

SHTN 00-04 Guidance on Management of Medical Devices and Equipment in Scotland's Health and Social Care Services

This guidance has been updated with reference to the European Union legislative framework or requirements and the new UK Regulations and systems from January 2021.

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1. Executive Summary

Brief

- 1.1 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.
- 1.2 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.
- 1.3 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

- 1.4 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 5, Roles and Responsibilities, targeted information is provided for these groups according to their respective key roles and remits.
- 1.5 There are legal considerations as the design, manufacture and supply of medical devices are regulated in the UK through legislation. The UK Medical Device Regulations 2002⁹¹, as amended⁹², and specific UK Health & Safety legislation, such as the Provision and Use of Work Equipment Regulations (PUWER)^{46, 178}, 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.
- 1.6 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.
- 1.7 In addition, there have been various practices and initiatives carried out in Scotland which require inclusion in this guidance, e.g. Incident Reporting Investigation Centre (IRIC) incident reporting system, NHSScotland's Shared Services Clinical Engineering Programme⁶¹, trial on a central point of monitoring for safety alerts and the use of unique device identification (UDI).

- 1.8 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, Medicines and Healthcare Products Regulatory Agency (MHRA).

Purpose

- 1.9 The UK Competent Authority, MHRA, published the principal medical devices guidance ¹ for the UK. Currently there is no specific all-encompassing Scottish guidance for medical devices and equipment.
- 1.10 This document therefore aims to provide public sector health organisations (NHS Boards and Local Authorities) 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.
- 1.11 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; e.g. MHRA ², Care Inspectorate Scotland ⁹, Healthcare Improvement Scotland (HIS) ³, Audit Scotland ⁴, NHS National Services Scotland (NHS NSS) ⁵, Health and Safety Executive (HSE) ⁶, National Audit Office (NAO) ⁷;
 - aligns with relevant guidance issued by professional bodies; e.g. National Association of Medical Device Educators & Trainers (NAMDET) ¹⁰, Association of British Health Tech Industries (ABHI) ¹¹, Institute of Physics and Engineering in Medicine (IPEM) ¹², The Institute of Healthcare Engineering and Estate Management (IHEEM) 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;
 - encourages a nationally unified and collaborative approach to working.

Intended Audience

- 1.12 This guidance is primarily intended for NHSScotland and Scottish Local Authorities (LA) 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 Provider Executives and Directors;
 - Health 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 including staff, social care workers, informal carers, patients, service users, visitors and contractors. Equipment may be issued or prescribed to patients for them to use autonomously. As users, they will need to be adequately instructed in relevant elements of this guidance.

2. Introduction

Background

2.1 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 in order 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: Management Process

2.2 The Scottish Government's Healthcare Quality Strategy for NHS Scotland⁶⁴ commits to ensure the NHS Scotland Property and Asset Management Policy, CEL 35 (2010)⁴⁸, 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.

- 2.3 Through the referencing of key published guidance, this guidance outlines a systematic approach to the life management of medical devices and equipment i.e. Asset Management, Procurement and Production, Acquisition, Storage and Distribution, Commissioning, Competency through Education and Training, Repair, Maintenance and Modification, Usage, Off label use, Single Use and Decontamination/Infection Control, Loaning Equipment, Decommissioning, Recycling and Disposal and Replacement (see Figure 1).

Objectives

Safety

- 2.4 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 applying to the product and the Provision and Use of Work Equipment Regulations 1998 (PUWER)¹⁷⁸. 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 PUWER¹⁷⁸, the organisation must ensure that the equipment is used and maintained in accordance with the manufacturer instructions.

Efficiency

- 2.5 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.
- 2.6 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.
- 2.7 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

- 2.8 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.
- 2.9 Compliance goals:
- compliance with statutory requirements, regulations and standards;
 - ensuring that quality management systems are in place within all organisations regarding the administration of device and equipment management, and are accredited where required.
- 2.10 Standardisation goals:
- providing a sound foundation to ensure a consistent approach to device and equipment management in Scotland;
 - consideration of the concept of a National Medical Equipment Management (MEM) System that would be risk informed and linked to national Asset Management strategy and process. Such a system would provide a national oversight of procurement and maintenance contract activities across Scotland in line with NHS Scotland Asset and Facilities Annual Reporting ²¹⁸. 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.

Locating all documents in one place

- 2.11 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 local authorities. Many documents, produced by various sources, might not always be readily available i.e. 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.
- 2.12 Document location goal
- access to all appropriate information and documentation in a single document.

Scope

- 2.13 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 Medical Devices Regulations 2002 ⁹¹ (SI 2002 No 618, as amended ⁹²) .
- healthcare equipment used in NHS and Local Authorities within Scotland, for example hoists, beds, walking aids, wheelchairs and falls prevention equipment.

2.14 Private sector and third sector organisations that supply services to NHS and Local Authorities 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 Local Authority policy particular to, or wrapped into, such contracts. It is the responsibility of the NHA and LA to include this requirement under their contracts.

Note:

Further information:

MHRA guidance 'Regulating medical devices from 1 January 2021' ²⁴⁹

MHRA general guidance on Medical Devices Regulations and Safety ²²³.

3. What are medical devices and equipment?

- 3.1 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 ⁹².
- 3.2 The World Health Organisation ⁶⁵ 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'
- 3.3 Health technology needs to be supported with an appropriate systematic and structured management approach throughout its entire lifecycle.
- 3.4 In this guidance, medical devices and medical equipment are considered as overlapping subcategories of health technology (see Figure 2).

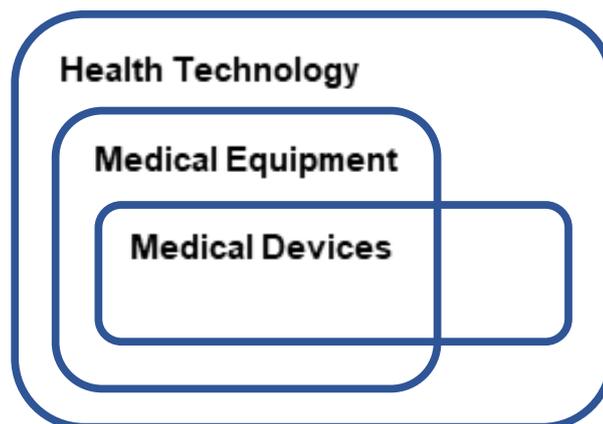


Figure 2: Nested family of equipment used in healthcare

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

- 3.5 Decisions about whether a product is a medical device or not is based on the principal intended purpose of the product, as stated by its manufacturer, and upon its mode of action:
 - a medical device is a product which is designed and manufactured with an 'intended medical purpose' on human subjects as its 'principal intended action'. It acts in vivo or in vitro on diseases, injuries, disabilities, anatomy, or on physiological or pathological state;
 - products that are primarily drugs are not medical devices.

Medical Devices

3.6 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 form (PAQ)⁶⁶. Scotland has adopted the Department of Health and Social Care's form and this has been made available through Health Facilities Scotland's Reports & Information webpage.

3.7 The UK Medical Devices Regulations 2002⁹¹ (SI 2002 No 618, as amended⁹²) (UK MDR) states in its definitions that:

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

- 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
- 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;

Active Implantable Medical Devices

3.8 According to the UK MDR⁹², “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) and 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

3.9 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.

3.10 There is no clear-cut definition for the term medical equipment:

- The World Health Organisation (WHO) defines medical equipment ⁶⁷ 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 ⁶⁸. 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.
- the MHRA classifies Borderline devices. These might not fall within the definition of a medical device but are used for a medical purpose and are in practice used and managed alongside equipment falling under the WHO definition for medical equipment. 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.
- the standard BS EN 60601-1: 'Medical electrical equipment - Part 1: General requirements for basic safety and essential performance' ²¹⁹, 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.
- the standard BS EN 61010-1: 'Safety requirements for electrical equipment for measurement, control, and laboratory use. General requirements' ²²⁰, classifies electrical laboratory equipment as equipment which measures, indicates, monitors, inspects or analyses materials, or is used to prepare materials, and includes in vitro diagnostic (IVD) equipment and notes that this equipment may also be used in areas other than laboratories, e.g. self-test IVD equipment to be used in the home.

3.11 Neither the UK Medical Devices Regulations 2002 ⁹¹ (SI 2002 No 618, as amended ⁹²) 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 considered to come within the definition of a medical device.

3.12 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 within this document, plus Borderlines with medical devices, MHRA ⁶⁹ and the EC Borderline Manual ¹⁷¹).

Software

- 3.13 Physical medical devices increasingly incorporate software while standalone software can also meet the definition of a medical device. Standalone software that can meet the definition of a medical device 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. Medical device software is used across the breadth of healthcare from primary care to the acute sector, while many solutions (e.g. 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.
- 3.14 Rapid increases in consumer computer processing power in the past 20 years has driven an equally rapid advance in the application of software in medicine. Medical device regulations have not kept pace with these advances, and are only now being updated to fully account for the risks associated with medical device software. This includes consideration of cybersecurity, interoperability, risk classification of medical device apps and the physical characteristics of the host device where appropriate. The Data Protection Act 2018 is also applicable if patient data is handled.
- 3.15 The EU has introduced EU 2017/745 Medical Devices Regulations (EUMDR). This introduces a broad sweep of changes for medical device regulation in the EU (see further chapters). For software, two of these changes are of particular significance:
- A change to the medical definition, broadening it to encompass devices intended for prediction and prognosis of disease.
 - A change to the classification of software, lowering the threshold for devices to be assigned a higher risk class.

In combination, these changes simultaneously increase the range of software that may be in scope of the regulations, and increase the requirements.

- 3.16 The EU MDR will not apply in Great Britain. However, the Northern Ireland Protocol requires that Northern Ireland (NI) continue to align with EU rules for medical devices therefore, the EU MDR will apply within NI from May 2021. However, the Northern Ireland Protocol requires that Northern Ireland (NI) continue to align with EU rules for medical devices therefore, the EU MDR will apply within NI from May 2021. The Medicines and Medical Devices Act 2021 provides the UK government with the powers to amend the current UK MDR 2002 regulations through secondary legislation. The government intends to use these powers to improve and strengthen medical device regulations, supporting patient safety, access and availability of medical devices and the attractiveness of the UK market to industry.
- 3.17 The barriers for developing and distributing software are typically lower than that of physical devices, and software can be therefore be developed and distributed widely with relative ease. There is also a lack of awareness that software may fall under the scope of medical device legislation. Taken together, these increase the risk of non-CE or non-UKCA marked software being used for a medical purpose, and off-label

use of a medical device (section 6 within this guidance document). In both cases, the liability for using the unregulated device lies with the healthcare institution using it.

- 3.18 Guidance on the current legislation from the MHRA ⁷⁰ and the EU ^{171,265} provide an excellent starting point when trying to determine whether a piece of software meets the definition of a medical device and therefore comes within scope of the regulations.

If software falls within scope of the regulations, then conformance is typically demonstrated by adherence to a set of harmonised standards. For software, the key standard is BS EN 62304²⁶⁶, BS EN ISO 14971⁹⁰, BS EN ISO 13485⁸⁴ and BS EN 62366²⁶⁷ are also important and equally apply to physical devices.

Medicines

- 3.19 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).
- 3.20 Those of these that are not explicitly discounted as a medical device, e.g. 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 ⁷¹.

4. Legal Framework, Standards, National Policy and Guidance

- 4.1 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

- 4.2 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 regulations e.g. the Health and Safety Executive.
- 4.3 UK Regulations are made under an Act of Parliament. This creates a new law or changes an existing law. An Act is a Bill that has been approved by both the House of Commons and the House of Lords and been given Royal Assent by the Monarch. Taken together, Acts of Parliament make up what is known as Statute Law in the UK. UK Transposition Regulations are a specific type of legislation that applied the requirements of European Directives into UK national regulations.

UK Legislation

- 4.4 Following the end of the EU-exit transition period, the EU Medical Devices Regulation (MDR) and In Vitro Diagnostic Medical Devices Regulation (IVDR) (see 4.12) will not be transposed into law in Great Britain. In this context, it is important to be aware of the distinction between Great Britain – England, Scotland and Wales – and the United Kingdom, which comprises Great Britain and Northern Ireland. The MDR and IVDR will not be implemented in England, Scotland and Wales. Northern Ireland will have a special status as EU rules will continue to apply there. The UK Medical Devices Regulations 2002 (as amended)⁹², which implement the Directives for active implantable medical devices, medical devices and in vitro diagnostic medical devices (IVDs) in the UK (see 4.10), continue to have effect in Great Britain.

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.:

- the UK Medical Devices Regulations 2002 (SI 2002 No 618⁹¹, as amended^{72, 92});
 - the UK General Product Safety Regulations 2005⁹³ (SI 2005 No 1803).
- 4.5 These regulations are safety regulations under the Consumer Protection Act 1987⁹⁴ (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.

- 4.6 The UK Conformity Assessment (UKCA) mark ²⁵⁰ is being introduced for certain goods being placed on the Great Britain market for which European CE marking applied (see 4.20). The UKCA mark will apply to medical devices, including IVDs, in Great Britain. The UKCA mark is not recognised in the EU or European Economic Area (EEA). Manufacturers of medical devices can use the UKCA mark voluntarily until 30 June 2023. The UK MHRA will continue to recognize European CE marking (see 4.20) until 30 June 2023. From 1 July 2023, a UKCA mark will be required in order to place a device on the Great Britain market. Manufacturers of Class I device and general IVDs can self-certify against the UKCA mark. Higher-risk medical devices and IVDs will require a UKCA certificate I from a UK Approved Body ²⁵¹ to affix the UKCA mark.
- 4.7 In addition to using the UKCA mark, manufacturers placing products on the market in Great Britain, need to appoint a UK Responsible Person (for non-UK based manufacturers) ²⁴⁹ and register with the MHRA ²⁴⁹. MHRA has published new guidance on registration requirements. MHRA will only accept device registrations from companies or UK Responsible Persons established in the UK or from Authorized Representatives based in Northern Ireland. An on-line system for registering devices has been set up (MHRA DORS ²⁵²). Registration requires information to be provided on the manufacturer, the device(s) and UK Responsible Person. The deadline for registration are:
- 1 January 2021 for manufacturers of Class I medical devices, IVDs and custom-made devices and that are either based in the UK or whose Authorized Representatives are based in Northern Ireland;
 - 1 May 2021 for active implantable medical devices, Class III medical devices, Class IIb implantable medical devices and IVD List A devices;
 - 1 September 2021 for Class IIb non-implantable medical devices, Class IIa medical devices, IVD List B devices, self-test IVD products;
 - 1 January 2022 for Class I medical devices and general IVDs from manufacturers or Authorized Representatives not based in the UK.
- 4.8 There are further statutory requirements applying in the UK under the Provision and Use of Work Equipment Regulations 1998 ⁴⁶, 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 e.g. patient hoists the Lifting Operations and Lifting Equipment Regulations 1998 ⁸⁷, commonly known as LOLER, will apply. Where work equipment involves working with ionising radiation The Ionising Radiations Regulations 2017 ³⁵ will apply.

European Union (EU) Directives

- 4.9 Within the EU market jurisdiction area an EU Directive is an agreed form of legislation that is applied to the Member States, which set out the objective or policy which the EU requires to be implemented by each state. The Member States must then pass the relevant local domestic legislation to implement the terms of the Directive within an agreed time period.

EU Medical Device Directives

4.10 From 1993 onwards, medical devices have been covered by three EU Directives which have intended to ensure that a device does not compromise the clinical condition or safety of the patient, the safety and health of users, and where applicable any third party. The Directives also ensure that a device achieves its intended purpose as designated by the manufacturer, and that any risks associated with the use of the device are acceptable when weighed against the benefits to the patient and compatible with a high level of protection of health and safety.

4.11 Medical devices fall into 1 of 3 categories, each category is governed by a separate EU directive until May 2021. These Directives were transposed into UK law by the Medical Device Regulations 2002 ⁹¹:

- Medical Devices – covered by the Medical Devices Directive (Directive 93/42/EEC) ²⁴. This Directive covers most medical devices ranging from simple bandages to orthopaedic implants and high-technology radiology equipment;
- In Vitro Diagnostic Medical Devices – covered by the In Vitro Diagnostic Medical Devices Directive (Directive 98/79/EC) ²⁵. This Directive covers any medical device, reagent, reagent product, kit, instrument, apparatus or system which is intended to be used in-vitro for the examination of substances derived from the human body, such as blood grouping reagents, pregnancy testing or Hepatitis B test kits;
- Active Implantable Medical Devices – covered by the Active Implantable Medical Devices Directive (Directive 90/385/EEC) ²⁶. This Directive covers all powered medical devices implanted and left in the human body, such as pacemakers, implantable defibrillators, implantable infusion pumps, cochlear implants and implantable neuromuscular stimulators.

EU Medical Device Regulations

4.12 The EU has revised its legal framework for regulation of medical devices. Two European Regulations – one on medical devices ²⁷ (note: this now incorporates Active Implantable Medical Devices plus stand-alone software as a medical device) and the other on In Vitro Diagnostic Medical Devices ²⁸ - were adopted by the European Council and Parliament, and entered into force in May 2017. At the end of their respective transition periods, these overwrite member state legislation previously enacted to comply with the preceding Directives.

Note 1: Medical Device Regulations - Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC ²⁷

Note 2: In Vitro Diagnostic Medical Devices - Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU ²⁸

- 4.13 The EU Regulations are intended to update the system by:
- stricter ex-ante [pre-calculated] control for high-risk devices via a new pre-market scrutiny mechanism with the involvement of a pool of experts at EU level;
 - the reinforcement of the criteria for designation and processes for oversight of Notified Bodies;
 - the inclusion of certain aesthetic devices which present the same characteristics and risk profile as analogous [similar] medical devices under the scope of these Regulations;
 - the introduction of a new risk classification system for in vitro diagnostic medical devices in line with international guidance;
 - improved transparency through the establishment of a comprehensive EU database on medical devices and of a device traceability system based on Unique Device Identification (UDI);
 - the introduction of an “implant card” containing information about implanted medical devices for a patient;
 - the reinforcement of the rules on clinical evidence, including an EU-wide coordinated procedure for authorisation of multi-centre clinical investigations;
 - the strengthening of post-market surveillance requirements for manufacturers;
 - improved coordination mechanisms between EU countries in the fields of vigilance and market surveillance;
 - up-classing the risk classification of almost all medical device software.
- 4.14 The central principle of the EU regulations is that all medical devices should be safe and perform as intended. They should achieve the performance intended by their manufacturer and be designed and manufactured in such a way that, during intended conditions of use, they are suitable for their intended purpose. In doing so, they should have risks that are accepted by the manufacturer when weighed against the benefits to the patient, and should not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons. The Global Harmonization Task Force (GHTF) guidance document: Summary Technical Documentation (STED) for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices ⁸⁸ gives some background.
- 4.15 To govern the process of demonstrating compliance, the Regulations require manufacturers to establish, implement, document and maintain a medical device quality management system e.g. BS EN ISO 13485:2016 ⁸⁹ to ensure the ongoing quality, safety and performance of their medical device or IVD medical device. Risk management should be an implicit and continuous repetitive process throughout the entire lifecycle of any device, requiring regular systematic updating. BS EN ISO 14971:2019 ⁹⁰ is the standard for medical device risk management therefore meeting the requirements of this standard can help demonstrate compliance with the Medical Device Regulations requirements

- 4.16 More information on the regulations for medical devices can be found via the European Commission Regulatory Framework. Please note that medical devices placed on the European market prior to these regulations coming into force still need to be CE marked, but do not have to conform to the requirements of the regulations, i.e. they can still be placed on the market and CE marked if they comply with the Directives before 2020/2022.
- 4.17 Within the European Union itself, the Medical Device Regulations (Regulation (EU) 2017/745) ²⁷ and the In Vitro Diagnostic Medical Devices Regulations (Regulation (EU) 2017/746) ²⁸ entered into force on 25 May 2017. Once fully applied, they will replace the medical devices, in vitro diagnostic medical devices and active implantable medical devices directives. The regulations include obligations that organisations will need to meet by 26 May 2021 for medical devices and 26 May 2022 for in vitro diagnostic devices.
- 4.18 Post May 2021 under the EU regulations, the provisions of Article 120 – Transitional Provisions ²²⁴ - apply to those devices with a CE mark under the Medical Devices Directive and with a conformity assessment certificate expiring between May 2021 and May 2024, which can be placed on the market for the duration of the certificate i.e. until its expiration date, or 27 May 2024, whichever is the sooner. However, the following restrictions apply from May 2021: the manufacturer must ensure no significant changes are made to the device, and comply with the Post Market Surveillance and Vigilance obligations of the regulations.
- 4.19 The European Commission has published a factsheet ⁸³ for healthcare professionals and health organisations which contains information about the impending changes in medical device regulations for those who buy, use and manage medical devices and for health organisations that develop medical devices for use in-house. Its document index webpage for healthcare professionals and health organisations ⁸⁴ points to additional information.

Note: Additional information:

European Commission Regulatory Framework ¹⁰⁰ information on the new regulations for Medical devices

CAMD MDR/IVDR Transition Subgroup ¹⁰¹

CE Marking

- 4.20 A CE mark (Conformité Européenne, meaning European Conformity) 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. In the main, all devices used in frontline healthcare will carry a CE mark.
- 4.21 All medical devices require being CE marked prior to being placed on the market within the European Union market jurisdiction area, with two exceptions: devices for clinical investigation and devices described as custom made i.e. 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.

- 4.22 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. Once a device has been placed on the EU market by its manufacturer, users can continue to use it until the expiry date of its respective conformity certificate, or 27 May 2024, whichever is the sooner, but these older devices will still need to meet post-market requirements of the 2017 regulations starting from 26 May 2021. This is relevant to users in Great Britain as the UK MHRA has stated that it will continue to recognize European CE marking until 30 June 2023. Therefore, in Great Britain, the recognition of CE-marked devices with certificates of conformity against the EU Directives will continue until the expiration of the certificate or 30 June 2023, whichever is the sooner.
- 4.23 Whilst 2017 EU regulations are in transition, manufacturers can still choose to CE mark their products according to the current, but outgoing, regulations. However, it is best practice for manufacturers to comply with the new regulations. Users and purchasers should be aware that devices that were placed on the market under the out-going regulations may be legitimately used and may still be available to purchase after the transition date governed by the period of validity of each respective CE marking certificate of conformity.

Devices exempt from CE marking

- 4.24 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.
- 4.25 Under Article 15 of the MDR ⁷⁴, manufacturers are required to have within their organisation a person responsible for regulatory compliance who should oversee the conformity requirements but cross checks should be made in health organisations when encountering exempted products by staff with the requisite expertise before they are introduced.
- 4.26 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 organisation, (under a Health Institution Exemption under the 2017 EU Medical Device Regulations: Regulation 2017/745); (See the MHRA Health institution exemption draft for public consultation ¹⁴²);
 - 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 ¹³⁷;

- an in vitro diagnostic medical device (IVD) for performance evaluation;
- a non-compliant device used in exceptional circumstances i.e. if there is no legitimate alternative available (humanitarian grounds via MHRA approval using the approval form: Humanitarian use of device - application form ⁷⁷.

Exceptional/concessional use of non-conforming devices

- 4.27 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. ⁷⁸
- 4.28 The supply and use of a non-conforming medical device for the treatment of a single named patient can occur 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;
 - it is for humanitarian reasons and the appropriate MHRA application form ⁷⁹ 'use of a non-UKCA/CE marked device on humanitarian grounds' has been completed and approved.

Note: Additional information:

Exceptional use of non-conforming (non-CE marked) devices ⁸⁰

- 4.29 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.
- 4.30 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.

Products without an intended medical purpose

- 4.31 The EU Medical Device Regulations: Regulation (EU) 2017/745 ²⁷ brings in clear detail concerning regulation of products which a manufacturer claims are only for aesthetic or other non-medical purposes e.g. cosmetic contact lenses, breast augmentation / implants, dermal fillers, liposuction equipment etc. but which are similar to medical devices in terms of functioning and risk profile.
- 4.32 These groups of products were included in the Medical Device Regulations: Regulation (EU) 2017/745 in Annex XVI ⁸¹ to introduce requirements around the manufacturing and surveillance of these previously unregulated products to protect the health and safety of users.

Note: Additional information:

MHRA Guidance on Products without an intended medical purpose ⁸¹

Expected Future Regulatory Changes

- 4.33 The UK regulations will be updated through the Medicines and Medical Devices Act 2021 ²⁵³. The Act gives the Secretary of State a delegated power to amend or supplement the Device Regulations in the UK, independently of the way they are regulated in EU.

Note: Detailed up-to-date information can be referenced on the MHRA's website:

Regulating medical devices in the UK ²⁴⁹

Health and Social Care Regulations

- 4.34 The Public Bodies (Joint Working) (Scotland) Act 2014 ⁹⁶ legislates for closer working and integration between Health Boards and Local Authorities and sets out:
- nationally agreed outcomes, which apply across health and social care, and for which NHS Boards and Local Authorities are held jointly accountable;
 - a requirement on NHS Boards and Local Authorities 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 ⁹⁶ - 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: Additional information:

Supporting Scottish Government standard:
Health and Social Care Standards: my support, my life ¹⁷³

Scottish Health Council Policy, Legislation and Guidance section ⁹⁷

Standards

- 4.35 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.
- 4.36 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. In the UK, such standards are identified as 'designated standards' and in the EU as 'harmonised standards'. Three lists of UK designated standards for medical devices have been published ²⁵⁴. These lists of standards apply to:
- Medical devices;
 - Active implantable medical devices;
 - In vitro diagnostic medical devices.

Quality Standards

- 4.37 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.
- 4.38 Standards can be categorised into four different groups:
- basic standards (covers broad issues and has applicability across multiple industries) e.g. ISO 9001 ¹⁰²;
 - group standards (covers the essential principles of a distinct group of equipment e.g. medical equipment) e.g. BS EN 60601-2-24:2015 ¹⁰³ 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) e.g. ISO 7886-1:2017 ¹⁰⁴ Sterile hypodermic syringes for single use - Part 1: Syringes for manual use;
 - process standards (which can cover Basic or Group) e.g. ISO 55001 ¹⁰⁵ which focuses on developing a proactive lifecycle asset management system, supports optimisation of assets and cost reductions whilst meeting performance and safety requirements.
- 4.39 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 106 which is incorporated under a Royal Charter¹⁰⁷ (and which is formally designated as the National Standards Body (NSB)¹⁰⁸ 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 and schedules in connection therewith.

Key Management Standards

- 4.40 The Medical Device Directives, the UK 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 13485:2016⁸⁹. This QMS Standard also details requirements for incorporation of risk management within the QMS.
- 4.41 BS EN ISO 14971:2019⁹⁰ 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.
- 4.42 Other suitable systems include the ISO 55000²²⁶ series, BS70000¹⁰⁹ or ISO 9001:2015¹⁰² standards.
- 4.43 Organisations using and managing medical devices and equipment must have a recognised management standard in place with regard to their equipment and device management process.

Guidance

- 4.44 Guidance is exactly what it says, a guide and can add deeper interpretation and understanding to help clarify what is described in the regulations. Following guidance is not compulsory however by doing so the health organisation generally will comply with the law.
- 4.45 MHRA publish guidance on regulation and the safe use of medical devices 2. An example of MHRA guidance on the safe use of medical devices are Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use²⁶³. 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.

- 4.46 In addition to guidance published by the MHRA, additional guidance on EU regulation of medical devices has been compiled by the EU Commission (Medical Devices Oversight Group (MDCG) ¹⁷² and the Notified Bodies Oversight Group (NBOG) ²²⁵.
- 4.47 Health Facilities Scotland published guidance ⁵⁷ that are applied to estates and facilities within NHSScotland, for example, Scottish Health Technical Memorandum (SHTM), Scottish Health Technical Notes on waste management, Scottish Health Facilities Notes (SHFN),
- 4.48 The SHTM 00 series guidance contains a suite of nine core subjects:
- Scottish Health Technical Memorandum 00: Policies and principles (applicable to all Scottish Health Technical Memoranda in this series);
 - Scottish Health Technical Memorandum 01: Decontamination;
 - Scottish Health Technical Memorandum 02: Medical gases;
 - Scottish Health Technical Memorandum 03: Ventilation systems;
 - Scottish Health Technical Memorandum 04: Water systems;
 - Scottish Health Technical Memorandum 05: Reserved for future use;
 - Scottish Health Technical Memorandum 06: Electrical services;
 - Scottish Health Technical Memorandum 07: Environment and sustainability.
 - Scottish Health Technical Memorandum 08: Specialist services
- 4.49 Health Protection Scotland (HPS) also published various guidance such as National Infection Prevention and Control Manual including Safe Management of Care Equipment.

Note: Other relevant information

HPS – Equipment decontamination and infection control precautions ¹¹²

Health Facilities Scotland (HFS) homepage – Decontamination and built environment ¹¹³

Infection Control – National Infection Prevention and Control Manual (NIPCM) ⁵⁶

Regulations, Guidance and Standards, EBME Seminar, Justin McCarthy: 2017 ⁸²

- 4.50 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

- 4.51 Additional guidance may be produced by appropriate professional organisations, for examples the NAMDET (National Association of Medical Devices Educators and Trainers) ¹³⁴, IET (The Institution of Engineering and Technology) ¹⁴ or IPEM (Institute of Physics and Engineering in Medicine) ¹².

Unique Device Identification (UDI)

UDI context

- 4.52 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.
- 4.53 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.
- 4.54 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, e.g. vehicles, publications, currency, aviation, retail, etc. but historically, this has not been formally achieved across the medical device industry globally.
- 4.55 Regulators globally have started to include requirements for unique device identification (UDI) as part of regulations, initially in the USA, with the IMDRF agreeing some principles for a UDI system in a UDI Application Guide ²⁵⁵. The European Regulations covering both medical devices and in vitro diagnostic medical devices introduce a mandatory UDI system with a supporting database (EUDAMED) and medical device nomenclature to facilitate adequate device identification of medical devices through their manufacture, distribution and use on patients.
- 4.56 Custom-made devices are not required to carry UDI.

UDI design

- 4.57 The European Commission is developing its own medical device nomenclature, based on the Italian Classificazione Nazionale Dispositivi medici (CND) medical device nomenclature to support the regulatory implementation of UDI under its EUDAMED database. Noting that in the USA, the FDA use the Global Medical Device Nomenclature (GMDN) operating under its own Global Unique Device Identification Database (GUDID), the CND nomenclature is to be mapped to the GMDN nomenclature for operators within EUDAMED.

- 4.58 As this CND based European Medical Device Nomenclature (EMDN) is not expected to be ready immediately, prior to the EU Medical Device Regulations concerning UDI entering full force and further, under the European Union (Withdrawal) Act 2018 ²⁰⁰, the UK is free to make its own medical device nomenclature arrangements. In the meantime, both the MHRA and NHS England have contracted into GMDN but in Scotland the putting in place of any interim arrangement would be a devolved matter and is unresolved at time of writing.
- 4.59 On 6 June 2019, the European Commission designated issuing entities, appointed to operate a system for assignment of UDI's Decision (EU) 2019/939 ¹⁹⁹. These comprise:
- GS1 AISBL ²⁵⁷;
 - Health Industry Business Communications Council (HIBCC) ²⁵⁸;
 - International Council for Commonality in Blood Banking Automation (ICCBBA) ²⁵⁹;
 - Informationsstelle für Arzneispezialitäten - IFA GmbH ²⁶⁰.
- 4.60 Health organisations and professionals using medical devices and in vitro diagnostic medical devices may therefore need to handle any of these four issuers UDI's; however, in practice, these devices are predominantly expected to be carrying GS1 UDI's as this option is more favoured by device manufacturers and NHSScotland has procured a national GS1 license.

UDI key structure components

- **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;
 - **Unique Device Identifier (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.
- 4.61 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.
- 4.62 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):
- **Unique Device Identifier - Device Identifier (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;
 - **Unique Device Identifier - Production Identifier (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 Software as a Medical Device (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.

UDI regulatory setting

4.63 The MHRA provides a concise overview of obligations for Health Institutions in its MHRA: Health Institutions - One Pager ⁸⁶. In summary:

- The UDI system will allow for things like safety alerts, potential recalls, as well as surveillance tasks more generally;
- For Class III implantable medical devices, health organisations should store and keep preferably by electronic means the UDI of the devices which they have supplied or with which they have been supplied;
- Health organisations may also be required to do this for other devices.

4.64 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.

- 4.65 The UDI system will have a longer phase-in time (e.g. the requirement applies for class III and implantable devices in May 2021 and class A IVDs in May 2027)
- 4.66 Within Part VIII of the UK Medical Devices (Amendments etc.) (EU Exit) Regulations 2019 ⁷², Regulations 90 to 96 adopt the body of the EU Regulations relating to UDI, reinterpreting the regulatory control element and giving the UK government authority over which standards and systems it uses in relation to UDI, with the freedom to choose not to use those prescribed within the EU Regulations.
- 4.67 The Medical Devices Regulations (Regulation (EU) 2017/745) ²⁷ contain the requirements in the following sections:
- Article 27, Unique Device Identification system;
 - Article 28, UDI database;
 - Article 29, Registration of devices;
 - Article 34, Functionality of EUDAMED;
 - Annex VI, Information to be submitted upon the registration of devices and economic operators in accordance with Articles 29(4) and 31, core data elements to be provided to the UDI database together with the DUI-DI in accordance with Articles 28 and 29, and the UDI system.
- 4.68 The In Vitro Diagnostic Medical Devices Regulations (Regulation (EU) 2017/746) ²⁸ contain similar requirements in the following sections:
- Article 24, Unique Device Identification system;
 - Article 25, UDI database;
 - Annex VI, Information to be submitted upon the registration of devices and economic operators in accordance with Articles 26(3) and 28, core data elements to be provided to the UDI database together with the UDI-DI in accordance with Articles 25 and 26 and the UDI system.
- 4.69 Under Article 103(1) of the MDR's, the European Commission formed the Medical Devices Coordination Group (MDCG). This group has produced guidance documents on UDI and on a European database on medical devices (EUDAMED). These can be accessed through the MDCG Guidance index page ¹⁷².
- 4.70 The setup is to be implemented through a new and specially commissioned European database for Medical Devices and In Vitro Diagnostic Medical Devices, called the 'European database on medical devices', (EUDAMED) ²⁰¹. This database will be publicly accessible and free to access. The European Commission intend that this will improve openness by making data available and increasing both the quantity and quality of data, and by enhancing the identification and traceability of medical devices.

- 4.71 The European Commission's roll-out timescale is laid out by its Medical Device Coordination Group (MDCG) in MDCG 2019-4 Timelines for registration of device data elements in EUDAMED ²⁰². (Note however that this may be open to revision owing to the complexity of the project.)
- 4.72 UK Medical Devices Information System (MDIS): Under the direction of the Medicines and Medical Devices Act 2021, a UK Medical Devices Information System (MDIS) is expected to be established in 2022.

The purpose of the UK MDIS is to link unique device identifier (UDI) codes to patient identifiers and other clinical information to improve patient safety and knowledge regarding the real world performance of medical devices by:

- Improving the traceability of medical devices by linking the UDI code, patient identifiers, date, procedure, location and physician in an electronic searchable database- Surgical Devices and Implants Core Data Module.
- Improving the surveillance of all medical devices within scope of the UK MDIS by linking the core data module with generic longitudinal (i.e. over time) information collated from hospital information systems - the Surgical Devices and Implants Registry Clinical Data Module
- Improving the knowledge of outcomes with medical devices for specific specialty areas by collection of additional clinical information and patient related outcomes and experience - Registry Speciality Specific Modules.

UDI impact on health organisations and providers

- 4.73 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 etc. for greater public benefit.
- 4.74 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.
- 4.75 The Scottish Government's Unique Device Identifier Programme Board has been set up to oversee the work of building an accessible, national approach to track and trace Class III and IIb implantable Medical Devices (from purchase to implantation) to improve patient safety and comply with the Medical Devices Regulations applying in the UK. The work will include amalgamating proof of concept and pilot project work that has been running across several Scottish health board areas.
- 4.76 The GS1 Healthcare User Group has published guidance in November 2019 that offers recommendations on medical device and IVD Field Safety Corrective Actions and Recalls using Unique Device Identifiers and GS1 Standards ²⁰³. A key

recommendation is the use of a pro forma spreadsheet that has been developed to exchange UDI based product information between manufacturers/suppliers, their customers and the MHRA for handling field safety corrective actions and product recalls.

- 4.77 More specific information on systems and process around UDI in Scottish health organisations and providers is anticipated from the Scottish Government in the run-up to the regulations concerning UDI entering full force.

Note 1: Additional information:

UDI design and standardisation:

IMDRF UDI Working Group: UDI Guidance, Unique Device Identification (UDI) of Medical Devices, 9 Dec 2013 ²⁰⁴

IMDRF UDI Working Group: Unique Device Identification system (UDI system) Application Guide, 21 March 2019 ²⁰⁵

MDRF UDI Working Group: Principles of Labelling for Medical Devices and IVD Medical Devices, 21 Mar 2019 ²⁰⁶

GS1: Guide on Unique Device Identification (UDI) ²⁰⁷

Note 2: Medical device nomenclature:

MedTech Europe: Medical device nomenclature for IVD Regulation (EU) 2017/746 and MD Regulation (EU) 2017/745 ²⁰⁸

EC: MDCG 2018-2 Future EU medical device nomenclature – Description of requirements ²⁰⁹

The World Health Organisation's global perspective on nomenclature of medical devices ²¹²

Note 3: Established worldwide medical device nomenclature systems:

GMDN, under GMDN Agency ²¹³

UMDNS, under ECRI Institute ²¹⁴

Note 4: Health organisation and provider resources:

Example of GS1 spreadsheet for managing field safety corrective actions ²¹⁰

NHS eProcurement Strategy, April 2014 ²¹¹

5. Roles and Responsibilities

- 5.1 In order to provide a robust system of management for medical devices and equipment, organisations must 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.
- 5.2 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.
- 5.3 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: The detail within each summary and the legislation and guidance highlighted are not exhaustive.

- 5.4 Summaries include the following roles:
- Medical Device and/or Equipment Users;
 - Chief Executive;
 - Medical Director / Person with organisational oversight of Clinical Care;
 - Responsible Director;
 - Medical Device and Equipment Risk Managers;
 - Departmental 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 (previously known as Equipment Coordinator)

Medical Device and/or Equipment Users

- 5.5 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 1998 ⁴⁶). 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, that any necessary calibration or maintenance has been performed and they have access to any necessary instructions for use;
 - 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 ²³);
 - ensuring safe storage to protect from environmental contamination.
- 5.6 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.
- 5.7 Health and Social Care professionals also provide devices which are then used by others, such as users or carers and again they are personally accountable for ensuring users and carers have received appropriate training and know how to use the device that has been provided.
- 5.8 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 ³⁹, Scottish Health Innovations Ltd (SHIL) ⁴⁰, and collaborative work opportunities with academic partner organisations, making good use of these.
- 5.9 The MHRA's guidance document, Devices in Practice: Checklists for using medical devices, MHRA June 2014 ⁴¹ provides a set of useful safety checklists for users.
- Key sections of the document to read:**
- 5.10 Sections: 2, 3, 4, 5, 6, 8.

Key legislation to be familiar with:

- UK Medical Devices Regulations 2002 (SI 2002 No 618 ⁹¹, as amended ^{92, 72});
- The Medical Devices (Amendment etc.) (EU exit) Regulations 2019 ⁷²;
- Medical Devices Regulations (Regulation (EU) 2017/745) ²⁷;
- In Vitro Diagnostic Medical Devices Regulations (Regulation (EU) 2017/746) ²⁸.

Additional guidance to be familiar with:

- MHRA Collection: guidance on using medical devices safely ⁴²;
- Devices in Practice: Checklists for using medical devices, MHRA June 2014 ⁴¹;
- Medical Device Driving Licence, NAMDET ⁴³.

Chief Executive

- 5.11 The Chief Executive has overall accountability for ensuring the organisation has 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.
- 5.12 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.
- 5.13 This also includes the following of requirements of The Duty of Candour Procedure (Scotland) Regulations 2018 ⁴⁷, as guided by the Scottish Government's Organisational duty of candour: guidance ⁵⁰.
- 5.14 It is essential they designate a senior individual e.g. a director or board member, to have specific and all-inclusive responsibility for the management of medical devices and equipment.

Key sections of the document to read:

- 5.15 Sections: 1, 2, 3, 4, 5, 8.

Key legislation to be familiar with:

- Health and Safety at Work etc. Act (HASAWA) 1974 ⁴⁴;
- Management of Health and Safety at Work Regulations 1999 ⁴⁵;
- Provision and Use of Work Equipment Regulations 1998 ⁴⁶;
- The Duty of Candour Procedure (Scotland) Regulations 2018 ⁴⁷;
- Public Contracts (Scotland) Regulations 2015 (which transpose the public procurement Directive) ²⁹;
- Procurement (Scotland) Regulations 2016 ³⁰;
- UK Medical Devices Regulations 2002 (SI 2002 No 618 ⁹¹, as amended ^{92, 72});

- Medical Devices Regulations (Regulation (EU) 2017/745) ²⁷ ;
- In Vitro Diagnostic Medical Devices Regulations (Regulation (EU) 2017/746) ²⁸ .

Additional guidance to be familiar with:

- Scottish Government CEL 35 (2010) ⁴⁸ ;
- Scottish Government CEL 43 (2009) ⁴⁹ ;
- Scottish Government CEL 05 (2012) ¹⁸ ;
- Scottish Government Organisational duty of candour: guidance ⁵⁰ ;
- Better Equipped to Care?, Audit Scotland 2004 ⁵¹ ;
- SHTM 00 Best practice guidance for healthcare engineering: Policies and Principles, Health Facilities Scotland ⁵² ;
- The National Audit Office report of 10 June 1999: The Management of Medical Equipment in NHS Acute Trusts in England ⁵³ .

Medical Director / Person with organisational oversight of Clinical Care

- 5.16 The Medical Director has a role in communicating across professional culture barriers within healthcare from a board level perspective, playing a vital role in shaping the organisation's culture and strategic vision, communicating this to front-line staff and advocating for patients and service users. In terms of medical devices and equipment, this manifests as sharing responsibility with other executive directors for strategic decisions concerning governance and service design around equipment, and duty of candour adverse event framework, managing adverse incidents/events larger than one health board etc.

Key sections of the document to read:

- 5.17 Sections: 1, 2, 3, 4, 5, 8.

Key legislation to be familiar with:

- Health and Safety at Work etc. Act (HASAWA) 1974 ⁴⁴ ;
- Management of Health and Safety at Work Regulations 1999 ⁴⁵ ;
- Provision and Use of Work Equipment Regulations 1998 ⁴⁶ ;
- Public Contracts (Scotland) Regulations 2015 (which transpose the public procurement Directive) ²⁹ ;
- Procurement (Scotland) Regulations 2016 ³⁰ ;
- UK Medical Devices Regulations 2002 (SI 2002 No 618 ⁹¹, as amended ^{92, 72});
- The Medical Devices (Amendment etc.) (EU exit) Regulations 2019 ⁷² ;
- Medical Devices Regulations (Regulation (EU) 2017/745) ²⁷ ;

- In Vitro Diagnostic Medical Devices Regulations (Regulation (EU) 2017/746) ²⁸ ;
- The Duty of Candour Procedure (Scotland) Regulations 2018 ⁴⁷

Additional guidance to be familiar with:

- Scottish Government CEL 35 (2010) ⁴⁸ ;
- Scottish Government CEL 43 DL(2009) ⁴⁹ ;
- Scottish Government CEL 05 (2012) ⁵⁴ ;
- Healthcare Improvement Scotland's Learning from adverse events through reporting and review, A national framework for Scotland: July 2018 ⁵⁵ ;
- Better Equipped to Care?, Audit Scotland 2004 ⁵¹ ;
- SHTM 00 Best practice guidance for healthcare engineering: Policies and Principles, Health Facilities Scotland ⁵² ;
- The National Audit Office report of 10 June 1999: The Management of Medical Equipment in NHS Acute Trusts in England ⁵³ ;
- Health Protection Scotland, Compendium of HAI Guidance ⁵⁶ .

Responsible Director

5.18 The senior executive with delegated responsibility for medical equipment management will be responsible for ensuring that:

- the Chief Executive is kept up to date with appropriate and timely information regarding the organisation's medical devices and equipment;
- an efficient and effective medical equipment procurement plan is in place for the organisation;
- the operational lifecycle of medical equipment is appropriately managed, monitored and controlled (preferably by a technical expert, in-house or contractor e.g. Medical Physics Manager or Clinical Engineer);
- any appropriate committee's or groups relating to medical equipment are chaired and managed accordingly e.g. 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 the document to read:

5.19 Sections: 1, 2, 3, 4, 5, 8.

Key legislation to be familiar with:

- Health and Safety at Work etc. Act (HASAWA) 1974 ⁴⁴ ;
- Management of Health and Safety at Work Regulations 1999 ⁴⁵ ;
- Provision and Use of Work Equipment Regulations 1998 ⁴⁶ ;
- Public Contracts (Scotland) Regulations 2015 (which transpose the public procurement Directive) ²⁹ ;
- Procurement (Scotland) Regulations 2016 ³⁰ ;
- UK Medical Devices Regulations 2002 (SI 2002 No 618 ⁹¹, as amended ^{92, 72});
- The Medical Devices (Amendment etc.) (EU exit) Regulations 2019 ⁷² ;
- Medical Devices Regulations (Regulation (EU) 2017/745) ²⁷ ;
- In Vitro Diagnostic Medical Devices Regulations (Regulation (EU) 2017/746) ²⁸ .

Additional guidance to be familiar with:

- Scottish Government CEL 35 (2010) ⁴⁸ ;
- Scottish Government CEL 43 (2009) ⁴⁹ ;
- Scottish Government CEL 05 (2012) ¹⁸ ;
- Better Equipped to Care?, Audit Scotland 2004 ⁵¹ ;
- The National Audit Office report of 10 June 1999: The Management of Medical Equipment in NHS Acute Trusts in England ⁵³ ;
- SHTM 00 Best practice guidance for healthcare engineering: Policies and Principles, Health Facilities Scotland ⁵² ;
- Health Protection Scotland, Compendium of HAI Guidance ⁵⁶ .

Medical Devices and Equipment Risk Managers

5.20 This officer acts in support of the Responsible Director role, in the capacity of the lead medical device risk management 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.

5.21 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 risk management expert and whose role covers those of the Medical Device Safety Officer (MDSO) as specified in:

- Section 2.1 Management responsibility in the MHRA's UK guidance document, Managing Medical Devices, MHRA 2021 ⁵⁸ ;
- by the MHRA and NHS England in directive Medical Device Alerts ²²⁹.

5.22 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 Incidents and Alerts Safety Officer or Responsible Director roles illustrated elsewhere in this guidance or may sit separately beside them.

Knowledge & skills requirements

5.23 Competency equivalence with that of the NHS Education for Scotland ¹¹⁴ supported, National School of Healthcare Science higher specialist scientists training programme curriculum in Clinical Biomedical Engineering ¹¹⁵. See also the Scottish Government's Healthcare Science webpage ¹¹⁶.

5.24 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. To underwrite this assurance, they should maintain membership of an appropriate statutory register, or voluntary register which is accredited by the Professional Standards Authority, in the same way that doctors and nurses are required to maintain GMC and NMC registration.

Role

- 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 e.g. clinical governance, clinical specialism teams, quality improvement, risk management, occupational health & 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

- 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) any medical devices and equipment safety committees. These committees may be both internal to organisations and or external, either governmental or e.g. professional body based.

Key sections of the document to read:

5.25 Sections: 1, 2, 3, 4, 5, 6, 7, 8.

Key legislation to be familiar with:

- Health and Safety at Work etc. Act (HASAWA) 1974 ⁴⁴ ;
- Management of Health and Safety at Work Regulations 1999 ⁴⁵ ;
- Provision and Use of Work Equipment Regulations 1998 ⁴⁶ ;
- Public Contracts (Scotland) Regulations 2015 (which transpose the public procurement Directive) ²⁹ ;
- Procurement (Scotland) Regulations 2016 ³⁰ ;
- UK Medical Devices Regulations 2002 (SI 2002 No 618 ⁹¹, as amended ^{92, 72});
- The Medical Devices (Amendment etc.) (EU exit) Regulations 2019 ⁷² ;
- Medical Devices Directive (Directive 93/42/EEC) ²⁴ ;
- In Vitro Diagnostic Medical Devices Directive (Directive 98/79/EC) ²⁵ ;
- Active Implantable Medical Devices Directive (Directive 90/385/EEC) ²⁶ ;
- Medical Devices Regulations (Regulation (EU) 2017/745) ²⁷
- In Vitro Diagnostic Medical Devices Regulations (Regulation (EU) 2017/746) ²⁸ ;
- The Waste Electrical and Electronic Equipment Regulations 2013 ¹⁹² .

Additional guidance to be familiar with:

- Managing Medical Devices, MHRA 2021 ⁵⁸ ;
- MHRA Collection: guidance on using medical devices safely ⁴² ;
- Scottish Government CEL 35 (2010) ⁴⁸ ;

- Scottish Government CEL 43 (2009) ⁴⁹ ;
- Scottish Government CEL 05 (2012) ¹⁸ ;
- Better Equipped to Care?, Audit Scotland 2004 ⁵¹ ;
- The National Audit Office report of 10 June 1999: The Management of Medical Equipment in NHS Acute Trusts in England ⁵³ ;
- SHTM 00 Best practice guidance for healthcare engineering: Policies and Principles, Health Facilities Scotland ⁵² ;
- Health Protection Scotland, Compendium of HAI Guidance ⁵⁶ ;
- Devices in Practice: Checklists for using medical devices, MHRA June 2014 ⁴¹ ;
- Medical Device Driving Licence, NAMDET ⁴³ ;
- <https://www.procurementjourney.scot/procurement-journey> ³¹ ;
- <https://www.gov.scot/policies/public-sector-procurement/> ³² ;
- Health Facilities Scotland Guidance ⁵⁷ ;
- Scottish Health Technologies Group (SHTG) ²⁰ .

Relevant environmental and infrastructure factors - standards guidance and legislation:

- Scottish Health Technical Memorandum 06-01: Electrical services supply and distribution Part A: Design considerations ³³ ;
- BS 7671:2018, Requirements for Electrical Installations, IET Wiring Regulations ³⁴ ;
- The Ionising Radiation (Medical Exposure) Regulations 2017 (IRMER) ³⁶ ;
- The Control of Artificial Optical Radiation at Work Regulations 2010 ³⁷ ;
- The Electromagnetic Compatibility Regulations 2016 (EMC) ³⁸ .

Departmental Managers

5.26 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 National Infection Prevention and Control Manual (NIPCM) ²³;
- 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 log book, 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 / executive leads.

5.27 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 of the document to read:

5.28 Sections: 1, 2, 3, 4, 5, 6 (Adverse Incident/Event Reporting), 7, 8.

Key legislation to be familiar with:

- Health and Safety at Work etc. Act (HASAWA) 1974 ⁴⁴ ;
- Management of Health and Safety at Work Regulations 1999 ⁴⁵ ;
- Provision and Use of Work Equipment Regulations 1998 ⁴⁶ ;
- Public Contracts (Scotland) Regulations 2015 (which transpose the public procurement Directive) ²⁹ .

Additional guidance to be familiar with:

- Scottish Government CEL 35 (2010) ⁴⁸ ;
- Scottish Government CEL 43(2009) ⁴⁹ ;
- Scottish Government CEL 05 (2012) ¹⁸ ;
- Health Facilities Scotland Guidance ⁵⁷ ;
- National Infection Prevention and Control Manual ²³ ;
- Health Protection Scotland, Compendium of HAI Guidance ⁵⁶ .

Technical Specialists

5.29 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 quality management system is in place covering all aspects of medical equipment lifecycle management, in compliance with Managing Medical Devices MHRA 2021 ⁵⁸;
- supporting the Medical Equipment Group and appropriate others with technical expertise;
- 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 Incidents and Alerts Safety Officer 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 the document to read:

5.30 Sections: 1, 2, 3, 4, 5, 6, 7, 8.

Key legislation to be familiar with:

- UK Medical Devices Regulations 2002 (SI 2002 No 618 ⁹¹, as amended ^{92, 72});
- The Medical Devices (Amendment etc.) (EU exit) Regulations 2019 ⁷²;
- In Vitro Diagnostic Medical Devices Directive (Directive 98/79/EC) ²⁵;
- Medical Devices Regulations (Regulation (EU) 2017/745) ²⁷;
- In Vitro Diagnostic Medical Devices Regulations (Regulation (EU) 2017/746) ²⁸;

- Public Contracts (Scotland) Regulations 2015 (which transpose the public procurement Directive) ²⁹ ;
- Procurement (Scotland) Regulations 2016 ³⁰ .

Additional guidance to be familiar with:

- Managing Medical Devices, MHRA 2021 ⁵⁸ ;
- MHRA Collection: guidance on using medical devices safely ⁴² ;
- Scottish Government CEL 35 (2010) ⁴⁸ ;
- Scottish Government CEL 43 (2009) ⁴⁹ ;
- Devices in Practice: Checklists for using medical devices, MHRA June 2014 ⁴¹ ;
- Medical Device Driving Licence, NAMDET ⁴³ ;
- <https://www.procurementjourney.scot/procurement-journey> ³¹ ;
- <https://www.gov.scot/policies/public-sector-procurement/> ³² ;
- Scottish Government CEL 05 (2012) ¹⁸ ;
- Health Facilities Scotland Guidance ⁵⁷ ;
- Scottish Health Technologies Group (SHTG) ²⁰ .

Relevant environmental and infrastructure factors - standards guidance and legislation:

- Scottish Health Technical Memorandum 06-01: Electrical services supply and distribution Part A: Design considerations ³³ ;
- BS 7671:2018, Requirements for Electrical Installations, IET Wiring Regulations ³⁴ ;
- The Ionising Radiations Regulations 2017 ³⁵ ;
- The Ionising Radiation (Medical Exposure) Regulations 2017 (IRMER) ³⁶ ;
- The Control of Artificial Optical Radiation at Work Regulations 2010 ³⁷ ;
- The Electromagnetic Compatibility Regulations 2016 (EMC) ³⁸ .

Specialist Multi-disciplinary and Professional Expert Groups

- 5.31 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, e.g. Medical Device Equipment Management Group; Clinical Governance Group etc. 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, e.g. NHSScotland Shared Services Clinical Engineering Programme ⁶¹, and National Managed Diagnostic Networks, e.g. MPNet ⁶².

Key sections of the document to read:

5.32 Sections: 1, 2, 3, 4, 5, 6 (Adverse Incident/Event Reporting), 7, 8.

Key legislation to be familiar with:

- Provision and Use of Work Equipment Regulations 1998 ⁴⁶ ;
- Public Contracts (Scotland) Regulations 2015 (which transpose the public procurement Directive) ²⁹ ;
- Procurement (Scotland) Regulations 2016 ³⁰ ;
- UK Medical Devices Regulations 2002 (SI 2002 No 618 ⁹¹, as amended ^{92, 72});
- The Medical Devices (Amendment etc.) (EU exit) Regulations 2019 ⁷² ;
- Medical Devices Regulations (Regulation (EU) 2017/745) ²⁷ ;
- In Vitro Diagnostic Medical Devices Regulations (Regulation (EU) 2017/746) ²⁸ .

Additional guidance to be familiar with:

- Scottish Government CEL 35 (2010) ⁴⁸ ;
- Scottish Government CEL 43 (2009) ⁴⁹ ;
- Scottish Government CEL 05 (2012) ¹⁸ ;
- Better Equipped to Care?, Audit Scotland 2004 ⁵¹ ;
- The National Audit Office report of 10 June 1999: The Management of Medical Equipment in NHS Acute Trusts in England ⁵³ ;
- Health Facilities Scotland Guidance ⁵⁷ ;
- Health Protection Scotland, Compendium of HAI Guidance ⁵⁶ .

Staff who procure medical devices or equipment

5.33 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 & skills requirements of procurement officers in relation to this guidance

5.34 The Scottish Government's National Procurement Competency Framework ²⁴⁷ 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

5.35 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.

Pre-acquisition checklist for purchasers

5.36 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) ¹⁸] 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 form (PAQ) ⁶⁶ fit with the acquisition brief, including product declaration of conformity?;
- is the product clinically and/or cost effective? This may be validated by consulting Healthcare Improvement Scotland's Technologies and medicines webpage ¹⁹, where the organisation can seek advice and guidance from Scottish Health Technologies Group (SHTG) ²⁰, the Scottish Intercollegiate Guidelines Network (SIGN) ²¹ and Healthcare Improvement Scotland's NICE Guidance and Scotland ²² 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 National Infection Prevention and Control Manual ²³ 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 Pre-acquisition questionnaire form (PAQ) ⁶⁶;
- 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 pre-acquisition questionnaire form (PAQ) ⁶⁶;
- 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 & conditions?
- can the purchase be aggregated with other concurrent similar requirements?

5.37 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. For further guidance, please consult the Framework Agreement page. 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

5.38 What is the anticipated total spend over the lifetime of this requirement including any extensions excl. VAT e.g. whole life cost, ongoing cost, support costs?

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

Key sections of the document to read

5.40 Sections: 2, 3, 4, 5, 6 (Procurement and Acquisition, Adverse Incident/Event Reporting, Decommissioning, Recycling and Disposal, Transfer of Ownership).

Key legislation to be familiar with:

- UK Medical Devices Regulations 2002 (SI 2002 No 618 ⁹¹, as amended ^{92, 72});
- The Medical Devices (Amendment etc.) (EU exit) Regulations 2019 ⁷²;
- In Vitro Diagnostic Medical Devices Directive (Directive 98/79/EC) ²⁵;
- Medical Devices Regulations (Regulation (EU) 2017/745) ²⁷;
- In Vitro Diagnostic Medical Devices Regulations (Regulation (EU) 2017/746) ²⁸;
- Public Contracts (Scotland) Regulations 2015 (which transpose the public procurement Directive) ²⁹;
- Procurement (Scotland) Regulations 2016 ³⁰.

Additional guidance to be familiar with:

- Scottish Government Procurement Journey Update ³¹;

- Scottish Government Public Sector Procurement ³²

Relevant environmental and infrastructure factors - standards guidance and legislation:

- Scottish Health Technical Memorandum 06-01: Electrical services supply and distribution Part A: Design considerations ³³;
- BS 7671:2018, Requirements for Electrical Installations, IET Wiring Regulations ³⁴;
- The Ionising Radiations Regulations 2017 ³⁵;
- The Ionising Radiation (Medical Exposure) Regulations 2017 (IRMER) ³⁶;
- The Control of Artificial Optical Radiation at Work Regulations 2010 ³⁷;
- The Electromagnetic Compatibility Regulations 2016 (EMC) ³⁸

Incidents and Alerts Safety Officer

All NHS Boards and Local Authorities should have a role within their organisation entitled Incidents and Alerts Safety Officer. In accordance with CEL 43(2009) 49, 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, reporting to IRIC ⁶³ as appropriate;
- receiving emails from Health Facilities Scotland (HFS) 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 Health Facilities Scotland (HFS);
- promoting equipment safety by staff education and training in conjunction with HFS;
- building and maintaining communication links with HFS and with relevant technical specialists / relevant exec team member (for clinical groups);
- attending Incidents and Alerts Safety Officers' conferences and seminars and periodic Incidents and Alerts Safety Officer group national meetings; and
- monitoring internal cascade systems to ensure alerts/notices are received, assessed and acted upon.

Key sections of the document to read:

5.41 Sections: 1, 2, 3, 4, 5, 6 (Adverse Incident/Event Reporting), 7, 8.

Key legislation to be familiar with:

- UK Medical Devices Regulations 2002 (SI 2002 No 618 ⁹¹, as amended ^{92, 72});
- The Medical Devices (Amendment etc.) (EU exit) Regulations 2019 ⁷²;
- In Vitro Diagnostic Medical Devices Directive (Directive 98/79/EC) ²⁵;
- Medical Devices Regulations (Regulation (EU) 2017/745) ²⁷;
- In Vitro Diagnostic Medical Devices Regulations (Regulation (EU) 2017/746) ²⁸

Additional guidance to be familiar with:

- Managing Medical Devices, MHRA 2021 ⁵⁸;
- MHRA Collection: guidance on using medical devices safely ⁴²;
- Scottish Government CEL 35 (2010) ⁴⁸;
- Scottish Government CEL 43 (2009) ⁴⁹;
- Scottish Government CEL 05 (2012) ¹⁸;
- Devices in Practice: Checklists for using medical devices, MHRA June 2014 ⁴¹;
- Medical Device Driving Licence, NAMDET ⁴³;
- Health Facilities Scotland Guidance ⁵⁷.

6. Management of Equipment and Devices

Management

- 6.1 Risk management is a key component in demonstrating regulatory compliance for managing medical devices.
- 6.2 The requirements for risk management concerning the manufacture of medical devices were laid out in the UK Medical Devices Regulations 2002 (SI 2002 No 618⁹¹, as amended^{92, 72});
- 6.3 Organisations providing and using health technology, medical devices and equipment must have a robust recognised management standard 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 1998¹⁷⁸, place duty around this on those who own, operate or have control over all work equipment.
- 6.4 Scottish Government CEL 35 (2010)⁴⁸ 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 report of 10 June 1999: The Management of Medical Equipment in NHS Acute Trusts in England⁵³, 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 National Audit Office'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 Quality Management System (QMS) are following long established best practice. A commonly used standard is BS EN ISO 13485:2016⁸⁹.
- 6.5 Awareness of BS EN ISO 14971:2019⁹⁰ should also be considered as the UK's national standard, adopting 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.
- 6.6 Other suitable systems include ISO 9001: 2015¹⁰², ISO 55000²²⁶ and BS70000¹⁰⁹. The United Kingdom Accreditation Service (UKAS) is currently running a Medical Physics and Clinical Engineering (MPACE)¹²⁵ accreditation pilot for BS70000 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)⁶², is to await the outcome of the UKAS pilot before championing any one particular quality standard.

- 6.7 It is vital that organisations are proactive with regard 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 and reporting requirements ²¹⁸.
- 6.8 The NHSScotland Shared Services Clinical Engineering Programme's National Medical Equipment Framework Project 61 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.
- 6.9 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 ²⁶⁴. 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.

Procurement and Acquisition

Evaluation of new and existing technologies

- 6.10 The benefits to evaluating new and existing technologies are:
- the promotion and faster uptake of new medical technologies within the NHS and Health and Social Care;
 - the encouragement of collaborative research, between both industry and the healthcare providers, to generate evidence on the clinical utility (clinical usefulness), cost effectiveness and/or healthcare system benefits of selected technologies;
- 6.11 It is important that clinicians, scientific, technical colleagues and fellow Technical User Group (TUG) stakeholders are involved as early as possible in the procurement stage and throughout the equipment life management process.
- 6.12 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

(including reference to clinical and cost effectiveness). 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.

- 6.13 The Scottish Health Technologies Group (SHTG) ²⁰ is a national HTA agency. It provides evidence support and advice to NHSScotland on the use of new and existing health technologies which are not medicines and which are likely to have significant implications for people's care. SHTG accepts referrals for health technology assessment via their Scottish Health Technologies Group (SHTG) ²⁰ website.

Note: Additional information:

NICE Medical Technologies Evaluation Programme Guide ¹²⁷

HIS Procurement information ²²¹

CEL 05 (2012) 18 on Technical User Groups (TUG)

Purchasing of Commercial Products

- 6.14 Led by the Scottish Government, the Scottish Model of Procurement ¹²⁸ 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

- 6.15 The procurement 'journey' can follow any one of three routes:

- those purchases under £50k;
- those between £50k and the (OJEU) threshold (the Official Journal of the European Union, the home to all public sector contracts above a certain value) as of 1st January 2020 set at £122,976 for Scottish NHS Boards ²³¹ as Central Government Authorities under Schedule 1 of The Public Contracts (Scotland) Regulations 2015 ²⁹, and as amended;
- those above the OJEU threshold.

- 6.16 The £50k threshold is written into the Procurement Reform Act (Scotland) 2014 ¹²⁹ 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 – Preparing for the UK Leaving the EU, Action Note PPN 02/19(2) March 2019 ¹³⁰

Note: Additional Information: Using the link listed below, follow the appropriate pathway.

<https://www.procurementjourney.scot/procurement-journey> 31

Terms and Conditions of Supply

6.17 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.

Storage and distribution

- 6.18 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.
- 6.19 There is a risk of equipment being damaged or stolen or it being used before safety checks are completed.
- 6.20 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 e.g. secure storage cabinets, carts.
- 6.21 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 etc.) where practical with access limited to only those necessary individuals.
- 6.22 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.
- 6.23 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.

- 6.24 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

- 6.25 Whenever an order has been raised, the details of any medical equipment ordered i.e. order number / ward / department / site must be forwarded by Procurement or the Department/ Ward Manager to the organisation's competent persons e.g. Medical Physics or Joint Loan Equipment Store. This will allow it to be recorded into the organisations medical equipment management system.
- 6.26 Once received, organisations must check that all equipment and accessories ordered including operating and service manuals have been delivered complete and undamaged.
- 6.27 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.
- 6.28 All such equipment, must be delivered to the relevant commissioning department, e.g. 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.
- 6.29 Once acceptance testing is complete e.g. electrical safety testing, the equipment details should be updated within the organisation's asset register by the competent persons following the local agreed process e.g. unique identifier number / radio-frequency identification tag or label attached.
- 6.30 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.

Education, Training and Instruction

Education and training (staff, carers and patients)

- 6.31 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.
- 6.32 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

- 6.33 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.
- 6.34 On top of this, and as part of their continual professional development (CPD) activities, staff may attend conferences 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.
- 6.35 Consideration should be given to eLearning resources for medical devices and equipment accessible through eLearning portals and local face-to-face and hands-on educational programmes.
- 6.36 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.

Training specific to the equipment/device

- 6.37 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.
- 6.38 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 concerning certain products.
- 6.39 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.
- 6.40 Any shortcomings in the instructions should be reported as an adverse incident (following local procedures).

Note: Additional Information:

Version 2.0

See Section 6 of MHRA Guidelines Managing Medical Devices:2021 ⁵⁸

See: National Association of Medical Device Educators and Trainers (NAMDET) 134, Medical Devices Drivers Licence (MDDL) ⁴³

In-House Manufacturing

What are custom made and in-house manufactured devices?

- 6.41 The MHRA guidance Custom Made Devices ¹³⁵ 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.
- 6.42 In-house manufactured devices ¹³⁶ 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 Quality management system of the manufacturing process, including reviewing and risk management etc, should be in place, to comply with the relevant Essential Requirements of the UK Medical Device Regulations.
- 6.43 Institute of Physics and Engineering in Medicine produced 'Best-practice guidance for the in-house manufacture of medical devices and non-medical devices ²⁶⁸, 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.

What is a clinical investigation?

- 6.43 The MHRA guidance clinical investigations of medical devices ¹³⁷ 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.
- 6.44 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.

What is a legal entity?

- 6.45 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.

6.46 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.

6.47 Manufacturers of custom-made devices shall:

- Comply with the Essential Requirements (UK MDR (SI 2002 No 618 ⁹¹, as amended ^{92, 72});
- establish, document, implement and maintain, keep up to date and continually improve a quality management system.;
- Draw up a Statement confirming that the custom-made device to the Essential Requirements (UK MDR (SI 2002 No 618 ⁹¹, as amended ^{92, 72}). Examples of custom-made device statement can be found in MHRA guidance¹³⁵;
- Draw up technical documentation (UK MDR (SI 2002 No 618 ⁹¹, as amended ^{92, 72});
- Draw up Post Market Clinical Follow Up (PMCF) plan;
- Report any Vigilance case (UK MDR (SI 2002 No 618 ⁹¹, as amended ^{92, 72}).

Usage

6.48 The user should use the devices and equipment in accordance with manufacturer instructions and with local procedure.

6.49 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.

6.50 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 HSE document INDG236, Maintaining portable electric equipment in low-risk environments ²⁴⁸ ;
- 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.

- 6.51 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.
- 6.52 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.
- 6.53 When a fault, discrepancy or issue is detected with the device, follow the local procedure for reporting and the actions dictated.
- 6.54 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

- 6.55 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 trials. This vigilance system is administered by the MHRA ²¹⁵ 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.
- 6.56 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 ⁶³ in Scotland but the MHRA ²¹⁵ 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?

- 6.57 Healthcare Improvement Scotland(HIS) defines an Adverse Event on its Learning from adverse events website ²³² 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
- 6.58 Health Facilities Scotland (HFS) defines an Adverse Incident on its IRIC Adverse Incidents webpage ²³³. 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. HFS issues a Safety Action Notice outlining system and procedure requirements relating to management

of adverse incidents (National adverse incident reporting and safety alert systems for medical devices, estates & facilities, and social care equipment SAN(SC)2001²³⁴).

- 6.59 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 e.g. to the Health & Safety Executive under the Reporting of Injuries Diseases and Dangerous Occurrences Regulations 2013 (RIDDOR)¹⁷⁴. Near misses should be managed in accordance with local policy.

What are the causes of adverse incidents/events?

- 6.60 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, misuse, inadequate maintenance or failure to plan for replacement.

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

- 6.61 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, e.g. 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.

Guidance on reporting systems

- 6.62 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.
- 6.63 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 Devices⁵⁸ and CEL 35 (2010)⁴⁸;
- Incidents and Alerts Safety Officer responsibilities;
- the process for receiving, evaluation 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.

Reporting to external agencies

6.64 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.

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 Executive⁶ as set out in the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR)^{174, 235};
- events involving health, social care, estates and facilities equipment to the Incident Reporting and Investigation Centre (IRIC)⁶³ within Health Facilities Scotland as set out in CEL 43 (2009)⁴⁹;
- suicides of individuals in contact with mental health services to Healthcare Improvement Scotland³;
- significant Adverse Event Reviews commissioned for category 1 events to Healthcare Improvement Scotland;
- sudden deaths associated with medical or dental care to the Procurator Fiscal²³⁷;
- information governance events to the eHealth Division²³⁹ within Scottish Government and the Information Commissioners Office²⁴⁰;
- ionising radiation adverse events to the Warranted Inspector for IR(ME)R²⁴¹;

[Source: HIS Learning from adverse events: A national framework (3rd Edition)⁵⁵]

6.65 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.

- 6.66 The Scottish Government Letter CEL 43(2009)⁴⁹ and its addendum¹¹⁷ 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.
- 6.67 Health Facilities Scotland's Incident Reporting and Investigation Centre (IRIC)⁶³ provide that central co-ordination. IRIC is a specialist safety and risk management unit and its mission is to improve the safety of equipment and facilities in Scotland's health and social care services. It does this by delivering two national services to Scotland's NHS boards and local authorities. Further information on IRIC can be found on their website⁶³.

Adverse incident/event learning and improvement

- 6.68 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'¹²³ highlights the process and details of how this system should be employed and how we can improve our services by following this systematic approach.
- 6.69 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.
- 6.70 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.
- 6.71 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 Community of Practice¹²⁴ page. Organisations are encouraged to share

learning from events. More detailed of programme works and requirements can be found in HIS learning from adverse events website¹²³.

- 6.72 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.

The implementation guidance has been published in Scottish Government website (<https://www.gov.scot/publications/organisational-duty-candour-guidance/>) and the duty of candour e-learning module is available on Turas.

- 6.73 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.

- 6.74 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 Community of Practice ¹²⁴ page.

What is a safety alert/notice?

- 6.75 Safety alerts/notice 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.

- 6.76 Few organisations such as HSE, HIS, HFS, HPS etc. publish and distribute safety alerts/notices to NHSScotland and Local Authorities.

- 6.77 IRIC distributes the alerts/notices through the Incidents and Alerts Safety Officer 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.

- 6.78 Incidents and Alerts Safety Officers carry out a subsequent local distribution which targets the affected services, wards and departments. Locally any identified actions should be taken and monitored and when required escalated to senior management with appropriate records being kept. HFS hold a current list of Incidents and Alerts Safety Officers however the responsibility to report any detail changes in writing to HFS immediately rests with the Boards and Local Authorities.

National Patient Safety Alert

- 6.79 Engaging the four nations the UK Regulator MHRA develop safety alerts including National Patient Safety Alerts/NatPSA) ^{256, 262} for both medical devices and equipment, NSS (IRIC) lead on the dissemination of such alerts in Scotland. In "Unusual Circumstances" where the alert is considered to be not appropriate in Scotland, NSS (IRIC) will engage the "relevant" Scottish Government colleagues for approval of any variation in action.

- 6.80 IRIC is responsible for distributing NatPSA s to all NHS Boards and local authorities in Scotland. Once distributed, copies of the alert can be downloaded from the MHRA website ¹⁹⁵.

Estates and Facilities Notice (EFN)

- 6.81 IRIC partners with NHS Improvement and counterparts in other devolved health systems to publish 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.
- 6.82 IRIC distributes EFNs to all NHS Boards and local authorities in Scotland. Once distributed, copies of the notice can be downloaded from the HFS website Publications page ¹⁹⁶.

Safety Action Notice (SAN)

- 6.83 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 in England by NHS Improvement.
- 6.84 IRIC distributes SANs to all NHS Boards and local authorities in Scotland. Once distributed, copies of the SAN can be downloaded from the HFS website Publications page ¹⁹⁶.

Manufacturers Field Safety Notice (FSN)

- 6.85 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, e.g. supplier. FSNs give information about what needs to be done to reduce the specified risks of using the medical device.
- 6.86 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 ¹⁹⁵.
- 6.87 On receipt, all FSNs should be routed through the Incidents and Alerts Safety Officer as a single contact point. The Incidents and Alerts Safety Officer has a critical role in ensuring FSNs are appropriately distributed, acted upon and documented.
- 6.88 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?

- 6.89 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 ¹¹⁷.

What is the National Safety Alert Oversight Group (NSAOG)?

6.90 This group was established in 2015 when it was agreed that a group should be established to increase information sharing and collaboration between organisations responsible for handling alerts/notices to Scotland. Member organisations are:

- Healthcare Improvement Scotland;
- Health Facilities Scotland;
- Health Protection Scotland (HPS);
- National Procurement;
- Scottish Government;
- Yellow Card Centre Scotland;
- Incidents and Alerts Safety Officers representing NHS Boards and local authorities.

Further information can be found on the NSAOG website ²⁴⁵.

Maintenance and Repair of Reusable Devices

6.91 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.

6.92 Before maintenance and repair or refurbishment, all devices must be decontaminated (as appropriate) following Scottish Health Memorandum guidance ¹⁶³, infection control standards in the Health Protection Scotland, Compendium of HAI Guidance ⁵⁶ and Managing Medical Devices, MHRA 2021 ⁵⁸ and appropriate maintenance and repair and decontamination records kept.

Maintenance

6.93 The health 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 manufacturers specification.

6.94 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 quality management system.

6.95 Where other regulations apply e.g. The Ionising Radiations Regulations 2017³⁵, or the Lifting Operations and Lifting Equipment Regulations 1998⁸⁷, mandatory tests should be carried out in addition to the maintenance and testing recommended by the manufacturer in the instructions for use supplied with the device as recommended through HSE guidance in respect of the Provision and Use Work Equipment 1998¹⁷⁸, not instead of them.

Repair and refurbishment

6.96 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.

6.97 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

6.98 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. 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.

- 6.99 There are various reasons for off-label use e.g. 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 or using a product that is not UKCA/CE marked as a medical device for a medical purpose.
- 6.100 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 e.g. any changes to process or impact on patient with a minimal being an annual review.
- 6.101 In relation to risk assessment under The Management of Health and Safety at Work Regulations 1999 ⁴⁵, the HSE state that a Competent Person ¹⁴³ 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 e.g. clinical governance group and/or the Medical Device Equipment Management Group.
- 6.102 For clarity, it should be noted that health and safety related legislation ¹⁴⁴ is also applicable to employers providing equipment (including devices) for use in the workplace.

Note: Additional Information:

MHRA Guide ¹⁴⁵

HSE Management of health and safety at work ¹⁴⁶

Use of Non-Medical Devices for Medical Purposes

- 6.103 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.
- For detailed information about Borderlines, consult the MHRA guidance on Borderlines with medical devices ⁶⁹;
 - 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 and their Re-manufacture and Reprocessing

Single-use

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

Note:

MHRA leaflet - Single-use devices/equipment ¹⁴⁷

Single patient use

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

Reprocessing of single-use devices

- 6.106 Single-use devices are designed to be used on an individual patient during a single procedure and then discarded. The MHRA accept that reprocessing of single use devices has been common practice, however, 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 ¹⁴⁸, could expose patients and staff to risks which outweigh the perceived benefits of using the devices.
- 6.107 When a single use device is supplied non-sterile and needs to be sterilized prior to use, the sterilization process should be in accordance with the manufacturer's instructions.

Re-manufacturing of single-use devices

- 6.108 Re-manufacturing of single-use devices is where a company obtains a CE mark for the re-manufacturing of single-use devices. 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.
- 6.109 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.
- 6.110 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: Additional Information:

MHRA guidance:

UK Guidance on Re-manufacturing of Single Use Medical Devices ¹⁴⁹

Reprocessing/Decontamination

- 6.111 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. Spaulding classification is generally used.

Classification	Type of Procedure	Example 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, vaginal specula, 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 where necessary)

Table 1: Spaulding Classification

- 6.112 Detailed guidance on decontamination can be found in HFS website.

Note: Further information:

See: Health Facilities Scotland's Guidance documents on decontamination ¹⁵⁰

See: Decontamination and Infection Control ¹⁵¹

Loaning Equipment

Loaning equipment out

- 6.113 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 instructions for use, must also be provided.

- 6.114 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.
- 6.115 Understanding the time and personnel commitment needed to ensure successful and safe delivery would be useful for installation. This should take into account, e.g. 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.
- 6.116 This information should be documented and retained within a formal delivery and commissioning log process.

Collection of loaned-out equipment

- 6.117 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.
- 6.118 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 e.g. any decontamination requirements.

Loaning equipment in

- 6.119 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 Health Facilities Scotland's master indemnity agreement web page ¹⁷⁵ 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.
- 6.120 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

- 6.121 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 & Responsibilities GUID 5002 ¹⁶³ is in place to minimise Healthcare Associated Infections (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 ECG recorder.

- 6.122 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: Further information: National Decontamination Guidance on Loan Devices ¹⁶³

Decommissioning, Recycling and Disposal

Decommissioning

- 6.123 Decommissioning aims to make devices safe and unusable, while minimising damage to the environment. Any device deemed unfit for use should be decommissioned.
- 6.124 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.
- 6.125 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.
- 6.126 For devices that are mobile or housed in general facilities, safety checks, such as power disconnection and cooling system disconnection, should be carried out.
- 6.127 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 ³⁵ and with The Ionising Radiation (Medical Exposure) Regulations 2017 ³⁶.
- 6.128 If a device stores patient identifiable data, this should be certified as securely erased to an appropriate standard, such as BS ISO/IEC 15408 ²²⁷ and British HMG Infosec Standard 5 (IS5) ²⁶¹, before disposal. Data on any device should be forensically unrecoverable i.e. patient data must be permanently wiped and unrecoverable.

Recycling and disposal

- 6.129 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, e.g. a waste wheelchair would be handled differently from a used single use surgical tool.
- 6.130 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 3 (SHTN 3) ¹⁶⁵, available from the HFS web site ¹⁹⁶.

- 6.131 All medical devices that are to be disposed of, must be recorded, handled and stored in accordance with Scottish Health Protection Notice (SHPN) ⁵⁷ standards and in accordance with Health and Safety, Carriage of Dangerous Goods Regulations ²²⁸.
- 6.132 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 ¹⁵²).
- 6.133 Excess electrical medical devices and equipment may be returned to the original supplier under The Waste Electrical and Electronic Equipment Regulations (WEEE) ²⁴⁶, such as (non-infected) dialysis machines, analysers, medical freezers and cardiology equipment.

Note: Additional information:

HFS Guidance for Disposal and Recycling of Medical Devices ¹⁶⁶

SEPA Export of Waste Medical Devices ¹⁶⁷

SEPA WEEE Regulations Waste decision tree ¹⁶⁸

Donation of equipment - global citizenship programme

- 6.134 It is important to make a donation through NHSScotland Global Citizenship Programme ¹⁵². The first port of call of disposal of suitable surplus equipment to follow the organisation policy. If this is not available, each organisation must incorporate this into their local policy. Determination of suitability is critical in ensuring that the resources required to handle projects are kept in scale with the overall benefits offered through the programme.
- 6.135 In its International Development Strategy ¹⁵³, the Scottish Government highlights that the Beyond Aid Agenda's holistic approach to sustainable development requires all government, local government, public bodies, private sector, communities and individuals to adapt their behaviour in support of the UN Sustainable Development goals ¹⁵⁴, including global citizenship ¹⁵⁵. Focus is on, but not limited to, an identified cohort of Partner Countries from the world's developing countries.
- 6.136 Global citizenship is about encouraging people to develop the knowledge, skills and values they need to engage with others in the belief that collectively we can make a difference.
- 6.137 A Global Citizen has been described by Oxfam ¹⁵⁶ as 'someone who understands the wider world and their place in it, taking an active role in their community and working with others to make our planet more equal, fair and sustainable'.
- 6.138 The NHSScotland Global Citizenship Programme Board ¹⁵⁷ and the NHSScotland Global Citizenship Champions Network ¹⁵⁸ identified the donation of surplus medical equipment to partner countries as a priority, acknowledging the number of challenges to be overcome.
- 6.139 The wider guidance available on donating equipment to low and middle income countries notes that it is important to ensure that only appropriate medical devices

and supplies are donated. Although donations may seem well intentioned, to the recipient many may not be beneficial in practice.

- 6.140 Organisations may dispose of surplus medical equipment that may be suitable for the Global Citizenship Programme. Prior to dispatch, any equipment suitably selected for donation must be checked and tested to ensure that its condition is within the manufacturer's acceptable operating tolerances. Consideration should be made on the suitability of the donation regarding the logistics of its transfer and storage plus on testing, maintenance, availability of spare parts, ongoing manufacturer instruction provision, training and support and its ultimate disposal impact at its destination.
- 6.141 Guidance on the categories of equipment that may be useful in a low and middle income country setting (noted by WHO⁶⁸) can be obtained from the Global Citizenship Programme Board Surplus Kit Working Group. As a wide range of organisations including the NHSScotland consider overseas donations without being aware of all the steps required, a new Short Life Working Group has been formed to develop a Scotland wide framework, reporting to the Chief Medical Officer's Global Health Executive Committee. This will be available late 2021. Those who wish engagement should contact the Global Health Coordination Unit.

Note: Additional information:

The Scottish Medical Physics and Clinical Engineering Diagnostic Network (MPNET)⁶² acts as an 'umbrella' for collaborative working amongst Medical Physics and Clinical Engineering departments in NHS Scotland.

Getting involved in Global Citizenship ¹⁵⁹

Global Citizenship in the Scottish Health Service ¹⁶⁰

Tropical Health and Education Trust's toolkit for medical equipment donations to low-resource settings ¹⁶¹

World Health Organisation - Donation of medical equipment ¹⁶²

- 6.142 Clinical and Biomedical Engineering services can help by:
- identifying local medical equipment being replaced, due for replacement or surplus to requirements that may be useable for donation to partner countries and notifying the Global Citizenship Surplus Kit Working Group, either directly or through MPNET ⁶², who will reconcile the suitability of the equipment offered with the needs of the partnership countries along with their ability to put the equipment into clinical use;
 - providing practical/technical advice/support including provision of technical manuals;
 - embedding 'Global Citizenship' into their medical equipment disposal policies by considering donation as the first step with respect to the disposal aspect of medical equipment life-cycle management.

Transfer of Ownership

- 6.143 Refer to guidance in Section 10.4, Sale or donation for reuse, of Managing Medical Devices, MHRA 2021 ⁵⁸.

Replacement Process

- 6.144 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 can not 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.

7. Managing Equipment in Community Settings

Use of Medical Devices/Equipment in Community Settings

- 7.1 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.
- 7.2 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 ²²².
- 7.3 This system can provide early alerts from the power or water companies to possible outages or support in the event of an unexpected outage.
- 7.4 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: Additional Information:

Good Practice Guide for the Provision of Community Equipment Services ¹⁶⁹

COSLA Protocol for the Provision of Equipment in Care Homes ¹⁷⁰

Health Institution Exemption (HIE) ¹⁴¹

8. References

Legislation

Scottish legislation

Ref No.	Title of document / Location	Publisher	Website Link to Document
29	The Public Contracts (Scotland) Regulations 2015	Scottish Government	http://www.legislation.gov.uk/ssi/2015/446/contents/made
30	Procurement (Scotland) Regulations 2016	Scottish Government	http://www.legislation.gov.uk/sdsi/2016/9780111030868/contents
47	The Duty of Candour Procedure (Scotland) Regulations 2018	Scottish Government	http://www.legislation.gov.uk/ssi/2018/57/made
96	Public Bodies (Joint Working) (Scotland) Act 2014	Scottish Government	https://www2.gov.scot/Topics/archive/Adult-Health-SocialCare-Integration/About-the-Bill
129	Procurement Reform (Scotland) Act 2014	Scottish Government	https://www.legislation.gov.uk/asp/2014/12/contents

UK legislation

Ref No.	Title of document / Location	Publisher	Website Link to Document
35	The Ionising Radiations Regulations 2017	UK Government	http://www.legislation.gov.uk/ukxi/2017/1075/contents/made
36	The Ionising Radiation (Medical Exposure) Regulations 2017	UK Government	http://www.legislation.gov.uk/ukxi/2017/1322/regulation/1/made
37	The Control of Artificial Optical Radiation at Work Regulations 2010	UK Government	http://www.legislation.gov.uk/ukxi/2010/1140/contents
38	The Electromagnetic Compatibility Regulations 2016	UK Government	http://www.legislation.gov.uk/ukxi/2016/1091/contents
44	Health and Safety at Work etc. Act 1974	UK Government	https://www.legislation.gov.uk/ukpga/1974/37/introduction
45	The Management of Health and Safety at Work Regulations 1999	UK Government	http://www.legislation.gov.uk/ukxi/1999/3242/made
46	Provision and Use of Work Equipment 1998	Health and Safety Executive	http://www.legislation.gov.uk/ukxi/1998/2306/made
72	The Medical Devices (Amendment etc.) (EU exit) Regulations 2019	UK Government	http://www.legislation.gov.uk/ukdsi/2019/9780111179260/pdfs/ukdsi_9780111179260_en.pdf
73	Regulating medical devices in the event of a no-deal Brexit	UK Government	https://www.gov.uk/guidance/regulating-medical-devices-in-the-event-of-a-no-deal-scenario
91	Medical Devices Regulations 2002 (SI 2002 No 618)	UK Government	http://www.legislation.gov.uk/ukxi/2002/618/introduction/made

Ref No.	Title of document / Location	Publisher	Website Link to Document
92	Medical Devices (Amendment) Regulations 2012 (1426)	UK Government	http://www.legislation.gov.uk/ukxi/2012/1426/made
93	General Product Safety Regulations 2005	UK Government	http://www.legislation.gov.uk/ukxi/2005/1803/contents/made
94	Consumer Protection Act 1987	UK Government	http://www.legislation.gov.uk/ukpga/1987/43?timeline=false
95	Consumer Rights Act 2015	UK Government	http://www.legislation.gov.uk/ukpga/2015/15/contents/enacted
176	Ionising Radiation (Medical Exposure) Regulations 2017: guidance	UK Government	https://www.gov.uk/government/publications/ionising-radiation-medical-exposure-regulations-2017-guidance
186	Sale and Supply of Goods Act 1994	UK Government	https://www.legislation.gov.uk/ukpga/1994/35/contents
187	Law Reform (Contributory Negligence) Act 1945	UK Government	http://www.legislation.gov.uk/ukpga/Geo6/8-9/28/contents/scotland
188	The Employers' Liability (Compulsory Insurance) Regulations 1998	UK Government	http://www.legislation.gov.uk/ukxi/1998/2573/contents/made
189	The General Product Safety Regulations 2005	UK Government	http://www.legislation.gov.uk/ukxi/2005/1803/contents/made
190	The Lifting Operations and Lifting Equipment Regulations 1998	UK Government	http://www.legislation.gov.uk/ukxi/1998/2307/contents/made
191	The Pressure Systems Safety Regulations 2000	UK Government	http://www.legislation.gov.uk/ukxi/2000/128/contents/made
192	The Waste Electrical and Electronic Equipment Regulations 2013	UK Government	http://www.legislation.gov.uk/ukxi/2013/3113/contents/made
193	Trade Descriptions Act 1968	UK Government	https://www.legislation.gov.uk/ukpga/1968/29/contents
194	Unfair Contract Terms Act 1977 Chapter 50	UK Government	http://www.legislation.gov.uk/ukpga/1977/50/scotland
200	European Union (Withdrawal) Act 2018	UK Government	https://www.legislation.gov.uk/ukpga/2018/16/data.pdf
246	The Waste Electrical and Electronic Equipment Regulations 2013	UK Government	http://www.legislation.gov.uk/ukxi/2013/3113/introduction/made

European legislation

Ref No.	Title of document / Location	Publisher	Website Link to Document
24	COUNCIL DIRECTIVE 93/42/EEC concerning medical devices	The Council of European Communities	https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1993L0042:20071011:en:PDF
25	DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on in vitro diagnostic medical devices	The European Parliament and the Council of the European Union	https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1998L0079:20031120:en:PDF
26	COUNCIL DIRECTIVE on the approximation of the laws of the Member States relating to active implantable medical devices (90/385/EEC)	The European Parliament and the Council of the European Union	https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1990L0385:20071011:en:PDF
27	REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON MEDICAL DEVICES	The European Parliament and the Council of the European Union	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R0745
28	REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON IN VITRO DIAGNOSTIC MEDICAL DEVICE	The European Parliament and the Council of the European Union	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R0746
74	Article 15 Person responsible for regulatory compliance	The European Parliament and the Council of the European Union	https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32017R0745&from=EN#d1e2842-1-1
138	REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON MEDICAL DEVICES	The European Parliament and the Council of the European Union	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R0745
139	REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON MEDICAL DEVICES	The European Parliament and the Council of the European Union	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R0745
140	REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON MEDICAL DEVICES	The European Parliament and the Council of the European Union	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R0745
199	Commission Implementing Decision (EU) 2019/939	European Commission	https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019D0939&from=EN

Standards

Ref No.	Title of document / Location	Publisher	Website Link to Document
34	BS 7671:2018 Requirements for Electrical Installations. IET Wiring Regulations	British Standards Institution (BSI)	https://shop.bsigroup.com/ProductDetail?pid=00000000030342613
89	BS EN ISO 13485:2016 Medical devices. Quality management systems. Requirements for regulatory purposes	British Standards Institution (BSI)	https://shop.bsigroup.com/ProductDetail?pid=00000000030353196
90	BS EN ISO 14971:2019 Medical devices. Application of risk management to medical devices	British Standards Institution (BSI)	https://shop.bsigroup.com/ProductDetail?pid=00000000030407615&creative=435194702595&keyword=iso%2014971%20standard&matchtype=b&network=g&device=c&gclid=CjwKCAjwgOGCBhAIEiwA7FU-XklrsVpCcq97ngxU-uN7tX9Mk_mhhOjmcYUlaGQqleh0H2DV-wd8chhoChSsQAvD_BwE&gclid=aw.ds
102	ISO 9001 Quality Management	British Standards Institution (BSI)	https://www.bsigroup.com/en-GB/iso-9001-quality-management/
103	BS EN 60601-2-24:2015 Medical electrical equipment. Particular requirements for the basic safety and essential performance of infusion pumps and controllers	British Standards Institution (BSI)	https://shop.bsigroup.com/ProductDetail/?pid=00000000030178084
104	ISO 7886-1:2017 Sterile hypodermic syringes for single use — Part 1: Syringes for manual use	British Standards Institution (BSI)	https://www.iso.org/standard/64790.html
105	ISO 55001:2014(en) Asset management — Management systems — Requirements	ISO (the International Organization for Standardization)	https://www.iso.org/obp/ui/#iso:std:iso:55001:ed-1:v1:en
106	BSI Home Page	British Standards Institution (BSI)	https://www.bsigroup.com/en-GB/
109	BS 70000:2017 Medical physics, clinical engineering and associated scientific services in healthcare. Requirements for quality, safety and competence	British Standards Institution (BSI)	https://shop.bsigroup.com/ProductDetail/?pid=00000000030323397
219	BS EN 60601-1:2006+A12:2014: Medical electrical equipment. General requirements for basic safety and essential performance	British Standards Institution (BSI)	https://shop.bsigroup.com/ProductDetail?pid=00000000030375902
220	BS EN 61010-1:2010+A1:2019 - TC, - Tracked Changes: Safety requirements for electrical equipment for measurement,	British Standards Institution (BSI)	https://shop.bsigroup.com/ProductDetail?pid=00000000030393426

Ref No.	Title of document / Location	Publisher	Website Link to Document
	control, and laboratory use. General requirements		
226	ISO 55000 :2014	British Standards Institution (BSI)	https://www.bsigroup.com/en-GB/Asset-Management/
227	ISO/IEC 15408-1:2009 [ISO/IEC 15408-1:2009] Information technology — Security techniques — Evaluation criteria for IT security — Part 1: Introduction and general model	British Standards Institution (BSI)	https://www.iso.org/standard/50341.html

Guidance

Scottish guidance

Ref No.	Title of document / Location	Publisher	Website Link to Document
3	Healthcare Improvement Scotland Home page	Healthcare Improvement Scotland	http://www.healthcareimprovementscotland.org/
4	Audit Scotland Home page	Audit Scotland	https://www.audit-scotland.gov.uk/
5	NHS National Services Scotland Home page	NHS National Services Scotland	https://nhsns.org/
9	Care Inspectorate Scotland Home Page	Care Inspectorate Scotland	https://www.careinspectorate.com/
18	Key Procurement Principles	Scottish Government Directorate for Health Finance and Information	https://www.sehd.scot.nhs.uk/mels/CEL2012_05.pdf
19	Healthcare Improvement Scotland Home page	Healthcare Improvement Scotland	http://www.healthcareimprovementscotland.org/our_work/technologies_and_medicines.aspx
20	Scottish Healthcare Technologies Group Home Page	Healthcare Improvement Scotland	http://www.healthcareimprovementscotland.org/our_work/technologies_and_medicines/shtg.aspx
21	Scottish Intercollegiate Guidelines Network (SIGN) Home Page	Healthcare Improvement Scotland	https://www.sign.ac.uk/index.html
22	Healthcare Improvement Scotland's NICE Guidance	Healthcare Improvement Scotland	http://www.healthcareimprovementscotland.org/our_work/technologies_and_medicines/shtg.aspx

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	and Scotland Home Page		medicines/nice_guidance_and_scotland.aspx
23	National Infection Prevention and Control Manual	NHS National Services Scotland	http://www.nipcm.hps.scot.nhs.uk/
31	Procurement Journey Update	Scottish Government	https://www.procurementjourney.scot/procurement-journey
32	Public Sector Procurement	Scottish Government	https://www.gov.scot/policies/public-sector-procurement/
33	Scottish Health Technical Memorandum 06-01: Electrical services supply and distribution Part A: Design considerations	Health Facilities Scotland	https://www.nss.nhs.scot/health-facilities/health-facilities-publications-and-guidance/our-publications/
39	Innovation in Health	NHS Scotland Health Innovation Assessment Portal	https://www.hiap-scotland.org
40	Scottish Health Innovations Ltd (SHIL)	NHS Scotland	https://www.shil.co.uk/
48	A Policy for Property and Asset Management in NHSScotland	Scottish Government Capital Planning and Asset Management Division	https://www.sehd.scot.nhs.uk/mels/CEL2010_35.pdf
49	Safety Of Health, Social Care, Estates and Facilities Equipment: NHS Board and Local Authority Responsibilities	Scottish Government Capital Planning and Asset Management Division	https://www.sehd.scot.nhs.uk/mels/cel2009_43.pdf
50	Organisational duty of candour: guidance	Scottish Government	https://www.gov.scot/publications/organisational-duty-candour-guidance/
51	Better equipped to care? Follow-up report on managing medical equipment	Audit Scotland	https://www.audit-scotland.gov.uk/report/better-equipped-to-care-follow-up-report-on-managing-medical-equipment
52	SHTM 00 Best practice guidance for healthcare engineering Policies and Principles	Health Facilities Scotland	https://www.nss.nhs.scot/health-facilities/health-facilities-publications-and-guidance/our-publications/
55	Learning from adverse events through reporting and review	Healthcare Improvement Scotland	http://www.healthcareimprovementscotland.org/our_work/governance_and_assurance/management_of_adverse_events/national_framework.aspx
56	Compendium of Healthcare Associated Infection Guidance	Health Protection Scotland	https://www.hps.scot.nhs.uk/web-resources-container/compendium-of-

Ref No.	Title of document / Location	Publisher	Website Link to Document
			healthcare-associated-infection-guidance/
57	Health Facilities Scotland publications	Health Facilities Scotland	https://www.nss.nhs.scot/health-facilities/health-facilities-publications-and-guidance/our-publications/
61	Clinical Engineering Programmes	NHS Scotland Shared Services	https://www.sharedservices.scot.nhs.uk/health-portfolio/programmes/clinical-engineering/
62	National Network Management Service MPNet	National Services Scotland	https://www.mcns.scot.nhs.uk/types-of-network/national-networks-in-scotland/diagnostic-networks/mpnet6/
63	Health Facilities Scotland Incident Reporting and Investigation Centre (IRIC)	Health Facilities Scotland	https://www.nss.nhs.scot/health-facilities/incidents-and-alerts/view-safety-alerts/
64	The Healthcare Quality Strategy for NHS Scotland	Scottish Government	https://www.gov.scot/publications/healthcare-quality-strategy-nhsscotland/
97	Scottish Health Council Policy, Legislation and Guidance section	Scottish Health Council	http://scottishhealthcouncil.org/patient-public-participation/policy-and-legislation.aspx#.Xc2DHeRCfIW
112	Roles & Responsibilities for Reusable Patient Care Equipment and Environmental Decontamination	Health Protection Scotland	https://www.hps.scot.nhs.uk/web-resources-container/roles-responsibilities-for-reusable-patient-care-equipment-and-environmental-decontamination/
113	Health Facilities Scotland Homepage	Health Facilities Scotland	https://www.nss.nhs.scot/health-facilities/health-facilities-publications-and-guidance/our-publications/
114	NES Healthcare Science Homepage	NHS Education for Scotland	https://www.nes.scot.nhs.uk/education-and-training/by-discipline/healthcare-science/physical-sciences/clinical-scientists.aspx
116	Scottish Government's Healthcare Science webpage.	Scottish Government	https://www2.gov.scot/Topics/Health/NHS-Workforce/Healthcare-Science
117	Addendum to CEL 43 (2009): Safety Of Health, Social Care, Estates and Facilities Equipment: NHS Board and Local Authority Responsibilities	Scottish Government Directorate for Finance, eHealth and Pharmaceuticals	https://www.sehd.scot.nhs.uk/mels/cel_2009_43add.pdf
119	How to report an Adverse Incident	Health Facilities Scotland	https://www.nss.nhs.scot/publications/iric-adverse-incident-report-form/
120	Yellow Card Centre Scotland Homepage	NHS Scotland	https://www.yccscotland.scot.nhs.uk/Pages/default.aspx
123	Learning from adverse events through reporting and review A national framework for Scotland	Healthcare Improvement Scotland	http://www.healthcareimprovementscotland.org/our-work/governance-and-assurance/learning-from-adverse-events/national-framework.aspx

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124	Adverse Events	NHS Education for Scotland	http://www.knowledge.scot.nhs.uk/adverse-events.aspx
126	NHS Scotland Shared Services National Medical Equipment Framework Project	NHS Scotland	https://www.sharedservices.scot.nhs.uk/health-portfolio/programmes/clinical-engineering/
128	Procurement Journey	Scottish Government	https://www.procurementjourney.scot/scottish-model-of-procurement
131	TURAS Learn Homepage	NHS Education for Scotland	https://learn.nes.nhs.scot/
150	Health Facilities Scotland's Guidance publications - decontamination	Health Facilities Scotland	https://nhsnss.org/services/facilities/hfs-publications/guidance-publications/decontamination/
152	Scottish Global Health Coordination Unit	NHS Scotland	https://www.scottishglobalhealth.org/
153	Global Citizenship: Scotland's International Development Strategy	Scottish Government	https://www.gov.scot/publications/global-citizenship-scotlands-international-development-strategy/
155	Active Global Citizenship	NHS Scotland	https://www.scottishglobalhealth.org/active-global-citizenship/
157	NHS Scotland Global Citizenship Programme Board	Scottish Government	https://www.gov.scot/groups/nhs-scotland-global-citizenship-programme-board/
158	NHS Board Champions	NHS Scotland	https://www.scottishglobalhealth.org/champions/
159	Getting involved in Global Citizenship	NHS Scotland	https://www.scottishglobalhealth.org/getting-involved-process/
160	Global Citizenship in the Scottish Health Service	Royal College of Physicians and Surgeons of Glasgow	https://rcpsg.ac.uk/college/this-is-what-we-stand-for/policy/global-citizenship
163	National Decontamination Guidance on Loan Medical Devices (Reusable): Roles & Responsibilities GUID 5002	Health Facilities Scotland	https://nhsnss.org/services/facilities/hfs-publications/guidance-publications/decontamination/
164	Health Facilities Scotland Guidance Publications webpage	Health Facilities Scotland	https://www.nss.nhs.scot/health-facilities/health-facilities-publications-and-guidance/our-publications/
165	NHSScotland Waste Management Action Plan 2016 - 2020	Health Facilities Scotland	https://www.nss.nhs.scot/health-facilities/health-facilities-publications-and-guidance/our-publications/
166	Guidance for Disposal and Recycling of Medical Devices	Health Facilities Scotland	https://nhsnss.org/services/facilities/hfs-publications/guidance-publications/decontamination/

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167	Export of Waste Medical Devices	Scottish Environmental Protection Agency (SEPA)	https://www.sepa.org.uk/media/154402/wst-g-038-export-of-medical-devices.pdf
168	A 'decision tree' used by producers to decide if a product might come within the scope of the WEEE Regulations	Scottish Environmental Protection Agency (SEPA)	https://www.sepa.org.uk/media/62694/waste-electrical-electronic-equipment_decision-tree.pdf
169	Good Practice Guide for the Provision of Community Equipment	Scottish Government Healthier Scotland Joint Improvement Team	https://www2.gov.scot/Topics/Health/Support-Social-Care/Independent-Living/Equipment-Adaptations/good-practice/equipmentGPG
170	Protocol for the Provision of Equipment in Care Homes	COSLA	https://www2.gov.scot/Topics/Health/Support-Social-Care/Independent-Living/Equipment-Adaptations/Carehomes-Protocol
173	Health and Social Care Standards: my support, my life	Scottish Government	https://www.gov.scot/publications/health-social-care-standards-support-life/pages/1/
175	Master Indemnity Agreement (for suppliers)	Health Facilities Scotland	https://www.nss.nhs.scot/publications/master-indemnity-agreement/
177	Waste Electrical and Electronic Equipment (WEEE)	SEPA	https://www.sepa.org.uk/regulations/waste/waste-electrical-and-electronic-equipment-weee/
196	Health Facilities Scotland Publications IRIC Safety Alerts	Health Facilities Scotland	https://www.nss.nhs.scot/health-facilities/incidents-and-alerts/check-youve-received-our-safety-alerts/safety-action-notices/
197	Health Facilities Scotland Incidents and Alerts Safety Officer	Health Facilities Scotland	https://www.nss.nhs.scot/health-facilities/incidents-and-alerts/find-your-equipment-co-ordinator/
218	NHS Scotland assets and facilities 2017: annual report	Scottish Government	https://www.gov.scot/publications/annual-state-nhsscotland-assets-facilities-report-2017/
221	Healthcare Improvement Scotland procurement information	Healthcare Improvement Scotland	http://www.healthcareimprovementscotland.org/about_us/corporate_documents/procurement.aspx
231	New EU procurement thresholds from 1 January 2020: SPPN 8/2019	Scottish Government	https://www.gov.scot/publications/new-eu-procurement-thresholds-from-1-january-2020/
232	HIS Learning from adverse events	Healthcare Improvement Scotland	http://www.healthcareimprovementscotland.org/our_work/governance_and_assurance/learning_from_adverse_events.aspx
233	HFS Adverse Incidents	Health Facilities Scotland	https://www.nss.nhs.scot/publications/iric-adverse-incident-report-form/

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234	HFS SAN(SC)2001	Health Facilities Scotland	https://www.nss.nhs.scot/health-facilities/incidents-and-alerts/check-youve-received-our-safety-alerts/safety-action-notices/
237	Procurator Fiscal Homepage	Crown Office and Procurator Fiscal	https://www.copfs.gov.uk/
239	eHealth Division - About us page	Scottish Government	https://www.ehealth.scot/about-us/
240	Information Commissioners Office Scotland	ICO	https://ico.org.uk/about-the-ico/who-we-are/scotland-office/
241	HIS IR(ME)R Inspection Guidance	Health Facilities Scotland	http://www.healthcareimprovementscotland.org/our_work/inspecting_and_regulating_care/ionising_radiation_regulation.aspx
242	Mental Welfare Commission for Scotland	Mental Welfare Commission for Scotland	https://www.mwscot.org.uk/
243	Duty of Candour Guidance	NHS Education for Scotland	https://www.gov.scot/publications/organisational-duty-candour-guidance/
245	National Safety Alert Oversight Group (NSAOG)	NHS Education for Scotland	http://www.knowledge.scot.nhs.uk/adverse-events/alerts/national-safety-alerts-oversight-group.aspx
247	The Scottish Government's National Procurement Competency Framework	Scottish Government	https://www.gov.scot/publications/scottish-procurement-competency-framework/

UK guidance

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1	An introductory guide to the medical device regulation (MDR) and the in vitro diagnostic medical device regulation (IVDR)	Medicines and Healthcare products Regulatory Agency	https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/640404/MDR_IVDR_guidance_Print_13.pdf
2	Medicines and Healthcare Products Regulatory Agency Home page	Medicines and Healthcare products Regulatory Agency	https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency
6	Health and Safety Executive Home page	Health and Safety Executive	https://www.hse.gov.uk/
7	National Audit Office Home page	National Audit Office	https://www.nao.org.uk/
8	Care Quality Commission Home page	Care Quality Commission	https://www.cqc.org.uk/

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10	National Association of Medical Device Educators and Trainers Home Page	National Association of Medical Device Educators and Trainers	https://namdet.org/
11	Association of British HealthTech Industries Home Page	Association of British HealthTech Industries	https://www.abhi.org.uk/
12	Institute of Physics and Engineering in Medicine Home Page	Institute of Physics and Engineering in Medicine	https://www.ipem.ac.uk/Home.aspx
13	Institute of Healthcare Engineering and Estate Management Home Page	Institute of Healthcare Engineering and Estate Management	https://www.iheem.org.uk/
14	Institution of Engineering and Technology Home Page	Institute of Engineering and Technology	https://www.theiet.org/
41	Guidance: Devices in practice: checklists for using medical devices	Medicines and Healthcare products Regulatory Agency	https://www.gov.uk/government/publications/devices-in-practice-checklists-for-using-medical-devices
42	Medicines and Healthcare products Regulatory Agency (MHRA) guidance on using medical devices safely.	Medicines and Healthcare products Regulatory Agency	https://www.gov.uk/government/collections/medical-devices-safety-guidance
43	Medical Device Driving Licence	National Association of Medical Device Educators and Trainers (NAMDET)	http://www.mddl.org.uk/mddl/index.php
53	The Management of Medical Equipment in NHS Acute Trusts in England	NHS Executive	https://www.nao.org.uk/wp-content/uploads/1999/06/9899475.pdf
58	Guidance for healthcare and social services organisations on managing medical devices in practice.	Medicines and Healthcare products Regulatory Agency	https://www.gov.uk/government/publications/managing-medical-devices
66	Pre-acquisition questionnaire (PAQ) form	Department of Health	https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/744199/FORM_-_PreAcquisition_Questionnaire_Sep_2018_.doc
69	Borderlines with Medical Devices V 1.1	Medicines and Healthcare products Regulatory Agency	https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/521458/Borderlines_with_medical_devices.pdf
70	Medical devices: software applications (apps)	Medicines and Healthcare products Regulatory Agency	https://www.gov.uk/government/publications/medical-devices-software-applications-apps
71	Borderlines between medical devices and medicinal products	Medicines and Healthcare products Regulatory Agency	https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/521420/Borderlines_between_medical_devices_and_other_products_such_as_personal_protective_equipment_cosmetics_and_biocides_.pdf

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77	Application for the use of a non CE-marked device on humanitarian grounds	Medicines and Healthcare products Regulatory Agency	https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/516994/Humanitarian_use_of_device_-_application_form.doc
79	Application for the use of a non CE-marked device on humanitarian grounds	Medicines and Healthcare products Regulatory Agency	https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/516994/Humanitarian_use_of_device_-_application_form.doc
80	Exceptional use of non-CE marked medical devices	Medicines and Healthcare products Regulatory Agency	https://www.gov.uk/guidance/exceptional-use-of-non-ce-marked-medical-devices
81	Guidance for products without an intended medical purpose (Annex XVI) under the new Medical Device Regulation (EU 2017/745)	Medicines and Healthcare products Regulatory Agency	https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/748131/Guidance_leaflet_on_Annex_XVI_products_.pdf
82	Regulations, Guidance and Standards presentation	EBME Electronic and Biomedical Engineering	https://www.ebme.co.uk/seminar/transcriptions/regulations-guidance-and-standards
85	Medical devices: EU regulations for MDR and IVDR	Medicines and Healthcare products Regulatory Agency	https://www.gov.uk/guidance/medical-devices-eu-regulations-for-mdr-and-ivdr
86	Key changes set out in the MDR and IVDR	Medicines and Healthcare products Regulatory Agency	https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/643768/MHRA_Health_Institutions_One_Pager_final_.pdf
87	Safe use of lifting equipment Lifting Operations and Lifting Equipment Regulations 1998. Approved Code of Practice and guidance	Health and Safety Executive	http://www.hse.gov.uk/pubns/books/l113.htm
99	Further guidance note on the regulation of medicines, medical devices and clinical trials in a no-deal Brexit	Medicines and Healthcare products Regulatory Agency	https://www.gov.uk/government/publications/further-guidance-note-on-the-regulation-of-medicines-medical-devices-and-clinical-trials-if-theres-no-brexit-deal
115	Clinical Biomedical Engineering (2017)	National School of Healthcare Science	https://curriculum.nshcs.org.uk/programmes/hsst/HPE3-1
125	Medical Physics and Clinical Engineering (MPACE)	UKAS United Kingdom Accreditation Service	https://www.ukas.com/services/technical-services/development-of-new-areas-of-accreditation/current-pilot-projects/medical-physics-and-clinical-engineering-mpace/
127	Medical Technologies Evaluation Programme Process guide	NICE National Institute for Health and Clinical Excellence	https://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-medical-technologies/Medical-technologies-evaluation-programme-process-guide.pdf
130	Procurement Policy Note – Preparing for the UK Leaving the EU	UK Government Cabinet Office	https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/790425/PPN-0219.pdf
132	E Learning for Healthcare	NHS Health Education for England	https://www.e-lfh.org.uk/

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134	National Association of Medical Device Educators and Trainers (NAMDET) Home Page	National Association of Medical Device Educators and Trainers (NAMDET)	https://namdet.org/
135	Custom-Made Devices	Medicines and Healthcare products Regulatory Agency	https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/398428/Custom_made_devices.pdf
136	Guidance In-House manufacture of medical devices	Medicines and Healthcare products Regulatory Agency	https://www.gov.uk/government/publications/in-house-manufacture-of-medical-devices/in-house-manufacture-of-medical-devices
137	Clinical investigations of medical devices – guidance for manufacturers	Medicines and Healthcare products Regulatory Agency	https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/741719/Guidance_for_mfrs_on_clinical_trials_September_2018.pdf
141	Health institution exemption for IVDR/MDR	Medicines and Healthcare products Regulatory Agency	https://www.gov.uk/government/consultations/health-institution-exemption-for-ivdrmdr
142	Draft guidance on the health institution exemption (HIE) – IVDR and MDR	Medicines and Healthcare products Regulatory Agency	https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/675419/Health_institution_exemption_draft_for_public_consultation.pdf
143	A competent person	Health and Safety Executive	http://www.hse.gov.uk/involvement/competentperson.htm
144	Work equipment and machinery	Health and Safety Executive	http://www.hse.gov.uk/work-equipment-machinery/index.htm
145	Medical devices: off-label use	Medicines and Healthcare products Regulatory Agency	https://www.gov.uk/government/publications/medical-devices-off-label-use
146	Management of health and safety at work	Health and Safety Executive	http://www.hse.gov.uk/pubns/books/l21.htm
147	Single-use medical devices	Medicines and Healthcare products Regulatory Agency	https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/743384/Single_use_medical_devices_leaflet_250918.pdf
148	Single-use medical devices: implications and consequences of re-use	Medicines and Healthcare products Regulatory Agency	https://www.gov.uk/government/publications/single-use-medical-devices-implications-and-consequences-of-re-use
149	UK guidance on re-manufacturing of Single-use medical devices.	Medicines and Healthcare products Regulatory Agency	https://www.gov.uk/government/publications/single-use-medical-devices
151	Guidance on decontamination and infection control, including surgical instruments, dental equipment, endoscopes and benchtop steam sterilizers.	Department of Health and Social Care and Medicines and Healthcare Products Regulatory Agency	https://www.gov.uk/government/collections/decontamination-and-infection-control
161	Making it work A toolkit for	Tropical Health and Education Trust	https://www.thet.org/wp-content/uploads/2017/07/Making-it-Work.pdf

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	medical equipment donations to low-resource settings		
174	Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013 (RIDDOR)	Health and Safety Executive	http://www.hse.gov.uk/simple-health-safety/reporting-accidents-ill-health.htm?utm_source=hse.gov.uk&utm_medium=refferal&utm_campaign=riddor&utm_content=home-page-popular
178	Provision and Use of Work Equipment Regulations 1998 (PUWER)	Health and Safety Executive	http://www.hse.gov.uk/work-equipment-machinery/puwer.htm
179	Guidance on Employers Liability (Compulsory Insurance) Regulations	Health and Safety Executive	http://www.hse.gov.uk/pubns/hse40.pdf
180	The Electricity at Work Regulations 1989	Health and Safety Executive	http://www.hse.gov.uk/pUbns/priced/hsr25.pdf
181	Work on electrical equipment, machinery or installations	Health and Safety Executive	http://www.hse.gov.uk/electricity/withequip.htm
182	Control of Substances Hazardous to Health (COSHH)	Health and Safety Executive	http://www.hse.gov.uk/coshh/
183	Medical devices: the regulations and how we enforce them	Medicines and Healthcare products Regulatory Agency	https://www.gov.uk/government/publications/report-a-non-compliant-medical-device-enforcement-process/how-mhra-ensures-the-safety-and-quality-of-medical-devices
184	Health and safety regulation... a short guide	Health and Safety Executive	http://www.hse.gov.uk/pubns/hsc13.pdf
195	Alerts and recalls for drugs and medical devices	Medicines and Healthcare products Regulatory Agency	https://www.gov.uk/drug-device-alerts
211	NHS eProcurement Strategy, April 2014	Department of Health	https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/344574/NHS_eProcurement_Strategy.pdf
215	Medical devices: guidance for manufacturers on vigilance	Medicines and Healthcare products Regulatory Agency	https://www.gov.uk/government/collections/medical-devices-guidance-for-manufacturers-on-vigilance
222	Priority register system for people in need	Office of Gas and Electricity Markets (OFGEM)	https://www.ofgem.gov.uk/consumers/household-gas-and-electricity-guide/extra-help-energy-services/priority-services-register-people-need
223	Medical devices regulation and safety	Medicines and Healthcare products Regulatory Agency	https://www.gov.uk/topic/medicines-medical-devices-blood/medical-devices-regulation-safety
228	Carriage of Dangerous Goods (CDG)	Health and Safety Executive	https://www.hse.gov.uk/cdg/

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229	Improving medical device incident reporting and learning	Medicines and Healthcare products Regulatory Agency	https://www.cas.mhra.gov.uk/ViewandAcknowledge/ViewAlert.aspx?AlertID=102147
230	Central Alerting System	Medicines and Healthcare products Regulatory Agency	https://www.cas.mhra.gov.uk/ViewandAcknowledge/ViewAttachment.aspx?Attachment_id=101880
235	HSE RIDDOR: Types of reportable incidents	Health and Safety Executive	https://www.hse.gov.uk/riddor/reportable-incidents.htm
236	Blood: authorisations and safety reporting	UK Government	www.gov.uk/blood-authorisations-and-safety-reporting#report-a-serious-adverse-event-or-reaction-related-to-blood
238	Healthcare Quality Improvement Partnership Homepage	HQIP	https://www.hqip.org.uk/
244	HSE Safety alerts in health and social care	Health and Safety Executive	https://www.hse.gov.uk/healthservices/safety-alerts.htm
248	Maintaining portable electric equipment in low-risk environments	Health and Safety Executive	http://www.hse.gov.uk/pubns/indg236.pdf

European guidance

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78	Conformity Assessment	European Commission	https://ec.europa.eu/growth/single-market/goods/building-blocks/conformity-assessment/
83	Factsheet for healthcare professionals and health institutions	European Commission	https://ec.europa.eu/docsroom/documents/35963/attachments/1/translations/en/renditions/native
84	Healthcare Professionals and Healthcare Institutions	European Commission	https://ec.europa.eu/growth/sectors/medical-devices/getting-ready-new-regulations/healthcare-professionals-and-health_en
98	New EU rules on medical devices to enhance patient safety and modernise public health	European Commission	https://ec.europa.eu/growth/content/new-eu-rules-medical-devices-enhance-patient-safety-and-modernise-public-health-0_en
100	Medical Devices Homepage	European Commission	https://ec.europa.eu/growth/sectors/medical-devices_en
101	Competent Authorities for Medical Devices CAMD MDR/IVDR Transition Subgroup	Competent Authorities for Medical Devices	https://www.camd-europe.eu/mdr-ivdr-implementation/about-transition-subgroup/
118	SECTION 2 Vigilance Article 87 Reporting of serious incidents and field safety corrective actions	The European Parliament and the Council of the European Union	https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32017R0745&from=EN#d1e6855-1-1

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171	MANUAL ON BORDERLINE AND CLASSIFICATION IN THE COMMUNITY REGULATORY FRAMEWORK FOR MEDICAL DEVICES Version 1.22 (05-2019)	European Commission	https://ec.europa.eu/docsroom/document/s/35582/
172	Medical Devices Co-ordination Group Guidance	European Commission	https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/guidance_en
201	European database on medical devices (EUDAMED)	European Commission	https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/eudamed_en
202	MDCG 2019-4 Timelines for registration of device data elements in EUDAMED	Medical Device Coordination Group (MDCG)	https://ec.europa.eu/docsroom/documents/34921/attachments/1/translations/en/renditions/native
208	MedTech Europe: Medical device nomenclature for IVD Regulation (EU) 2017/746 and MD Regulation (EU) 2017/745	Med Tech Europe	https://www.medtecheurope.org/news-and-events/news/medical-device-nomenclature-for-ivd-regulation-eu-2017-746-and-md-regulation-eu-2017-745/
209	MDCG 2018-2 Future EU medical device nomenclature – Description of requirements	Medical Device Coordination Group (MDCG)	https://ec.europa.eu/docsroom/documents/28668
224	Factsheet for Manufacturers of Medical Devices	European Commission	https://ec.europa.eu/docsroom/documents/33622/attachments/1/translations/en/renditions/native
225	NBOG Documents	European Commission	https://www.nbog.eu/nbog-documents/

International guidance

Ref No.	Title of document / Location	Publisher	Website Link to Document
65	Medical equipment maintenance programme overview	World Health Organization	https://apps.who.int/iris/bitstream/handle/10665/44587/9789241501538_eng.pdf?sequence=1
67	World Health Organization Medical Devices definitions	World Health Organization	https://www.who.int/medical_devices/definitions/en/
68	Core Medical Equipment	World Health Organization	https://www.who.int/medical_devices/priority/core_equipment/en/
88	Summary Technical Documentation (STED) for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices	Global Harmonisation Task Force	http://www.imdrf.org/docs/ghtf/archived/sg1/technical-docs/ghtf-sg1-n063-2011-summary-technical-documentation-ivd-safety-conformity-110317.pdf
154	Sustainable Development Goals	United Nation	https://www.un.org/sustainabledevelopment/sustainable-development-goals/

Ref No.	Title of document / Location	Publisher	Website Link to Document
156	What is global citizenship	Oxfam	https://www.oxfam.org.uk/education/who-we-are/what-is-global-citizenship
162	Medical Devices - Donation of Medical Equipment	World Health Organization	https://www.who.int/medical_devices/management_use/manage_donations/en/
198	IMDRF Documents page	International Medical Devices Regulators Forum (IMDRF)	http://www.imdrf.org/documents/document_s.asp
203	Recommendations on Medical Device and IVD Field Safety Corrective Actions and Recalls using Unique Device Identifiers & GS1 Standards	GS1 Healthcare User Group	https://www.gs1uk.org/sites/default/files/061119_Field_Safety_Corrective_Actions_document.pdf
204	UDI Guidance Unique Device Identification (UDI) of Medical Devices	International Medical Device Regulators Forum	http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-udi-guidance-140901.pdf
205	Unique Device Identification system (UDI system) Application Guide	International Medical Device Regulators Forum	IMDRF UDI Working Group: Unique Device Identification system (UDI system) Application Guide, 21 March 2019
206	Principles of Labelling for Medical Devices and IVD Medical Devices	International Medical Device Regulators Forum	http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-190321-pl-md-ivd.pdf
207	GS1 Guide on Unique Device Identification (UDI) implementation in the USA and in the EU	GS1 Healthcare User Group	https://www.gs1.org/sites/default/files/docs/healthcare/position-papers/gs1_udi_guide_final_20170324.pdf
210	GS1 Spreadsheet	GS1 Healthcare User Group	Example of GS1 spreadsheet for managing field Safety corrective actions
212	Nomenclature of medical devices	World Health Organization	https://www.who.int/medical_devices/innovation/mde_nomenclature/en/
213	GMDN - the standard for naming and grouping medical devices	GMDN Agency	https://www.gmdnagency.org/services/gmdn
214	Universal Medical Device Nomenclature System™ (UMDNS) Manage your medical devices with our international nomenclature and computer coding system	ECRI Institute	https://www.ecri.org/solutions/umdns
107	Wikipedia description of Royal Charter	Wikipedia	https://en.wikipedia.org/wiki/Royal_charter
108	Wikipedia description of National Standards Body	Wikipedia	https://en.wikipedia.org/wiki/Standards_organization#National_standards_bodies

Additional references added in March 2021

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249	Regulating medical devices from 1 January 2021	Medicines and Healthcare products Regulatory Agency	https://www.gov.uk/guidance/regulating-medical-devices-from-1-january-2021
250	Medical devices: conformity assessment and the UKCA mark	Medicines and Healthcare products Regulatory Agency	https://www.gov.uk/guidance/medical-devices-conformity-assessment-and-the-ukca-mark
251	Medical devices: UK approved bodies	Medicines and Healthcare products Regulatory Agency	https://www.gov.uk/government/publications/medical-devices-uk-approved-bodies
252	DORS Registration Guidance Information	Medicines and Healthcare products Regulatory Agency	https://aic.mhra.gov.uk/era/drsystem.nsf/a508926735cb834f802576880054e0c3/193ee9596802397d802577f0003861bf?OpenDocument
253	Medicines and Medical Devices Act 2021	UK Government	https://bills.parliament.uk/bills/2700
254	Designated standards: medical devices	Office for Product Safety and Standards and Department of Health and Social Care	https://www.gov.uk/government/publications/designated-standards-medical-devices
255	Unique Device Identification (UDI) Application Guide	International Medical device Regulators Forum	http://www.imdrf.org/workitems/wi-udi-application-guide.asp
256	Safety-critical alerts are changing at MHRA	Medicines and Healthcare products Regulatory Agency	https://www.gov.uk/government/news/safety-critical-alerts-have-changed-at-the-mhra--2
257	GS1 Homepage	GS1	https://www.gs1.org/terms-use
258	Health Industry Business Communications Council (HIBCC) Homepage	HIBCC	https://www.hibcc.org/
259	International Council for Commonality in Blood Banking Automation (ICCBBA) Homepage	ISBT 128	https://www.iccbba.org/
260	Informationsstelle für Arzneispezialitäten - IFA GmbH Homepage	IFA GmbH	https://www.ifaffm.de/en/home.html
261	Secure sanitisation of storage media	National Cyber Security Centre	https://www.ncsc.gov.uk/guidance/secure-sanitisation-storage-media
262	Medical device safety information produced by the MHRA	Medicines and Healthcare products Regulatory Agency	https://www.gov.uk/drug-device-alerts/medical-device-safety-information-produced-by-the-mhra

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263	Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use	Medicines and Healthcare products Regulatory Agency	https://www.gov.uk/government/publications/safety-guidelines-for-magnetic-resonance-imaging-equipment-in-clinical-use
264	Management and use of IVD point of care test devices	Medicines and Healthcare products Regulatory Agency	https://www.gov.uk/government/publications/in-vitro-diagnostic-point-of-care-test-devices/management-and-use-of-ivd-point-of-care-test-devices
265	Guidance document Medical Devices - Scope, field of application, definition - Qualification and Classification of stand alone software - MEDDEV 2.1/6	European Commission	https://ec.europa.eu/docsroom/documents/17921/attachments/1/translations
266	BS EN 62304:2006+A1:2015 Medical device software. Software life-cycle processes	British Standards Institution (BSI)	https://shop.bsigroup.com/ProductDetail?pid=000000000030287754
267	BS EN 62366-1:2015+A1:2020 Medical devices. Application of usability engineering to medical devices	British Standards Institution (BSI)	https://shop.bsigroup.com/ProductDetail?pid=000000000030359003
268	Best-practice guidance for the in-house manufacture of medical devices and non-medical device	Institute of Physics and Engineering in Medicine	https://www.ipem.ac.uk/Portals/0/IHM%20best-practice%20guidance%20FINAL.pdf?ver=2021-01-18-101840-073