NHS National Services Scotland

Guidance on Safe Management of Medical Devices and Equipment in Scotland's Health and Social Care Services

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NHSScotland Assure

Quality in the healthcare environment

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Executive summary

Brief

Organisations need to demonstrate ongoing compliance with statutory health and safety legislation in relation to the health technology that they utilise across the system. They also need to assure protection of the public through comprehensive management of risk, by engaging the appropriate professionally assured expertise in accordance with established professional regulation and standards.

Health technology sits at the interface between high-end science and medicine. It includes medical devices and equipment and is both systemic and essential in the delivery of modern healthcare: its deployment requires multi-professional input to assure prudent, pertinent, safe and effective adoption and application.

Medical devices and equipment are fundamental to the care experience of every service user or patient, and this is set to intensify as the national clinical strategy encourages an increased use of technology. The nature and range of technologies present significant risks and effective management is therefore critical for integration of medical technology and delivery of safe and effective care services.

Overview

This guidance recognises prime groups within the parties holding an interest and provides a focus for them to be equipped to discharge their particular responsibilities across three dominant themes: use, acquisition and manufacture. In Section 4, Roles and Responsibilities, targeted information is provided for these groups according to their respective key roles and remits.

There are legal considerations as the design, manufacture and supply of medical devices are regulated in the UK through legislation. The Medical Device Regulations (MDR) 2002 (see ref 1) and specific UK Health and Safety legislation, such as the Provision and Use of Work Equipment Regulations 1998 (PUWER) (see ref 2), identify criteria that must be met. PUWER itself includes the conditions and the way in which equipment can be used, the appropriateness of training and qualifications of equipment users, and the provision of instructions.

There are many specialist guidance documents published by various NHS, government and professional bodies in Scotland and the UK. These documents may be located on a multitude of ever changing on-line and paper publication resources, some of them will quickly fall obsolete or be superseded owing to the changing legislative and regulatory landscape. There are issues around operating with an assured level of consistency nationally.

In addition, there have been various practices and initiatives carried out in Scotland which require inclusion in this guidance, for example Incident Reporting Investigation Centre (IRIC) incident reporting system, Medical Device Policy Framework, Medical Device e-Learning Modules and so on.

The guidance is developed in conjunction with various stakeholders and approved by the Guidance on Management of Medical Devices and Equipment in Scotland Steering Group. The Group is made up of the representatives from Scottish Government, Health and Social Care professionals including Consultants, Senior Procurement and Clinical Engineering leads, Facilities and Occupational Health and Safety Leads, Incident Alerts Safety Officers and Medicines and Healthcare Products Regulatory Agency (MHRA).

Purpose

This document is aimed to provide public sector health and care organisations (NHS Boards and Local Authorities (LA) with a one-stop compendium of published guidance, legislation, standards and policy in Scotland relating to health technology, medical devices and equipment. Recognition is given to relevant guidance documents from across all political regions of the UK.

This guidance is intended to support safe and effective medical devices and equipment risk management practice that:

- complies with current Regulations, Standards and Scottish Government policy
- aligns with relevant guidance issued by NHSScotland, Scottish Government policies, Authorities and national bodies; for example, MHRA (see ref 3), Care Inspectorate Scotland (see ref 4), Healthcare Improvement Scotland (HIS) (see ref 5), Audit Scotland (see ref 6), NHS National Services Scotland (NHS NSS) (see ref 7), Health and Safety Executive (HSE) (see ref 8), National Audit Office (NAO) (see ref 9)
- aligns with relevant guidance issued by professional bodies; for example, National Association of Medical Device Educators and Trainers (NAMDET) (see ref 10), Association of British Health Tech Industries (ABHI) (see ref 11), Institute of Physics and Engineering in Medicine (IPEM) (see ref 12), The Institute of Healthcare Engineering and Estate Management (IHEEM) (see ref 13)
- endorses the ongoing provision of appropriate training and documentation for users and maintenance staff and engaging in collaboration with the equipment and devices industry to reinforce understanding
- aligns with national polities and initiatives
- encourages a nationally unified and collaborative approach to working

Over the last few years, the number of changes in regulations, guidance and increased clinical initiatives has steadily increased. The aim of this guidance is to provide easier and quicker access to the most up to date information on medical devices and equipment for health boards and LAs. Many documents, produced by various sources, might not always be readily available for example not online, not current or simply difficult to locate.

Therefore, this guide will aim to identify and consolidate the existing information but not replace it. The objective is to have a single document that where necessary clarifies and explains the detail, identifies what guidance is available and provides links to other informative documentation.

Document location goal:

- access to all appropriate information and documentation in a single document

Intended audience

This guidance is primarily intended for NHSScotland and Scottish LAs and for the third and private sector organisations that interface with these. Within these organisations the guidance is primarily intended for the following professional groups:

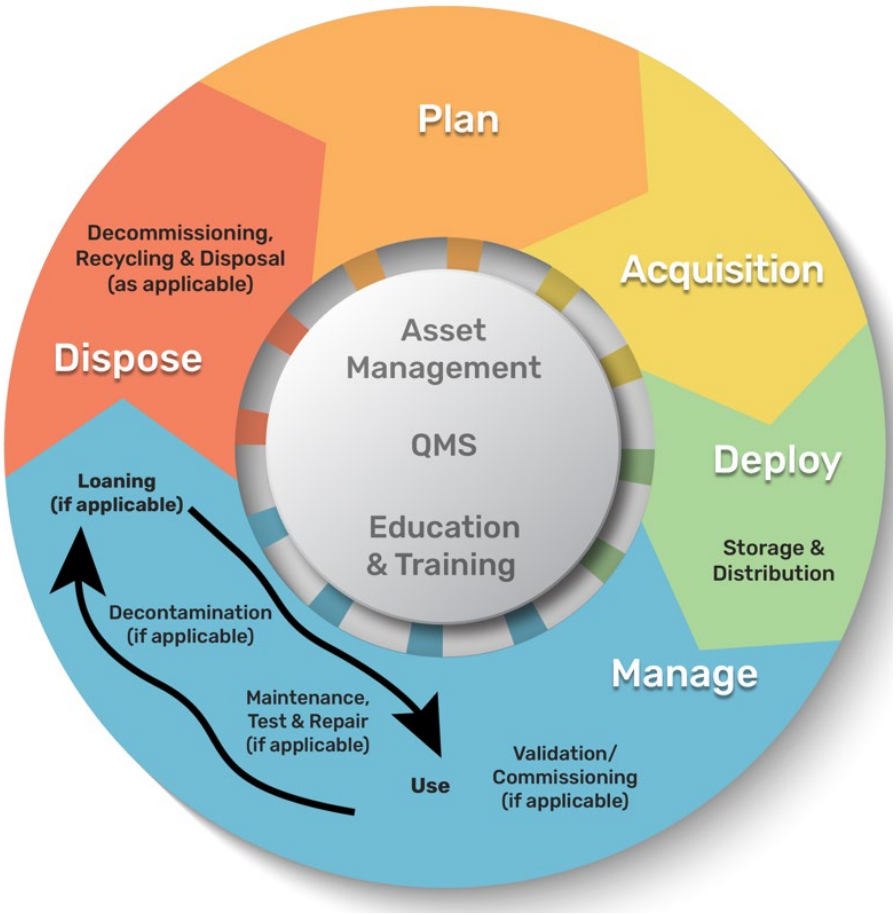
- Health and Social Care Provider Executives and Directors
- Health and Social Care System and Clinical Service Managers
- Medical Device Risk Management Experts including; Clinical Engineering and Medical Equipment Management, Healthcare Scientists and Engineers, Clinical Informatics and IT Professionals, Decontamination Managers, Researchers and Innovators
- Procurement Officers
- equipment users or providers including staff, social care workers, service users and contractors. Equipment may be issued or prescribed to patients for them to use autonomously. As the provider, they will need to provide a copy of instruction of use and training/ guidance of use, decontamination and maintenance and so on as indicated in this guidance

1. Introduction

Background

1.1. Ensuring there is an effective management system in place for medical devices and equipment is critical to the provision of healthcare. Health technology, medical devices and equipment are vital for the delivery of a range of services covering diagnosis, therapy, monitoring and rehabilitation. They must be procured, managed and maintained appropriately to provide high quality patient care. Additionally, they must meet clinical, financial and information governance requirements to minimise the risk of adverse incidents/ events occurring. Failure to manage health technology, medical devices and equipment proactively can be a significant risk to organisations and can lead to the same types of adverse incidents/ events occurring repeatedly. Management systems in place must cover product recalls, adverse incidents/ events and near misses as part of the overall proactive medical equipment management strategy required to minimise repeated occurrences.

Figure 1.1 - Device Life Cycle



Note 1: Modifications of devices should be avoided whenever possible (see 5.112-5.116 off-label use).

1.2. The Scottish Government's Healthcare Quality Strategy for NHSScotland (see ref 14) commits to ensure the NHSScotland Property and Asset Management Policy, Chief Executive Letter (CEL) 35 (2010) (see ref 15), establishes an aligned approach to arrangements required by Boards for the safe and effective operation of their assets including premises, medical equipment vehicles and IT. It lays down the framework for the performance and management of equipment in Scotland.

1.3. Through the referencing of key published guidance, this guidance outlines a systematic approach to the life management of medical devices and equipment for instance for instance Acquisition, Incoming Goods Check, Storage and Distribution, Validation/ Commissioning, Use, Maintenance/ Test/ Repair, Decontamination, Loaning, Decommissioning, Recycling and Disposal (see Figure 1.1).

Objectives

Safety

1.4. It is critical that medical devices and equipment are suitable for purpose and maintained in a safe and reliable condition and complies with the requirements of the Medical Device Regulations (MDR) applying to the product and the Provision and Use of Work Equipment Regulations 1998 (PUWER) (see ref 2). Any organisation that operates equipment holds responsibility for its safe use and must take appropriate steps to protect anyone who interacts with it. The title to the equipment may be owned by the organisation itself or by another legal entity. These can be a leasing company or a manufacturer who loans equipment to the organisation operating it, including situations in which consumables are purchased for it. In all cases, under PUWER (see ref 2), the organisation must ensure that the equipment is used and maintained in accordance with the manufacturer instructions.

Efficiency

1.5. It is important that staff are supported to work as efficiently as possible and avoid having to search for equipment or find equipment that is faulty or not properly maintained. Having a systematic approach to the management of medical devices and equipment can minimise these time-consuming episodes. Such a systematic approach includes equipment standardisation, an equipment library system, equipment physical location knowledge/ tracking and accessible equipment registers. Using standardised training packages can reduce re-training time and costs when staff move from organisation to organisation.

1.6. Savings can be maximised by systematic forward investment planning, based upon risk-based needs assessment coupled with aggregated purchasing in line with local and national standardisation of equipment through national procurement contracting work streams.

1.7. Efficiency improvement goals:

- improving joint working to reduce staff times searching for equipment through effective provision arrangements based on sound equipment management practice
- ensuring there are competent staff trained in using the devices they have and ensuring that the equipment is fully functioning when required

Compliant with regulations and standards

1.8. Compliance with current and future legislation is not negotiable, however many regulations can be open to interpretation. This inevitably creates variations in methodology across health and social care organisations. A standardised approach for Scotland should be an aspiration for all: by working with other organisations to develop systems 'Once for Scotland' may reduce work, aid adoption of best practice and help validate associated decision-making.

1.9. Compliance goals:

- compliance with statutory requirements, regulations and standards
- appropriate ensuring that Quality Management Systems (QMS) are in place within all organisations regarding the administration of device and equipment management, and are accredited where required

Note 2: A QMS is a documented responsibilities, procedures and records to achieve quality policies and objectives, for examples to meet customer and regulatory requirements and continuously improve effectiveness and efficiency.

1.10. Standardisation goals:

- providing a sound foundation to ensure a consistent approach to device and equipment management in Scotland
- National Medical Equipment Management (MEM) System is now in place. This system would provide a national oversight of procurement and maintenance contract activities across Scotland in line with NHSScotland Asset and Facilities Annual Reporting (see ref 16). As well as supporting the risk management process, a national system could deliver significant cost savings by providing data on variation of equipment, training, and professional practices across the country. This would also support improved cross organisation collaboration

Scope

1.11. The principles of this guidance document will apply to all medical devices and equipment, however, sections that apply to implantable devices, and in vitro diagnostic (IVD) medical devices are covered in more detail in other documents (see reference guide):

- medical devices as defined in UK MDR 2002 (see ref 1) (Statutory Instruments (SI) 2002 No 618 as amended
- healthcare equipment used in NHS and Local Authorities (LA) within Scotland, for example hoists, beds, walking aids, wheelchairs and falls prevention equipment

1.12. Private sector and third sector organisations that supply services to NHS and LA are also bound to comply with this guidance. Those that operate under contract to NHS and Local Authority may also be bound by NHS or LA policy particular to, or wrapped into, such contracts. It is the responsibility of the NHS and LA to include this requirement under their contracts (see ref 17).

Note 3: Further information -

- Medicines and Healthcare Products Regulatory Agency (MHRA) guidance 'Regulating medical devices from 1 January 2021 (see ref 3)
- MHRA general guidance on Medical Devices Regulations and Safety (see ref 18)

2. What are medical devices and equipment?

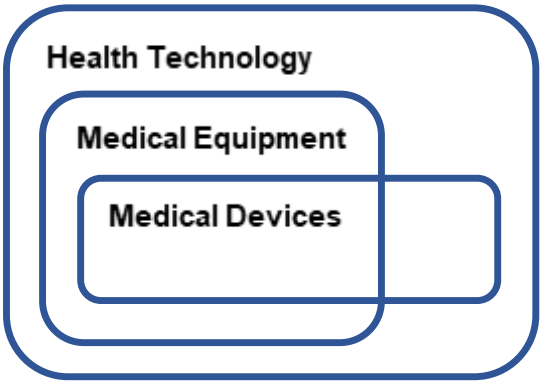
2.1. There are multiple interpretations for the terms health technology and for medical equipment, but medical devices are explicitly defined within the UK Medical Devices Regulations (MDR) (see ref 1).

2.2. The World Health Organisation (WHO) (see ref 19) defines health technology as 'the application of organised knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of life' and clarifies that the term is used interchangeably with 'Health-care Technology'.

2.3. Health technology needs to be supported with an appropriate systematic and structured management approach throughout its entire lifecycle.

2.4. In this guidance, medical devices and medical equipment are considered as overlapping subcategories of health technology (see Figure 2.1).

Figure 2.1 - Nested family of equipment used in healthcare



How to identify a medical device or in vitro medical device (including software)

2.5. Decisions about whether a product is a medical device or not are based on the principal intended purpose of the product, as stated by its manufacturer, and upon its mode of action. If there is any doubt, it is recommended to ask the device's manufacturer. It is also recommended to refer to borderlines guidance Borderline products: how to tell if your product is a medical device and which risk class applies on GOV.UK website and/ or confirm with Medicines and Healthcare Products Regulatory Agency (MHRA) borderlines team (Devices.Borderlines@mhra.gov.uk).

2.6. Products that do not have a principal intended medical purpose are not considered to be medical devices, even if they are used for the prevention of disease as a secondary purpose. Products that have a multiple purpose and used within a medical environment may be medical devices where a manufacturer cites a specific medical purpose. Products that are primarily drugs are not medical devices.

Medical devices

2.7. The first point of contact in trying to establish whether a device is truly a medical device, or not, is by asking the supplier/ seller to share the conformity certification of the device. This can be requested with the standardised pre-acquisition questionnaire (PAQ) form (see ref

20). Scotland has adopted the Department of Health and Social Care's form, and this has been made available through Health Facilities Scotland's (HFS's) Reports and Information webpage (HFS is now a part of NHSScotland Assure).

2.8. The MDR 2002 (see ref 1) states in its definitions that

"medical device" means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, together with any software necessary for its proper application, 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

- *diagnosis, prevention, monitoring, treatment or alleviation of disease*
- *diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap*
- *investigation, replacement or modification of the anatomy or of a physiological process, or*
- *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;

2.9. In Vitro Diagnostic (IVD) Medical Device

"a medical device which is

a) a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in combination, and

b) intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:

- *concerning a physiological or pathological state, or*
- *concerning a congenital abnormality, or*
- *to determine the safety and compatibility with potential recipients, or*
- *to monitor therapeutic measures and includes a specimen receptacle but not a product for general laboratory use, unless that product, in view of its characteristics, is specifically intended by its manufacturer to be used for in vitro diagnostic examination".*

Active implantable medical devices

2.10. According to the UK MDR (see ref 1) - “active implantable medical device” means a medical device which:

- relies for its functioning on a source of electrical energy or a source of power other than that generated directly by the human body or by gravity; and is intended to be totally or partially introduced into the human body (whether surgically or medically, including being introduced into a natural orifice)
- which is intended to remain in the human body after completion of the surgical or medical procedure during which it is introduced, even if it is intended to administer a medicinal product or incorporates as an integral part a substance which, if used separately, would be a medicinal product

Medical equipment

2.11. Medical equipment is generally used in the direct or indirect care of patients and can include equipment that is not regulated as a medical device.

2.12. There is no clear-cut definition for the term medical equipment.

2.13. The WHO defines medical equipment (see ref 21) as medical devices requiring calibration, maintenance, repair, user training and decommissioning - activities usually managed by clinical staff. WHO also categorises a comprehensive range of medical devices as hospital medical equipment (see ref 22). This equipment is used for the specific purposes of diagnosis and treatment of disease or rehabilitation following disease or injury. It can be used alone or in combination with any accessory, consumable or other piece of medical equipment. Medical equipment excludes implantable, disposable or single-use medical devices.

2.14. The British Standard (BS) EN 60601-1: 'Medical electrical equipment - Part 1: General requirements for basic safety and essential performance' (see ref 23), defines medical electrical equipment as a subset of medical devices. It also defines the patient environment, in which intentional or unintentional contact may occur between a patient and the equipment or with other people who are touching the equipment. Other health technology which are not medical devices may be present in this zone and may be required to conform to this standard.

2.15. The standard BS EN 61010-1: 'Safety requirements for electrical equipment for measurement, control, and laboratory use. General requirements' (see ref 24), classifies electrical laboratory equipment as equipment which measures, indicates, monitors, inspects or analyses materials, or is used to prepare materials, and includes IVD equipment and notes that this equipment may also be used in areas other than laboratories, for example self-test IVD equipment to be used in the home.

2.16. Neither the MDR 2002 (see ref 1) nor the MHRA specifically define medical equipment but the MHRA notes in its guidelines on borderlines that not all equipment used in a healthcare environment or used by a healthcare professional will be for these reasons, in these guidelines, medical equipment is represented as overlapping with medical devices rather than as a subset, both being subcategories of health technology (see Figure 2.1 within this document, MHRA Borderlines with medical devices (see ref 25) and the EC Borderline Manual (see ref 26).

Software

2.17. Software may fall under the scope of medical device legislation. This increases the risk of non-CE (Conformité Européenne, meaning European Conformity) or non-UK Conformity Assessment (UKCA) marked software being used for a medical purpose, and off-label use of a medical device (section 5 within this guidance document). In both cases, the liability for using the unregulated device lies with the healthcare institution using it. The MHRA published comprehensive guidance on software as a medical device (see ref 27).

2.18. Software in a medical device (SiMD) is software within the system. This can include hardware and software working within the context of a medical device system.

2.19. Software as a Medical Device (SaMD) is intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device.

2.20. SaMD encompasses everything from spreadsheets, scripts, functional documents and apps to desktop or cloud-based applications. They range from simple calculators to complex machine learning algorithms and artificial intelligence (AI). SaMD is used across the breadth of healthcare from primary care to the acute sector, while many solutions (for example user apps) are directly aimed at lay users. Examples include, but are not limited to, clinical calculators for drug, radiotherapy treatment planning systems, surgical planning systems, and data-processing and image-processing tools for diagnosis.

2.21. SiMD and SaMD requires UKCA or CE mark, as it falls within scope of the regulations, then conformance is typically demonstrated by adherence to a set of harmonised standards. The key standards for SaMD and SiMD are BS EN 62304 (see ref 28), BS EN International Organisation for Standardisation (ISO) 14971 (see ref 29), BS EN ISO 13485 (see ref 30) and BS EN 62366 (see ref 31) are also important and equally apply to physical device. IEC60601 is applicable for SiMD and SaMD as it contains requirements in clause 14 for Programmable Electronic Medical Systems (PEMS).

2.22. Further information can be found in the MHRA guidance on SaMD and Artificial Intelligence as Medical Device (AIaMD) as a medical device change program (see ref 27). The document provides clarifications on definitions, qualifications, classifications, the regulatory requirements for example pre and post market surveillance, additional recommendations for the manufacturers and other parties involved to achieve regulatory compliance. The guidance also provides examples of SaMD and the flowchart to be used to determine

whether a piece of software meets the definition of a medical device and therefore comes within scope of the regulations. The guidance also highlights the important matters relating to the intended purpose.

2.23. The change programme also considers the challenges and opportunities posed by AIaMD, and to address wider issues of transparency of AI (both explainability and interpretability), and adaptivity (retraining of AI models).

2.24. MHRA established the Software Group to assure the safety of SaMD and ensure the UK public have access to technology that meets a clinical need. The Group works across the MHRA to achieve this aim for SaMD and AIaMD through:

- assisting with pre-market and post-market enquiries from manufacturers
- conducting technical file reviews and post-market surveillance activities
- reviewing of technical and clinical aspects of clinical investigations and exceptional use authorisations
- ensuring medical device regulation is fit for purpose, meets the needs of software as well as AI, and is supported by robust guidance
- engaging with stakeholders including industry, healthcare organisations and professionals, as well as patients and public to support the functions noted above

Medicines

2.25. Some products are hard to distinguish between being a medicine or a medical device, for example cosmetics, food supplements or biocidal products (a chemical substance or microorganism intended to destroy, deter, render harmless, or exert a controlling effect on any harmful organism by chemical or biological means).

2.26. Those of these that are not explicitly discounted as a medical device, for example products falling under Regulation (EC) No 1223/2009 on cosmetic products, are classified as borderlines until their classification as a medicinal product or a medical device has been decided. Further advice is available within the MHRA guide, Borderlines between medical devices and medicinal products (see ref 32).

3. Legal framework, standards, national policy and guidance

3.1. The aim for statutory compliance for any organisations means that they are following the laws on any given issue. The legal framework is made up of regulations, guidance and standards. Understanding what the differences between them is very important.

Regulations

3.2. Regulations are generally written to cover a wide range of situations and therefore may not be specific on certain matters. They are normally supported with formal guidance, most likely from the organisation that's been responsible for the policy.

3.3. Manufacturers who intend to supply medical devices within the UK need to be compliant with the following UK regulations unless repealed by the enactment of superseding UK legislation.:

- Medical Devices Regulations (MDR) 2002 (see ref 1)
- the UK General Product Safety Regulations 2005 (see ref 33) (SI 2005 No 1803)

3.4. MDR specifies requirements that legal manufacturers of medical devices must meet to legally place a device on the market. The regulations make sure that medical devices placed on the UK market are safe and effective for patients, the public, and health and care professionals.

3.5. These regulations are safety regulations under the Consumer Protection Act 1987 (see ref 34) (a product liability directive, introducing a regime of strict liability for damage arising from defective products to regulate the safety of consumer products) and as such, manufactures must comply with their statutory duties as listed within the regulations.

3.6. There are further statutory requirements applying in the UK under the Provision and Use of Work Equipment Regulations 1998 (see ref 2), commonly known as PUWER, that place duties on organisations who own, operate or have control over work equipment including key issues such as maintenance, inspection, training and instruction. In addition, if the equipment involves lifting equipment for example patient hoists, the Lifting Operations and Lifting Equipment Regulations 1998 (see ref 35), commonly known as LOLER, will apply. Where work equipment involves working with ionising radiation The Ionising Radiations Regulations 2017 (see ref 36) will apply.

UK medical device regulations

3.7. Devices are regulated under the UK MDR 2002 (see ref 1) which, prior to the end of the transition period (following the UK's departure from the EU), gave effect in UK law to the directives listed below:

- Directive 90/385/EEC on active implantable medical devices (EU Active Implantable Medical Devices Directive (AIMDD)) (see ref 37)
- Directive 93/42/EEC on medical devices (EU Medical Devices Directive (MDD)) (see ref 38)
- Directive 98/79/EC on in vitro diagnostic (IVD) medical devices (EU in vitro diagnostic (IVDD)) (see ref 39)

3.8. This means that the current Great Britain route to market and UKCA marking requirements are based on the requirements derived from the above EU legislation.

3.9. Since 26 May 2021, the EU Medical Devices Regulation (Regulation 2017/745) (EU MDR) has applied in EU Member States and Northern Ireland. The in vitro Diagnostic Medical Devices Regulation (Regulation 2017/746) (EU IVDR) has applied in EU Member States and Northern Ireland since 26 May 2022. As these EU regulations did not take effect during the transition period, they were not EU law automatically retained by the EU (Withdrawal) Act 2018 and therefore do not apply in Great Britain.

3.10. All medical devices, including IVDs, custom-made devices and systems or procedure packs must be registered with the MHRA before being placed on the Great Britain market. Manufacturers must comply with relevant product marking and conformity assessment requirements for medical devices. Devices can be registered using the Medicines and Healthcare Products Regulatory Agency (MHRA) Device Online Registration system (MHRA DORS) (see ref 40). Registration requires information to be provided on the manufacturer, the device(s) and UK Responsible Person. Manufacturers wishing to place a device on the Great Britain market need to register with the MHRA. The MHRA will only accept registration of devices from manufacturers where the manufacturer is based in the UK. If the manufacturer is based outside the UK, they must appoint a UK Responsible Person. This UK Responsible Person will then assume certain responsibilities on behalf of the manufacturer, including registering the device with the MHRA (see ref 40).

3.11. The Medicines and Medical Devices Act 2021 (see ref 41) introduced powers to amend the UK medical devices regulations - bringing an opportunity to develop a more robust regime that prioritises patient safety. In 2021, UK Government carried out consultation on the future medical device regulation in the United Kingdom (see ref 42). The outcomes of the consultation were published in 2022 detailing the intention of UK Government to amend the regulations in areas such as the scope of the Regulations, the classification, the economic operators, registration and UDI, Approved Bodies, conformity assessments, clinical investigation and performance studies, post-market surveillance, vigilance, market surveillance, IVD medical devices, SaMD, implantable devices, other product specific changes, environmental sustainability and public health impacts, alternative routes to market, transitional arrangements (see ref 43).

3.12. In April 2023, the government put in place legislation that amends The Medical Device Regulations 2002 (UK MDR) to extend the acceptance of CE marked medical devices on

the Great Britain market. This will support the ongoing safe supply of medical devices to Great Britain and ease the transition to the future regulatory framework for medical devices.

3.13. The MHRA have published a roadmap outlining the intended timelines for delivering the future regulatory framework for medical devices (ref 44). The roadmap contains the activities that have been delivered in 2021-2023 and the planned activities in 2024-2025, aiming for the future core regulations will come into force in 2025.

3.14. CE marked medical devices can be placed on the Great Britain market to the timelines as illustrated in the following Figure 3.1 and Figure 3.2).

Figure 3.1 - Timeline for placing CE marked medical devices on GB market (taken from transition periods under new UK SI (publishing.service.gov.uk))

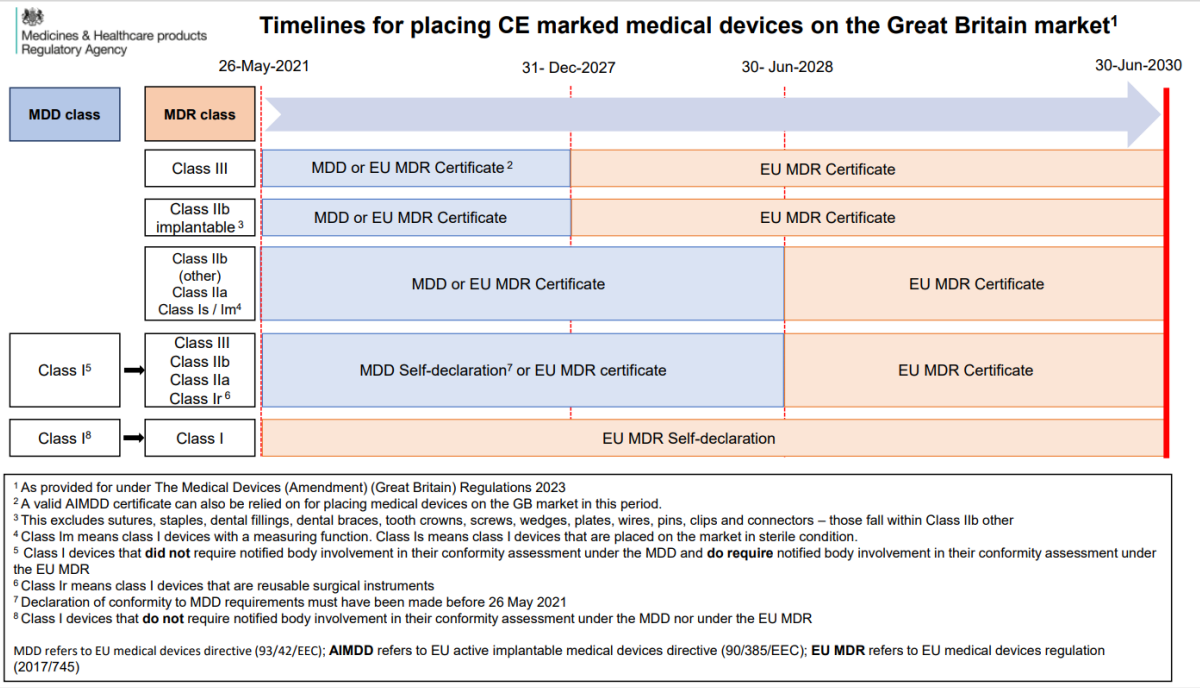
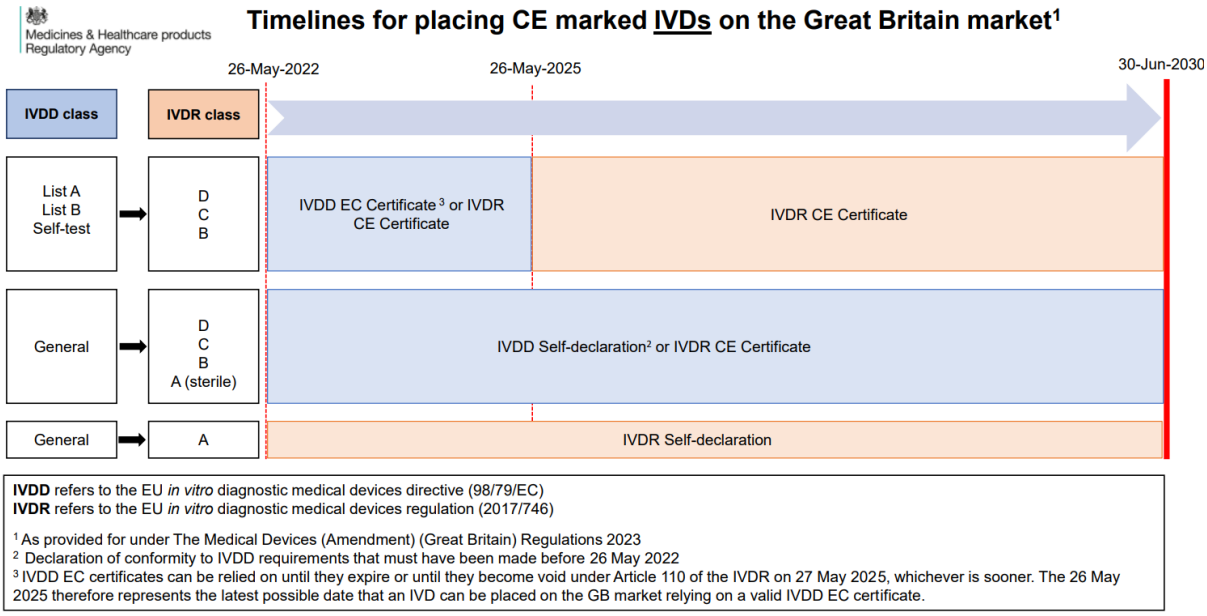


Figure 3.2 -Timeline for placing CE marked IVDR on the GB market (taken from transition periods under new UK SI (publishing.service.gov.uk))



3.15. The UK Government will introduce legislation that strengthens post-market surveillance requirements, expected to apply from mid-2024. The World Trade Organisation (WTO) published notification of the draft Post-Market Surveillance Requirements Statutory Instrument (PMS SI) on 26 July 2023, to provide opportunity to WTO members to comment within 60 days of publication The draft PMS SI includes:

- detail on what must be included as part of a PMS system, including the methods for collecting PMS data to support improved capturing of PMS data and harmonisation across manufacturers
- enhanced serious incident reporting obligations for manufacturers to support the detection of safety issues sooner
- more stringent requirements for manufacturers to conduct periodic reviews of their PMS data, including for implantable medical devices. This aims to support manufacturers in earlier detection of trends/ signals that may have an impact on the safety of a medical device

UKCA marking

3.16. The UKCA marking is the conformity marking to declare the products meets the relevant essential requirements being placed on the market in Great Britain (England, Scotland and Wales) (see ref 45)). For medical devices, UKCA marking requirements are currently based on the requirements of the relevant Annexes to the Medical Device Directives which have been modified by UK MDR (see ref 1).

3.17. The UKCA marking was introduced since 1 January 2021. Great Britain (GB) is still accepting CE marked devices (see Figure 3.1 and Figure 3.2).

3.18. The manufacturers of non-sterile and non-measuring Class I devices and general IVDs can self-certify against the UKCA marking. However, conformity assessment by an Approved Body is required for UKCA marking (see ref 45). The MHRA designates UK Approved Bodies to perform conformity assessments against the relevant requirements for the UKCA marking. The list of UK Approved bodies for medical devices can be found in (see ref 46).

CE marking and international recognition

3.19. A CE mark is a symbol applied to products to indicate that they conform with relevant presiding regulations regarding health and safety or environmental protection. The CE mark is a legal requirement when placing a medical device on the market in the EU.

3.20. All medical devices require being CE marked prior to being placed on the market within the European Economic Area (EEA) (see ref 47), with two exceptions: devices for clinical investigation and devices described as custom made for instance devices for a specific patient as prescribed by a healthcare professional. The CE Mark demonstrates the device is compliant with the Essential Requirements of the EU Directives, or with the General Product Safety Requirements of the EU Regulations. The Essential Requirements and General Safety and Performance Requirements are contained in Annex 1 of the respective legislation.

3.21. The CE marking process is the responsibility of the manufacturer of a medical device. Owners and operators of medical devices should be aware that there is a time restriction on devices that were placed on the market under the EU Directives on how long these devices can continue to be used. For the use in GB market, see timeline above (Figure 3.1 and Figure 3.2).

3.22. The current legislation cuts off acceptance of CE marking at 2030, the intention is to allow these devices on the GB market for longer subject to certain requirements. In the meantime, the UK continues to progress the development of a framework for international recognition, including through targeted engagement with stakeholders, building on the outline proposals for alternative routes to market which were included in our 2021.

3.23. Under specific circumstances some medical devices are exempted from the requirement to carry the CE mark. It is vital that people responsible for acquiring medical devices are fully conversant with the regulatory requirements applicable to that particular medical device.

3.24. Products with the following exemption categories will not carry the CE mark and will require managing with their respective particular regulatory arrangements:

- a device manufactured and used solely within a health/ care organisation, (under a Health Institution Exemption under the 2017 EU Medical Device Regulations: Regulation 2017/745 (see ref 48)
- a custom-made device - although it must still meet the requirements in the regulations and the type of device must be clearly labelled 'custom-made device'

- undergoing a clinical investigation - it must be clearly labelled 'exclusively for clinical investigation' and meet the requirements for CE marking as far as possible - centres accepting pre-market products under the clinical investigation must take the necessary precautions to protect the health and safety of patients, in line with MHRA guidance clinical Investigations of medical devices (see ref 49)
- an in vitro diagnostic medical device (IVD) for performance evaluation
- a non-compliant device used in exceptional circumstances for example. if there is no legitimate alternative available (humanitarian grounds via MHRA approval using the approval form: Humanitarian use of device - application form (see ref 50)

Exceptional/ concessional use of non-conforming devices

3.25. A non-conforming product or device is one that does not conform to product requirements as identified and is controlled normally via a quality system, to prevent its unintended use or delivery. However, a manufacturer can apply to supply a medical device that does not comply with the law to protect a patient's health if there is no legitimate alternative available. This is called an exceptional use of a non-UKCA/ CE marked medical device. The same provision may be made for custom made devices that have not complied with the standard European Commission conformity assessment procedure (see ref 51).

3.26. The supply and use of a non-conforming medical device for the treatment of a single named patient can occur for humanitarian reasons in exceptional circumstances if:

- the clinician responsible for the patient's treatment supports the manufacturer's application
- there is no alternative UKCA/ CE marked device available for this treatment
- it can be demonstrated that mortality or morbidity is significantly reduced if the device is used compared to alternative compliant treatment
- the appropriate MHRA application form (see ref 50) 'use of a non-UKCA/ CE marked device on humanitarian reasons' has been completed and approved

Note 4: Additional information - Exceptional use of non-conforming (non-UKCE marked) devices (see ref 52).

3.27. It is critical to prevent non-conforming products from reaching frontline staff unless under the conditions given above and just as important is eliminating the root cause of unauthorised non-conforming products entering procurement chain.

3.28. There are many ways organisations label or highlight non-conforming products such as affixing tags, signs or stickers, tape or ribbons, labelled bins, boxes or bags, descriptions written directly on the product, painting a warning mark, electronically using for example barcodes or storing it in a specifically identified area. Each organisation should have an agreed method for highlighting non-conforming devices to ensure consistency which must be highlighted in their policy and/ or Standard Operating Procedure (SOP).

Health and social care regulations

3.29. The Public Bodies (Joint Working) (Scotland) Act 2014 (see ref 53) legislates for closer working and integration between Health Boards and Local Authorities (LAs) and sets out:

- nationally agreed outcomes, which apply across health and social care, and for which NHS Boards and LAs are held jointly accountable
- a requirement on NHS Boards and LAs to integrate health and social care budgets (consideration should be given to joint funding of medical devices and equipment); see section 22 of the Act (see ref 53) - Co-operation re-equipment
- a requirement on partnerships to strengthen the role of clinicians and care professionals, along with the third and independent sectors, in the planning and delivery of services

Note 5: Additional information - Supporting Scottish Government standard:

- Health and Social Care Standards: my support, my life (see ref 54)
- Scottish Health Council Policy, Legislation and Guidance section (see ref 55)

Standards

3.30. It is crucial to understand that standards are voluntary and are not law. They represent an agreed detailed process, requirements, technical requirements or processes that ought to be implemented if following that standard.

3.31. Standards can have a role in supporting regulatory requirements. While remaining voluntary, meeting a recognised standard can provide a presumption of conformity with regulatory requirements.

3.32. From 1 January 2021, the GB regulatory framework enables the relevant Secretary of State to ‘designate’ standards for regulatory conformity purposes, to meet the required levels of safety or energy efficiency. The Office for Product Safety and Standards (OPSS) leads and co-ordinates the designation process across government, and British Standards Institution (BSI) updates OPSS on new or revised standards to be considered for designation. For medical device standards, MHRA assess whether the standards put forward are suitable for the purpose of providing a presumption of conformity to relevant essential requirements of UK MDR. BSI remains responsible for the quality technical adequacy of the standard. A standard may be designated a standard in full or with restriction, or not be designated. A transition period will be allocated when a new designated standard replaces an existing designated standard.

3.33. In the UK, such standards are identified as ‘designated standards’ and in the EU as ‘harmonised standards’. There is a statutory ‘presumption of conformity’ that the product meets the essential requirements that apply to that product covered by the standard.

3.34. Three lists of UK designated standards for medical devices have been published. These lists of standards apply to:

- medical devices (see ref 56)
- active implantable medical devices (see ref 57)
- IVD medical devices (see ref 58)

3.35. A copy of certain standards is available in Barbour and can be accessed by health and social care staff via the knowledge network website (reference - Library Search). Appendix A provides examples of medical device related standards available via knowledge network.

Quality standards

3.36. A standard is a document that sets out best practice, minimum performance, or most up to date criteria set for devices and systems. A coding system is used and accepted by peer manufacturers to show the device or equipment is compatible and conforms to the essential quality, performance and safety criteria set out by the industry experts. Where equipment may be sold in another country, the use of an agreed international standard shows that equipment or devices presenting the symbol can be used safely within the agreed countries or regions, irrespective of where it was manufactured. However, care must be taken as not all countries or regions adopt all standards from other countries or regions.

3.37. Standards can be categorised into four different groups:

- basic standards (covers broad issues and has applicability across multiple industries) for example International Organisation for Standardisation (ISO) 9001 (see ref 59)
- group standards (covers the essential principles of a distinct group of equipment for example medical equipment) for example BS EN 60601-2-24:2015 (see ref 60) Medical electrical equipment. Particular requirements for the basic safety and essential performance of infusion pumps and controllers
- product standards (more detailed and specific to a particular type of product including design and construction alongside functional requirements deemed essential to safety performance) for example ISO 7886-1:2017 (see ref 61) Sterile hypodermic syringes for single use - Part 1: Syringes for manual use
- process standards (which can cover Basic or Group) for example ISO 55001 (see ref 62) which focuses on developing a proactive lifecycle asset management system, supports optimisation of assets and cost reductions whilst meeting performance and safety requirements

3.38. There are few organizations publishing standards such as:

- **ISO** - International Organisation for Standardisation. The acronym ISO is derived from the Greek word "isos" meaning equal. At its inception it was decided to give it one short all-purpose name due to the different acronyms “International Organisation for Standardisation" would have worldwide. ISO formed two joint committees with the International Electrotechnical Commission (IEC) to develop standards and terminology in the areas of electrical and electronic related technologies

- **CEN (European Committee for Standardization), CENELEC (European Committee for Electrotechnical Standardization) and ETSI (European Telecommunications Standards Institute) draft and maintain European Standards (ENs)** - These are abbreviated to ENs owing to the more literal translation from French/ German as European Norms
- **BS** - British Standards are the standards produced by the BSI Group (see ref 63) which is incorporated under a Royal Charter (see ref 64) (and which is formally designated as the National Standards Body (NSB) (see ref 65) for the UK). The BSI Group produces British Standards under the authority of the Charter, which lays down BSI's objectives. BSI sets up standards of quality for goods and services, prepares and promotes the general adoption of British Standards.

Key management standards

3.39. The Medical Device Directives, the Medical Device Regulations and the EU Medical Device Regulations require manufacturers to implement a Quality Management System (QMS), for which the most relevant standard is BS EN ISO 13485:2016 (see ref 30). This QMS Standard also details requirements for incorporation of risk management within the QMS.

3.40. BS EN ISO 14971:2019 (see ref 29) is the standard for risk management and meeting the requirements of this standard can help the health organisation to demonstrate compliance to the regulatory requirements as a manufacturer.

3.41. Other suitable systems include the ISO 55000 (see ref 66) series, BS 70000 (see ref 67) or ISO 9001: 2015 (see ref 59) standards.

Guidance

3.42. Guidance is exactly what is says, a guide and can add deeper interpretation and understanding to help clarify what is described in the regulations and standards. Following guidance is not compulsory however by doing so the health and care organisation generally will comply with the law. The guidance can also provide best practices matters that are not described in the regulations.

3.43. MHRA publish guidance on regulation and the safe use of medical devices. An example of MHRA guidance on the safe use of medical devices are Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use (see ref 68). These guidelines provide safety information for users of magnetic resonance imaging (MRI) equipment in clinical use based on the experience of MHRA and contributing organisations on safe use of MRI equipment.

3.44. In addition, the MHRA published and will publish more guidance related to medical devices and to support the implementation of UK MDR (see Table B.1 Appendix B).

Note 6: It is recommended to subscribe to these pages to be automatically notified when the guidance is updated.

3.45. For additional guidance applicable for EU regulation of medical devices has been compiled by the EU Commission (Medical Devices Oversight Group (MDCG) (see ref 69) and the Notified Bodies Oversight Group (NBOG) (see ref 70).

3.46. Health and Safety Executive (HSE) published guidance on various topics related to medical devices and equipment used in health and social care settings, for instances bed and bed rails, diathermy, hoist, sling, sharp, birthing pool, respiratory protective equipment, pneumatic air tube transport system for pathology specimen etc. These can be found in HSE website (see ref 71).

3.47. Health Facilities Scotland (HFS) (HFS is now a part of NHSScotland Assure) published guidance (see ref 72) that are applied to estates and facilities within NHSScotland, for example, Scottish Health Technical Memorandums (SHTM), Scottish Health Technical Notes (SHTN) on waste management and Scottish Health Facilities Notes (SHFN).

3.48. The SHTM 00 series guidance contains a suite of nine core subjects:

- SHTM 00 - Healthcare Engineering - Policies and principles of best practice guidance (applicable to all SHTMs in this series)
- SHTM 01 - Decontamination
- SHTM 02 - Medical gases
- SHTM 03 - Ventilation systems
- SHTM 04 - Water systems
- SHTM 05 - Reserved for future use
- SHTM 06 - Electrical services
- SHTM 07 - Environment and sustainability
- SHTM 08 - Specialist services

3.49. Health Protection Scotland (HPS) (HPS is now a part of NHSScotland Assure) also published various guidance such as National Infection Prevention and Control Manual (NIPCM) including Safe Management of Care Equipment.

Note 7 - other relevant information:

- NHSScotland Assure - Equipment decontamination and infection control precautions
- NHSScotland Assure homepage - Publication and Guidance (see ref 72)
- Infection Control - NIPCM (see ref 89)
- Regulations, Guidance and Standards, Electronic and Biomedical Engineering (EBME) Seminar, Justin McCarthy: 2017 (see ref 73)

3.50. Some formal official guidance documents are called Approved Codes of Practice, and these carry a slightly higher status when referring to guidance. These detailed documents must be given careful consideration.

3.51. Additional guidance may be produced by appropriate professional organisations, for example the National Association of Medical Devices Educators and Trainers (NAMDET) (see ref 10), IET (The Institution of Engineering and Technology) (see ref 74) or IPEM (Institute of Physics and Engineering in Medicine) (see ref 12).

The medical devices policy framework

3.52. The Medical Devices Policy Framework and Action Plan has been developed by Scottish Government Medical Devices and Legislation Unit, through engagement with NHS Boards and Local Authority Incident Safety Officers. The Framework encompasses several existing programmes of work, including MDR preparedness and importantly draws on patient insight work recently undertaken by the Unit.

3.53. The Framework aim is to improve patient safety and outcomes in medical devices delivered though four key themes:

- assurance of implementation of UK MDR relating to primarily NHS Boards and the national guidance SHTN 00-04 in Scotland
- improving and utilising medical device data at national level and maximising its use to improve patient safety
- improving the information available to patients about the devices they use
- improving infrastructure for medical devices at national level with a first key step to establish a National Medical Devices Committee (MDC)

3.54. Within these themes the Framework is focused on improving the foundations needed to support medical devices policy. Prioritised national actions will be delivered through partnership, particularly with the NHSScotland Scan for Safety Programme being led by National Services Scotland (NSS), the national Incident Reporting and Investigation Centre (IRIC) also NSS and with support from Health Improvement Scotland (HIS) and NHS Education for Scotland (NES).

3.55. The MDC has been established in Scotland to provide leadership, direction and decision making to NHSScotland in preparation for the MHRA future medical devices regulatory regime which is expected to be in place in 2025. MDC Terms of Reference can be found on the Scottish Government website.

Unique device identification (UDI)

UDI context

3.56. The application of a UDI system will allow more accurate device identification within supply chain, safety alerts, medical device recall management and surveillance tasks more generally.

3.57. The practice adopted by product manufacturers of attaching their own unique identification numbers to each product they produce is long established. These are typically in the form of a model/ catalogue number and/ or a serial number. These numbers typically take the form of combinations of numerals, letters and symbols that are human-readable and as barcodes that are machine readable.

3.58. Conceptually, the manufacturers, users and other related parties can use the product's unique identification number to track and manage whatever happens to the product across its entire lifetime. On a production line, a product can first to start out with its own unique identification number label and then during production, distribution, use and disposal, as processes are applied, each event can be logged into an appropriate database. Using the unique identification number as the key, these databases may also be linked together to yield yet more powerful information. Identification numbers that are unilaterally generated by individual product manufacturers are not necessarily unique nor have any common structure. Internationally, several organisations have created standardised systems for generating and issuing unique index numbers to manufacturers and organisations invested in labelling their physical assets with a globally unique number. There are also many examples of standards and systems to unify serial numbering in different industries, for example vehicles, publications, currency, aviation, retail, and so on but historically, this has not been formally achieved across the medical device industry globally.

3.59. Regulators globally have started to include requirements for UDI as part of regulations, initially in the USA, with the International Medical Devices Regulators Forum (IMDRF) agreeing some principles for a UDI system in a UDI Application Guide (see ref 75).

UDI key structure components

3.60. The key components are

- **Unique Device Identifier Database (UDID)** - The UDID is a central Medical Device master database containing all essential information to identify devices in a given jurisdiction region for market regulation and is the designated source for device identification information within the region
- **UDI** - The UDI is a series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard. It allows the unambiguous identification of a specific medical device on the market

3.61. It must be human readable, via the Human Readable Interface (HRI) and may also be machine readable, Automatic Interface and Data Capture (AIDC) feature such as a bar

code. The word 'Unique' does not necessarily imply serialisation of individual production units.

3.62. The UDI is composed of two parts: such that the UDI is the Device Identifier (UDI-DI) linked together in a chain or series with the Production Identifier (UDI-PI):

- **UDI-DI** - The Device Identifier of the UDI is a static unique numeric or alphanumeric code specific to a model and that is also used as the 'access key' to information stored in the UDID
- **UDI-PI** - The Production Identifier of the UDI is a dynamic numeric or alphanumeric code that identifies the unit of device production when one or more of the following is included on the package label of the device. The different types of Production Identifier(s) include:
    - the lot or batch within which a device was manufactured
    - the serial number of a specific device
    - the expiration date of a specific device
    - the date of manufacture (may not be required if other production identifiers are on the label)
    - the version, for SaMD
    - the Distinct Identification Code (DIC), when applicable
    - this number is an essential identifier for medical products of human origin
- **UDI Carrier** - The UDI Carrier is the visible display of the UDI on the device label, on the device itself and on higher levels of device packaging. In addition to the UDI, the UDI Carrier can also hold other identifiers not considered part of the UDI which support sharing of standardised non-UDI information between trading partners.
- **Basic UDI-DI** - The common code for a group of products having the same intended use, risk classification, design, manufacturing characteristics and is associated with the medical device nomenclature used under the jurisdiction region's UDI system. The Basic UDI-DI is an administrative number that appears in the technical documentation for the product and in its database entries, but it does not appear on the product.

Device nomenclature

3.63. It is a coding system to identify a medical device without the need for terms or descriptions which may not be understood across different languages.

3.64. Currently there is no global consensus on device nomenclature. Some countries such as the US, Canada, Australia, Singapore use Global Medical Device Nomenclature (GMDN). While European countries use the European Medical Device Nomenclature (EMDN).

3.65. The UK Government response to the 2021 MDR consultation indicated towards maintaining the status quo of using GMDN nomenclature as the preferred option to allow for harmonisation with other major jurisdictions (although not the EU and to avoid additional costs of moving to a new system) (see ref 49).

UK UDI plans

3.66. The application of a UDI system will allow more accurate device identification within supply chain, safety alerts, medical device recall management and surveillance tasks more generally.

3.67. A new UK Medical Device Regulatory regime will be implemented in a phased approach which includes UDI requirements. By July 2025, updated UK Medical Device Regulations will place a legal responsibility on all NHSScotland boards to store UDI data, for class III and IIb devices. This will be a requirement alongside manufacturer responsibilities in the provision of this data for devices

3.68. While the detail of regulation is not currently available, the intent and direction of regulation can be determined from the published UK Government response to the public consultation on UK medical device regulation:

- to define 'UDI' within the medical devices regulations, with intention to utilise a definition aligned with other jurisdictions such as the EU
- to require manufacturers to assign UDI before they are placed on the market, to require reusable devices to bear a permanent UDI carrier and to include requirements for Basic UDI to identify device models
- UDI to be introduced for class III medical devices and some class IIb implantable medical devices only to assign a Basic UDI-DI to these devices before applying to an approved body for conformity assessment, and not for manufacturers of all medical devices
- to require the UDI or Basic-UDI to be provided in circumstances that are aligned with those stipulated in the EU MDR and IVDR
- to designate issuing entities, similar to EU, which are GS1 AISBL (see ref 76); Health Industry Business Communications Council (HIBCC) (see ref 77); International Council for Commonality in Blood Banking Automation (ICCBBA) (see ref 78); and Informationsstelle für Arzneispezialitäten (IFA) GmbH (see ref 79)
- to require manufacturers to keep an up-to-date list of all assigned UDIs for their medical devices as part of the technical documentation and be subject to the retention periods which will be specified
- to require economic operators and healthcare professionals/ health intuitions to store the UDI numbers for implantable medical devices

3.69. The MHRA will issue guidance on UDI including the distinction between Basic UDI-DI and other forms of identifiers (for example unit of use DI), the triggers that would result in a requirement to apply a new UDI-DI and so on.

3.70. The UK Medical Device Outcome Registry (MDOR) has been launched. The UK MDOR is a mandatory collection within England but voluntary participation to the Devolved Administration. In Scotland, some of the objectives of the UK MDOR will be provided by the NHSScotland Scan for Safety Programme.

UDI impact on Scotland's health organisations and providers

3.71. In addition, Health organisations should provide patients with implantable devices with an implant card, which bears the patient's identity, as well as rapid access to certain information, including:

- the identification of the device, including the device name, serial number, lot number, the UDI, the device model, and the name, address and website of the manufacturer
- warnings, precautions or measures to be taken by the patient or a healthcare professional
- the expected lifetime of the device and any necessary follow-up

3.72. Health organisations and professionals using medical devices and IVD medical devices may therefore need to handle any of these four issuers UDI's; however, in practice, are predominantly expected to be carrying GS1 UDI's as this option is more favoured by device manufacturers.

3.73. Healthcare professionals based in the health organisations and providers will be stakeholders in UDI as the guardians of systems implemented to manage safe and effective provision and use of medical devices. UDI's offer a unified means to aid the joining up medical device manufacturing and vigilance and incident data, patient data, Equipment Management data, stock control data and so on for greater public benefit.

3.74. Health organisations and providers should store and keep, preferably by electronic means, the UDI of implantable devices they have supplied/ administered patients with. Health organisations should ensure that the full UDI for the implant is added to the patient's electronic medical records. The health organisations should also provide means to allow the patient rapid access to this information at any point post implantation. The UDI database should take account of any national systems and processes that are put in place.

3.75. The NHSScotland Scan for Safety Programme delivered by NSS in partnership with Scottish Government and Health Boards will provide a Once for Scotland approach to the capture and use of UDI for Class III and Class IIB medical devices used in acute care.

Note 8 - additional information:

UDI design and standardisation

- IMDRF UDI Working Group: UDI Guidance, Unique Device Identification (UDI) of Medical Devices, 9 December 2013 (see ref 80)
- IMDRF UDI Working Group: Unique Device Identification system (UDI system) Application Guide, 21 March 2019 (see ref 75)
- MDRF UDI Working Group: Principles of Labelling for Medical Devices and IVD Medical Devices, 21 March 2019 (see ref 81)
- GS1: Guide on Unique Device Identification (UDI) (see ref 82)

Note 9 - Medical device nomenclature:

- MedTech Europe: Medical device nomenclature for IVD Regulation (EU) 2017/746 and MD Regulation (EU) 2017/745 (see ref 48)
- EC: MDCG 2018-2 Future EU medical device nomenclature - Description of requirements (see ref 83)
- The World Health Organisation's global perspective on nomenclature of medical devices (see ref 84)

Note 10 - Established worldwide medical device nomenclature systems:

- GMDN, under GMDN Agency (see ref 85)
- Universal Medical Device Nomenclature System (UMDNS), under ECRI Institute (see ref 86)

Note 11 - Health organisation and provider resources:

- Example of GS1 spreadsheet for managing field safety corrective actions (see ref 87)
- NHS eProcurement Strategy, April 2014 (see ref 88)

4. Roles and responsibilities

4.1. Chief Executive Letter (CEL) 35 (2010) introduced a policy for property and asset management for NHSScotland. The policy instructed all NHSScotland bodies must have appropriate Board level and supporting governance, accountability, and reporting arrangements in place to ensure the efficient and effective planning, operation, management and disposal of assets.

4.2. In order to provide a robust system of management for medical devices and equipment, organisations must have 'Medical Device/ Equipment Quality Management System (QMS) (policy, Standard Operating Procedures (SOPs) and records) and engage expert staff with a working knowledge of policy, regulations, standards and guidance related to medical devices and equipment. Organisations must apply Duty of Candour when managing adverse incidents/ events involving harm in accordance with the respective legislative and policy requirements.

4.3. This internal management system must have clear lines of accountability from Board level to front line and must ensure that, where appropriate, it extends to and covers external partners or contractors such as general practitioners, residential and care homes or community based services. Understanding who is accountable and for what, must be made clear and be documented including in particular any areas where there is or may be joint accountability. Accountability should be consistent with roles of the professions engaged and within their respective scopes of practice, professional qualifications and registration.

4.4. Summaries illustrating principal aspects of the role, responsibilities and expertise of key officers and professional groups, which contribute to the operation of the management system governing medical devices and equipment within organisations, are set out below. The summaries are designed to allow professional groups to recognise each other's areas of expertise. Comparison between summaries may reveal joint working and professional networking opportunities.

Note 12: The detail within each summary and the legislation and guidance highlighted are not exhaustive.

Note 13: E-learning modules on medical devices are available for health and social care staff (see paragraph 5.18).

4.5. Summaries include the following roles:

- Chief Executive
- Responsible Director
- Medical Device and/ or Equipment Users
- Departmental Managers

- Medical Device and Equipment Risk Managers
- technical specialists or persons responsible for devices and equipment
- specialist multi-disciplinary and professional expert groups
- staff who procure medical devices or equipment
- Incidents and Alerts Safety Officers (IASO) (previously known as Equipment Coordinator)

Medical device and/ or equipment users

4.6. Within the array responsibilities within their individual jobs, health technology users have particular responsibilities concerning safe and effective use of this equipment. The employing organisation is responsible for ensuring their staff are trained and refreshed appropriately in the use of the equipment they provide them with (Provision and Use of Work Equipment Regulations (PUWER) 1998 (see ref 2). The person with most immediate responsibility around managing a medical device or piece of equipment is the front-line user. User responsibilities include:

- ensuring they have been appropriately trained about the equipment they use, in accordance with the requirements of their employer
- checking equipment prior to its use, including, as applicable, that the device is within its shelf life, its physical condition is acceptable, if any necessary calibration or maintenance has been performed and they have access to any necessary instructions for use (IFU)
- performing any necessary day-to-day maintenance of that equipment prior to its use
- identifying and reporting faulty equipment and usability issues promptly
- managing infection prevention and control issues connected with the equipment they use in accordance with national and local policy (see the National Infection Prevention and Control Manual (NIPCM) (see ref 89)
- ensuring safe storage to protect from environmental contamination

4.7. An individual healthcare professional that uses the device in a way not intended, or against the instructions of the manufacturer, may be personally liable for any consequences. Users are reminded that such use would constitute ‘off-label’ use of the device.

4.8. Health and Social Care professionals also provide devices which are then used by others, such as patients, users or carers and again they are personally accountable for ensuring patients, users and carers have received appropriate training and know how to use the device that has been provided.

4.9. It should be noted that users can also be innovators, as they are in a prime position to spot technological gaps and the potential for refinements in existing products. When users spot these or think of a new way of solving a problem they encounter, treating and protecting their ideas, they should be aware of the Scottish Innovation Hubs in health boards (see ref

90), InnoScot Health (see ref 91), and collaborative work opportunities with academic partner organisations, making good use of these.

4.10. The Medicines and Healthcare Products Regulatory Agency (MHRA's) guidance document, Devices in Practice: Checklists for using medical devices, MHRA June 2014 (see ref 92) provides a set of useful safety checklists for users.

Key sections of SHTN 00-04 to read:

4.11. Sections: 1, 2, 3, 4, 5, 6.

4.12. Turas medical device e-learning level 1 and 2.

4.13. Key legislation to be familiar with:

- UK Medical Devices Regulations (MDR) 2002 (see ref 1)
- The Medical Devices (Amendment etc.) (EU exit) Regulations 2019 (see ref 93)
- Medical Devices Regulations (Regulation (EU) 2017/745) (see ref 94)
- In Vitro Diagnostic (IVD) Medical Devices Regulations (Regulation (EU) 2017/746) (see ref 95)

4.14. Additional guidance to be familiar with:

- MHRA Collection: guidance on using medical devices safely (see ref 96)
- Devices in Practice: Checklists for using medical devices, MHRA June 2014 (see ref 92)
- Medical Device Driving Licence, National Association of Medical Device Educators and Trainers (NAMDET)

Chief Executive

4.15. The Chief Executive has overall accountability for ensuring the organisation has a medical device management policy, robust and effective systems and controls in place to meet standards and regulatory requirements for the management of medical devices and equipment including appropriate systems of training.

4.16. This includes ensuring that a functional management structure, procedures to manage risks relating to medical equipment, a system for reporting adverse incidents/ events and the dissemination of safety (alert) notifications, is in place.

4.17. This also includes the following requirements of The Duty of Candour Procedure (Scotland) Regulations 2018, as guided by the Scottish Government's Organisational duty of candour: guidance (see ref 97).

4.18. It is essential they designate a senior individual for example a director or board member, to have specific and all-inclusive responsibility for the management of medical devices and equipment.

4.19. Chief Executives should also ensure the procedures for reporting incidents to Incident Reporting Investigation Centre (IRIC) and cascading IRIC safety alerts are instructed to all staff, contractors and private or independent service providers who provide care, staff, equipment, buildings or other services or facilities for the direct care of patients or clients

Key sections of SHTN 00-04 to read:

4.20. Executive summary and sections: 1, 2, 3, 4.

4.21. Turas medical device e-learning level 1.

4.22. Key legislation to be familiar with:

- Health and Safety at Work etc. Act (HASAWA) 1974 (see ref 98)
- Management of Health and Safety at Work Regulations 1999 (see ref 99)
- Provision and Use of Work Equipment Regulations 1998 (see ref 2)
- The Duty of Candour Procedure (Scotland) Regulations 2018 (see ref 97)
- Public Contracts (Scotland) Regulations 2015 (which transpose the public procurement Directive) (see ref 100)
- Procurement (Scotland) Regulations 2016 (see ref 101)
- UK Medical Devices Regulations 2002 (see ref 1)
- Medical Devices Regulations (Regulation (EU) 2017/745) (see ref 94)
- In Vitro Diagnostic Medical Devices Regulations (Regulation (EU) 2017/746) (see ref 95)

4.23. Additional guidance to be familiar with:

- Scottish Government CEL 35 (2010) (see ref 15)
- Scottish Government CEL 43 (2009) (see ref 102)
- Scottish Government CEL 05 (2012) see ref 103)
- Scottish Government Organisational duty of candour: guidance (see ref 97)
- Better Equipped to Care?, Audit Scotland 2004 (see ref 104)
- Scottish Health Technical Memorandum (SHTM) 00 Best practice guidance for healthcare engineering: Policies and Principles, NHSScotland Assure (see ref 105)
- The National Audit Office (NAO) report of 10 June 1999: The Management of Medical Equipment in NHS Acute Trusts in England (see ref 106)

Responsible director

4.24. Responsible Director for Medical Device/ Equipment is a designated executive lead responsible for the overall management of medical devices and equipment.

4.25. Details responsibility include ensuring:

- the Chief Executive is kept up to date with appropriate and timely information regarding the organisation's medical devices and equipment
- the implementation of medical device policy, systems, control and procedures
- the operational lifecycle of medical equipment is appropriately managed, monitored and controlled (preferably by a technical expert, in-house or contractor for example Medical Physics Manager or Clinical Engineer)
- the establishment and management of the Medical Device/ Equipment Management Group/ Committee within the organisation, any appropriate committee's or groups relating to medical equipment are chaired and managed accordingly, for example, the Medical Equipment Management Group
- patient safety issues are handled and managed effectively
- new technologies are appropriately managed into service
- planning takes into account advice from the Scottish Health Technologies Group (SHTG) and other national guidance bodies and provides a Board or regional view on their guidance
- topics and information needs are put forward to technology assessment bodies and planners at national levels
- appropriate liaison relating to cross health board issues occurs

Key sections of SHTN 00-04 to read:

4.26. Executive summary and sections: 1, 2, 3, 4.

4.27. Turas medical device e-learning level 1 and 2, IRIC modules.

4.28. Key legislation to be familiar with:

- Health and Safety at Work etc. Act (HASAWA) 1974 (see ref 98)
- Management of Health and Safety at Work Regulations 1999 (see ref 99)
- Provision and Use of Work Equipment Regulations 1998 (see ref 2)
- Public Contracts (Scotland) Regulations 2015 (which transpose the public procurement Directive) (see ref 100)
- Procurement (Scotland) Regulations 2016 (see ref 101)
- UK Medical Devices Regulations 2002 (see ref 1)
- The Medical Devices (Amendment etc.) (EU exit) Regulations 2019 (see ref 93)
- Medical Devices Regulations (Regulation (EU) 2017/745) (see ref 94)
- In Vitro Diagnostic Medical Devices Regulations (Regulation (EU) 2017/746) (see ref 95)

4.29. Additional guidance to be familiar with:

- Scottish Government CEL 35 (2010) (see ref 15)
- Scottish Government CEL 43 (2009) (see ref 102)
- Scottish Government CEL 05 (2012) (see ref 103)

- Better Equipped to Care?, Audit Scotland 2004 (see ref 104)
- The National Audit Office report of 10 June 1999: The Management of Medical Equipment in NHS Acute Trusts in England (see ref 106)
- SHTM 00 Best practice guidance for healthcare engineering: Policies and Principles, NSS website (see ref 105)
- NHSScotland Assure, Compendium of Healthcare Associated Infections (HAI) Guidance (see ref 89)

Medical devices and equipment risk managers

4.30. This officer acts in support of the Responsible Director role, in the capacity of the lead medical device expert within an organisation. As such they will be expected to have an operational working knowledge and detailed technical understanding of legislation, standards and guidance covered across this guidance document.

4.31. Within the organisation it is essential to have frontline operational managers and staff who also have a formal responsibility (not necessarily a full-time commitment) for medical devices and equipment. These individuals should carry out duties overseen by the organisation's lead medical device expert.

4.32. Part of the role would be to monitor and ensure that the system for managing medical devices and equipment is functioning as it should and critically to encourage and support the reporting of adverse incidents to IRIC and other appropriate official agencies. Depending on how individual organisations realise this role, it may overlie that of the IASO or Responsible Director roles illustrated elsewhere in this guidance or may sit separately beside them.

Knowledge and skills requirements

4.33. Clinical Scientists, Clinical Technologists or Facilities Management Officers covering this role should be able to demonstrate technical and leadership equivalence as this is the appropriate level of knowledge skills and training necessary for assurance of protection of the public, for example being a registered Chartered Engineer. To underwrite this assurance, they should maintain membership of an appropriate statutory register, or voluntary register which is accredited by the Professional Standards Authority.

4.34. Competency equivalence with that of the NHS Education for Scotland (NES) (see ref 107) supported, National School of Healthcare Science higher specialist scientists training programme curriculum in Clinical Biomedical Engineering (see ref 108) or Chartered Engineer status from a relevant institution such as Institute of Physics and Engineering in Medicine (IPEM) (see ref 12), Institution of Engineering and Technology (IET) (see ref 74), Institute of Healthcare Engineering and Estate Management (IHEEM) (see ref 13). See also the Scottish Government's Healthcare Science webpage (see ref 109).

Role

4.35. The role of medical device and equipment risk managers are:

- to promote the safe use of medical devices and equipment across the organisation and provide expert advice to all staff in relation to the safety of medical devices and equipment
- to make links across the organisation between multi-professional specialist groups for example clinical governance, clinical specialism teams, quality improvement, risk management, occupational health and safety, eHealth, research and development, procurement and logistics, property and asset management
- to improve the quality of reporting of medical device adverse incidents within the organisation and to oversee the onward reporting of all appropriate adverse incidents to IRIC, ensuring that data quality is maintained
- to act as the essential link between the identification and implementation of (local and national) medical devices safety initiatives and local strategic/ operational activities to improve the safety of medical devices and equipment

Responsibilities

4.36. The responsibilities of medical device and equipment risk managers are:

- taking an active role in any national medical devices and equipment networks (where applicable), continuously looking to improve their personal knowledge of medical devices and equipment and professionally networking where opportunities arrive
- promoting the improved reporting of, and learning from, medical devices adverse incidents/ events within their organisation
- supporting medical device and equipment adverse event reporting and investigations within their organisation, assist in reviewing all medical device and equipment event reports to ensure data quality for local and national learning. Where necessary, investigating local adverse medical device and equipment events as required
- keeping updated on local adverse event trends
- using local event trends to support strategic and operational plans within the organisation to reduce the number of events relating to medical devices and equipment
- attending (as required) the medical devices and equipment safety committees. These committees may be both internal to organisations and or external, either governmental or for example professional body based.

Key sections of SHTN 00-04 to read:

4.37. Executive summary and sections: 1, 2, 3, 4.

4.38. Turas medical device e-learning level 1 and 2, IRIC modules.

4.39. Key legislation to be familiar with:

- Health and Safety at Work etc. Act (HASAWA) 1974 (see ref 98)
- Management of Health and Safety at Work Regulations 1999 (see ref 99)

- Provision and Use of Work Equipment Regulations 1998 (see ref 2)
- Public Contracts (Scotland) Regulations 2015 (which transpose the public procurement Directive) (see ref 100)
- Procurement (Scotland) Regulations 2016 (see ref 101)
- UK Medical Devices Regulations 2002 (see ref 1)
- The Medical Devices (Amendment etc.) (EU exit) Regulations 2019 (see ref 93)
- Medical Devices Directive (Directive 93/42/EEC) (see ref 38)
- In Vitro Diagnostic Medical Devices Directive (Directive 98/79/EC) (see ref 39)
- Active Implantable Medical Devices Directive (Directive 90/385/EEC) (see ref 37)
- Medical Devices Regulations (Regulation (EU) 2017/745) (see ref 94)
- In Vitro Diagnostic Medical Devices Regulations (Regulation (EU) 2017/746) (see ref 95)
- The Waste Electrical and Electronic Equipment Regulations 2013 (see ref 110)

4.40. Additional guidance to be familiar with:

- Managing Medical Devices, MHRA 2021 (see ref 111)
- MHRA Collection: guidance on using medical devices safely (see ref 96)
- Scottish Government CEL 35 (2010) (see ref 15)
- Scottish Government CEL 43 (2009) (see ref 102)
- Scottish Government CEL 05 (2012) (see ref 103)
- Better Equipped to Care?, Audit Scotland 2004 (see ref 104)
- The NAO report of 10 June 1999: The Management of Medical Equipment in NHS Acute Trusts in England (see ref 106)
- SHTM 00 Best practice guidance for healthcare engineering: Policies and Principles, Health Facilities Scotland (see ref 105)
- NHSScotland Assure, Compendium of HAI Guidance (see ref 89)
- Devices in Practice: Checklists for using medical devices, MHRA June 2014 (see ref 92)
- Medical Device Driving Licence, NAMDET
- Procurement Journey (see ref 112)
- Public sector procurement (see ref 113)
- NHSScotland Assure Guidance (see ref 72)
- SHTG (see ref 114)

4.41. Relevant environmental and infrastructure factors - standards guidance and legislation:

- SHTM 06-01: Electrical services supply and distribution part A: Design considerations (see ref 115)
- British Standards (BS) 7671:2018, Requirements for Electrical Installations, IET Wiring Regulations (see ref 116)

- The Ionising Radiation (Medical Exposure) Regulations 2017 (IRMER) (see ref 117)
- The Control of Artificial Optical Radiation at Work Regulations 2010 (see ref 118)
- The Electromagnetic Compatibility Regulations 2016 (EMC) (see ref 119)

Departmental managers

4.42. Managers have a responsibility to ensure that medical devices and equipment within their areas of control are used in a safe manner. This includes:

- having appropriate processes in place to ensure manufacturer's instructions are adhered to
- identifying and addressing their staff's training needs
- ensuring equipment or device operators are adequately trained, competent and confident to use the equipment or device
- identifying hazards and assessing and addressing risks associated with these hazards in relation to medical equipment within their departments and operational areas of responsibility. Managing any additional ongoing work on monitoring and reviewing the hazards and risks
- ensuring appropriate reporting of adverse incidents/ events where a medical device or equipment is involved
- ensuring the equipment is looked after during daily use
- ensuring that equipment is safely stored and decontaminated in line with Chapter 1.5 and Appendix 7 of the NIPCM (see ref 89)
- ensuring that equipment is current in terms of regular inspections and that representation of the equipment's status is kept accurate in equipment inventory records
- ensuring safety alerts/ notices relating to devices or equipment are responded to appropriately and promptly
- being able to evidence, where appropriate an equipment logbook, traceability records, maintenance and test records and any validation reports
- being able to evidence provision of manufacturer's instructions for installation, operation, validation, testing and maintenance and that these are added to validation reports
- when required, liaising with the organisation's Medical Devices Committee (MDC)/ executive leads

4.43. Managers can also play an important role in identifying equipment needs and advising on the procurement process for their area and service(s), reporting identified needs in line with their organisation's asset management policy and through its asset management structures.

Key sections SHTN 00-04 to read:

4.44. Executive summary and sections: 1, 2, 3, 4, 5, 6.

4.45. Turas medical device e-learning level 1 and 2; IRIC modules.

4.46. Key legislation to be familiar with:

- Health and Safety at Work etc. Act (HASAWA) 1974 (see ref 98)
- Management of Health and Safety at Work Regulations 1999 (see ref 99)
- Provision and Use of Work Equipment Regulations 1998 (see ref 2)
- Public Contracts (Scotland) Regulations 2015 (which transpose the public procurement Directive) (see ref 100)

4.47. Additional guidance to be familiar with:

- Scottish Government CEL 35 (2010) (see ref 15)
- Scottish Government CEL 43 (2009) (see ref 102)
- Scottish Government CEL 05 (2012) (see ref 103)
- NHSScotland Assure Guidance (see ref 72)
- NIPCM (see ref 89)
- NHSScotland Assure, Compendium of HAI Guidance (see ref 89)

Technical specialists

4.48. In this guidance the term Technical Specialist covers the lead Consultant level experts who carry organisation-wide responsibility in the fields of Medical Physics and Clinical Engineering, in Laboratory Medicine, in Facilities Management, in Infection Prevention and Control, and in eHealth and Health Informatics. The Technical Specialist, for example the Head of Medical Physics or Clinical Engineering, is the operational and strategic lead for medical equipment lifecycle management within an organisation. Their responsibilities include:

- production of a medical equipment strategy, management policies and operational procedures/ systems of work
- production of long, medium and short term equipment procurement plans
- ensuring a QMS is in place covering all aspects of medical equipment lifecycle management, in compliance with Managing Medical Devices MHRA 2021 (see ref 111)
- supporting the Medical Equipment Group and appropriate others with technical expertise
- promoting equipment safety by staff education and training
- contract management where required and appropriate
- involvement with national groups relating to medical equipment management and health technology assessment and innovation
- Involvement with their organisation's IASOs and relevant executive team member(s)
- forward investment planning
- acquisition governance

- maintaining communication links with manufacturers' professional and trade bodies for updates on product information and instructions
- medical device risk management
- supporting and advancement healthcare
- innovation

Key sections of SHTN 00-04 to read:

4.49. Executive summary and sections: 1, 2, 3, 4, 5, 6.

4.50. Turas medical device e-learning level 1 and 2; IRIC modules.

4.51. Key legislation to be familiar with:

- UK Medical Devices Regulations 2002 (see ref 1)
- The Medical Devices (Amendment etc.) (EU exit) Regulations 2019 (see ref 93)
- In Vitro Diagnostic Medical Devices Directive (Directive 98/79/EC) (see ref 39)
- Medical Devices Regulations (Regulation (EU) 2017/745) (see ref 94)
- In Vitro Diagnostic Medical Devices Regulations (Regulation (EU) 2017/746) (see ref 95)
- Public Contracts (Scotland) Regulations 2015 (which transpose the public procurement Directive) (see ref 100)
- Procurement (Scotland) Regulations 2016 (see ref 101)

4.52. Additional guidance to be familiar with:

- Managing Medical Devices, MHRA 2021 (see ref 111)
- MHRA Collection: guidance on using medical devices safely (see ref 96)
- Scottish Government CEL 35 (2010) (see ref 15)
- Scottish Government CEL 43 (2009) (see ref 102)
- Devices in Practice: Checklists for using medical devices, MHRA June 2014 (see ref 92)
- Medical Device Driving Licence, NAMDET
- Procurement Journey (see ref 112)
- Public sector procurement (see ref 113)
- Scottish Government CEL 05 (2012) (see ref 103)
- NHSScotland Assure Guidance (see ref 72)
- SHTG (see ref 114)

4.53. Relevant environmental and infrastructure factors - standards guidance and legislation:

- SHTM 06-01: Electrical services supply and distribution Part A: Design considerations (see ref 115)
- BS 7671:2018, Requirements for Electrical Installations, IET Wiring Regulations (see ref 116)

- The Ionising Radiations Regulations 2017 (see ref 36)
- The Ionising Radiation (Medical Exposure) Regulations 2017 (IRMER) (see ref 117)
- The Control of Artificial Optical Radiation at Work Regulations 2010 (see ref 118)
- The Electromagnetic Compatibility Regulations 2016 (EMC) (see ref 119)

Specialist multi-disciplinary and professional expert groups

4.54. The role of the various specialist groups or committees is ultimately to provide expertise and ongoing assurance in relation to the monitoring and validation of medical devices and equipment planning, management and strategy. Within organisations, groups, for example Medical Device Equipment Management Group; Clinical Governance Group and so on form nodes in a network of local expertise. There are also a range of specialist groups nationally that provide support and guidance with regard to the management of devices and equipment, for example NHSScotland Shared Services Clinical Engineering Programme (see ref 120), and National Managed Diagnostic Networks, for example Medical Physics and Clinical Engineering Diagnostic Network (MPNet) (see ref 121).

Key sections of SHTN 00-04 to read:

4.55. Executive summary and sections: 1, 2, 3, 4, 5, 6.

4.56. Turas medical device e-learning level 1 and 2, IRIC modules as appropriate

4.57. Key legislation to be familiar with:

- Provision and Use of Work Equipment Regulations 1998 (see ref 2)
- Public Contracts (Scotland) Regulations 2015 (which transpose the public procurement Directive) (see ref 100)
- Procurement (Scotland) Regulations 2016 (see ref 100)
- UK Medical Devices Regulations 2002 (see ref 1)
- The Medical Devices (Amendment etc.) (EU exit) Regulations 2019 (see ref 93)
- Medical Devices Regulations (Regulation (EU) 2017/745) (see ref 94)
- In Vitro Diagnostic Medical Devices Regulations (Regulation (EU) 2017/746) (see ref 95)

4.58. Additional guidance to be familiar with:

- Scottish Government CEL 35 (2010) (see ref 15)
- Scottish Government CEL 43 (2009) (see ref 102)
- Scottish Government CEL 05 (2012) (see ref 103)
- Better Equipped to Care?, Audit Scotland 2004 (see ref 104)
- The National Audit Office report of 10 June 1999: The Management of Medical Equipment in NHS Acute Trusts in England (see ref 106)

- NHSScotland Assure Guidance (see ref 72)
- NHSScotland Assure, Compendium of HAI Guidance (see ref 89)

Staff who procure medical devices or equipment

4.59. All staff procuring health technology products should operate within the procurement governance arrangements in place within their own organisations. All acquisitions will require appropriate scrutiny to ensure they are pertinent to the need in hand.

The knowledge and skills requirements of procurement officers in relation to this guidance

4.60. The Scottish Government's National Procurement Competency Framework (see ref 122) sets out the skills and competency levels required by public sector staff involved in the procurement process. Procurement officers must be appropriately qualified according to their individual role requirements in line with this.

The role of procurement officers in relation to this guidance

4.61. Procurement officers involved with health technology acquisition will include responsibility for:

- project managing equipping competition and tendering projects using national public contract management systems. Project related activities include scheduling, costing, specifying, purchasing, delivery and cost control elements of health technology related procurement projects
- controlling procurement activities within the organisation applying procurement strategy compliant protocols
- acting as a product specialist, providing specialist technical advice on acquisition of health technology equipment utilised in organisations
- liaising and negotiating with contractors, suppliers plus in-organisation specialists and multi-professional governance groups

Note 14: In Local Authorities, the Departmental Manager may perform this role.

Pre-acquisition checklist for purchasers

4.62. Purchasers of health technology equipment should take account of the following points before proceeding with any purchase:

- is a purchase essential?
- is the product type appropriate for the application and have all the relevant procurement Technical User Group (TUG) (as defined in CEL 05 (2012) (see ref 103)) stakeholders been involved in the specification for the acquisition and in any competitive contract award process?

- do the supplier's pre-acquisition declarations summarised in the Pre-acquisition questionnaire (PAQ) form (see ref 20) fit with the acquisition brief, including product declaration of conformity?
- does the product have UK Conformity Assessment (UKCA) or CE (Conformité Européenne, meaning European Conformity) marking and the relevant standards to be complied?
- is the product clinically and/ or cost effective? This may be validated by consulting Healthcare Improvement Scotland's Technologies and medicines webpage (see ref 5), where the organisation can seek advice and guidance from SHTG (see ref 114), the Scottish Intercollegiate Guidelines Network (SIGN) (see ref 123) and Healthcare Improvement Scotland's National Institute for Health and Care Excellence (NICE) Guidance and Scotland (see ref 124) webpage
- can the product be disposed of and if it is re-usable, can it be maintained and decontaminated within the acquiring organisation's sustainable infrastructure constraints and in compliance with NIPCM (see ref 89) requirements? Decontamination services within organisations may require suppliers to provide more detailed information on decontamination of products than provided in section 8 of the standard PAQ form (see ref 20)
- is the product compatible with the organisation's IT infrastructure and data security requirements? IT services within organisations may require suppliers to provide more detailed information on data security of products than provided in section 9 of the standard PAQ form (see ref 20)
- have alternative demand management options been considered, where appropriate?
- is there a robust and approved business case/ budget?
- is there an existing call-off contract award in place within the organisation, or nationally, for devices matching the scope of the acquisition requirement?
- can the organisation use an existing Contract/ Framework Agreement in accordance with its terms and conditions?
- can the purchase be aggregated with other concurrent similar requirements?

4.63. Procurement officers should work closely with the appropriate Technical Specialists in seeking answers to the above questions:

- for positive answers to the bulleted questions above, organisations are advised to consider very carefully what reassurance it offers regarding both legal compliance and value for money. In some cases, the organisation may still need to develop a strategy and determine the appropriate steps of the Procurement Journey to take
- for negative answers to the bulleted questions above, Care and Support Services (C&SS) must consider the Specific Considerations and Rules for C&SS Contracts

Estimated value of requirement

4.64. What is the anticipated total spend over the lifetime of this requirement including any extensions excluding VAT for example whole life cost, ongoing cost, support costs?

4.65. Scottish Government public contracts regulation thresholds to identify the most appropriate plan to follow.

Key sections of SHTN 00-04 to read

4.66. Sections: 1, 2, 3, 4, 5.

4.67. Turas medical device e-learning level 1 and 2.

4.68. Key legislation to be familiar with:

- UK Medical Devices Regulations 2002 (see ref 1)
- The Medical Devices (Amendment etc.) (EU exit) Regulations 2019 (see ref 93)
- In Vitro Diagnostic Medical Devices Directive (Directive 98/79/EC) (see ref 39)
- Medical Devices Regulations (Regulation (EU) 2017/745) (see ref 94)
- In Vitro Diagnostic Medical Devices Regulations (Regulation (EU) 2017/746) (see ref 95)
- Public Contracts (Scotland) Regulations 2015 (which transpose the public procurement Directive) (see ref 100)
- Procurement (Scotland) Regulations 2016 (see ref 101)

4.69. Additional guidance to be familiar with:

- Scottish Government Procurement Journey Update (see ref 112)
- Scottish Government Public Sector Procurement (see ref 113)

4.70. Relevant environmental and infrastructure factors - standards guidance and legislation:

- SHTM 06-01: Electrical services supply and distribution part A: Design considerations (see ref 115)
- BS 7671:2018, Requirements for Electrical Installations, IET Wiring Regulations (see ref 116)
- The Ionising Radiations Regulations 2017 (see ref 36)
- The Ionising Radiation (Medical Exposure) Regulations 2017 (IRMER) (see ref 117)
- The Control of Artificial Optical Radiation at Work Regulations 2010 (see ref 118)
- The Electromagnetic Compatibility Regulations 2016 (EMC) (see ref 119)

Incidents and alerts safety officer

4.71. CEL 43 (2009) (see ref 102) set the arrangements for the reporting of adverse incidents, the dissemination of safety advice and the control of risks relating to health, social care, estates and facilities equipment. All NHS Boards and Local Authorities should have a role within their organisation entitled IASO (previously known as Equipment Coordinators). In accordance with CEL 43 (2009) (see ref 102), a single point of contact within each

organisation should be nominated into this role (in NHS Boards it is suggested to be a Risk Manager). Their duties include:

- ensuring managers and staff are aware of the procedures for reporting adverse incidents/ events and for implementing safety advice
- monitoring all adverse incidents/ events reports from within own organisation including detecting trends and reporting to IRIC (see ref 125) as appropriate
- receiving emails from NHSScotland Assure notifying of alerts, notices and bulletins, and cascading within own organisation
- monitoring relevant websites for information on equipment safety and management issues
- discussing equipment safety issues with NHSScotland Assure where appropriate
- promoting equipment safety by staff education and training in conjunction with NHSScotland Assure
- building and maintaining communication links with NHSScotland Assure and with relevant technical specialists/ relevant exec team member (for clinical groups)
- attending periodic IASO group national meetings/ events
- monitoring internal cascade systems to ensure alerts/ notices are received, assessed and acted upon

Key sections of SHTN 00-04 to read:

4.72. Executive summary and sections: 1, 2, 3, 4, 5, 6.

4.73. Turas medical device e-learning level 1 and IRIC modules.

4.74. Key legislation to be familiar with:

- UK Medical Devices Regulations 2002 (see ref 1)
- The Medical Devices (Amendment etc.) (EU exit) Regulations 2019 (see ref 93)
- In Vitro Diagnostic Medical Devices Directive (Directive 98/79/EC) (see ref 39)
- Medical Devices Regulations (Regulation (EU) 2017/745) (see ref 94)
- In Vitro Diagnostic Medical Devices Regulations (Regulation (EU) 2017/746) (see ref 95)

4.75. Additional guidance to be familiar with:

- Managing Medical Devices, MHRA 2021 (see ref 111)
- MHRA Collection: guidance on using medical devices safely (see ref 96)
- Scottish Government CEL 35 (2010) (see ref 15)
- Scottish Government CEL 43 (2009) (see ref 102)
- Scottish Government CEL 05 (2012) (see ref 103)
- Devices in Practice: Checklists for using medical devices, MHRA June 2014 (see ref 92)
- Medical Device Driving Licence, NAMDET

- NHSScotland Assure Guidance (see ref 72)

5. Management of equipment and devices

Management

5.1. Risk management is a key component in demonstrating regulatory compliance for managing medical devices.

5.2. The requirements for risk management concerning the manufacture of medical devices were laid out in the UK Medical Devices Regulations (MDR) 2002 (see ref 1).

5.3. Organisations providing and using health technology, medical devices and equipment must have a Quality Management System (QMS) in place to support their equipment and device management process. There are a number of options available, and the choice is normally made taking into consideration the organisations size, complexity and needs. Management of key issues such as maintenance, inspection, training and instruction must be covered. The requirements of the Provision and Use of Work Equipment Regulations (PUWER) 1998 (see ref 2), place duty around this on those who own, operate or have control over all work equipment.

5.4. The Scottish Government Chief Executive Letter (CEL) 35 (2010) (see ref 15) states under Health Board processes relating to management of medical devices and equipment, that any in-house medical device or equipment maintenance department should be externally accredited. The National Audit Office (NAO) report of 10 June 1999: The Management of Medical Equipment in NHS Acute Trusts in England (see ref 106), highlighted numerous benefits of accreditation of internal maintenance departments under a recognised quality standard. This instruction is long established, and points laid out in the NAO's report are still highly relevant and have been persistently reiterated in guidance that has followed it. Organisations implementing an external audited and formally accredited QMS are following long established best practice. A commonly used standard is British Standard (BS) EN ISO 13485:2016 (see ref 30), which can be accessed via Barbour Index on Knowledge Network.

5.5. Awareness of BS EN ISO 14971:2019 (see ref 29) should also be considered as the UK's national standard, adopting International Organisation for Standardisation (ISO) 14971:2019 which was developed specifically for medical device/ system manufacturers to manage identification of hazards associated with a medical device, estimate and evaluate related risks in order to control them and to monitor the effectiveness of the controls at all stages of the medical device's lifecycle. An organisation operating the device becomes a stakeholder in managing these risks, so an appropriate operational understanding of this standard by those using and maintaining the device is good practice. If the organisation also manufactures medical devices, the manufacturing enterprise within the organisation may use this standard for management of the associated risks.

5.6. Other suitable systems include ISO 9001: 2015 (see ref 59), ISO 55000 (see ref 66) and BS 70000 (see ref 67). The United Kingdom Accreditation Service (UKAS) is currently running

a Medical Physics and Clinical Engineering (MPACE) (see ref 126) accreditation pilot for BS 70000 across the UK. In Scotland, a number of centres have adopted a variety of these quality system standards and the position from the Scottish Medical Physics and Clinical Engineering Diagnostic Network (MPNET) (see ref 121), is to await the outcome of the UKAS pilot before championing any one particular quality standard.

5.7. It is vital that organisations are proactive regarding to how they manage medical devices and equipment, including employing longer term planning for equipment replacement and procurement; serious consideration should be given to centralising budgets for planned purchases in future years. There should also be a formal strategy in place identifying those medium to long-term device or equipment requirements that considers cost, performance and any residual risks potentially arising from the equipment's lifecycle. This should be linked with NHSScotland Assets and Facilities property and asset management planning (see ref 16).

5.8. The NHSScotland Shared Services Clinical Engineering Programme's National Medical Equipment Framework Project (see ref 120) aims to join up the approach to the management of medical equipment across Scotland. Participation in such national networks is aimed to improve quality, safety and introduce standardisation and that it may deliver efficiencies.

5.9. The management and use of point of care testing (POCT) in vitro diagnostic (IVD) devices in primary and secondary care requires particular attention and involves managerial, scientific, technical, clinical and nursing staff (see ref 127). Key issues that need to be addressed include:

- identifying a clinical need before implementation of a POCT service
- considering involvement of the local hospital laboratory in the management of the service
- clarifying lines of accountability for POCT management
- ensuring that managers of POCT services are aware of their responsibilities under clinical governance

5.10. The management of Software as a Medical Device (SaMD) is also of importance. Key issues that need to be addressed include:

- ensuring that SaMD is included within existing Medical Device Policies, ensuring there is clear governance and responsibilities to permit assurance of compliance with UK MDR requirements and existing Scottish guidance
- achieving compliance requires partnership between eHealth and existing medical equipment management systems, ensuring a whole lifecycle approach is taken to asset management
- at Board/ Local Authority level the need to establish a local stakeholder group, including eHealth and medical device management leads to stocktake current position as regards eHealth software inventory and whole lifecycle IT asset management

- ensuring that wider staff who are using are aware of their responsibilities including safety reporting

Education, training and instruction

Education and training (staff, carers and patients)

5.11. Education and Training is a key element in medical equipment and device safety. Organisations must ensure adequate training programmes are in place for users and ensure these training programmes are repeated regularly, where necessary.

5.12. All professionals working for an organisation have a personal duty to ensure their own skills and training remains up to date. Organisation's must ensure that continuous professional development and training activities include the safe use of medical devices during annual staff appraisal. Competency assurance should be continuous.

General training

5.13. Staff will enter their individual specialist roles with prerequisite professional training and, where mandatory, registration in line with their professional scopes of practice. The learning associated with this will include some general training on health technology, medical devices and equipment that they would be expected to interact with in the course of their work.

5.14. On top of this, and as part of their Continual Professional Development (CPD) activities, staff may attend study events and advancement/ update training courses on specific types of equipment or on devices that utilise new medical techniques. CPD activities may also involve mentoring, support and shadowing of colleagues.

5.15. Consideration should be given to eLearning resources for medical devices and equipment accessible through eLearning portals for example, Turas and local face-to-face and hands-on educational programmes.

5.16. These systems are building a consistent, accessible and user friendly training process bringing an array of benefits: reduction in the need for re-training (and its associated costs) when staff move from organisation to organisation, standardised training content ensuring all staff are taught the right thing at the right time, and a lead into standardising equipment that would ultimately reduce the types and makes of medical devices and equipment used within the various organisations.

5.17. To support the awareness and understanding of the safe use of medical devices and MDRs the Scottish Government Medical Devices and Legislation Unit (MDLU), in partnership with the Incident and alerts Safety Officer (ISO) Network, is taking forward work to provide learning modules for Health and Social Care staff.

5.18. The modules are hosted on TURAS, the secure digital platform managed by NHS Education for Scotland (NES) that hosts learning and development materials for Health and Social Care staff in Scotland. Turas platform is accessible to all staff working in NHS, Local Authorities, General Dental Practices and so on in Scotland. The content of the modules will be split into 3 levels curated for specific audiences, and aimed at supporting health and social care staff understand their responsibilities for medical devices and equipment in their roles:

- **level 1** - general awareness is aimed at all Health and Social Care staff and covers the key elements that all staff should know about medical devices and using them safely. Level 1 has now been published on TURAS, or by navigating to Healthcare Science - CPD resources - Medical Devices - Medical Devices and Medical Device Regulations Learning Modules.
- **level 2** - your responsibilities for medical devices will be aimed at all staff who use, provide, loan or supply a medical device and will cover more in-depth information for staff who come into contact with or provide medical devices as part of their role, including what they should know about a device prior to use. Provisional timeline to publish on TURAS in later in 2023.
- **level 3** - medical devices lifecycle will provide specific training modules for the different elements of the medical device lifecycle. Level 3 is likely to progressed once a refresh of SHTN-04 has been undertaken.
- Incident Reporting Investigation Centre (IRIC) e-learning module can also be found in Turas.
- 'Connect Me: Remote Health Pathways is a monitoring technology to enable people outside of traditional healthcare settings greater choice and flexibility to receive, record and send clinically relevant information about their current health and wellbeing (see Remote health monitoring, Turas, Learn website').

Note 15: If staff is not registered to TURAS, they may be required to create their own account through the following NHS Education for Scotland website. If Learn isn't automatically included, navigate to 'My Turas' in the top right-hand corner and choose an option to Add Applications (including Learn).

5.19. Other useful training resources related to medical devices/ equipment can be found in TURAS.

Training specific to the equipment/ device

5.20. Manufacturers are responsible for supplying appropriate instructions with their products, taking into account any potential variation in the knowledge and training of the intended user.

5.21. Within organisations, clear responsibilities should exist for ensuring that the manufacturer's instructions are passed on to all users and, where appropriate, carers. The manufacturer's instructions may need to be supplemented with additional local training. Local management arrangements should be in place to oversee the following of manufacturers' instructions and

to ensure that they are accessible to relevant staff. This may mean writing Standard Operating Procedures (SOPs) concerning certain products.

5.22. When manufacturers update their information, health boards and local authorities should have a protocol for keeping track of all sets of instructions they hold or have issued to users to enable replacement of existing instructions with revised versions. Consideration should also be made to updating the content of relevant training.

5.23. Any shortcomings in the instructions should be reported as an adverse incident (following local procedures).

Note 16 - additional information:

- Section 6 of Medicines and Healthcare Products Regulatory Agency (MHRA) Guidelines Managing Medical Devices:2021 (see ref 111)
- National Association of Medical Device Educators and Trainers (NAMDET) (see ref 10), Medical Devices Drivers Licence (MDDL)

Acquisition (procurement, loaned) and in-house manufacturing

Procurement process

5.24. Health and care organisations should have process and responsibility on the procurement of medical devices/ equipment to comply with the documented purchasing policy.

5.25. Depending on type and quantity of products, the procurement process that may cover:

- purchase specification
- approved supplier list or via Professional Electronic Commerce Online System (PECOS), Procurement Manager NHS national framework
- pre-purchase questionnaire
- assessment
- development of contract/ service level agreement
- acceptance checks

5.26. Specification may consider:

- compliance with the Regulations (for example UKCA mark), Standards (for example BS EN ISO), national policy (see note 16) and guidance
- compatibility with other existing equipment/ system/ process/ facilities
- functionality, quality and performance
- capacity/ quantity
- installation, maintenance, repair and other contract services (if required)
- utility services for example, electricity, steam, water and so on

- training
- sustainability and end-of-life disposal
- check Safety Action Notices (SANs)
- equity

Note 17: National policy, for example, certain instruments are required to be sourced as single use: Endodontic reamers and files (ref CMO(2007)5 - Important advice for dentists on re-use of endodontic instruments and variant Creutzfeldt-Jakob Disease (vCJD)), tonsillectomy instruments for adults (such as individuals born before 1997 (CMO(2015)02 Adenotonsillar Surgical Procedures: Revision Of Advice On Single Use Vs Reusable Instruments), small implants (HDL(2007)4 - Decontamination: migration to single-use pre-sterilised individually wrapped small orthopaedic implants, Migration to single-use pre-sterilised individually wrapped small orthopaedic implants in NHSScotland Government Letter 9 April 2009 "Decontamination - Migration to single use pre-sterilised individually wrapped implants - remaining specialities".

5.27. The specification of newly purchase devices/ equipment should be developed in consultation with the user, and other key relevant personnel. This depend on the products, for example, consultation with Infection Prevention and Control team and/ or Decontamination Lead is critical before acquiring reusable products required to be cleaned, disinfected/ sterilized.

5.28. All incoming goods should be subjected to acceptance checks to ensure they meet the specifications.

5.29. Upon receipt, the devices should be inspected to verify:

- the devices received are matched with the do
- the packaging integrity and labelling are satisfactory
- Incoming Goods Inspection Record is completed

Then mark or label the device as satisfactory before store or distribution. Consideration should be given to any periodic cleaning requirements of the storage location or of the equipment being stored in line with policy and guidance.

5.30. For a large equipment, means should be provided to ensure the equipment delivered and installed on site is fit for purpose. Pre-installation checks should be undertaken to establish that the area in which the equipment is installed, and the quality/ quantity of all services are to the required standard. Installation and commissioning tests should be carried out to confirm the equipment is safe for use and perform as intended. Acceptance of the installation should be based on the test data generated after any required changes have been made at the installation site.

Evaluation of new and existing technologies

5.31. The benefits to evaluating new and existing technologies are:

- ensuring best value for money and optimal resource utilisation

- enabling the objective assessments of clinical effectiveness, cost effectiveness and safety, alongside patient views and the expert opinion of clinicians
- enhancing consistency and transparency of decision making on health technologies and thereby increasing understanding of issues around equity of access to technologies across Scotland
- to promote the faster uptake of new medical technologies within the NHS and health and social care
- the encouragement of collaborative research and evidence gathering, between both industry and the healthcare providers, to generate evidence on the value of technologies within the health and care setting.

5.32. Health Technology Assessment (HTA) is a multi-disciplinary process that uses explicit methods to assess the value of a health technology at points in its lifecycle. The HTA process is comparative, systematic, transparent and involves multiple stakeholders. The purpose of HTA is to inform health policy and decision-making to promote an efficient, safe, sustainable, equitable and high-quality health system.

5.33. The Scottish Health Technologies Group (SHTG) (see ref 114), part of healthcare Improvement Scotland, is Scotland's nation HTA agency for health technologies. SHTG provides advice to NHSScotland on the use of new and existing health technologies. The evidence captured within SHTG advice helps to identify health technologies that can improve or transform health outcomes, and deliver patient and system value:

- SHTG's remit covers devices, diagnostics, procedures, talking therapies and digital healthcare (in other words, all technologies that are not medicines)
- SHTG accepts referrals for health technology assessment via the referral page on the SHTG website (see ref 114)
- SHTG seeks to align its work programme to key decision making structures, to ensure that their advice is relevant to stakeholders and remains impactful.
- NHS boards are required to consider advice from SHTG. That does not mean that every board has to follow SHTG advice, but boards are encouraged to have formal mechanisms in place to receive, consider, and communicate SHTG advice.

Note 18 - SHTG referral process is open to all, contact his.evidence@nhs.scot before submitting the request.

Note 19 - additional information:

- National Institute for Health and Care Excellence (NICE) Medical Technologies Evaluation Programme Guide (see ref 128)
- Healthcare Improvement Scotland (HIS) Procurement information
- CEL 05 (2012) (see ref 103) on Technical User Groups (TUG)
- Scottish Healthcare Technologies Group (see ref 114)

Purchasing of commercial products

5.34. Led by the Scottish Government, the Scottish Model of Procurement (see ref 112) is applied by all of the Scottish Public Sector with the aim being to deliver genuine public value beyond simply cost and/ or quality in procurement. It is essential that the Scottish Model of Procurement' is integral to all procurement activity across NHS Boards and Local Authorities.

5.35. The procurement 'journey' can follow any one of three routes:

- those purchases under £50k
- those between £50k and the Official Journal of the European Union (OJEU) threshold (the home to all public sector contracts above a certain value) as of 1 January 2020 set at £122,976 for Scottish NHS Boards (see ref 129) as Central Government Authorities under Schedule 1 of The Public Contracts (Scotland) Regulations 2015 (see ref 100), and as amended
- those above the OJEU threshold

5.36. The £50k threshold is written into the Procurement Reform Act (Scotland) 2014 (see ref 130) and would require an amendment to be altered, the OJEU threshold is reviewed biannually, and the UK will continue to use this threshold for the foreseeable future, see Procurement Policy Note (PPN) - Preparing for the UK Leaving the EU, Action Note PPN 02/19(2) March 2019 (see ref 131).

Note 20 - more information can be found in the Procurement Journey Website (see ref 113).

Terms and conditions of supply

5.37. Responsible organisations should:

- check that the specification of newly delivered equipment matches the purchase order detail together with the relevant tender award specification
- ensure that new equipment is subjected to an acceptance test procedure and that new equipment is not signed off for payment without acceptance test approval. This is the responsibility of Medical Physics/ Clinical Engineering or appropriate others. In the absence of Medical Physics or Clinical Engineering, this service can be provided by another, competent and appropriate Healthcare Professional
- perform electrical safety, commissioning, agreed maintenance service level agreement (SLA) and provide user training to support all end-users as part of the acceptance test procedure
- ensure that the performance and safety checks are completed and instructions together with training are provided to the end user. This is the responsibility of the prescribing healthcare professional
- provide for appropriate ongoing equipment management support requirements

5.38. Upon receipt of the delivery, it is important to check the packaging has appropriate labels and symbols for storage, expiry date, CE/ UKCA marking and so on. BS EN ISO 15223-

1:2021 provide the list of symbols used by the manufacturer on its packaging or in the accompanying information (Appendix C).

In-house manufacturing and custom-made devices

5.39. What are custom made and in-house manufactured devices?

- the MHRA guidance Custom Made Devices (see ref 132) states that custom made is an item manufactured specifically in accordance with a written prescription of a registered medical practitioner, or other authorised person, intended for the sole use of a particular patient. However, it does not include mass-produced products which need to be adapted to meet the specific requirements of any professional user and devices which are mass-produced by means of industrial manufacturing processes in accordance with the written prescriptions of any authorised person.
- In-house manufactured devices (see ref 133) are devices that would require UKCA/ CE marking as a medical device if they were to be marketed or passed on to a separate legal entity. There is an exemption from UKCA/ CE marking requirements if a device is manufactured and used within one legal entity, which it is recommended the appropriate QMS of the manufacturing process, including reviewing and risk management and so on, should be in place, to comply with the relevant Essential Requirements of the Medical Device Regulations.

Note 21 - the UK MDR 2002 specifies that the exemption is only applicable to IVD medical devices. However, it can apply to all medical devices if guidance is followed (see ref 134).

5.40. Manufacturers of custom-made devices shall:

- comply with the Essential Requirements (UK MDR (SI 2002 No 618 (see ref 1)
- establish, document, implement and maintain, keep up to date and continually improve a QMS
- draw up a statement confirming that the custom-made device to the Essential Requirements (UK MDR (SI 2002 No 618 (see ref 1). Examples of custom-made device statement can be found in MHRA guidance (see ref 132)
- draw up technical documentation (UK MDR (SI 2002 No 618 (see ref 1)
- draw up Post Market Clinical Follow Up (PMCF) plan
- report any Vigilance case (UK MDR (SI 2002 No 618 (see ref 1)

5.41. Institute of Physics and Engineering in Medicine (IPEM) produced ‘Best-practice guidance for the in-house manufacture of medical devices and non-medical devices’ (see ref 135), including software in both cases, for use within the same health institution. The organisation performing in-house manufacturing is advised to read and consider this guidance.

5.42. Typical services producing custom made devices are; Physiotherapy, Maxillofacial, Dental and Prosthetic and Orthotic services that are normally within the remit of Rehab Engineering Departments.

What is a clinical investigation?

5.43. A clinical evaluation, on the other hand, is a systematic and planned process to continuously generate, collect, analyse and assess the clinical data pertaining to a device in order to verify the safety and performance, including clinical benefits, of the device when used as intended by the manufacturer.

5.44. The MHRA guidance clinical investigations of medical devices (see ref 49) describes a clinical investigation as an investigation of a non-UKCA/ CE marked device by its manufacturer to assess, in the field, aspects of its safety or performance where this cannot be adequately demonstrated by other means. There is a regulated process for carrying out a clinical investigation that requires authorisation by the Secretary of State for Health through the MHRA.

What is a legal entity?

5.45. A healthcare provider is a legal entity, or a sub-set of a legal entity, which provides health care under NHS Service Agreements; it may operate on one or more sites. This includes NHS Boards and Local Authorities with social care responsibilities working in co-operation with an NHS Health Care Provider.

Storage and distribution

5.46. Organisations should be extremely cautious when storing equipment. Large or multiple deliveries of equipment can create storage challenges, particularly prior to the checking and testing process being completed by the relevant professional. In many situations, equipment can be left in corridors or other public areas which can risk breaching fire safety or health and safety guidelines. Storage issues should also be considered within the department/ ward or location the equipment is intended for and should be clean and in a good state of repair.

5.47. There is a risk of equipment being damaged or stolen or it being used before safety checks are completed.

5.48. Areas where equipment or devices are expected to be delivered should have sufficient access and storage space identified prior to delivery along with any additional equipment required for example secure storage cabinets, carts.

5.49. Consideration should be given to security to avoid theft or damage from environmental hazards. Where practicable these areas should be monitored with CCTV cameras and/ or alarms (fire/ smoke detection, intruder alarms and so on) where practical with access limited to only those necessary individuals.

5.50. Follow the requirements of storage in accordance with the instructions and symbols on the packaging. BS EN ISO 15223-1:2021 provides the list of symbols used on medical device and its description (appendix C). Consider stock rotation, battery shelf life and be aware of

any specific temperature and/ or humidity levels and the power requirements certain types of equipment or medicines will require while in storage and undergoing distribution.

5.51. Consideration should be given to health and safety requirements concerning lifting and manual handling of equipment during storage and distribution. Equipment should be adequately protected to avoid damage, whether crated or not.

5.52. Consideration should be given to any periodic cleaning requirements of the storage location or of the equipment being stored in line with policy and guidance.

Commissioning

5.53. Whenever an order has been raised, the details of any medical equipment ordered for instance order number/ ward/ department/ site must be forwarded by Procurement or the Department/ Ward Manager to the organisation's competent persons for example, Medical Physics or Joint Loan Equipment Store or Estate and Facility and so on. This will allow it to be recorded into the organisations medical equipment management system.

5.54. Once received, organisations must check that all equipment and accessories ordered including operating and service manuals have been delivered complete and undamaged.

5.55. Certain equipment is required to be tested and commissioned onsite, prior to use, in accordance with relevant standards and guidance. There should be a signing off process to ensure commissioning has been done satisfactorily. Records are to be kept in accordance with local procurement, medical equipment management and information governance policy. These should include the tracking of devices necessary for effective management of equipment including maintenance and training and for management of product field safety notices, recalls and adverse incidents/ events.

5.56. All such equipment must be delivered to the relevant commissioning department, for example, Medical Physics or Joint Loan Equipment Store, or if overly large, these items may be delivered directly to the location where they will be used provided that all appropriate checks to be undertaken. Commissioning arrangements should be planned prior to delivery and take place at an agreed location.

5.57. Once acceptance testing is complete, for example, electrical safety testing, the equipment details should be updated within the organisation's asset register by the competent persons following the local agreed process for example unique identifier number/ radio-frequency identification tag or label attached.

5.58. Consideration should be given to the risk rating of the equipment and what training is required and listed appropriately. Once appropriate competency-based training and instruction has been provided to the department/ users, the medical device or equipment can be delivered to the appropriate ward or department.

Usage

5.59. Devices/ equipment should be used by trained staff, in accordance with local procedures incorporating manufacturer's instruction. Significant deviation from manufacturer instruction can be deemed as off-label use.

5.60. The local procedures should be:

- written based on the manufacturer instructions, local and national policy and guidance
- clearly written, legible and easily understood
- easily available and accessible to the user along with the manufacturer instructions

5.61. Before use:

- the device and equipment must pass any required tests and be current on its maintenance programme
- the users must visually check equipment, cables and plugs/ power adaptors for any discernible physical damage or signs that something is abnormal before each and every use. For further guidance consult the Health and Safety Executive (HSE) document INDG236 - Maintaining portable electric equipment in low-risk environments (see ref 136)
- the user must be trained and competent on the operation and user day-to-day safety and performance checking. The competency should be reviewed on a regular basis and recorded
- The user must check quality and conditions of equipment/ devices as per training, including decontamination status. For sterile devices, the sterility indicator(s) must be attached, and the packaging must be intact

5.62. Responsibility for noticing occurrence of equipment faults is shared between the users of the equipment and the relevant technical support department that carries out maintenance on the equipment. Day-to-day equipment safety checking by users is an essential aspect of managing the risk associated with these devices.

5.63. Medical device electrical equipment is designed to remain safe to patients and users in the event of a single fault arising. Periodic tests are designed to detect occurrences of single fault conditions and such faults may not have already become apparent to users.

5.64. When a fault, discrepancy or issue is detected with the device, follow the local procedure for reporting and the actions dictated.

5.65. When the device is involved in an adverse incident/ event, refer to the section on Adverse Incident/ Event Reporting within this document below.

Vigilance procedures

5.66. For manufacturers, the need for a formal vigilance procedure is established by the Regulations, through which they, their Authorised Representatives, health professionals

and others must report certain problems, which arise in the use of medical devices and in clinical investigations. This vigilance system is administered by the MHRA (see ref 137) as the Competent Authority (for the UK) and requires each manufacturer to have a procedure in place for post market surveillance and reporting of adverse incidents. Under national policy in Scotland, IRIC performs incident reporting and investigation tasks in liaison with the MHRA.

5.67. Medical device or equipment users should have an active role in the operation of the Vigilance System; their involvement is vital for the system to work successfully. It is the users, training staff and the maintenance engineers that can identify actual or suspected adverse incidents/ events involving devices or equipment and who can communicate with the manufacturer and/ or competent authority (via IRIC (see ref 125) in Scotland but the MHRA (see ref 137) directly in other parts of the UK), who can then implement an investigation and agree any corrective actions required.

Adverse incident/ event reporting

What is an adverse incident/ adverse event?

5.68. HIS defines an Adverse Event on its Learning from adverse events website (see ref 138) as an event that could have caused a near miss, or did result in, harm to people or groups of people. This is a general definition that covers events involving a multitude of factors. Near misses should be reviewed regularly to promote learning and system improvements

5.69. NHSScotland Assure defines an Adverse Incident on its IRIC Adverse Incidents webpage (see ref 125). Adverse incident is an event specifically involving medical devices, that causes, or has the potential to cause, unexpected or unwanted effects involving the health and safety of patients, users or others. NHSScotland Assure issues a SAN outlining system and procedure requirements relating to management of adverse incidents (National adverse incident reporting and safety alert systems for medical devices, estates and facilities, and social care equipment SAN(SC)20/01 (see ref 139).

5.70. In handling adverse events and incidents, NHS Board or Local Authority definitions should be used, and local procedures followed, including any parallel requirements to report for example to the HSE under the Reporting of Injuries Diseases and Dangerous Occurrences Regulations 2013 (RIDDOR) (see ref 140). Near misses should be managed in accordance with local policy.

What are the causes of adverse incidents/ events?

5.71. Medical device and equipment-related adverse incidents/ events can be caused by a wide range of contributory factors including design flaws, manufacturing defects, material degradation, poor instructions for use (IFU), misuse, inadequate maintenance or failure to plan for replacement.

What steps should be taken when an adverse incident/ event happens?

5.72. When an adverse incident/ event occurs, refer to local policy and procedures but in general the process should be as follows:

- attend to any casualties
- preserve any evidence
- follow Fatal Accident procedures if there has been a death
- retain any devices suspected of being directly or indirectly involved in secure storage if this can be done safely. Where an adverse incident/ event involves a machine, for example a ventilator, a record should be made of all readings, settings and positions of switches, valves, dials, gauges and indicators. Digital photographs can be very useful for this
- implement any containment or corrective actions to minimise immediate risks
- report the adverse incident/ event via local incident reporting/ risk management system
- inform the manufacturer or supplier using their complaints procedure
- report to IRIC and/ or other relevant external agencies (see 6.69) and retain quarantined devices until release has been authorised by IRIC or a relevant Technical Specialist and/ or the relevant legal enforcement

Incident reporting to external agencies

5.73. The organisation should ensure there are appropriate arrangements in place to enable both local reporting and reporting to external agencies so individuals can easily meet the reporting requirements. For example, onward reporting to external agencies could be managed centrally by a specialist team.

5.74. Depending on the type and outcome, specific events must be reported to external organisations. For example:

- deaths and injuries due to a work-related accident to the Health and Safety Executive 6 as set out in the RIDDOR 1995 (see ref 140 and 141)
- events involving health, social care, estates and facilities equipment to the IRIC (see ref 125) within NHSScotland Assure as set out in CEL 43 (2009) (see ref 102)
- suicides of individuals in contact with mental health services to HIS (see ref 5)
- significant Adverse Event Reviews commissioned for category 1 events to HIS
- sudden deaths associated with medical or dental care to the Procurator Fiscal (see ref 142)
- information governance events to the eHealth Division (see ref 143) within Scottish Government and the Information Commissioners Office (see ref 144)
- ionising radiation adverse events to the Warranted Inspector for Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) (see ref 145)

[Source: HIS Learning from adverse events: A national framework (3rd Edition) (see ref 146)]

5.75. Adverse incidents/ events can happen in any organisation and when they do, there is a duty to learn from what happened and to prevent the same thing happening again. In Scotland, each NHS board and Local Authority has an adverse event reporting system that enables local problems to be identified and resolved. However, when devices and equipment are involved, the underlying problems may affect multiple boards/authorities and a centrally co-ordinated approach makes sense.

5.76. The Scottish Government Letter CEL 43(2009) (see ref 102) and its addendum (see ref 17) sets out NHS Board and Local Authority Chief Executive responsibilities for Safety of Health, Social Care, Estates and Facilities Equipment. It describes the requirement to ensure that procedures exist for the reporting of adverse incidents, the dissemination of safety advice and the control of risks relating to health, social care, estates and facilities equipment.

5.77. IRIC (see ref 125) has a remit to support the improvement of the safety of medical devices, equipment, personal protective equipment (PPE), estates and facilities in Scotland's health and social care services through incident reports and safety alerts. IRIC has responsibility for coordinating investigation of reports submitted by NHS boards and Local Authorities in Scotland (see ref 125).

5.78. Addendum to CEL 43 (2009) published on Nov 2013 set the requirement for Chief Executives to ensure the procedures of reporting incidents to IRIC and cascading IRIC safety alert are extended to all contractors and private or independent service providers who provide care, staff, equipment, buildings or other services or facilities for the direct care of patients or clients.

Note 22: Non-healthcare professionals such as patients or their representatives, should report incidents to the MHRA yellow card system Other Reporting | Making medicines and medical devices safer (more information can be found in the MHRA website).

Adverse incident/ event learning and improvement

5.79. It is important that we learn from adverse events to ensure we improve the quality and safety of care. The information provided from local adverse event reviews alongside other data and intelligence enables us to anticipate and prevent future safety problems. Taking responsive action to the learning identified from these different sources is crucial. A National Framework for Scotland document entitled 'Learning from adverse events through reporting and review' (see ref 147) highlights the process and details of how this system should be employed and how we can improve our services by following this systematic approach.

5.80. In the Framework, events are assembled into three categories:

- **category I** - events that may have contributed to or resulted in permanent harm, for example unexpected death, intervention required to sustain life, severe financial loss

- **category II** - events that may have contributed to or resulted in temporary harm, for example initial or prolonged treatment, intervention or monitoring required, temporary loss of service, significant financial loss, adverse local publicity
- **category III** - events that had the potential to cause harm but no harm occurred, for example near miss events (by either chance or intervention) or low impact events where an error occurred, but no harm

5.81. The category of the event will help to define the level of review required however; this should not be the only determining factor in deciding on the level of review. Near miss events or more complex lower severity adverse events might also merit a higher-level review if there is potential for learning.

5.82. In every organisation, learning from adverse events is essential to continually improve the delivery of person-centred, safe and effective care. See NHS Education for Scotland (NES) Community of Practice (see ref 148). Organisations are encouraged to share learning from events. More detailed of programme works and requirements can be found in HIS learning from adverse events website (see ref 147).

5.83. Part of managing adverse events involves compliance with the Duty of Candour regulations. Under the Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016 (The Act) and The Duty of Candour Procedure (Scotland) Regulations 2018, it is a legal duty for the organisation to activate the procedure when an unintended or unexpected incident has resulted, or could have resulted in, harm or death.

5.84. The implementation guidance has been published in Scottish Government website (more information can be found in the Scottish Government 'Organisational duty of candour: guidance') and the duty of candour e-learning module is available on Turas.

5.85. Organisations currently have a requirement to publish an annual report on when the duty has been applied. This will include the number of events, how the organisation has implemented the duty and what learning and improvements have been put in place.

5.86. In every organisation, learning from adverse events is essential to continually improve the delivery of person-centred, safe and effective care. More information can be found in the NHS Education for Scotland Community of Practice (see ref 148).

What is a safety alert/ notice?

5.87. Safety alerts/ notices are communications which are used to highlight risks that were previously unknown, or which need to be managed differently in light of new information. An alert/ notice can provide guidance on managing risks as well as sources of further information and support.

5.88. A number of organisations such as HSE, HIS, NHSScotland Assure, Public Health Scotland and so on publish and distribute safety alerts/ notices to NHSScotland and Local Authorities.

5.89. All organisations should have a formal policy for the handling of safety notifications which clearly defines executive responsibility and associated system of delegation to the nominated Incidents and Alerts Safety Officer (IASO).

5.90. Local details should include the following key elements:

- Chief Executive's responsibility
- an Executive Director's responsibilities. In the case of Health Boards, this should be the director with responsibility for medical equipment as defined in MHRA Managing Medical Devices (see ref 111) and CEL 35 (2010) (see ref 15)
- IASO responsibilities
- the process for receiving, evaluating and filtering of notifications and distribution of alerts/ notices including distribution of lessons learned
- responsibilities of Managers and staff designated to take action in response to Safety Alerts/ Notices
- record keeping
- reporting and monitoring of internal cascade systems including adverse events, alerts/ notices received, assessed and acted on

5.91. IRIC distributes the alerts/ notices through the IASO at each NHS board and local authority in Scotland. This is a general distribution which means every organisation receives a copy of the alert/ notice, regardless of whether they purchased the affected products.

5.92. Health and care organisations should have a management system for reporting, reviewing and learning from all types of adverse events. Incidents and Alerts Safety Officers Network (ISON) should manage the alerts including:

- log the incoming alert
- review and distribute locally targeting the affected services, wards and departments. The affected departments identify actions to be taken and feedback to the relevant personnels including IASO
- monitor and when required escalate the actions to senior management

5.93. NHSScotland Assure hold a current list of IASOs however the responsibility to report any detail changes in writing to NHSScotland Assure immediately rests with the Boards and Local Authorities.

National patient safety alert

5.94. Engaging the four nations the UK Regulator MHRA develop safety alerts including National Patient Safety Alerts (NatPSA) (see refs 149 and 150) for both medical devices and equipment, NHSScotland Assure (IRIC) lead on the dissemination of such alerts in Scotland. In "Unusual Circumstances" where the alert is considered to be not appropriate in Scotland, IRIC will engage the "relevant" Scottish Government colleagues for approval of any variation in action.

5.95. IRIC is responsible for distributing NatPSAs to all NHS Boards and local authorities in Scotland. Once distributed, copies of the alert can be downloaded from the MHRA website (see ref 151).

Estates and facilities notice

5.96. IRIC partners with counterparts in other devolved health systems to publish Estates and Facilities Notice (EFNs). Each partner proposes suitable subject matter and manages the publication process for those notices if agreed with the other partners. Once published, EFNs are distributed on the same day across all four UK health systems.

5.97. IRIC distributes EFNs to all NHS Boards and local authorities in Scotland. Once distributed, copies of the notice can be downloaded from the National Services Scotland (NSS) website Publications page (see ref 125).

Safety action notice

5.98. SANs are a Scotland-only format used to manage safety issues which affect Scotland but none of the other UK health systems. SANs are also used to produce Scottish versions of equipment-related Patient Safety Alerts which are published by NHS England.

5.99. IRIC distributes SANs to all NHS Boards and local authorities in Scotland. Once distributed, copies of the SAN can be downloaded from the NSS website Publications page (see ref 125).

Manufacturers field safety notice

5.100. A Field Safety Notice (FSN) is an important communication about the safety of a medical device that is sent to customers by a device manufacturer or their representative, for example supplier. FSNs give information about what needs to be done to reduce the specified risks of using the medical device.

5.101. Medical device legislation requires manufacturers to inform MHRA about any Field Safety Corrective Action being undertaken where death or serious injury might result. MHRA subsequently monitors compliance with all Field Safety Notices and posts copies on its website (see ref 151).

5.102. On receipt, all FSNs should be routed through the IASO as a single contact point. The IASO has a critical role in ensuring FSNs are appropriately distributed, acted upon and documented.

5.103. If an FSN is received it must be acted upon. NHS Boards and local authorities must therefore have robust systems in place to receive FSNs. This is to include handling of Unique Device Identifier (UDI) reference information received from the manufacturer or supplier concerned.

What about contracted service providers?

5.104. NHS Boards and local authorities must also ensure the same level of compliance with national safety alert/ notice arrangements by organisations delivering publicly funded care services through contracts and partnership agreements, for example primary care, Public Private Partnerships and community-based health and social care services. This ensures that patients and service users experience the same level of safety when accessing publicly funded health and social care services regardless of the point of use. All contracts should include the model wording to be added to contracts with private contractors (see ref 152).

Maintenance and repair of devices

5.105. A reusable or multi-use medical device is defined as a device that is not a single use device and which is intended by the manufacturer to be reprocessed.

5.106. Before maintenance and repair or refurbishment, all devices must be decontaminated (as appropriate) following Scottish Health Technical Memorandum (SHTM) guidance (see ref 72), infection control standards in the NHSScotland Assure, Compendium of Healthcare Associated Infections (HAI) Guidance (see ref 89) and Managing Medical Devices, MHRA 2021 (see ref 111) and appropriate maintenance and repair and decontamination records kept.

Maintenance

5.107. The organisation's medical device management policy must cover the provision of maintenance and repair of all medical devices and equipment, including reconditioning and refurbishment. The organisation is responsible for ensuring its medical devices are maintained appropriately, which includes:

- ensuring maintenance staff are appropriately trained and refreshed as necessary
- how each device should be maintained and repaired, and by whom
- arrangements for maintenance and repair needs being included as part of the risk assessment process
- arrangements for the most suitable persons/ providers to carry out the work
- arrangements to ensure items subject to inspection, maintenance, repair or disposal are decontaminated beforehand
- the timescale for planned maintenance
- the timescale for repairs to be completed
- maintenance databases are validated for their intended use and functionality
- fitting spare parts in accordance with the manufacturer's specification

5.108. The frequency and type of planned preventive maintenance should be specified, in line with the manufacturer's instructions in the first instance, taking account of the expected usage

and the environment in which, it is to be used. Services have the right to undertake a risk managed approach to planned preventative maintenance that involves not following verbatim manufacturer's planned preventative maintenance instructions provided that it is fully documented. However, they would take on liability otherwise covered by the manufacturer's lifecycle risk control measures built into a product's UKCA/ CE marking through the manufacturer's QMS.

5.109. Where other regulations apply for example, The Ionising Radiations Regulations 2017 (see ref 36), or the Lifting Operations and Lifting Equipment Regulations 1998 (see ref 35), mandatory tests should be carried out in addition to the maintenance and testing recommended by the manufacturer in the IFU supplied with the device as recommended through HSE guidance in respect of the Provision and Use Work Equipment 1998 (see ref 2), not instead of them.

Repair and refurbishment

5.110. The organisation's medical device management system must cover provision for the repair of reusable medical devices and equipment, including reconditioning and refurbishment. The operating organisation is responsible for ensuring that its medical devices and equipment are maintained and repaired appropriately. Repair work may be carried out by appropriately trained personnel under the original manufacturer/ supplier or its agent, by a third-party repair organisation, or in-house within the organisation.

5.111. Fully refurbishing is the complete rebuilding of a device already placed on the market or put into service, or the making of a new device from used devices, to bring it into conformity with its product type UKCA/ CE marking under the medical devices' regulations, combined with the assignment of a new lifetime to the refurbished device.

Off label use

5.112. Medical devices should be used as described by the manufacturer in their instructions. However, if (for example clinical reasons) the organisation requires to use the device in any other way, this is considered to be 'off-label' use (see ref 153). Without the manufacturer's approval, use of the device will be at the user own risk and the user or the organisation could become liable for civil claims for damages from injured patients or their families if something goes wrong with the device and/ or an adverse event occurs. Patient must be informed during the consent procedure and a note made on their records that a medical device is used off-label.

5.113. There are various reasons for off-label use for example, using an existing medical device for a different purpose than it is designed for, modifying a medical device for a new purpose different from original design intention.

5.114. A detailed and formal risk assessment must be carried out by an authorised person and documented, specifying the reasons why the manufacturer's instructions were not followed

and what control measures had been put in place to maintain safety standards. The risk assessment must be reviewed as and when required for example, any changes to process or impact on patient with a minimal being an annual review.

5.115. In relation to risk assessment under The Management of Health and Safety at Work Regulations 1999 (see ref 99), the HSE state that a Competent Person (see ref 154) is someone who has sufficient training and experience or knowledge and other qualities that allow them to assess or assist staff properly. The level of competence required will depend on the complexity of the situation and the particular need. In risk assessments relating to off-label use of medical devices, any such risk assessments must have the approval of the appropriate local governance group for example clinical governance group and/ or the Medical Device Equipment Management Group.

5.116. For clarity, it should be noted that health and safety related legislation and guidance (see ref 155) is also applicable to employers providing equipment (including devices) for use in the workplace.

Note 23 - additional information:

- MHRA Guide (see ref 153)
- HSE Management of health and safety at work (see ref 156)

Use of non-medical devices for medical purposes

5.117. It is important to discriminate whether such a device is health technology and a Borderline or is a device that is not intended to be used as a medical device by the manufacturer that a practitioner within an organisation intends to use for the purposes that would otherwise classify it as a medical device.

5.118. For detailed information about Borderlines, consult the MHRA guidance on Borderlines with medical devices (see ref 25).

5.119. For use of non-CE marked products as if they were medical devices, refer to the sub-section on Modification In-House Manufacturing and Use within Section 6, Management of Equipment and Devices within this guidance document.

Single use medical devices

5.120. A single-use device (SUD) is used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used again, even on the same patient.

5.121. Single use device symbol is included in the packaging and/ or Manufacturer's IFU (see Figure 5.1).

Note 24 - some medical devices are available in both single use and in reusable product forms.

5.122. Reusing a single-use device without considering the consequences identified in the MHRA's guidance document, Single-use medical devices: implications and consequences of reuse (see ref 157), could expose patients and staff to risks which outweigh the perceived benefits of using the devices.

Figure 5.1 - Single use device symbol

5.123. SUDs can be supplied sterile or non-sterile. See symbols in Figure 5.2.

Figure 5.2 - Sterile and non-steril symbols

Note 25: Scottish government policy that NHSScotland Boards require to source single use pre-sterilized individually wrapped implants (HDL(2007)4 - Decontamination: migration to single-use pre-sterilised individually wrapped small orthopaedic implants and Migration to single-use pre-sterilised individually wrapped small orthopaedic implants in NHSScotland).

5.124. When a SUD is supplied non-sterile and needs to be sterilized prior to use, the sterilization process should be in accordance with the manufacturer's instructions. It is best practice not to reprocess single use devices multiple times unless there is sufficient evidence of validation that the quality of devices are not impaired as a result of multiple reprocessing.

Figure 5.3 - Do not resterilize symbol

5.125. The symbol (Figure 5.3) indicates the SUD must not be re-sterilized.

Note 26: MHRA leaflet - SUD/ equipment (see ref 158).

Single patient use

Figure 5.4 - Single patient use symbol

5.126. Single-patient use means the medical device may be used for more than one episode of use on **one patient only** then discarded.

5.127. The device may undergo some form of **reprocessing** (to make good the device for reuse by any or a combination of cleaning, disinfection/ decontamination, sterilization, refurbishment or repackaging) between each use on the one patient. These devices must not be reprocessed exceeding the maximum number of cycles specified by the manufacturer.

5.128. Single use device symbol is included in the packaging and/ or IFU (Figure 5.4)

Re-manufacturing of single-use devices

5.129. Re-manufacturing of SUD is where a company obtains a CE mark for the re-manufacturing of SUD. A re-manufactured single-use device may not necessarily have components changed in all re-manufacturing episodes. There will be some components that will be being re-used from used devices.

5.130. Re-manufacturing must be conducted only by registered manufacturers and is not permitted with Class I medical devices as there would be no external or independent assessment of CE mark compliance.

5.131. Re-manufacturing can cover a range of equipment supplied in a single use form, such as pulse oximeter sensors, ultrasound catheters, compression sleeves, and most laparoscopic equipment such as scalpels, forceps, graspers and trocars, non-invasive devices like tourniquet cuffs, bed alarms and blood pressure cuffs.

Note 27 - additional information:

- MHRA guidance - UK Guidance on Re manufacturing of Single Use Medical Devices (see ref 159)

Reprocessing/ decontamination

5.132. Decontamination is the combination of processes (including cleaning, disinfection and sterilization) used to render medical devices safe for handling by staff and for use on patients. The decontamination process may include cleaning and/ or disinfection and/ or sterilization. The appropriate level of decontamination process is determined by clinical procedure and must follow manufacturer's IFU. Spaulding classification is generally used.

Table 5.1 - Spaulding Classification

Classification	Type of procedure	Examples of devices	Level of decontamination required
Critical	Entering usually sterile tissues or entering the vascular system.	Needles, surgical instruments, implants.	Sterilization
Semi-critical	In contact with mucous or non-intact membrane but not penetrating sterile tissue.	Flexible endoscopes, endocavity probes.	High level disinfection by heat or chemical (Sterilization preferred where practicable)
Non-critical	In contact with intact skin only.	Blood pressure cuff, electrocardiogram leads, stethoscope, pulse oxymetry probe.	Cleaning (and low level disinfection as per IFU)

5.133. Detailed guidance on decontamination can be found on the NSS website.

Note 28 - additional information:

- NHSScotland Assure Guidance documents on decontamination (see ref 160)
- Decontamination and Infection Control (see ref 161)

Loaning equipment

Loaning equipment out

5.134. In cases where organisations lend equipment to other legal entities, it is imperative that it is delivered and commissioned in accordance with agreed local procedures and appropriate records are kept that are compliant with data protection requirements. The relevant documentation and instruction associated with safe use of the equipment, including manufacturer's written IFU, must also be provided.

5.135. The delivery of equipment should pay particular attention to safety issues such as delivery of the correct item and appropriate commissioning. Specific procedures relating to each different type of equipment will contribute to improved safety standards.

5.136. Understanding the time and personnel commitment needed to ensure successful and safe delivery would be useful for installation. This should take into account, for example, determining whether the equipment requires assembly, requires fixing, may cause load bearing issues, requires that a prescribing professional be present, or requires special

instructions for the end-user. It is also imperative to ensure the provision of appropriate training for end-users.

5.137. This information should be documented and retained within a formal delivery and commissioning log process.

Collection of loaned-out equipment

5.138. From the point of view of both economics and safety, providers will wish to have systems in place which ensures the appropriate collection of loaned equipment when users no longer require it. In some instances, returned equipment can have an impact on an organisational or departmental budget. Loan agreement should be checked including cost, term of contract, consumables, spare parts, services/ maintenance/ test, faulty items, end-life and so on.

5.139. Providing recipients of equipment with details of how to return equipment would be useful, giving contact details from the organisation and what action they should take should the equipment be returned, for example, any decontamination requirements.

Loaning equipment in

5.140. All devices on loan from other legal entities must be underwritten with an indemnity agreement which defines the device management requirements, responsibilities and liabilities. See NHSScotland Assure master indemnity agreement web page (see ref 162) for more details: this gives details of how a supplier can apply to be on the register and provides information for users/ companies on what to do if a company is not on it.

5.141. However, this agreement does not cover a health boards own responsibility to ensure that the equipment is commissioned into use and maintained whilst on loan and that a record of the loaned equipment should be entered on the appropriate health board equipment register. This record should record any deviation from the normal responsibilities around the equipment management of the loaned device.

Decontamination of loaned-in equipment

5.142. Decontamination requirements must be taken into account. Organisations have an obligation to ensure any loaned medical devices have been decontaminated and are appropriately processed at time of use. Additionally, National Decontamination Guidance on Loan Medical Devices (Reusable): Roles and Responsibilities GUID 5002 (see ref 163) is in place to minimise HAIs and harm to patients and staff. The appropriate level of rigour to apply will be dependent on the type of equipment and its level of exposure to contaminants; so surgical instruments and endoscopes would be managed in a different way to an Electrocardiogram (ECG) recorder.

5.143. The effective control of loan medical device decontamination presents challenges to theatres, clinics, sterile services, manufacturers and suppliers. Loan medical devices must be managed in a consistent way to ensure patient and staff safety.

Note 29 - Further information: National Decontamination Guidance on Loan Devices (see ref 163)

Decommissioning, recycling and disposal

Decommissioning

5.144. Decommissioning aims to make devices safe and unusable, while minimising damage to the environment. Any device deemed unfit for use should be decommissioned.

5.145. It is worthwhile contacting the manufacturer for information on decommissioning as they will be able to provide details of any environmental, disposal, recycling or structural requirements. If the manufacturer has ceased trading, contact the Regulatory Authority for further guidance.

5.146. Decommissioning should include decontamination. This is to ensure that an inappropriate person does not use the device and expose themselves and/ or others to hazards.

5.147. For devices that are mobile or housed in general facilities, safety checks, such as power disconnection and cooling system disconnection, should be carried out.

5.148. Decommissioning larger installations often involves removal from a purpose-built room or surroundings. Decommissioning of a device incorporating radioactive sources requires the oversight of the organisation's Radiation Protection Officer, who unusually sits within its Medical Physics department and must be carried out in accordance with The Ionising Radiations Regulations 2017 (see ref 36) and with The Ionising Radiation (Medical Exposure) Regulations 2017 (see ref 117).

5.149. If a device stores patient identifiable data, this should be certified as securely erased to an appropriate standard, such as BS ISO/IEC 15408 (see ref 164) and British HMG Infosec Standard 5 (IS 5) (see ref 165)), before disposal. Data on any device should be forensically unrecoverable for instance patient data must be permanently wiped and unrecoverable.

Recycling and disposal

5.150. A risk managed approach to disposal is required to segregate waste according to its level of contamination or its perceived potential level of contamination when being handled by waste management personnel further along the disposal chain, for example a waste wheelchair would be handled differently from a used single use surgical tool.

5.151. After being used on a patient, single-use devices must be segregated from other reusable devices and should not be returned to a Decontamination facility for reprocessing. Discarded (used and unused) devices may be classified as healthcare (clinical) waste. Comprehensive guidance on the management of waste is provided in Scottish Health Technical Note 03-01 (SHTN 03-01) (see ref 166), available from the NSS website (see ref 125).

5.152. All medical devices that are to be disposed of, must be recorded, handled and stored in accordance with SHTN 03-01, Scottish Government Records Management Health and Social Care Code of Practice (Scotland) 2020 (see ref 167) and in accordance with Health and Safety, Carriage of Dangerous Goods Regulations (see ref 168).

5.153. Organisations may choose, in accordance with their local policy, to offer or sell unused or unwanted equipment or to pass it to Developing Countries (see Scotland Global Citizenship Programme information. Where this involves donations of medical equipment to low and middle income countries or as part of a humanitarian response, there is national and international guidance available on the key considerations of a safe and effective donation (see ref 169)).

5.154. Excess electrical medical devices and equipment may be returned to the original supplier under The Waste Electrical and Electronic Equipment Regulations (WEEE) (see ref 110), such as (non-infected) dialysis machines, analysers, medical freezers and cardiology equipment.

5.155. As short life UK-wide collaboration, MedTech - Design for Life Working Group, has recently been set up to explore aspects to enable efficient reuse, remanufacture and materials recovery of medical devices at end of life and make recommendations for inclusion in a road map for transition to the circular economy that shows measurable change in the short, medium and longer term.

Note 30 - additional information:

- Scottish Environmental Protection Agency (SEPA) Export of Waste Medical Devices (see ref 170)
- SEPA WEEE Regulations Waste decision tree (see ref 171)

Donation of equipment

5.156. Decisions on the donation of surplus medical equipment rests with individual Health Boards and Local Authority in line with this guidance, their medical devices policy and local disposal policies. Healthcare providers should incorporate equipment donation guidance into their local policy to ensure that any donations that are progressed are done so in line with best practice and that essential preparatory steps such as the removal of patient identifiable data are made clear. As part of this all Healthcare providers should have in place an up-to-date Indemnity Agreement - this should include a provision that makes clear that responsibility for the issuing of safety communications for medical devices to healthcare providers rests with the relevant governing body for the receiving organisation or country.

5.157. Safely donated medical equipment can save lives and give health professionals throughout low-and-middle- income countries (LMICs) the tools they need to deliver quality care. However, the donation of medical equipment is complex and donating goods comes with risks and difficulties to both the donor and the recipient.

5.158. The World Health Organization (WHO) four core principles:

- a health care equipment donation should benefit the recipient to the maximum extent possible
- a donation should be given with due respect for the wishes and authority of the recipient, and in conformity with existing government policies and administrative arrangements of the receiving country
- there should be no double standard in quality: if the quality of an item is unacceptable in the donor country, it is also unacceptable as a donation
- there should be effective communication between the donor and the recipient, with all donations resulting from a need expressed by the recipient. Donations (solicited) should never be sent unannounced

5.159. On selling or donating used devices, as much as possible of the following information should be supplied with the device to the purchaser:

- a clear statement that the device is being resold/ donated
- a certificate of decontamination
- the user manuals and training requirements
- full details of maintenance and servicing requirements
- service history and manual

5.160. The NHS is committed to the ethical and sustainable donation of surplus kit to low resource settings where it is safe and appropriate to do so. In June 2021, the Chief Medical Officer (CMO) for Scotland commissioned Kids Operating Room, a Scottish global health charity, to lead a review of the standards required for donations of medical equipment to low-and-middle-income countries. This work resulted in the publication of the '10 Step Guide' and associated checklist, which was published by the Scottish Government, and endorsed by Scottish International Development Alliance. The 10 Step Guide provides a roadmap through the important considerations to making a safe and effective donation, including the importance of stopping a donation if you are not confident that it can be done in accordance with best practice. The Guide focuses on the donation of medical equipment, however the key messages are also applicable to other types of donated equipment, for example consumables, rehabilitation and therapeutic equipment.

5.161. Clinical and Biomedical Engineering services can help by providing practical/ technical advice/ support including provision of technical manuals for the equipment being donated (although you should check if these are available in the language of the recipient nation).

5.162. Before donating invasive/ semi-invasive reusable devices, for example, surgical instruments/ endoscopes, additional considerations should be explored:

- The device decontamination process and use are fully traceable
- The availability of decontamination methods including equipment and consumables to be used in accordance with manufacturer instructions

The NHSScotland Global Citizenship Programme

5.163. "*Global Citizenship is a way of living that recognises our world is an increasingly complex web of connections and interdependencies. One in which our choices and actions may have repercussions for people and communities locally, nationally or internationally.*" International Development Education Association Scotland

5.164. The NHSScotland Global Citizenship Programme aims to increase NHSScotland's global health contribution, by making it easier for all NHS staff to participate in global citizenship, both here in Scotland and overseas.

5.165. The Scottish Global Health Co-ordination Unit, which sits within the Scottish Government and supports the NHSScotland Global Citizenship Programme, does not fund or co-ordinate the donation of equipment (medical or otherwise) to LMICs. However, it can connect Health Boards and staff with others across the health system who have experience of donations for advice and support. It can also advise on known training opportunities - some of which may require funding from external sources.

Humanitarian support

5.166. Scottish Government Ready Scotland website provides advice on how to support humanitarian crises around the world in a safe and effective way. The needs in a humanitarian crisis are constantly shifting, and donated goods are not usually the best solution. It can take a lot of resources to manage, sort, and dispose of unneeded items in countries which are providing emergency support. Visit Ready Scotland for advice on supporting humanitarian causes, including donating and managing goods as part of that.

Note 31 - additional information:

- Tropical Health and Education Trust's toolkit for medical equipment donations to low-resource settings (see ref 172)
- WHO - Donation of medical equipment (see ref 173)
- '10 Steps to Safe Medical Equipment Donation' (Scottish Government, 2023)
- '10 Steps to Safe Medical Equipment Donations Checklist' (Scottish Government, 2023)
- Supporting documents - CMO's Short Life Working Group on Donating medical equipment Report (Scottish Government, 2023)
- The NHSScotland Global Citizenship Programme - Advice on donations (Scottish Government, 2023)
- Humanitarian support | Ready Scotland, Scottish Government
- Managing Medical Devices Guidance for health and social care organisations (MHRA, 2021)

- The Scottish Global Health Co-ordination Unit ScottishGHCU@gov.scot
- The Scottish Clinical Engineering Network

Transfer of ownership

5.167. Donation of equipment/ medical devices can be categorised as transfer ownership, thus agreement between all parties as per local policies should be confirmed. It is expected this will include the indemnity arrangements mentioned above and registration with national regulatory authorities as per usual practice in the recipient country.

5.168. Refer to guidance in Section 10.4, sale or donation for reuse, of Managing Medical Devices, MHRA 2021 (see ref 111).

Replacement process

5.169. For all organisations' devices, a stage is reached at which replacement of devices or equipment must be considered. This must be considered if any of the following criteria applies. If any of these apply, the device is no longer serviceable and should be replaced when it is: worn out beyond economic repair

- damaged beyond economic repair
- unreliable (check service history)
- clinically or technically obsolete
- older than the expected service life and its use cannot be extended, stated in the manufacturer's risk management file for the device
- out of manufacturer's support
- spare parts no longer available
- better value devices that are more cost-effective or clinically effective have become available
- unable to be cleaned effectively prior to disinfection and/ or sterilization

6. Managing equipment in community settings

6.1. The advice in this section is intended to supplement the other sections in Scottish Health Technical Note (SHTN) 00-04 and other guidance applicable to all medical equipment.

Medical equipment for home use

6.2. The healthcare organisation supplying or recommending medical equipment for home use is responsible for ensuring that the equipment complies with regulations relevant to the intended use. For example:

- medical devices should be UK Conformity Assessment (UKCA)/ Conformité Européenne, meaning European Conformity (CE) marked, comply with the Medical Device Regulations (MDR) and be intended for home use by lay persons
- medical electrical equipment and medical electrical systems used in the home healthcare environment should be manufactured in compliance with EN 60601 1 11:2015 (see ref 174)
- weighing scales should comply with the Non-Automatic Weighing Instruments Regulations 2016 and scales used for medical applications should be Class III accuracy or higher

6.3. The healthcare organisation should ensure that all equipment supplied or recommended is acceptance tested before first use and equipment supplied is added to a medical equipment inventory to facilitate management of medical device alerts.

6.4. The healthcare organisation supplying equipment for home use, should provide the following information to the users and clinicians:

- manufacturer instructions and the intended use
- training, including the limitation and warnings, for example, a pulse oximeter may have different performance characteristics as a result of skin pigmentation
- lifespan replacements, cleaning/ decontamination, and applicable class registrations
- how and who to report incident or near-misses or issues in the event of, system or device malfunction

Digital health solutions for home-use

6.5. This refers to devices for use at home with the provision to record and transmit health data. They may be regulated as medical devices if they meet the definition of a medical device. Digital health solutions include:

- devices that can transmit data to enable remote monitoring, for example, Bluetooth enabled digital scales, pulse oximeters, glucose monitors and sphygmomanometers (blood pressure monitors)
- PC and mobile software applications for use as a stand-alone application and/ or designed to work in conjunction with device hardware. This may meet the definition of Software as a Medical Device (SaMD)

6.6. Digital health solutions provided for individual patient use require the same level of diligence as for other medical equipment. They must meet the relevant regulatory requirements, for example UKCA/ CE marked and should be used in accordance with the intended use, as stated by the manufacturer.

Connect Me

6.7. The Connect Me service uses a person's own simple devices and sometimes small basic medical equipment to enable individuals to share information with health care professionals and/ or automated monitoring services." (see paragraph 5.18).

Community equipment services

6.8. The aim of Community Equipment Services is to effectively develop, deliver, manage, and monitor the provision of equipment for community patients from the point of assessment through to delivery, and the conclusion of the assessment process. This process sits within the framework of the overarching National Guidance on the Provision of Equipment and Adaptations and focuses primarily on the provision of community equipment.

6.9. In anticipation of any power or water outage, patients relying on critical medical equipment or access to water supplies in the community are encouraged to register on the priority register system for people in need (see ref 175).

6.10. This system can provide early alerts from the power or water companies to possible outages or support in the event of an unexpected outage.

6.11. It is anticipated that labels will be attached to health critical equipment that provides the customer with the emergency helpline number of 105 in the event of an outage; however, all users of community equipment and providers of equipment to home patients should check for any local Health Board or Local Authority variations to that process in order to advise on any special local policy or protocols.

Note 32 - additional information:

- Good Practice Guide for the Provision of Community Equipment Services (see ref 176)
- Convention of Scottish Local Authorities (COSLA) Protocol for the Provision of Equipment in Care Homes (see ref 177)

Appendix A Examples of standards available in Barbour Index (Knowledge Network)

Note 33: The standards below related quality management systems (QMS), risk management, laboratory, medical equipment, decontamination equipment and environment, respiratory protective equipment, estates and facilities and so on. Not all latest versions of the medical device standards are available via knowledge network.

Table A.1 - Examples of standards

Number	Title
BS EN ISO 13485:2016	Medical devices. Quality management systems. Requirements for regulatory purposes
BS EN ISO 9001:2015	Quality management systems. Requirements
BS EN ISO 9000:2015	Quality management systems. Fundamentals and vocabulary
BS EN ISO 19011:2018	Guidelines for auditing management systems
BS EN ISO 10005:2005	Quality management systems. Guidelines for quality plans
BS EN ISO 14971:2019	Medical devices. Application of risk management to medical devices
BS ISO 31000:2018	Risk management. Guidelines
BS EN 60601	Medical electrical equipment
BS EN ISO 15189:2012	Medical laboratories. Requirements for quality and competence
BS EN ISO/IEC 17025:2017	General requirements for the competence of testing and calibration laboratories
BS EN ISO 15223	Series Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied.
BS 285:2015	Sterilization. Steam sterilizers. Large sterilizers
BS EN ISO 17664:2017	Sterilization of health care products. Information to be provided by the medical device manufacturer for the processing of re-sterilizable medical devices
BS EN ISO 11607-2:2017	Packaging for terminally sterilized medical devices. Validation requirements for forming, sealing and assembly processes.
BS EN ISO 15883-2:2009	Washer-disinfectors. Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, and so on.

Number	Title
BS EN ISO 14644	Series Cleanrooms and associated controlled environments.
BS EN 17141:2020	Ventilation of buildings. Cleanrooms and associated controlled environments.
BS EN ISO/IEC 27001:2017	Information technology. Security techniques. Information security management systems. Requirements
BS EN 62304:2006+A1:2015	Medical device software. Software life cycle processes
BS 70000	Series Information technology. Software engineering
BS EN 62353:2014	Medical electrical equipment. Recurrent test and test after repair of medical electrical equipment
BS 8214:2016	Code of practice for fire door assemblies
BS 476-20:1987	Fire tests on building materials and structures. Method for determination of the fire resistance of elements of construction (general principles)
BS 476-21:1987	Fire tests on building materials and structures. Methods for determination of the fire resistance of loadbearing elements of construction
BS 476-22:1987	Fire tests on building materials and structures. Methods for determination of the fire resistance of non-loadbearing elements of construction
BS 476-23:1987	Fire tests on building materials and structures. Methods for determination of the contribution of components to the fire resistance of a structure
BS 476-24:1987	Fire tests on building materials and structures. Method for determination of the fire resistance of ventilation ducts
BS 476-3:2004	Fire tests on building materials and structures. Classification and method of test for external fire exposure to roofs
BS 476-31.1:1983	Fire tests on building materials and structures. Methods for measuring smoke penetration through doorsets and shutter assemblies. Method of measurement under ambient temperature conditions
BS 5041-4:1987	Fire hydrant systems equipment. Specification for landing valves for wet risers
BS 5306-0:2011	Fire protection installations and equipment on premises. Guide for selection of installed systems and other fire equipment.
BS 5306-1:2006	Fire extinguishing installations and equipment on premises. Hose reels and foam inlets.

Number	Title
BS 5306-4:2019	Fire extinguishing installations and equipment on premises. Specification for carbon dioxide systems
BS 5306-6.1:2009	Fire extinguishing installations and equipment on premises. Foam systems. Specification for low expansion foam systems
BS 5499-5:2002	Graphical symbols and signs. Safety signs, including fire safety signs. Signs with specific safety meanings
BS 5839-1:2017	Fire detection and fire alarm systems for buildings. Code of practice for design, installation, commissioning, and maintenance of systems in non-domestic premises
BS 750:2006	Specification for underground fire hydrants and surface box frames and covers
BS 6387:2013	Specification for performance requirements for cables required to maintain circuit integrity under fire conditions
BS 8558:2015	Guide to the design, installation, testing and maintenance of services supplying water for domestic use within buildings and their curtilages. Complementary guidance to BS EN 806
BS 5228-1:2009+A1:2014	Code of practice for noise and vibration control on construction and open sites. Noise
BS 5266	Series Emergency lighting
BS 5266-1:2016	Emergency lighting. Code of practice for the emergency lighting of premises
BS 4987-1:2005	Coated macadam (asphalt concrete) for roads and other paved areas. Specification for constituent materials and for mixtures
BS 4987-2:2010	Coated macadam (asphalt concrete) for roads and other paved areas. Specification for transport, laying and compaction of coated macadam.
BS 4211:2005+A1:2008	Specification for permanently fixed ladders
BS 149:2001	Respiratory protective devices

Appendix B MHRA guidance in relation to medical device

B.1 Below is a list of MHRA guidance (as of January 2024):

Table B.1 - MHRA guidance related to MDR

Title	Narrative	Weblink
Standard Implementation of medical devices future regime.	Core aspects of the future regime for medical devices to apply from 1 July 2025.	Implementation of medical devices future regime - for more information visit GOV.UK
Roadmap for the future regulatory framework for medical devices	Summary of the regulatory changes and actions taken since the consultation in 2021, and an intended timeline for the planned activities in 2024 -2025.	Implementation of medical devices future regime - for more information visit GOV.UK
Medical devices regulations: compliance and enforcement.	Information on MHRA's enforcement duties and how to report a non-compliant medical device.	Medical devices regulations: compliance and enforcement - for more information visit GOV.UK
Medical devices: EU regulations for MDR and IVDR (Northern Ireland).	What you need to know about the new EU Regulations for medical devices (MDR) and in vitro diagnostic medical devices (IVDR), and their implementation in Northern Ireland.	Medical devices: EU regulations for MDR and IVDR (Northern Ireland) - for more information visit GOV.UK
Medical devices: how to comply with the legal requirements in Great Britain.	What you need to know before you can place a medical device on the Great Britain market with a UKCA mark.	Medical devices: how to comply with the legal requirements in Great Britain - for more information visit GOV.UK
Register medical devices to place on the market.	How to register your medical devices with the MHRA for the markets in Great Britain and Northern Ireland.	Register medical devices to place on the market - for more information visit GOV.UK

Title	Narrative	Weblink
Medical devices: conformity assessment and the UKCA mark	How to conform with the legal requirements for placing medical devices on the market.	Medical devices: conformity assessment and the UKCA mark - for more information visit GOV.UK
Medical devices: UK approved bodies	UK approved bodies listed under Medical Devices Regulations 2002 (see ref 1).	Medical devices: UK approved bodies - for more information visit GOV.UK
Approved bodies for medical devices	UK approved bodies listed under Medical Devices Regulations 2002 (see ref 1)	Medical devices: UK approved bodies - for more information visit GOV.UK
Notify the MHRA about a clinical investigation for a medical device	How to notify the MHRA of your intention to carry out a clinical investigation for medical devices.	Notify the MHRA about a clinical investigation for a medical device - for more information visit GOV.UK
Medical devices: legal requirements for specific medical products	Guidance for manufacturers on the regulations that apply to prosthetic, orthotic and ophthalmic devices.	Medical devices: legal requirements for specific medical products - for more information visit GOV.UK
Custom-made medical devices in Great Britain	How to comply with the regulatory requirements for manufacturing custom-made medical devices.	Custom-made medical devices in Great Britain - for more information visit GOV.UK
Borderline products: how to tell if your product is a medicine	How the MHRA makes decisions on what is a medicinal product (borderline products).	Borderline products: how to tell if your product is a medicine - for more information visit GOV.UK
Borderlines between medical devices and medicinal products	How to distinguish between products that are regulated as medical devices and those regulated as medicinal products.	Borderlines between medical devices and medicinal products - for more information visit GOV.UK
Borderlines with medical devices and other products in Great Britain	Guidance on whether or not your product is a medical device.	Borderlines with medical devices and other products in Great Britain - for more information visit GOV.UK

Title	Narrative	Weblink
Borderline products: how to tell if your product is a medical device and which risk class applies	How the MHRA makes decisions on when a product is a medical device (borderline products), and which risk class should apply to a medical device.	Borderline products: how to tell if your product is a medical device and which risk class applies - for more information visit GOV.UK
IVD medical devices: guidance on legislation	Guidance explaining the main features of the Medical Devices Regulations 2002 (see ref 1) in relation to IVD medical devices.	In vitro diagnostic medical devices: guidance on legislation - for more information visit GOV.UK
Software and artificial intelligence (AI) as a Medical Device Change Programme	The MHRA have embarked upon an ambitious programme of reform to ensure that medical device regulation is fit for purpose for software, including AI.	Software and AI as a Medical Device Change Programme - for more information visit GOV.UK
Reporting adverse incidents involving Software as a Medical Device under the vigilance system	Information for manufacturers of Software as a Medical Device, detailing events that may cause indirect harm and are therefore reportable.	Reporting adverse incidents involving Software as a Medical Device under the vigilance system - for more information visit GOV.UK
Software and AI as a Medical Device	Information for manufacturers, healthcare organisations and professionals, researchers, patients and public on SaMD, including Artificial Intelligence as a Medical Device (AIaMD).	Software and AI as a Medical Device - for more information visit GOV.UK
Effective field safety notices (FSNs): guidance for manufacturers of medical devices	Advice on writing clear notices and maximising replies to your FSNs.	Effective FSNs: guidance for manufacturers of medical devices - for more information visit GOV.UK

Title	Narrative	Weblink
Regulatory status of software (including apps) used in the diagnosis, treatment and management of patients	Advice for manufacturers, members of the public and professional users of software or apps being used during the COVID-19 pandemic.	Regulatory status of software (including apps) used in the diagnosis, treatment and management of patients with coronavirus (COVID-19) - for more information visit GOV.UK
Guidance Virtual manufacturing of medical devices	Guidance for manufacturers who don't design or manufacture devices but place their names on the product.	Virtual manufacturing of medical devices - for more information visit GOV.UK
Good Machine Learning Practice for Medical Device Development: Guiding Principles	Ten guiding principles that can inform the development of Good Machine Learning Practice (GMLP).	GMLP for Medical Device Development: Guiding Principles - for more information visit GOV.UK
Guidance on applying human factors to medical devices	MHRA has published guidance on the importance of applying human factors to medical devices, so they are designed and optimised to minimise patient and user safety risks.	Guidance on applying human factors to medical devices - for more information visit GOV.UK
Medical devices: information for users and patient	Information and guidance on a range of medical devices for users and patients.	Medical devices: information for users and patients - for more information visit GOV.UK
Export medical devices	Order a certificate of free sale to export medical devices outside the UK.	Export medical devices - for more information visit GOV.UK

Title	Narrative	Weblink
Manufacturer's On-line Reporting Environment (MORE) platform API (Application Programming Interface) set up - user reference guide	Instructions for integrating with the new production MORE platform API.	MORE platform API set up - user reference guide - for more information visit GOV.UK
MORE Submissions - user reference guide	A step-by-step guide on using the MORE Platform for Submissions of device related incidents.	MORE Submissions - user reference guide - for more information visit GOV.UK
MORE Registrations - user reference guide	A step-by-step guide on using the MORE Platform for Registrations for Submissions of device related incidents.	MORE Registrations - user reference guide - for more information visit GOV.UK
FSN: what it is and why it's important	A flyer to circulate to customers alongside a field safety notice covering what it is and why it's important to take action.	FSN: what it is and why it's important - for more information visit GOV.UK
Managing medical devices	Guidance for healthcare and social services organisations on managing medical devices in practice.	Managing medical devices - for more information visit GOV.UK
IVD medical devices: procurement, safety, quality and performance	Guidance on the procurement of IVD medical devices, their safety, quality and performance.	IVD medical devices: procurement, safety, quality and performance - for more information visit GOV.UK
Exceptional use of non-UKCA marked medical devices	How a manufacturer can apply for approval to supply a non-compliant medical device on humanitarian grounds.	Exceptional use of non-UKCA marked medical devices - for more information visit GOV.UK
Medical devices: off-label use	What is considered off-label use of a medical device and examples of it.	Medical devices: off-label use - for more information visit GOV.UK

Title	Narrative	Weblink
Single-use medical devices: implications and consequences of re-use	Guidance for healthcare professionals on using single-use medical devices.	Single-use medical devices: implications and consequences of re-use - for more information visit GOV.UK
IVD point-of-care test devices	Advice and guidance on the management and use of point-of-care testing (POCT) IVD devices.	IVD point-of-care test devices - for more information visit GOV.UK
Bed rails: management and safe use	Guidance on managing and using bed rails safely.	Bed rails: management and safe use - for more information visit GOV.UK
Di(2-ethylhexyl) phthalate (DEHP) phthalates in medical devices	Information for manufacturers and users of medical devices containing plastic with DEHP phthalates.	DEHP phthalates in medical devices - for more information visit GOV.UK
Information about Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) for people with breast implants	This advice has been written by the Plastic, Reconstructive and Aesthetic Surgery Expert Advisory Group (PRASEAG) at the request of the MHRA - UK regulator. It is in the form of questions, asked of clinicians in consultation with their patients. Further information about PRASEAG can be found at the end of the document.	Information about BIA-ALCL for people with breast implants - for more information visit GOV.UK
Assistive technology: definitions, examples and safe use	Helps manufacturers and healthcare professionals understand the definition of assistive technology and the difference between medical devices and aids to daily living.	Assistive technology: definitions, examples and safe use - for more information visit GOV.UK
BIA-ALCL	Information for patients, public and health care professionals.	BIA-ALCL - for more information visit GOV.UK

Title	Narrative	Weblink
The use and regulation of pulse oximeters (information for healthcare professionals)	Information for healthcare professionals on how pulse oximeters are regulated, home use and issues to look out for when using the devices	The use and regulation of pulse oximeters (information for healthcare professionals) - for more information visit GOV.UK
Symptoms sometimes referred to as Breast Implant Illness	Information for clinicians and patients.	Symptoms sometimes referred to as Breast Implant Illness - for more information visit GOV.UK
Medical devices: sources of electromagnetic interference	Guidance on sources of electromagnetic interference and mitigating the risks.	Medical devices: sources of electromagnetic interference - for more information visit GOV.UK
Exemptions from Devices regulations during the coronavirus (COVID-19) outbreak	How to get fast-track approval of medical devices during COVID-19.	Exemptions from Devices regulations during the coronavirus (COVID-19) outbreak - for more information visit GOV.UK
Regulatory status of equipment being used to help prevent coronavirus (COVID-19)	There are different regulations which apply to devices and equipment including hand gels and personal protective equipment (PPE)	Regulatory status of equipment being used to help prevent coronavirus (COVID-19) - for more information visit GOV.UK
Medical devices clinical investigations during the coronavirus (COVID-19) outbreak	Advice for investigators and sponsors of ongoing clinical investigations.	Medical devices clinical investigations during the coronavirus (COVID-19) outbreak - for more information visit GOV.UK

Title	Narrative	Weblink
3D printing (additive manufacturing) of medical devices or component parts during the coronavirus (COVID-19) pandemic	The requirements for 3D printed products will depend on whether they are classed as medical devices, PPE or both.	3D printing (additive manufacturing) of medical devices or component parts during the coronavirus (COVID-19) pandemic - for more information visit GOV.UK
COVID-19 test approval: how to apply	How test manufacturers or distributors can apply for approval of their tests to sell on the UK market.	COVID-19 test approval: how to apply - for more information visit GOV.UK
Guidance How tests and testing kits for coronavirus (COVID-19) work	The different types of tests and testing kits for COVID-19, and the specifications for manufacturers.	How tests and testing kits for coronavirus (COVID-19) work - for more information visit GOV.UK
Assessment and procurement of coronavirus (COVID-19) tests	How the government assesses offers of COVID-19 tests from developers for procurement and use in the UK.	Assessment and procurement of coronavirus (COVID-19) tests - for more information visit GOV.UK
Specification for ventilators to be used in UK hospitals during the coronavirus (COVID-19) outbreak	This guidance sets out the clinical requirements based on the consensus of what is 'minimally acceptable' performance in the opinion of the anaesthesia and intensive care medicine professionals and medical device regulators.	Specification for ventilators to be used in UK hospitals during the coronavirus (COVID-19) outbreak - for more information visit GOV.UK
Leadless cardiac pacemaker therapy: guidance from an MHRA Expert Advisory Group with coronavirus (COVID-19)	Recommendations on leadless cardiac pacemaker therapy from MHRA Expert Advisory Group	Leadless cardiac pacemaker therapy: guidance from an MHRA Expert Advisory Group - for more information visit GOV.UK

Appendix C Symbols of medical devices (extracted from BS EN ISO 15223-1)

C.1 Example of symbols of medical devices (as of January 2024)

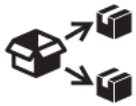
Table C.1 - Symbols

Symbol	Description	Symbol	Description
	Medical device manufacturer.		Potential biological risks associated with the medical device.
EC REP	Authorized representative in the European Community/ European Union.		Do not reuse. Medical device that is intended for one single use only.
	Date when the medical device was manufactured.		Consult instructions for use or consult electronic instructions for use.
	Date after which the medical device is not to be used.		Caution is necessary when operating the device or control close to where the symbol is placed, or operator awareness or action needed to avoid undesirable consequences.
LOT	Manufacturer's batch code so that the batch or lot can be identified.	LATEX	Contains the presence of dry natural rubber or natural rubber latex as a material of construction within the medical device or the packaging of a medical device.
REF	Manufacturer's catalogue number so that the medical device can be identified.		Contains or incorporates human blood or plasma derivatives.

Symbol	Description	Symbol	Description
SN	Manufacturer's serial number so that a specific medical device can be identified.		Medical device that contains or incorporates a medicinal substance.
	Entity importing the medical device into the locale.	BIO	Medical device that contains biological tissue, cells, or their derivatives, of animal origin.
	Entity distributing the medical device into the locale.	BIO	Medical device that contains biological tissue, cells, or their derivatives, of human origin.
#	Model number or type number of a product.		Contains hazardous substances. Medical device containing substances that can be carcinogenic mutagenic, reprotoxic (CMR), or substances with endocrine disrupting properties.
CC	Country of manufacture of products.		Medical device that contains nano materials.
STERILE	Medical device that has been subjected to a sterilization process.	1	Single patient multiple use. A medical device that may be used multiple times (multiple procedures) on a single patient.
STERILE A	Medical device that has been manufactured using accepted aseptic technique.	IVD	Medical device that is intended to be used as an in vitro diagnostic medical device.
STERILE EO	Medical device that has been sterilized using ethylene oxide.	CONTROL	Control material that is intended to verify the performance of another medical device.
STERILE R	Medical device that has been sterilized using irradiation.	CONTROL -	Negative control. A control material that is intended to verify the results in the expected negative range.

Symbol	Description	Symbol	Description
STERILE	Medical device that has been sterilized using steam or dry heat.	CONTROL +	Positive control. A control material that is intended to verify the results in the expected positive range.
STERILIZE	Medical device that is not to be resterilised.	Σ	Total number of tests that can be performed with the medical device.
NON STERILE	Medical device that has not been subjected to a sterilization process.	?	An in vitro diagnostic (IVD) medical device that is intended to be used only for evaluating its performance characteristics before it is placed on the market for medical diagnostic use.
	Medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information.		Sampling site. A medical device or blood processing application that includes a system dedicated to the collection of samples of a given substance stored in the medical device or blood container.
STERILE	Presence of a sterile fluid path within the medical device in cases when other parts of the medical device, including the exterior, might not be supplied sterile.		Fluid path. The presence of a fluid path. Note 34 - The term “fluid” means a liquid or gas.
STERILE VH2O2	Medical device that has been sterilized using vaporized hydrogen peroxide.		A medical device that is non-pyrogenic.
	Single sterile barrier system.	20 ml	The number of drops per millilitre.
	Two sterile barrier systems.	15 µm	An infusion or transfusion system of the medical device that contains a filter of a particular nominal pore size.

Symbol	Description	Symbol	Description
	Single sterile barrier system with protective packaging inside.		One way valve. A medical device with a valve that allows flow in only one direction.
	Fragile, handle with care Medical device that can be broken or damaged if not handled carefully.		Patient Name, The identification data of the patient.
	Keep away from sunlight. Medical device that needs protection from light sources.		Patient Identification Data.
	Protect from heat and radioactive sources. Medical device that needs protection from heat and radioactive sources.		A website where a patient can obtain additional information on the medical product.
	Keep dry. Medical device that needs to be protected from moisture.		The address of the health care centre or doctor where medical information about the patient may be found.
	Lower limit of temperature to which the medical device can be safely exposed.	31	The date that information was entered, or a medical procedure took place.
	Upper limit of temperature to which the medical device can be safely exposed.	MD	The item is a medical device.
	Temperature limits to which the medical device can be safely exposed.	A→文	The original medical device information has undergone a translation which supplements or replaces the original information.

Symbol	Description	Symbol	Description
	Humidity limitation. Range of humidity to which the medical device can be safely exposed.		Repackaging. A modification to the original medical device packaging configuration has occurred.
	Atmospheric pressure limitation. Range of atmospheric pressure to which the medical device can be safely exposed.	UDI	Unique device identifier. A carrier that contains unique device identifier information.

Abbreviations

ABHI: Association of British Health Tech Industries

AI: Artificial intelligence

AIMDD: Active Implantable Medical Devices Directive

AIaMD: Artificial Intelligence as Medical Device

AIDC: Automatic Interface and Data Capture

API: Application Programming Interface

BIA-ALCL: Breast Implant-Associated Anaplastic Large Cell Lymphoma

BS: British Standards

BSI: British Standards Institution

C&SS: Care and Support Services

CE: Conformité Européenne, meaning European Conformity

CEL: Chief Executive Letter COSLA Convention of Scottish Local Authorities

CMO: Chief Medical Officer

CMR: Carcinogenic Mutagenic, Reprotoxic

CPD: Continual Professional Development

CPAP: Continuous Positive Airway Pressure

DEHP: Di(2-ethylhexyl) phthalate

DIC: Distinct Identification Code

DORS: Device Online Registration Systems

EBME: Electronic and Biomedical Engineering

ECG: Electrocardiogram

EEA: European Economic Area

EFN: Estates and Facilities Notice

EMC: Electromagnetic Compatibility Regulations

EMDN: European Medical Device Nomenclature

FSNs: Field Safety Notices

GMDN: Global Medical Device Nomenclature

GMLP: Good Machine Learning Practice

HAI: Healthcare Associated Infections

HASAWA: Health and Safety at Work etc. Act

HFS: Health Facilities Scotland

HIBCC: Health Industry Business Communications Council

HIE: Health Institution Exemption

HIS: Healthcare Improvement Scotland

HPS: Health Protection Scotland

HRI: Human Readable Interface

HSE: Health and Safety Executive

HTA: Health Technology Assessment

IASO: Incident and Alert Safety Officer

ICCBBA: International Council for Commonality in Blood Banking Automation

IEC: Electrotechnical Commission

IET: Institution of Engineering and Technology

IFA: Informationsstelle für Arzneispezialitäten

IFU: Instructions for Use

IHEEM: The Institute of Healthcare Engineering and Estate Management

IPEM: Institute of Physics and Engineering in Medicine

IR(ME)R: Ionising Radiation (Medical Exposure) Regulations

IMDRF: International Medical Devices Regulators Forum

IRIC: Incident Reporting Investigation Centre

ISO: International Organisation for Standardisation

ISON: Incidents and Alerts Safety Officers Network

IVD: In Vitro Diagnostic

IVDR: In Vitro Diagnostic Medical Devices Regulation

LA: Local Authorities

LMICs: Low-and-Middle-Income Countries

LOLER: Lifting Operations and Lifting Equipment Regulations

MDC: Medical Devices Committee

MDCG: Medical Devices Oversight Group

MDD: Medical Devices Directive

MDDL: Medical Devices Drivers Licence

MDLU: Medical Devices and Legislation Unit

MDOR: Medical Device Outcome Registry

MDR: Medical Devices Regulations

MEML: Medical Equipment Management

MHRA: Medicines and Healthcare Products Regulatory Agency

MORE: Manufacturer's On-line Reporting Environment

MPNET: Medical Physics and Clinical Engineering Diagnostic Network

NAMDET: National Association of Medical Device Educators & Trainers

NAO: National Audit Office

NatPSAL: National Patient Safety Alerts

NBOG: Notified Bodies Oversight Group

NES: NHS Education Scotland

NICE: National Institute for Health and Care Excellence

NIPCM: National Infection Prevention and Control Manual

NSB: National Standards Body

NSS: National Services Scotland

OJEU: Official Journal of the European Union

OPSS: Office for Product Safety and Standards

PAQ: Pre-acquisition Questionnaire

PECOS: Professional Electronic Commerce Online System

PEMS: Programmable Electronic Medical Systems

PMS: Post-market Surveillance Requirements

POCT: Point-of-Care Testing

PPE: Personal Protective Equipment

PPN: Procurement Policy Note IVD

PRASEAG: Plastic, Reconstructive and Aesthetic Surgery Expert Advisory Group PUWER Provision and Use of Work Equipment Regulations

QMS: Quality Management System

RIDDOR: Reporting of Injuries Diseases and Dangerous Occurrences Regulations SaMD Software as a Medical Device

SAN: Safety Action Notices

SEPA: Scottish Environmental Protection Agency

SHFN: Scottish Health Facilities Notes

SHPN: Scottish Health Planning Notes

SHTG: Scottish Health Technologies Group

SHTM: Scottish Health Technical Memorandum

SHTN: Scottish Health Technical Notes

SI: Statutory Instruments

SIGN: Scottish Intercollegiate Guidelines Network

SiMD: Software in a Medical Device

SLA: Service Level Agreement

SOP: Standard Operating Procedure

SUD: Single Use Device

TUG: Technical User Group

UDI: Unique Device Identification

UDID: Unique Device Identifier Database

UDI-DI: Unique Device Identification Device Identifier

UDI-PI: Unique Device Identification Production Identifier

UKCA: UK Conformity Assessment

WEEE: Waste Electrical and Electronic Equipment Regulations

WHO: World Health Organisation

WTO: World Trade Organisation

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