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ADVICE NOTE

Advice on the production and sharing of Software in a Medical Context, including spreadsheets, scripting and functional documents.

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Intended Audience

Developers, clinical IT support providers, managers or other staff involved in the deployment, provision or management of software in a healthcare setting.

What is Software?

Software is simply defined as a set of instructions and data that tell a computer how to work. This definition applies equally to code written in a low-level programming language as to a formula in a spreadsheet.

Foreword February 2024

In the UK, medical device regulation is in a state of flux [1]. Embracing best practice is the pragmatic way to ensure due diligence and future compliance. Software (including spreadsheets, scripts and other functional documents) produced within healthcare institutions often fulfils the definition of a medical device, so departments developing software should act now. The EU Medical Device Regulations (EU MDR [2]) reflect current best practice, and whilst these regulations are technically not applicable in the UK (apart from Northern Ireland [3]), it is likely that future UK legislation will be at least as stringent [4, 5]. New regulations are expected to apply from 1 July 2025 [6]; until these are available, UK regulation [7] continues to be based on the EU Medical Device Directive (MDD [8]). An amendment to the UK MDR is expected prior to this to introduce additional post market surveillance requirements. Software that does not meet the definition of a medical device is still likely to be considered a Health IT System under information standards DCB0129 [9] and DCB0160 [10], which are mandatory in England. This advice note aims to outline the regulatory position for software development. In previous iterations this has predominantly been concerned with the sharing of software. Best practice, based on the EU MDR, also governs the life cycle of internally manufactured and used software, so will impact more institutions. This interim update aims to highlight these changes and signpost where further guidance on best practice can be found. The IPEM Best Practice Guidance document for In-House Manufacture of Medical Devices and Use [11] provides more detailed guidance on how to comply safely with best practice. Annex A of this IPEM document provides specific guidance on software.

Software is often developed within Health Institutions and frequently in Medical Physics & Clinical Engineering (MP&CE) departments as well as Clinical Informatics**.** It may be small scripts, which help to automate the clinical workflow or perform calculations, or complex programs stemming from research or clinical needs, possibly containing routines from other groups and from Open Source or commercial libraries. Software intended for such clinical use may therefore be considered a Medical Device. Those developing it or those looking to deploy it must therefore consider the regulations [2, 7] governing the production and distribution of Medical Devices, and the associated requirements and constraints. Under these regulations the group producing software acts as the manufacturer. Giving or selling Medical Device software to another hospital ('placing on the market') in the UK, will require conformity assessment and marking, depending on target market. There are three possible marks, CE, UKCA and UKNI, for the different UK and EU markets.

What constitutes a Medical Device is defined in the appropriate regulation (UK MDR [7] or EU MDR [2]) with further clarification for software in Medical Device (MEDDEV) Document 2.1/6 [12] and Medical Device Coordination Group (MDCG) Document 2019-11 [13], as well as on the MHRA website [14]. The MDCG reference is a good starting point. The core message is that if the software, standalone or embedded, controls clinical equipment or is used to influence clinical decisions then it is a medical device. If it merely stores, archives or transfers data, it is not a Medical Device. Software may also be considered an accessory for a medical device and the In-Vitro Diagnostic Regulations (IVDR [15]) may also be applicable, but these are not covered here. Scripts and macros are also software, and a script that changes the intended purpose of a non-medical device (e.g. a spreadsheet) or a medical device (e.g. a treatment planning system) might be considered to be a medical device in its own right. Similarly, whilst a general purpose Artificial Intelligence (AI) algorithm is not a medical device, a clinical software system that uses it may be. 'Apps' for mobile devices should also be included as Software. Software libraries, which do not provide a complete application, yet have demonstrable intended purposes compatible with the definition of a medical device may also need to be considered. Software is often extended and so decisions about whether it is a medical device should be reviewed regularly, especially when new functionality is added.
Currently a Medical Device can be designed, 'constructed' and used locally (i.e. within the same legal entity) without full conformity assessment, if appropriate precautions in methodology are used proportionate to the risk. However, it cannot be 'placed on the market', meaning that it cannot be sold or given to others as a working product for clinical use. IPEM have published a Best Practice Guidance document that describes this in the present regulatory framework for such '*in-house manufacture*' [11].

Considering the local situation first, the MDD requires that 'the software must be validated according to the state of the art taking into account the principles of Software Development Lifecycle (SDLC), Risk Management (RM), validation and verification'[8]. Although this is not at present legally required in Great Britain for in-house manufacture, state of the art is considered to be following current international standards, such as ISO 14971 (RM) and IEC 62304 (SDLC), described fully in the IPEM Best practice guidance [11]. The EU MDR [2] Article 5(5) strengthens this in a number of ways. Firstly, it requires that manufacture and use occurs under appropriate Quality Management Systems (QMS). It is recognised [3] that ISO 13485 is an appropriate QMS for medical device manufacture and is considered best practice. MDCG 2023-1[1] [16] states that compliance with ISO 15189 alone does not constitute an appropriate QMS for in-house manufacture of IVD. Aligning an existing ISO 9001 QMS to the minimum requirements [3] may potentially satisfy the MHRA but is yet unproven. Secondly, the decision to manufacture rather than procure an existing device on the market must be justified. This justification must be based on lack of availability or failure to meet performance requirements only and cannot be a solely financial justification. Health institutions must review experience gained from clinical use of the devices, making corrective actions as necessary. The EU MDR [2] Annex I contains general safety and

[1] MDCG 2023-1 was released after the UK's withdrawal from the EU and therefore without UK input.

performance requirements: the documentation for the device manufacture and use must be sufficient to demonstrate that processes ensure that these requirements are met. It is likely that all relevant documentation will need to be available for inspection by the MHRA.

To be '*placed on the market*', a Medical Device requires conformity assessment and marking, indicating that the manufacturer is satisfied that their production, testing and risk management processes conform to appropriate requirements, and that it has undergone clinical evaluation. Full guidance on this process is out of the scope of this advice note, but helpful detail is available [1]. A suitably qualified and experienced industrial partner might be useful in helping gain a conformity mark.

In addition to medical device regulation, the NHS has published two information standards for the manufacture (DCB0129 [9]) and deployment and use (DCB0160 [10]) of Health IT Systems. These standards are mandatory in England under the section 250 of the Health and Social Care Act 2012 [16]. The definition of a Health IT System is wider than that for a Medical Device, so it is more likely that these standards will apply [18]. The standards are aligned with ISO 14971 and the EU MDR [2]. Sharing of non-medical device health IT systems is not prohibited; however, DCB0160 places additional requirements on the adopting centre to consider hazards in the local environment. Further guidance is available in Annex A of the IPEM in-house manufacture best practice guidance [9].

The regulatory environment in the UK has been disrupted by both our exit from the EU and the novel coronavirus pandemic. We have therefore missed the delayed introduction of the EU MDR [2]. Until the government introduces legislation [0] and clarifies the situation, the existing UK MDR [7], based on the 1993 MDD [4], will continue to be enforced. Regulations in general follow best practice so it is unlikely that new UK legislation will be less stringent than the EU MDR [2], which reflects the current best practice. The aim of these regulations and of DCB012/0160 is to protect the patient by ensuring medical software is safe and clinically effective; the associated requirements also provide protection to the manufacturer, because by following the guidelines and requirements due diligence can be demonstrated.

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