NHS Ayrshire and Arran Management of Medical Equipment and Devices Policy – V1.0 Final

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V0.5	May 2025	Further draft incorporating CMT comments. Section 5.4.1 updated to reflect nursing management structure in HSCPs Several changes from ISS to be reviewed at 14th May MED WG	Business Manager – Acute Services (interim) Risk Manager Director of Acute Services
V0.6	27 May 2025	Section 2.0 – Bullet points 9-12 added to describe fully the measures in place to achieve successful management of medical equipment and devices. Section 5.0 – reference to Estates and Facilities updated to reflect local structure 'Estates and Clinical Support Services' Section 5.6.2 – First bullet point updated to clarify that 'Prior to purchase' equipment/devices undergo a cyber	Business Manager – Acute Services (interim) Risk Manager Director of Acute Services

		security and information Governance assessment Section 5.6.3 Added to include Assistant Director of Programmes responsibilities Section 5.6.4 (previously 5.6.3) updated to include 'scrutinise the purchase of equipment/devices is in compliance with NHSAA Capital Operating and Accounting Procedures', as a responsibility of IPB/IPBAG Section 5.7 – Remove 'Capital and revenue budgets are adequate to meet the requirements set out in this policy' from Director of Finance responsibilities (this is covered under section 5.6.4, IPB/IPBAG responsibilities) Section 5.8.1 – Bullet point 4 updated to note that a separate local approvals process will require to be in place for any recurring costs (as these would not be funded via capital funds). Bullet point 9 updated to reflect correct title of 'Digital Services'. Section 5.12 – updated to reflect that third-party contractors must provide risk assessments and method statements for the work being undertaken. Section 5.13 – bullet point 4 updated to clarify that shortfalls in the provision of medical equipment/devices will be brought to the attention of IPB/IPBAG in relation to the 10 year capital replacement plan Section 5.2.1 – addition of bullet points 4 and 5 to confirm Site Director UHA's responsibility to ensure firmware is patched with manufacturers security measures and assurance is received from suppliers re conforming to UKG Code of Practice for consumer IoT Security and the ETSI Cyber Security for Consumer Internet of Things Baseline Requirements, where applicable. Section 7.0 – Relevant Cyber Security Policies added	

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See section 7.0 – Related Documents	N/A

Contents

Click on the headings below to link to the relevant section.

1.0 Introduction

This document describes the responsibilities and procedures concerned with the management of Health and Social Care Estates and Facilities, Equipment and Devices (hereafter referred to as medical equipment and devices) in NHS Ayrshire & Arran. This includes all medical devices (including Software as a Medical Device and Software in a Medical Device) In Vitro Diagnostic devices, estates, facilities, social care equipment and personal protective equipment (PPE) (DL (2024) 32).

This is in place to help develop practices and systems which promote safe and effective use of medical equipment and devices, for staff, carers and patients who are responsible for the use and management of medical equipment and devices.

Medical equipment and devices have an important role in the monitoring, diagnosis, therapy, rehabilitation and care of patients within NHS Ayrshire & Arran.

Proactive management of medical equipment and devices supports the delivery of high-quality patient care and effective clinical and financial governance, which works to minimise the risk of adverse events, and the potential for harm caused if they do occur.

2.0 Purpose

The purpose of this policy is to ensure that a consistent approach is taken by all services in relation to management of medical equipment and devices. This policy exists to protect the wellbeing of staff, carers and patients by promoting systems that ensure medical equipment and devices used within Ayrshire & Arran's Health and Care System are managed successfully at every level. The prevention of mismanagement of medical equipment and devices is crucial in providing safe care, particularly in the current circumstances where these are used routinely throughout our Health and Care System.

3.0 Scope

This policy and supporting documentation applies to all medical equipment and devices issued and managed by NHS Ayrshire and Arran (Health) and used across Ayrshire & Arran Health and Care System. Topics covered include: procurement, medical devices on loan, standardisation, training, maintenance, repair, adverse events (including near misses), safety alerts, security, decontamination, decommissioning and disposal.

See also Section 7.0. 'Related Documents'.

4.0 Definition of Terms

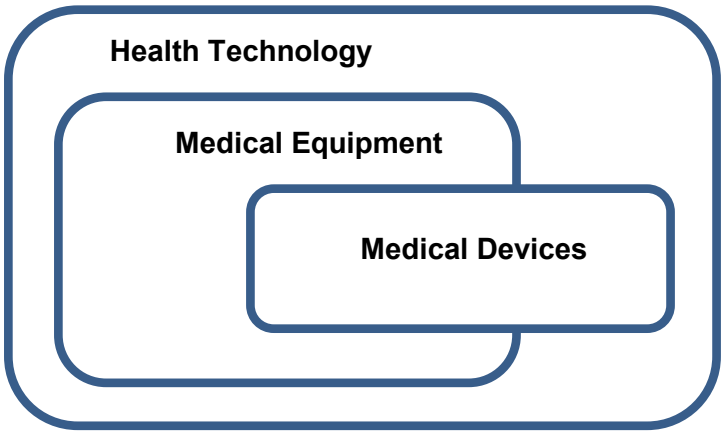
'Medical Devices and Equipment' (Please refer to SHTN-00-04 for full definition) There are multiple interpretations for the terms health technology and for medical equipment, but medical devices are explicitly defined within The UK Medical Devices Regulations (MDR) 2002.

The World Health Organisation (WHO) 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'.

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

In this policy, medical devices and medical equipment are considered as overlapping subcategories of health technology (see **Figure 1** below).

Figure 1 Nested family of equipment used in healthcare:



'Medical Device' means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by the manufacturer to be used specifically for the diagnostic and/or therapeutic purposes and necessary for its proper application, 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,
- Control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

'Medical Equipment' The World Health Organisation (WHO) defines medical equipment 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. 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.

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

'Acceptance' refers to the checks and tests to establish that the correct equipment has been delivered and that it is all in good working order. This allows the order to be signed off and paid for.

'Commissioning' is the process of putting a new piece of equipment into service and includes signing off building work or minor works, equipment configuration, training and attending to safety infrastructure.

'Installation' involves setting the equipment in good working order in the appropriate area.

Abbreviations

AHP = Allied Health Professional
CEL = Chief Executive Letter
DL = Director's Letter
HAI = Healthcare Associated Infection
HAI-SCRIBE = Healthcare Associated Infection Systems for Controlling Risk in the Built
Environment
HFS = Health Facilities Scotland
HSCP = Health and Social Care Partnership
CDU = Central Decontamination Unit
IPC = Infection Prevention and Control
IPB = Infrastructure Programme Board
IPBAG = Infrastructure Programme Board Advisory Group Meeting IRAS = Integrated Research Applications System
IRIC = Incident Reporting Investigation Centre
I&SS = Infrastructure and Support Services MHRA = Medicines and Healthcare products Regulatory Agency
CCGU = Clinical and Care Governance Unit
RSC = Radiation Safety Committee
SHTG = Scottish Health Technologies Group

5.0 Roles & Responsibilities

This policy is managed by the NHS Ayrshire & Arran Medical Equipment and Devices Working Group (in lieu of the NHS Ayrshire & Arran Medical Equipment and Devices Committee being established). All NHS Ayrshire & Arran staff including agency, bank, locum and students are affected by this policy and it also impacts on patients and carers who are issued with medical equipment/devices, and primary care and third-party contractors who are directly employed by or contracted to provide services to NHS Ayrshire & Arran, and who require to follow the principles of this policy in the management of equipment and devices.

It is recognised that, in practice, multiple individuals across various sectors (NHS, local authority and independent providers/contractors) all have responsibility for medical equipment and device safety including assessment, prescription, review and maintenance. This involves a number of complex interactions between all services.

It should be noted that there are items that will fall within the scope of Health, Social Care, Estates and Clinical Support Services Equipment and Devices as defined in DL (2024) 32 for example low cost tables and chairs, some items of PPE, plasters etc, that have not traditionally been defined and managed under local equipment/device policies, and as such will not currently be covered by this policy. This will be considered as part of the implementation plan that will be developed and overseen by the Medical Equipment and Devices Working Group, with a view to full implementation by the end of 2025/26. This document may therefore be subject to change following full implementation.

Staff have the following responsibilities:

5.1 NHS Ayrshire & Arran Chief Executive

The Chief Executive has overall responsibility for NHS Ayrshire & Arran Board affairs. Responsibility for ensuring the efficient, effective and safe planning, operation, management and disposal of medical equipment and devices for all NHS Ayrshire & Arran Services has been delegated to the Director of Acute Services.

5.2 Director of Acute Services

The Director of Acute Services has delegated responsibility for the Medical Equipment and Devices Policy and ensuring that appropriate governance is in place to support this, including the establishment of a Medical Equipment and Devices Committee and associated processes and procedures. The Director of Acute Services is responsible for keeping the Chief Executive up to date with information regarding the organisation's medical equipment and devices.

In addition, the Director of Acute Services has delegated the following responsibilities though their directorate structures:

5.2.1 Site Director (University Hospital Ayr)

Through their delegated management structures, the Site Director will ensure operational and strategic leadership for medical equipment.

Responsibilities include:

- Production of medical equipment strategy (which is ratified by the Clinical Director's Forum)
- Production of medical equipment management operational policies procedures and systems of work
- Maintaining equipment lifecycle plans and updating these on an annual basis
- Ensuring all firmware is patched with security measures issued by manufacturers
- Receive assurance from suppliers that they conform to the UKG Code of Practice for Consumer IoT Security and the ETSI Cyber Security for Consumer Internet of Things Baseline Requirements, where applicable
- Continual quality improvement of all aspects of medical equipment lifecycle management
- Chair and administrate the Medical Equipment Review Group (Of note, a Medical Equipment Review Group is not currently established within NHS Ayrshire & Arran; however the need for this is recognised and will form part of the (DL (2024) 32 Safety of Health, Social Care, Estates and Facilities Equipment: NHS Board and Local Authority responsibilities implementation plan which will be overseen by the Medical Equipment and Devices Working Group).
- Provide medical equipment expert advice to organisational committees
- Contract management
- Linking with national groups relating to Medical Equipment Lifecycle Management
- Appropriate engagement in equipment procurement programmes

5.2.2 Divisional General Manager for Diagnostics

Through their delegated management structures, the Divisional General Manager for Diagnostics will ensure that:

- Healthcare Scientists working in clinic or ward settings are adequately trained to use and care for the medical devices they require to perform their duties and that a record of the training is kept
- Every effort is made to release equipment to the relevant Scientific/Technical service as required for routine maintenance or calibration. The equipment may be on an external maintenance contract
- Agency and Bank staff only use medical equipment and devices that they are trained on

5.3 Executive Medical Director

The Executive Medical Director is responsible for ensuring doctors provide evidence of training in the specification, suitability and use of relevant medical equipment and devices. This can be agreed locally with Clinical Directors.

The Executive Medical Director has delegated the following responsibilities within their Directorate structure:

5.3.1 Deputy Medical Directors for Acute and Primary Care Services

The Associate Medical Directors for Acute and Primary Care Services are responsible for the monitoring of the following within Acute and Primary Care:

- Investment in training on medical equipment and devices
- Optimum utilisation of major items of medical equipment and devices.
- Appropriate engagement in medical equipment and devices procurement programmes. Of note, when purchasing major equipment, i.e. MRI scanners, Robots, subject matter experts should be consulted and representation obtained from Health and Safety Trade Union Representatives, as per Regulation 4a of the health and Safety at work Act 1974.

5.3.2 Director of Medical Education

The Director of Medical Education has responsibility for ensuring appropriate clinical skills education and education and training covering medical equipment and devices where appropriate. This is delegated through Medical Educators as per **section 5.8.5**.

5.3.3 Clinical Directors

Clinical Directors in hospital and HSCP settings must ensure that:

- All grades of doctors working within their service including locum doctors are appropriately trained on the medical devices they are expected to use in their working environment and that a record is kept of this
- Medical equipment is released to the relevant Scientific/Technical service as required for routine maintenance

5.3.4 Research, Development and Innovation (RDI)

The role of the Research, Development and Innovation (RDI) team is:

- To manage the governance arrangements for clinical trials involving medical device developments or modifications. NHS Ayrshire & Arran do not sponsor clinical trials involving medical devices, but will host studies sponsored by other organisations.
- R&D (Research and Development) management approval, ethics favourable opinion and Medical and Healthcare Products Regulatory Authority (MHRA) acceptance are applied for via the Integrated Research Applications System (IRAS). The NHS Ayrshire and Arran Research, Development and Innovation Team will process applications for local R&D Management approval ensuring all other applicable approvals are in place.

- Research in the NHS is governed nationally in line with the UK Policy Framework for Health and Social Care Research, NHS Research Scotland (NRS), National Institute for Health and Care Research (NIHR), MHRA, Nursing and Midwifery Council (NMC) and Health Research Authority (HRA) (when relevant in Scotland).
- Innovation activity, excluding the clinical trial component of innovation projects, is managed by the West of Scotland Innovation Hub: West of Scotland Innovation Hub | Innovation Hub.

5.3.5 Risk Manager – Incidents and Alerts Safety Officer (IASO - previously Equipment Coordinator)

As outlined within DL (2024) 32, the responsibility for some aspects of the Incidents and Alerts Safety Officer (previously known as the Equipment Co-ordinator) role have been delegated by the Executive Medical Director to the Risk Manager and are fulfilled by the Risk Management team. These duties include:

5.3.5.1 Safety Alerts

As outlined in the Safety Notice Distribution Policy

- To provide a single point of contact within NHS Ayrshire & Arran for the receipt, of Safety Alerts, to ensure that all safety alerts and similar communications such as field safety notices received are appropriately assessed before being issued to the service for action, when appropriate and relevant to do so
- Ensure a system is in place to facilitate the raising and sharing of Internal Safety Alerts
- Provide assurance and reporting around the above processes

5.3.5.2 Adverse Event Management

As outlined in the organisation's Adverse Event Policy and Adverse Event Policy Application Guidance:

- To ensure managers and staff are aware of their responsibilities for reporting, reviewing and learning from adverse events
- To provide a system, support and training to facilitate the management of adverse events within NHS Ayrshire & Arran, including the Datix Risk Management Information System
- Provide a framework to encourage and monitor the sharing and reporting of medical equipment/device related adverse events with external organisations such as the Health Facilities Scotland, Incident Reporting Investigation Centre (IRIC) when relevant to do so
- Build and maintain communication links with Health Facilities Scotland (HFS) and other NHS Boards and organisations by attending networking events such as the Incidents and Alerts Safety Officers meetings (Incidents and Alerts Safety Officers Network (IASON)) on behalf of NHS Ayrshire & Arran

5.4 Executive Nurse Director

The Executive Nurse Director is accountable for Infection Prevention and Control, and Nursing, Midwifery and Allied Health Professional standards and practice in the use of Medical Equipment and Devices. The following responsibilities are delegated through the Executive Nurse Director's Directorate structure:

5.4.1 Deputy Nurse Director, Director of Midwifery and Associate Nurse Directors for HSCPs

Through their management structures, the Deputy Nurse Director, Director of Midwifery and Associate Nurse Director's for HSCPs will ensure that:

- Nurses, midwives, and students working in ward, clinic and community settings are adequately trained to use and care for the medical equipment and devices they require to perform their duties and that a record of the training is kept.
- Responsibility for ensuring appropriate clinical skills education and education and training covering medical equipment and devices where appropriate, is delegated by the Deputy Nurse Director to the Chief Nurse Professional Development and as detailed in **Section 5.8.5.**
- Every effort is made to release equipment to the relevant Scientific/Technical service as required for routine maintenance
- Agency and Bank staff, only use, medical equipment that they are trained on

5.4.2 Director of Allied Health Professions

Through their management structures, the Director of Allied Health Professions will ensure that:

- AHPs working in ward, clinic and community settings are adequately trained to use and care for the medical devices they require to perform their duties and that a record of the training is kept
- Every effort is made to release equipment to the relevant Scientific/Technical service as required for routine maintenance
- Agency and Bank staff, only use, medical equipment that they are trained on

5.4.3 Director IPC Infection Control and the Infection Prevention and Control Team

Through their management structures, the Director for Infection Prevention and Control will:

- Ensure that manufacturer's instructions for use align with the national IPC policy requirements and advise NHS Ayrshire & Arran on safe implementation of these
- Ensure advice regarding any clinical infection risks identified in relation to the safe use or decontamination and disposal of medical devices is available to purchasers and users
- Ensure that policies and procedures on decontamination are appropriate and up to date
- Ensure HAI-SCRIBE documentation is adhered to when replacing medical devices that require specific environmental conditions (e.g. ventilation, water, drainage) for safe use or impact on the integrity of the built environment for installation

5.5 Directors of Health and Social Care Partnerships

The Directors of Health and Social Care Partnerships are responsible for the following within the community setting, as delegated through their Directorate Structures:

- Investment in training on medical equipment and devices within the community
- Optimum utilisation of major items of medical equipment and devices within the community.
- Appropriate engagement in medical equipment and devices procurement programmes within the community.
- Maintenance and servicing of medical devices and equipment
- Assurance of safe working practices to meet relevant standards and legislation

In addition, the Director of South Health and Social Care Partnership is responsible for the management of the NHS Community Equipment Store. Through their Directorate structures, they are responsible for ensuring effective operating procedures are in place for the management of equipment including referral pathways, stock control and maintenance.
Of note, a review is currently underway in relation to the management of the Community Equipment Store. It is recognised that an overarching policy with formal operating procedures, detailing clear roles and responsibilities, is required and this will be finalised on completion of the review. In the meantime, the management of equipment is managed via the Electronic Loan Management System (ELMS) and a variety of SOPs exist for the provision of individual equipment items.

5.6 Director of Infrastructure and Support Services (I&SS)

The Director of Infrastructure and Support Services is accountable for the Boards Infrastructure, including but not limited to Estates, New Builds, Digital and oversight/ delivery of the Boards Capital Plan. The following responsibilities are delegated through the Infrastructure and Support Services Directorate structure:

5.6.1 Assistant Director, Estates and Clinical Support Services

The Assistant Director, Estates and Clinical Support Services has overall responsibility for Estates, Support Services, Procurement and Logistics, including Decontamination. Within this, delegated responsibility for Medical Equipment and Devices is assigned as follows:

5.6.1.1 Head of Estates

The Head of Estates has responsibility for all equipment and devices procured and managed by Estates. Responsibilities to support safe and effective service delivery include:

- Contract Management
- Project Management
- Review Maintenance schedules
- Engagement with other stakeholders (as required)
- Procurement
- Professional lead and technical specialist for estates maintenance and to support services across the Board

5.6.1.2 Head of Procurement

The Head of Procurement will ensure

- That the Board's standing financial instructions are aligned to the Procurement Regulations and are made available to staff.
- That contracts between the organisation and vendors include Cyber security clauses and responsibilities to ensure that Cyber security is supported throughout the equipment's lifecycle, including vulnerability disclosure, patch provision, end of life notification and breach management.

Of note there are Delegated Purchasing Officers (DPOs) across the organisation and a Scheme of Delegation is in place that provides overall assurances in relation to procurement processes.

5.6.1.3 The Lead for Decontamination

The Lead for Decontamination is responsible for decontamination and sterilisation processes in the Central Decontamination Unit (CDU), Local Decontamination Units and Endoscopy Decontamination Units (EDU)

- SHTM 01-01 Parts A – F (SHTM 01-01) describe a framework for decontamination of medical devices in a Central Decontamination Unit.

- SHTM 01-05 Parts A-C describe a framework for Management, equipment and process of the decontamination of dental instruments in a Local Decontamination Unit (LDU).
- SHTM 01-06 – Parts A-E describe a framework for Decontamination of flexible thermolabile endoscopes and TOE ultrasound probes in EDUs.
- The Lead for Decontamination and the Authorising Engineer (Decontamination) have a responsibility to ensure the reprocessing equipment within NHS Ayrshire & Arran meets regulatory requirements via audit and equipment validation.
- The CDU decontamination requirements are bound by a legal framework and need to meet strict criteria which they are audited on. Failure to meet the standards set out in the audit programme would result in loss of licence to operate. This includes the requirement to ensure all equipment is asset tagged, recorded on a quality management system and there is a 10 year rolling replacement programme. Protocols for the management of this equipment is agreed nationally and there is a national collaborative group which makes strategic decisions.

5.6.2 Assistant Director of Digital Services

The Assistant Director of Digital Services will ensure that:

- Prior to purchase all equipment/devices intended for connection to the NHS network undergo a cyber security and Information Governance assessment to include software versions, patching practices and known vulnerabilities
- Advice is provided on equipment/device hardening following the principle of least privilege to ensure unused ports and services are disabled, default credentials changed and secure authentication enforced.
- Guidance is provided to suppliers around firmware and software updates which should be applied within 14 days of release
- Equipment/Devices are placed on a segmented network with tightly controlled access, where possible, but particularly when the security of a device/equipment cannot be assured or controlled by Digital Services
- Staff using medical equipment and devices are aware of their responsibility to recognise and report cyber incidents involving medical equipment and devices
- Ensure any cloud-hosted data storage utilised by medical equipment and devices is subject to supplier assurance checks, and that the storage meets the NCSC (National Cyber Security Centre) Cloud Computing Principles
- Provide other cyber security guidance when needed, with approval required including but not limited to encryption (in transit and at rest) and antivirus protection
- Ensure technical support is available in relation to items of software as a medical device

5.6.3 Assistant Director of Programmes

The Assistant Director of Programmes has responsibility for preparing and managing the Board's Capital Investment Plan through which provides funding for the purchase of new and replacement medical equipment. This includes:

- Liaising with Scottish Government around annual and additional in-year funding for capital investment
- Scrutiny with Finance on approved expenditure and ensuring that expenditure is spent in the relevant financial year
- Sharing the Boards plan with the National Equipment Group to identify opportunities for value added purchasing and to ensure that proposed equipment meets the funding criteria.

5.6.4 The Infrastructure Programme Board (IPB) and Infrastructure Programme Board Advisory Group (IPBAG)

The following are responsibilities of the IPB and IPBAG structure

- Allocation of annual budget and approval of the proposal for prioritisation of replacement of existing items (linked to **section 5.2.1** – responsible person for lifecycle planning will submit this proposal)
- Consideration of funding of additional equipment/devices, via the established capital prioritisation process as appropriate
- Scrutinise the purchase of equipment / devices is in compliance with the NHSAA Capital Operating and Accounting Procedures.

5.7 Director of Finance

The Director of Finance will be responsible for the monitoring of:

- Oversight of Capital expenditure on equipment, including Medical Equipment and Devices. (IPBAG/IPB will be responsible for allocation of annual budget and approval of proposal for priorities (replacement of existing) as per **section 5.6.3** above)
- Total replacement value
- Estimated replacement value for non-capitalised equipment items
- Net book value
- Annual depreciation
- Revenue expenditure for purchase, maintenance and support. - Lease expenditure

And will ensure that:

- Professional financial advice is available where required
- Standing financial instructions are in place and updated in line with the Code of Corporate Governance. Of note, responsibility for ensuring that the Board's Standing Financial Instructions are aligned to Procurement Regulations and are made available to staff, is delegated to the Head of Procurement **as detailed in 5.6.1.2**.
- All appropriate funding routes are considered

5.8 All NHS Ayrshire & Arran Directors

All Directors are accountable for the overall implementation of this policy and ensuring that procedures exist for the reporting of adverse events, the dissemination of safety advice and the control of risks relating to health, social care, estates and facilities equipment, including medical devices and digital equipment, for the equipment/devices within their remit.

In addition, the following responsibilities are delegated through Directorate management structures as below.

5.8.1 General Managers/Heads of Service and equivalent

General Managers/Heads of Service and equivalent will ensure that the procurement of medical equipment and devices is carried out correctly. It is acknowledged that some of this responsibility may be delegated to Assistant General Managers however, General Managers will ensure, in particular that:

- Standing Financial Instructions are followed. Of note, any procurement that constitutes Capital expenditure will require to go through the appropriate procurement process as per our SFIs/Procurement Operating Guidelines
- Any training for new medical equipment or devices that is required to be delivered by the supplier is included as part of the purchasing contract (**as per 5.8.6**)
- Applications for medical equipment and devices are adequately described, justified, costed and prioritised prior to submission
- Recurring costs are identified and included in the bid, noting that a separate local approvals process will require to be in place for any recurring costs (as these would not be funded via capital funds)
- The impact of the bid on other management groups has been considered and agreed (i.e. installation costs, maintenance and support costs, additional patient numbers etc)
- The Head of the relevant Scientific/Technical Department is consulted before medical equipment/devices are purchased and as appropriate during their use. Of note, when purchasing major equipment, i.e. MRI scanners, Robots, subject matter experts should be consulted and representation obtained from Health and Safety Trade Union Representatives, as per Regulation 4a of the health and Safety at work Act 1974.
- Infection control is consulted to ensure that the equipment/device can be safely used and decontaminated according to NHS Ayrshire & Arran Policy and Procedures
- Facilities are contacted to ensure the equipment can be disposed of according to NHS Ayrshire & Arran Policy
- Digital services is contacted prior to purchase to consider any networking or Cyber security requirements are met
- Revenue expenditure for purchase, maintenance and support is managed. Of note, the Head of Medical Physics/Clinical Engineering requires to be consulted regarding the provision of any maintenance and support.

- Optimum utilisation of major items of medical equipment and devices.

5.8.2 Service Managers and Locality Managers

Service Managers and Locality Managers will ensure that:

- Their department is adequately equipped to carry out its function
- Department staff members are adequately trained to use and care for the medical devices they require to perform their duties
- Safety Alerts relating to medical devices, staff and patient safety, are locally assessed and appropriate actions taken, including when appropriate, distributing to all staff members who may use the medical equipment/device in question. Maintaining a local assurance process to record alerts received, actions taken and responding to the Risk Management Safety Notice Distribution mailbox to confirm actions complete.
- Hazards relating to medical devices are identified, assessed and the risks associated with these hazards are managed and recorded on a risk register
- All medical equipment has a funded maintenance and replacement programme

5.8.3 Heads of Departments with responsibility for medical equipment/device maintenance

Heads of Departments (or equivalent) with responsibility for medical equipment/device maintenance will ensure that medical devices are fit-for-purpose, safe and effective, and will:

- Provide scientific and technical advice to the Board's medical equipment and devices procurement committees, General Managers, Heads of Service and medical equipment and device users
- Provide maintenance, repair, calibration, performance verification and safety testing services for medical equipment and devices
- Advise on medical equipment and devices management issues and identify medical equipment and devices that may need to be replaced for safety or operational reasons
- Lead and assist medical equipment and device users to carry out medical equipment and device evaluations
- Ensure that medical equipment and devices which have been obtained on loan for the purposes of evaluation comply with national guidance regarding indemnity
- Facilitate the prioritisation of requests
- Identify suitable programme leads for equipment and device management and procurement

5.8.4 Clinical Services that loan medical devices to patients and carers

Clinical Services that loan Medical Devices to patients and carers must ensure that:

- For devices that are owned by NHS Ayrshire & Arran and loaned to end users in the community, the responsibility for ensuring that the equipment/device is delivered and is safe to use is the responsibility of the service. Incident reporting to IRIC is also the responsibility of the service.
- For devices that are owned and managed by a commercial supplier, the manufacturer's pre-dispatch tests in combination with end user pre-use checks will assure safety. Record keeping is the responsibility of the manufacturer with input from the end user as appropriate. Incident reporting to the MHRA is the responsibility of the manufacturer who must also inform the relevant NHS Ayrshire & Arran service. NHS Ayrshire & Arran conducts periodic supplier audits. All suppliers must co-operate with and help facilitate, such audits.
- There is a robust process in place for the return of medical devices, accessories and equipment which have been loaned to patients.
- Patients relying on electrical power or a water supply for critical medical equipment in the community should be encouraged to register on the priority register system for people in need. This system can provide early alerts from the power or water companies to possible outages or support in the event of an unexpected outage.
- Applicable health critical equipment is labelled with the distribution network (power) operator emergency helpline number "105".

5.8.5 Clinical Educators (Nursing inclusive of Corporate Practice Development and Resuscitation and Deteriorating Patient Services), Medical Educators (Doctors) and Educators for other professional groups will ensure that:

- Appropriate clinical skills education is provided within their areas for their respective professional groups within NHS Ayrshire & Arran
- Education and training covering medical devices is provided where appropriate

These educators will support the design and development of workshops, study days or other relevant training in relation to the clinical skills requirements for their respective professional groups.

5.8.6 Staff Trainers

Training on **specialist medical equipment** is delivered by trainers within the relevant service. It is the responsibility of the service/department to identify and arrange the training requirements for their staff ensuring personal safety and the safety of others is not compromised and that those operating or maintaining equipment have the required skills and knowledge. Any training on specialist medical equipment that is essential for staff to carry out their duties should be captured under Job Specific/Role training and monitored accordingly. The ability to record this training is available on the LearnPro Course Booking System using a specially generated code for LearnPro and eESS. This code can be obtained by contacting the LearnPro digital team within Learning and Development directly. It should be noted that the Course Booking system can also prompt when refresher training is required.

As noted at 5.8.1, training on **medical equipment new to NHS Ayrshire & Arran** is delivered by the respective company most commonly on a Train the Trainer basis. Training will be part of the purchasing contract and this should be fully discussed and agreed with relevant team members for each specific piece of equipment prior to purchase.

5.9 All NHS Ayrshire & Arran staff, Agency, Bank and locum staff, and students

All NHS Ayrshire & Arran staff including agency, bank and locum staff and students have an individual responsibility to engage in equipment training for all medical equipment and devices that they use. This includes induction, competency maintenance, refresher and new equipment training programmes.

All NHS Ayrshire & Arran staff will:

- Carry out the appropriate day-to-day maintenance or calibration required of the user on the medical equipment and devices that they use
- Know how to safely and effectively operate the medical equipment and devices that they need to use to perform their duties
- Only use equipment and devices they have been trained on unless they are using these under direct supervision of another competent individual.
- Know how to decontaminate the medical equipment and devices that they use
- Check that medical equipment and devices are clean and in good working order prior to use
- Check the service label before use, and contact the department/company responsible for maintenance if the equipment/device is out with its service date. (Medical equipment/devices that have passed their “service due” date must only be used if there is a strong clinical need e.g. the medical equipment/device is attached to a long-term patient and there is no other equipment/device available). Sufficient spares will usually allow swapping equipment out for servicing.
- Know how to report faulty medical equipment and devices
- Know how to report adverse events where medical equipment/device may have been a contributing factor both locally (on Datix) and when appropriate to do so, nationally to IRIC

- Know how to safely store medical equipment/devices in order to protect them from environmental contamination and damage
- Liaise with members of the Medical Equipment and Devices Committee as required (This will be Medical Equipment and Devices Working Group in lieu of Committee being established)

5.10 Patients and Carers issued with medical equipment/device

Patients and carers issued with medical equipment/devices must:

- Attend training provided by the service on the relevant equipment and the associated procedures. Provision of the training and assessment of the acquired competency is the responsibility of the service.
- Know how to safely and effectively operate the medical devices that they need to use out with the hospital/clinic environment. Written evidence of this is held by issuing department.
- Check that medical devices are clean and in good working order prior to use.
- Carry out appropriate routine checks and maintenance on the medical devices that they use
- Know when to and how to obtain servicing for the equipment they use and understand the importance of this requirement
- Know how to report faulty medical devices and to whom
- Only use equipment they have been trained on or provided an appropriate level of instruction on. Instructions for use should be available and in a format that is appropriate to the abilities and understanding of the end user
- Know how to and to whom they should return medical equipment that they no longer need

5.11 Primary Care Practitioners

Primary Care Practitioners directly employed by NHS Ayrshire & Arran have a contractual responsibility to follow the NHS Ayrshire & Arran Management of Medical Equipment and Devices Policy.

Primary Care Practitioners who work as independent contractors to NHS Ayrshire & Arran have a professional responsibility to follow the principles of the NHS Ayrshire & Arran Management of Medical Equipment and Devices Policy.

5.12 Third-party contractors

NHS Ayrshire & Arran work with a range of third-party contractors who provide a range of services, including the supply and/or maintenance of medical devices and equipment. Anyone engaging with a third-party contractor should ensure they are fully aware of their roles and responsibilities prior to commencing work and this should be included in any contractual agreement between NHS Ayrshire & Arran and the third-party. This falls under the remit of the Control of Contractors Policy (please note this policy is currently under review as at March 2025). In particular, if any equipment requires installation such as wall mounting or requiring services such as water/electricity to be connected, then contractors must follow HAI-SCRIBE procedures and provide Risk assessments and method statements for the work being undertaken.

5.13 NHS Ayrshire & Arran Medical Equipment and Devices Committee

Please note that the NHS Ayrshire & Arran Medical Equipment and Devices Committee has not yet been established. In Lieu of this, arrangements for developing and auditing of policies and procedures to help ensure safe and effective management of medical equipment and devices is carried out via local subgroups which report into local governance structures, as described within this document. The requirement for an overarching Medical Equipment and Devices Committee is recognised. This will form part of the (DL) implementation plan which is overseen by the Medical Equipment and Devices Working Group and will report to Corporate Management Team. In the meantime,

The following will be the role of the NHS Ayrshire & Arran Medical Equipment and Devices Committee:

- To develop and audit policies and procedures to help ensure the safe and effective management of medical equipment and devices within the NHS Ayrshire & Arran, including to ensure that areas have robust criteria for ordering and clear lines of responsibility
- Examine guidance on medical equipment/device use and management from the MHRA, Health Facilities Scotland, Scottish Government, Scottish Health Technologies Group (SHTG) and other appropriate competent organisations and recommend appropriate responses to help ensure that NHS Ayrshire & Arran complies with the guidance
- To help ensure the standardisation of medical equipment/devices where appropriate
- To bring shortfalls in the provision of medical equipment/devices to the attention of the Director of Acute Services, the services concerned and IPB/IPBAG in relation to the 10 year capital replacement plan.
- To work with the Department of Nursing, Clinical Educators, Medical Directors, Clinical Directors, Allied Health Practitioners and Healthcare Scientists to ensure that all staff are competent in the use of medical equipment and devices relevant to the area where they work
- To monitor events (near misses and accidents) involving medical devices, working with the Clinical and Care Governance Unit (CCGU) to ensure that lessons are learnt to help avoid recurrences of events

5.14 NHS Ayrshire & Arran Medical Equipment Review Group

This role was previously fulfilled by the NHS Ayrshire & Arran Clinical Directorate Medical Resources Group which was joint Chaired by the Executive Medical Director and Executive Nurse Director and was stood-down pre-pandemic. The need for a Medical Equipment Review Group is recognised and this will form part of the 'Safety of Health, Social Care, Estates and Facilities Equipment: NHS Board and Local Authority Responsibilities' Implementation Plan which is overseen by the Medical Devices Policy Working Group.

The role of the NHS Ayrshire & Arran Medical Equipment and Devices Review Group will be:

- To manage the replacement of the Board's inventory of medical equipment and devices in line with the Board's targets and best clinical practice
- To balance financial and clinical risk in line with the available budget and report to the Director of Finance and Director for Acute Services
- To develop and manage replacement programmes of capital medical equipment in line with 10-year replacement plans
- Tie the equipment lifecycle planning in with NHS Ayrshire & Arran's overall capital plan and building strategy
- To ensure the correct governance is in place for the funded replacements

5.15 NHS Ayrshire & Arran Radiation Safety Committee

The NHS Ayrshire & Arran Radiation Safety Committee is Chaired by the Clinical Director for Imaging. The role of the Committee is to ensure that the use of medical devices involving ionising or non-ionising radiation is compliant with:

- Radiation Safety Documentation for NHS Ayrshire & Arran
- NHS Ayrshire & Arran - PN39 Radiation Safety Policy
- Ionising Radiations Regulations 2017
- Ionising Radiation (Medical Exposure) Regulations 2017
- Environmental Authorisations (Scotland) Regulations 2018
- Control of Artificial Optical Radiations at Work Regulations 2010

6 Document Statement

The policy sets out the responsibilities of staff managing medical equipment and devices within NHS Ayrshire & Arran. Successful management is achieved by verifying that medical equipment and devices are:

- Purchased according to standing instructions and regulations, and with due regard to national / international guidance
- Suitable for their intended purpose
- Used only by a competent member of NHS Ayrshire & Arran staff, or a patient or carer who has received appropriate training in the use of the equipment/device
- Used only in the appropriate environment for the designed use
- Traceable from equipment inventory records
- Maintained in a safe and reliable condition
- Disposed of safely at the end of their working life
- Replaced having regard to the procedures and guidance aligned with this policy
- Managed strategically with regard to the clinical services to be delivered and incorporating new ways of working and technological advances in treatment approach.
- Managed strategically taking cognisance of design / operational life of existing equipment to ensure that replacement is planned on a cyclical basis underpinned by a “lifecycle plan” which is integrated into the Board’s Asset Management Plans.
- Ensure that proposed new additional equipment is considered objectively and strategically taking cognisance of associated revenue costs and infrastructure requirements.
- Procurement of equipment is planned to maximise value for money opportunities via national frameworks and competitive tendering across suppliers.

7 Related Documents

Risk Management

Adverse Event Policy Approved by Risk and Resilience Scrutiny and Assurance Group (RARSAG)

Adverse Event Policy Application Guidance Approved by RARSAG

Risk Management Strategy Approved by NHS Ayrshire & Arran NHS Board

Safety Notice Distribution Policy Approved by RARSAG

Built Environment

HAI Scribe Procedures Operational Management

Finance/Procurement

Control of Contractors Policy (currently under review as at March 2025)

Standing Financial Instructions (Approved by Ayrshire and Arran NHS Board as part of the Code of Corporate Governance)
Procurement Operating Procedures November 2022
Procurement Scrutiny Group and procedures are in place and held locally (Available on request)
Code of Corporate Governance - Section F - Scheme of Delegation (Approved by Ayrshire & Arran NHS Board)
NHS Ayrshire & Arran Capital Operating & Accounting Procedures (Approved by Infrastructure Programme Board) (Please note, section 20.0 Procurement of Medical Equipment (Electro Medical Equipment) will require to be updated in line with the Management of Equipment and Devices Policy)

Transport/Ayrshire Urgent Care Services

Car User Policy

Operators Handbook - Commercial and Patient Carrying Vehicles

Operator's Policy - Pool Cars

Rules regarding display of number plates

Centre and Mobile Unit Bag Contents & Checks: Resuscitation Bags, GP Equipment Bags, Emergency Bags – Standard Operating Procedure:

(SOP available on request from Head of Primary and Urgent Care Services)

Management & Maintenance of Mindray Automated External Defibrillators – Standard Operating Procedure:

(SOP available on request from Head of Primary and Urgent Care Services)

Medical Physics, Imaging, Labs and Diagnostics

Medical Equipment Policy

Radiation Safety Documentation for NHS Ayrshire & Arran (Approved by Head of Service – Medical Imaging)

The following documents are held within the Laboratories Quality Management System database, Qpulse, and are only available to Area Laboratory Staff:

Pathology Management of equipment

Change Control, Validation & Qualification of Equipment and Processes

Area Laboratories Department of Biochemistry Standard Operating Procedure – Procurement and Management of Equipment

Area Laboratories – Department of Microbiology Standard Operating Procedure – Selection, Procurement and Management of Laboratory Equipment, Services, Reagents and Consumables

Area Laboratories – Department of Microbiology Standard Operating Procedure – Validation and Verification of Equipment, Reagents and Tests

Cyber/Information Security

Appropriate Use of IT Facilities Policy (currently under review as at May 2025)

Penetration Testing Policy

Password Policy

Secure Storage Communication and Transportation of Personal Information Policy

Access Control Policy

Information Security Policy

Cryptographic Controls Policy

Patch and Vulnerability Management Policy

8 References & Bibliography

The Medical Devices Regulations 2002. Statutory Instrument 2002 No.618. ISBN 0110423178.

In-house manufacture of medical devices, UK Government.

NSS: Health Facilities Scotland: Master Indemnity Agreement Terms and Conditions

UK Government: Medicines, medical devices and blood regulation and safety-guidance: Custom-made medical devices. From MHRA August 2013

Healthcare Improvement Scotland, Healthcare Associated Infection (HAI) Standards, February 2015 / Scoping Report, January 2021

World Health Organization (WHO) Medical Devices Definition

CEL35 (2010) A Policy for Property and Asset Management in NHS Scotland

SGHD/CMO (2024) 17 Medical Device Regulation (MDR) Preparedness and NHS Board Medical Devices Policies Guidance

DL (2024) 32 Safety of Health, Social Care, Estates and Facilities Equipment: NHS Board and Local Authority Responsibilities

Managing Medical Devices: Guidance for Healthcare and MHRA, 2021 Managing Medical Devices – Guidance for health and social care organisations

SHTN 00-04 Guidance on Management of Medical Devices and Equipment in Scotland's Health and Social Care Services, Health Facilities Scotland, 2021

Decontamination of medical devices in a Central Decontamination Unit (SHTM 01-01) | National Services Scotland (nhs.scot)

Health and Safety at Work Act 1974

Incidents and Alerts Safety Officer (IASO) Manual (link to be added when published)