as possible', which does not allow for economic consideration when judging risk acceptability. The EU MDR inserted an explanatory paragraph at Annex I.2

> *The requirement in this Annex to reduce risks as far as possible means the reduction of risks as far as possible without adversely affecting the benefit-risk ratio.*

Many medical devices, for example high frequency surgery equipment or hypodermic needles, do things to patients that would be completely unacceptable without taking account of the clinical benefit-risk ratio.

Among the hazards you should consider are any risks that might arise from poor useability of the product, inadequate instructions for use or reasonably foreseeable misuse.

4.4.2 Risk reduction steps and priorities

In reducing risk, you should apply measures in this order of priority:

1) eliminate or reduce risks as far as possible through safe design and manufacture;
2) where appropriate, take adequate protective measures, including adding alarms if necessary, in relation to risks that cannot be eliminated;
3) provide information for safety (warnings/precautions/contra-indications) and, where appropriate, training to users;
4) in your instructions for use (IFU) inform users of any residual risks.

4.4.3 Risk management Standards

For medical devices in particular, but applicable for other products, the relevant Standard is ISO 14971. The current edition of the EN version is published by BSI as BS EN ISO 14971:2019 *Medical devices — Application of risk management to medical devices*

The BSI Whitepapers series which you can sign up for here: https://www.bsigroup.com/en-GB/medical-devices/resources/whitepapers/ has an authoritative and useful guide (van Vroonhoven, 2020).

There is also a formal guidance document to ISO 14971, published by BSI as PD CEN ISO/TR 24971:2020 *Medical devices – Guidance on the application of ISO 14971.* This is important because some of the very helpful informative annexes in the previous ISO 14971:2007 version have been moved to the ISO/TR 24971:2020 guidance document.

4.4.4 Risk management documentation

In order to ensure ongoing compliance with necessary requirements, your risk management process needs to form part of your QMS.

A risk management file should be created for each medical or non-medical device and the results of your risk management deliberations and decisions included in this documentation.

For custom-made devices where the general characteristics, method of manufacture and application are common to a medical device 'family' with only the shape and size being different for each patient it can be acceptable to have in place a generic risk evaluation which is referred to in the documentation for each device made. The generic evaluation should be considered in each case and patient notes should include any specific additional applicable details or conclusions.

4.4.5 Medical device risk classification

If you were to design and manufacture a medical device and place it on the market, your route to conformity assessment would depend on the risk classification of the said device. Both the parts of UK MDR 2002+ based on the EU MDD, and the EU MDR have an annex setting out a set of rules that enable the manufacturer to determine the risk classification; Annex IX in the EU MDD and Annex VIII in the EU MDR. The EU MDR rules are in some respects stricter and some types of device (particularly software, either embedded in a physical device or a medical device in its own right) have been moved to higher classifications.

In developing the risk management plan for your medical device, it would be best-practice to investigate which risk category it would fall into if marketed. A PDF based app that takes you through the rules from the EU MDR is available on the IPEM website pointed to in section 4.3.1 above.
https://www.ipem.ac.uk/ScientificJournalsPublications/FreePublications.aspx

4.5 Design and development

4.5.1 Design and development cycle

A simplified diagram of the design and development cycle is shown in Figure 1.

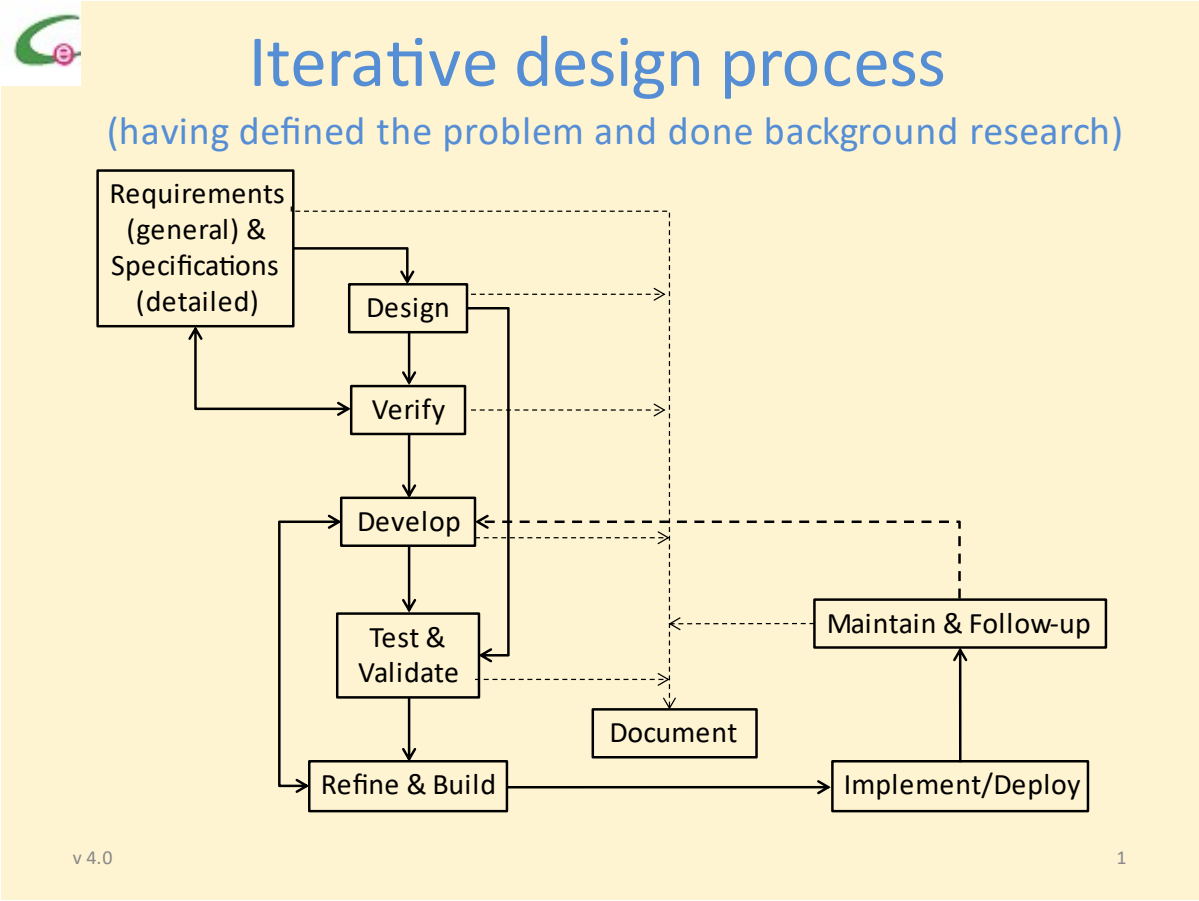

Figure 1 The iterative design process

Note the emphasis on documenting all the steps in the process.
Note also that there is not consistent agreement about the terms Verify and Validate or about Requirements and Specifications.

- Double arrows indicate a potentially iterative part of the process. You may go round those loops more than once.
- The link between Design and Test & Validate is intended to show that at the design stage you should be thinking about what tests you will carry out to validate prototypes and/or final versions of your medical device or non-medical product.
- Implement/Deploy is the stage at which you put your device/product into use.
- Maintain & Follow-up covers both routine maintenance and post-deployment surveillance and appropriate clinical follow-up which may lead back into the Develop stage.

Subclause 7.3 of ISO 13485 covers the design and development process and makes clear which steps must be documented. 7.3.6 covers verification and 7.3.7 covers validation

Some further notes are in Annex E.

This basic methodology is as valid for the development of software products as it is for hardware. We have included more details specific to medical device software in Annex A which will be further developed in a future issue of this guidance.

4.5.2 Essential safety and performance requirements

As part of the planning for your design by which you intend to meet your requirements and specification, you need to take account of the essential safety and performance requirements that are applicable to the type of product that you are proposing to manufacture, medical device or non-medical product. See 4.3 above.

4.6 Technical documentation

Both the MDD on which the UK MDR 2002+ are based and the EU MDR require technical documentation to be generated and kept. The EU MDR sets out in Annex II the requirements for this technical documentation under six headings and says that the documentation should be *'… in a clear, organised, readily searchable and unambiguous manner …'*. This clarity is absent from the EU MDD.

The six headings are:

1) Device description and specification, including variants and accessories;
2) Information to be supplied by the manufacturer;
3) Design and manufacturing information;
4) General safety and performance requirements;
5) Benefit-risk analysis and risk management;
6) Product verification and validation.

These headings and the associated detail, taken in context and applied proportionately, are a particularly useful guide to the sort of documentation that should be generated and kept up to date for any in-house development and use. This has links to particular sections in ISO 13485 e.g. *Design and development files* at 7.3.10 and the requirement for a *Medical device file* at 4.2.3 which should be … *compatible with applicable regulatory requirements*.

4.7 Clinical evaluation

Clearly, this applies only if you are developing a medical device.

4.7.1 The need for a clinical evaluation

A *clinical evaluation* is a systematic and planned process to continuously generate, collect, analyse and assess the clinical data relevant to a medical device in order to verify its safety, performance and clinical benefits when used as intended. It starts before a design is finalised and continues as post-deployment surveillance after a medical device has been put into use.

Both sets of medical device regulations, the UK MDR 2002+ and the EU MDR require a clinical evaluation to be carried out as part of the development of a medical device that is to be placed on the market. As noted above in section 1.2 and in detail in Annex B, the UK interpretation of the EU MDD does not cover IHMU. Additionally, the HIE as set out in Article 5.5 in the EU MDR does not explicitly call for a clinical evaluation of an IHMU device.

However, we consider, and MHRA have indicated, that a clinical evaluation appropriate to the proposed benefits and proportionate to the risk classification is a requirement for IHMU. Without it you cannot be certain that your medical device is safe and effective.

For a simple device with general characteristics similar to already existing devices it may be sufficient to rely on previously published literature, trials, textbooks etc. For custom-made devices where the general characteristics, method of manufacture and application are common to a device 'family' with only the shape and size being different for each patient it can be acceptable to have in place a generic clinical evaluation which is referred to in the

documentation for each device made. Patient notes should include specific details applicable in each case.

Medical devices that are not custom-made will need a specific clinical evaluation. If your proposed device is innovative this can be complex and may require animal work followed by a *clinical investigation* of a protype – a systematic investigation involving one or more human subjects, undertaken to assess the safety or performance of the device.

This is sometimes referred to as a *clinical trial,* but this is not the formal term. Clinical trial is the term used for medicinal products or vaccine trials which almost always involve double-blind processes.

If you decide that a clinical investigation is not required as part of your clinical evaluation of the proposed medical device, you should document your reasons for having come to that decision.

Ethical approval and local institutional research approval will be necessary for any clinical investigation, and for a medical device that is intended to be placed on the market approval from MHRA in the form of a 'letter of no objection' is required. It is not clear whether this is a requirement for a medical device that is only intended for in-house use. MHRA advice should be sought.

4.8 Device/Product Support

Before a newly manufactured medical or non-medical device is deployed into use you should give consideration to the support that should be in place and implement as appropriate. Some points below should have been dealt with in your consideration of the relevant 'essential safety and performance requirements'.

4.8.1 Labelling and Instructions for use

Both the UK MDR 2002+ (based on the EU MDR) and the EU MDD have explicit requirements for labelling and for the necessary instructions for use in their respective Annex I. The requirements are more detailed in the EU MDR. Some requirements may not be applicable, but all should be considered.

4.8.2 User training

Once again, the EU MDR is more explicit and detailed about user training so if you have used Annex I of this regulation as the basis for your design and development you should have already considered user training. If your device is a one-off novel medical device, you should consider the implications of this in your risk management plan. Similarly, if your device is to be issued to a patient, then suitable training and instructions should be provided.

4.8.3 Technical training

The people who have designed and manufactured the medical device may not be the people who are going to have the responsibility to support it technically into the future. Therefore, technical instructions and training for those who will be responsible should be part of the pre-deployment of the device(s).

4.8.4 Asset management

It will be essential that IHMU devices are given an asset number (or batch number if appropriate) and included on the relevant databases that your health institution uses. In this way a full service history will be started, and this will feed back into post deployment surveillance. For custom-made devices it will be necessary to link each device manufactured to the patient to whom it was issued.

In-house manufacturers should take account of government policy and MHRA guidance around application of Unique Device Identification (UDI) marking requirements as these develop.

4.8.5 Consumables and accessories

If your medical device requires consumables or particular accessories you will have considered the suitability and availability of these as part of your design process. You will have to be aware of any implications if the source of these were to change.

4.9 Post deployment surveillance and clinical follow-up

Once an in-house medical device has been manufactured and delivered to the clinical users it is not acceptable to then just forget about it. Surveillance is the monitoring of the performance and safety of a device following its deployment. Surveillance activities collect information on the device's effectiveness and on any problems arising with it, thereby informing any response actions that may need to be taken. The surveillance plan should be developed before the device is deployed. A range of appropriate methods of surveillance should be explored – potential stakeholders include clinical users, patients and technical support staff.

Two key elements of surveillance activities are vigilance and post deployment clinical follow-up.

Vigilance is the monitoring of incident data and includes the reporting of certain problems arising with a given medical device. The reporting and alert methods in the UK are overseen by the MHRA but these are implemented differently within England, Wales, Northern Ireland and Scotland. You must be familiar with and implement the system in place particular to your jurisdiction.

Clinical follow-up is the proactive collection and analysis of real-world clinical data, including the use of registries, against which the medical device's original clinical evaluation and risk-benefit assessment should be reviewed and revised as necessary. Such feedback can lead to future improvement opportunities.

5 Medical device software

As has already been noted, medical device software can either be embedded in and part of a physical medical device or be a medical device in its own right, running on a non-medical device platform such as a PC, tablet or smart phone.

All of the principles set out in section 4 above apply in general to medical device software. However, there are specific techniques of specifying, developing, testing and maintaining software and specific Standards that apply.

We have therefore devoted Annex A to the issue of medical device software with its own list of works cited. Annex A will be further developed in detail in future issues of this guide.

6 Works Cited

European Parliament and Council, 2017. *REGULATION (EU) 2017/745 on Medical Devices as amended by Regulation 2020/561.* [Online]
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8 Annexes

Annex A Medical Device and Health Software

As a placeholder for more detailed guidance to be developed, the following resources may be of use.

Scope articles

Since 2014 the IPEM journal SCOPE has published 13 articles on software and its development

SCOPE 28(2) June 2019
p.10 *Winds of change in software regulations.* Whitbourn J., Boddy I., Simpson A., Kirby J., Farley R. and Bird L.
p.14 *The new science of Bioinformatics.* Ganney P.

SCOPE 27(2) June 2018
p.20 *MDR: a brief introduction for software.* Ganney P.

SCOPE 26(3) September 2017
p.12 *Requirements specification* Cosgriff P., Willis D., Ganney P., Green A. and Trouncer R.

SCOPE 26(2) June 2017
p.10 *Project initiation & management.* Ganney P., Green A., Trouncer R. and Willis D.

SCOPE 26(1) March 2017
p.18 *Dr Ganney's top 10 tips for safer working software.* Ganney P.

SCOPE 25(3) Sept 2016
p.23 *The software lifecycle: common methodologies.* Ganney P., Cosgriff P., Green A., Trouncer R. and Willis D.
SCOPE 25(2) June 2016
p. 20 *The case for software testing: bugs have feelings too.* Green A., Cosgriff P., Ganney P., Trouncer R. and Willis D.

SCOPE 25(1) March 2016
p. 23 *In-house development of medical software* Cosgriff P., Ganney P., Willis D., Green A. and Trouncer R.

SCOPE 24(4) Dec 2015
p.22 *Writing quality software: setting the scene.* Trouncer R.

SCOPE 24(3) Sept 2015
p.14 *Software quality management: I know how to program!* Ross R.

SCOPE 24(1) March 2015
p.26 *ImageJ: image processing and analysis in Java.* James G.

SCOPE 23(1) March 2014
p. 16 *A bluffer's guide to 80000-1: clearing up the confusion.* Ganney P.

All are available to IPEM members via the website.

Textbook

The new (2nd) Edition of:

Clinical Engineering: A Handbook for Clinical and Biomedical Engineers Eds. Taktak, Ganney, Long and Axell. Academic Press 2020
has Section II *Information technology & software engineering*

Chapter 8 *Information communications technology* Ganney P.

Chapter 9 *Software engineering* Ganney P., Pisharody S., and Claridge E.

Chapter 10 *Web development* Ganney P., Pisharody S., and McDonagh E.

Standards of relevance to Health Software

Medical Software – published standards

BS EN 62304:2006+A1:2015[4] *Medical device software. Software life-cycle processes*

BS EN ISO 14971:2019 *Medical devices. Application of risk management to medical devices*

BS EN 60601-1:2006+A1:2013 *Medical electrical equipment. General requirements for basic safety and essential performance*

IEC 60601-1-6:2013[5] *Medical electrical equipment. General requirements for basic safety and essential performance. Collateral standard. Usability*

IEC 62366-1:2015+A1:2020 *Medical devices. Part 1: Application of usability engineering to medical devices*

PD ISO/TR 17791:2013 *Health informatics. Guidance on standards for enabling safety in health software*

BSI ISO/IEC 12207:2008 *Systems and software engineering – software lifecycle processes*

BS ISO/IEC 90003:2014 *Software engineering. Guidelines for the application of ISO 9001:2000 to computer software.*

BS EN 82304-1:2017 *Health Software – Part 1: General requirements for product safety*.

PD IEC/TR 80002-1:2009 *Medical device software. Guidance on the application of ISO 14971 to medical device software*

PD ISO/TR 80002-2:2017 *Medical device software - Part 2: Validation of software for regulated processes* [at WD stage]

PD IEC/TR 80002-3:2014 *Medical device software – Part 3: Process reference model of medical device software life cycle processes (IEC 62304)*

PD IEC/TR 62366-2:2016 *Medical devices – Part 2: Guidance on the application of usability engineering to medical devices*

Standards and guidelines relevant to the interconnection of ME equipment and ICT networks

BS EN 80001-1:2011 Application of risk management for IT-networks incorporating medical devices. Roles, responsibilities and activities

PD IEC/TR 80001-2-1:2012 *Application of risk management for IT-networks incorporating medical devices. Step-by-step risk management of medical IT-networks. Practical applications and examples*

PD IEC/TR 80001-2-2:2012 *Application of risk management for IT-networks incorporating medical devices. Guidance for the disclosure and communication of medical device security needs, risks and controls*

PD IEC/TR 80001-2-3:2012 *Application of risk management for IT-networks incorporating medical devices. Guidance for wireless networks*

PD IEC/TR 80001-2-4:2012 *Application of risk management for IT-networks incorporating medical devices. Application guidance. General implementation guidance for healthcare delivery organizations*

[4] Revision as Ed 2 at final draft stage
[5] Amendment 2 now issued by IEC but not yet available as a BS EN version

PD IEC/TR 80001-2-5:2014 *Application of risk management for IT-networks incorporating medical devices – Part 2-5: Application guidance – Guidance on distributed alarm systems*.

PD ISO/TR 80001-2-6:2014 *Application of risk management for IT-networks incorporating medical devices – Part 2-6: Guidance for responsibility agreements*.

PD ISO/TR 80001-2-7:2015 *Application of risk management for IT-networks incorporating medical devices - Part 2-7: Application Guidance - Guidance for Healthcare Delivery Organizations (HDOs) on how to self-assess their conformance with IEC 80001-1* [at CD stage]

PD IEC/TR 80001-2-8:2016 *Application of risk management for IT-networks incorporating medical devices Part 2-8: Application guidance - Guidance on standards for establishing the security capabilities identified in IEC 80001-2-2*

PD IEC/TR 80001-2-9:2017 Application of risk management for it-networks incorporating medical devices. Application guidance. Guidance for use of security assurance cases to demonstrate confidence in IEC TR 80001-2-2 security capabilities

Standards checked on BSI website on 2020-11-07

Annex B UK Regulatory situation as at January 2021

The current regulations in force regarding the manufacture of medical devices to be placed on the market are in the UK Medical Devices Regulations 2002 (SI 2002 No 618, as amended from time to time since) (The Medical Devices Regulations, 2002).

These are based on the three EU medical devices Directives for Active Implantable Devices, General Medical Devices (the EU MDD) and In-vitro Diagnostic Devices. The new EU Medical Devices Regulation (EU MDR) (European Parliament and Council, 2017) was also in force in the UK until 31st December 2020 (but not mandatory) but will not become directly applicable retained EU law after that date because its date of full application has been postponed until after the end of the Brexit transition period.

In September 2020 MHRA produced guidance on regulating medical devices from 1st January 2021 and updated this to in a final version, Regulating medical devices in the UK, on 31st December 2020. This sets out the situation from 1st January 2021 in respect of both GB (England, Wales and Scotland) and of Northern Ireland.

The Government also produced a new draft Statutory Instrument (SI) that further amends the UK MDR 2002; The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020. There is also a draft Explanatory Memorandum. Both are also available as PDF downloads. This new SI has now received Parliamentary approval and came into affect on 1st January 2021 at the end of the implementation period as part of the EU withdrawal agreement. We have referred to these amended UK regulations as the UK MDR 2002+.

A key feature of this new SI is that unlike the Medical Devices (Amendment etc) (EU exit) Regulations 2019 which it further amends in part, this new Amendment Regulation 2020 does not bring in requirements which were clearly based on the EU MDR and IVDR (but worded in a UK context) for the whole of the UK. Because of the Northern Ireland Protocol which was agreed with the EU as part of the Withdrawal Agreement, Northern Ireland will continue to apply the provisions of the EU MDR whilst GB will continue to apply the amended UK MDR 2002+. However, CE marking to the EU regulations (EU MDD or EU MDR) will be recognised until 30 June 2023 in GB.

The explanatory memorandum says at 7.16 …

Any devices that are in conformity with EU legislation (MDD, AIMDD, IVDD, MDR, IVDR) can continue to be placed on the market in GB until 30 June 2023. This is to provide manufacturers with time to adjust to future GB regulations that will be consulted on and published at a later date.

The final sentence of this paragraph is significant. It seems clear that these 2020 amendments to the earlier UK MDR 2002 and the allowance for CE marking are in effect a stop-gap measure whilst the UK government drafts new stand-alone medical devices regulations to take effect after June 2023. The form, scope, format and details of these new UK regulations are uncertain. In particular, the extent to which they will mirror or refer to the EU MDR is not known nor whether any exemption from full conformity assessment for in-house manufactured and used medical devices will be included. IPEM has formally asked to be included in the consultations promised.

The situation in Northern Ireland is different because of the Northern Ireland Protocol and the EU MDR will apply in full from 1st January 2021.

In-house manufacture and use (IHMU)

The EU MDR explicitly dealt with IHMU, clearly brought it within the new Regulation in Article 5.4 and then mandated a set of requirements in Article 5.5 which if followed, exempted the health institution from full conformity assessment for such medical devices. MHRA have referred to this as the 'health institution exemption' (HIE). The full text of Articles 5.4 and 5.5 are given in Annex C.

The EU MDD and the UK MDR 2002 were both silent on IHMU and the interpretation in the UK was and remains that this Directive did not cover such activity. Other EU member states took a different view and the EU Commission did not agree with the UK interpretation but as a Directive, different interpretations in different jurisdictions are possible. Consequentially in the UK as a whole until 1st January 2021 there was no regulatory framework around IHMU for general medical devices.

The MHRA and it predecessors had from time to time produced some guidance but have not kept the more detailed one (which is undated) currently accessible (MHRA, n.d.). A more recent guidance is from 2014 (MHRA, 2014). There is also the very recent on line guidance linked to above.

IPEM produced a detailed document in its Report series in 2004 (Wentworth, 2004). This is a particularly useful document in its basic concepts though it concentrated on medical electrical devices and most of the supporting documents and Standards referred to have now been long updated. Nevertheless it is well worth consulting.

The key messages as far as in-house manufacture and use is concerned are that for Northern Ireland the EU MRD Article 5.5 must be applied from 26th May 2021 and MHRA have provides a guidance document. In GB, for the time being, the UK 2002 MDR+ apply with no explicit regulatory requirements for IHMU. However other health and safety regulations may apply in some circumstances and these 'best-practice' guidelines will be useful even in the Northern Ireland context.

We do not know at present whether a similar exemption will be included in new GB regulations that will come into force at some time after 1st January 2021, probably to be fully applicable after 30th June 2023.

References

European Parliament and Council, 2017. *REGULATION (EU) 2017/745 on Medical Devices as amended by Regulation 2020/561.* [Online]
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Annex C EU MDR Articles 5.4 and 5.5

5.4. Devices that are manufactured and used within health institutions shall be considered as having been put into service.

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:

(a) the devices are not transferred to another legal entity,

(b) manufacture and use of the devices occur under appropriate quality management systems,

(c) the health institution justifies in its documentation that the target patient group's specific needs cannot be met, or cannot be met at the appropriate level of performance by an equivalent device available on the market,

(d) the health institution provides information upon request on the use of such devices to its competent authority, which shall include a justification of their manufacturing, modification and use;

(e) the health institution draws up a declaration which it shall make publicly available, including:

  (i) the name and address of the manufacturing health institution;

  (ii) the details necessary to identify the devices;

  (iii) a declaration that the devices meet the general safety and performance requirements set out in Annex I to this Regulation and, where applicable, information on which requirements are not fully met with a reasoned justification therefor,

(f) the health institution draws up documentation that makes it possible to have an understanding of the manufacturing facility, the manufacturing process, the design and performance data of the devices, including the intended purpose, and that is sufficiently detailed to enable the competent authority to ascertain that the general safety and performance requirements set out in Annex I to this Regulation are met;

(g) the health institution takes all necessary measures to ensure that all devices are manufactured in accordance with the documentation referred to in point (f), and

(h) the health institution reviews experience gained from clinical use of the devices and takes all necessary corrective actions.

Member States may require that such health institutions submit to the competent authority any further relevant information about such devices which have been manufactured and used on their territory. Member States shall retain the right to restrict the manufacture and the use of any specific type of such devices and shall be permitted access to inspect the activities of the health institutions.

This paragraph shall not apply to devices that are manufactured on an industrial scale.

Annex D Definitions of 'medical device', 'accessory for a medical device' and 'custom-made device'

From the UK MDR 2002 Regulation 2.—(1) as amended in 2008

"medical device" means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnosis or therapeutic purposes or both and necessary for its proper application, which—

(a) is intended by the manufacturer to be used for human beings for the purpose of-

  (i) diagnosis, prevention, monitoring, treatment or alleviation of disease,

  (ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,

  (iii) investigation, replacement or modification of the anatomy or of a physiological process, or

  (iv) control of conception; and

(b) does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, even if it is assisted in its function by such means,

and includes devices intended to administer a medicinal product or which incorporate as an integral part a substance which, if used separately, would be a medicinal product and which is liable to act upon the body with action ancillary to that of the device;

From the UK MDR 2002 Regulation 5.—(1)

"accessory" means an article which, whilst not being a medical device, is intended specifically by its manufacturer to be used together with a medical device to enable it to be used in accordance with the use of the medical device intended by its manufacturer.

"custom-made device" means a relevant device that is—

(a) manufactured specifically in accordance with a written prescription of a duly qualified medical practitioner or a professional user which gives, under his responsibility, specific characteristics as to its design; and

(b) intended for the sole use of a particular patient,

but does not include a mass-produced product which needs to be adapted to meet the specific requirements of the medical practitioner or professional user.

From the EU MDR Article 2

For the purposes of this Regulation, the following definitions apply:

(1) 'medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

  — diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,

— investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,

— providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

The following products shall also be deemed to be medical devices:

— devices for the control or support of conception;

— products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.

(2) 'accessory for a medical device' means an article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s);

(3) 'custom-made device' means any device specifically made in accordance with a written prescription of any person authorised by national law by virtue of that person's professional qualifications which gives, under that person's responsibility, specific design characteristics, and is intended for the sole use of a particular patient exclusively to meet their individual conditions and needs.

Additional note:

Article 1(2) of the EU MDR refers to a list in Annex XVI of groups of products without an intended medical purpose to which "the Regulation shall also apply".

The list includes "high intensity electromagnetic radiation (e.g. infra-red, visible light and ultra-violet) emitting equipment intended for use on the human body, including coherent and non-coherent sources, monochromatic and broad spectrum, such as lasers and intense pulsed light equipment, for skin resurfacing, tattoo or hair removal or other skin treatment."

These and other types of products listed are now also covered by the EU MDR.

Annex E Notes on the Engineering Design Process

Modified in red from http://www.sciencebuddies.org/engineering-design-process/engineering-design-process-steps.shtml

Key Info

- The engineering design process is a series of steps that engineers follow to come up with a solution to a problem. Many times the solution involves designing a product (like a machine or computer code) that meets certain criteria and/or accomplishes a certain task.
    - This process is different from the Steps of the Scientific Method, which you may be more familiar with. If your project involves making observations and doing experiments, you should probably follow the Scientific Method. If your project involves designing, building, and testing something, you should probably follow the Engineering Design Process. If you still are not sure which process to follow, you should read Comparing the Engineering Design Process and the Scientific Method.
- The steps of the engineering design process are to:
    - Define the problem;
    - Do background research;
    - Specify the requirements;
    - Brainstorm solutions;
    - Choose and verify the best solution;
    - Devise validation tests;
    - Do development work;
    - Build a prototype;
    - Test (validate) and redesign as necessary.
- Engineers do not always follow the engineering design process steps in order, one after another. It is very common to design something, test it, find a problem, and then go back to an earlier step to make a modification or change to your design. This way of working is called **iteration**, and it is likely that your process will do the same!

Note

verification asks the question 'Is the design proposal a true reflection of the requirements set out in the design specification?' Therefore, it comes in at a fairly early stage of the process.
ISO 13485 7.3.6 says:
Design and development verification shall be performed in accordance with planned and documented arrangements to ensure that the design and development outputs have met the design and development input requirements.

validation asks the question, 'Does the final product meet the original design specification?' Validation tests should be devised and agreed as an earlier part of the design process.
ISO 13485 7.3.6 says:
Design and development validation shall be performed in accordance with planned and documented arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use.

Annex F The history of ISO 13485

ISO 13485 started off in the late 1990s with the title *Quality systems. Medical devices. Particular requirements for the application of EN ISO 9001*. Although it became a stand alone Standard it remained closely aligned to ISO 9001 as that Standard was developed and revised. This was the case up to and including the 2012 Edition which was structurally aligned with the 2008 4th Edition of ISO 9001.

The 5th Edition of ISO 9001 in 2015 brought this Standards into line with the common High Level Structure that ISO had introduced in 2012 for management system standards such as ISO 14001 (Environmental management systems), ISO 45001 (Occupational health and safety) and ISO/IEC 27001 (Information security management systems).

The revision of ISO 9001 was a considerable restructuring with a less prescriptive, more risk based approach, perhaps suitable to its very wide applicability. In parallel and over the same time period, ISO 13485 was also being updated but its structure was not at this time brought into line with the High Level Structure and remained aligned with the structure of the 2008 4th Edition of ISO 9001.

As part of a scheduled review of ISO 13485:2016 in 2018 there was pressure from ISO on its relevant Technical Committee, TC 210, to structurally revise ISO 13485 to bring it into line with the High Level Structure as had happened with ISO 9001:2015. This was not accepted by the national member bodies including BSI, in considerable part because ISO 13485:2016 (still structurally aligned with ISO 9001:2008) was widely used in a medical device regulatory context in many jurisdictions including the EU. Additionally and significantly, the Food and Drugs Administration (FDA) in the USA had decided to adopt ISO 13485:2015 as the QMS framework for US manufacturers.

It is probable that ISO 13485 will be aligned with the ISO High Level Structure at its next revision but will remain the clear QMS Standard of choice for medical device manufacture and management.

The first NHS organisation to put in place a formal QMS is thought to be the MEMO organisation in Bristol and the second (or maybe third) was the Bioengineering Unit in Cardiff. (McCarthy & Hicks, 1991). Both were certified to ISO 9002 (i.e. did not include design and manufacture and covered service only). The adoption of QMS Standards has expanded very considerably since then and includes ISO 9001 in Radiotherapy applications and ISO 9001 or ISO 13485 in Clinical Engineering Departments.

Many departments now include design and development in the scope of their QMS and an increasing number are using the ISO 13485 framework.

Reference

McCarthy, J. & Hicks, B., 1991. Quality in healthcare: Application of the ISO 9000 standard. *Int. J. Health Care Quality Assurance,* 4(16), pp. 21 - 25.