



<b>Title:</b>	<b>Medical Device Policy</b>		
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<b>Ownership:</b>	██████████ Medical Director		
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<b>Links to Other Policies / Procedures:</b>	Risk Management Policy, Risk Assessment Procedure, Regional Ambulance Clinical Training and Education arrangements, medical gases procedures, NIAS IPC Policy and NIAS Vehicle and Equipment Decontamination Manual, Incident Reporting Procedures, Standard Operating Procedures.		

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## 1.0 INTRODUCTION:

### 1.1 Background:

Medical Devices improve health outcomes when used within the context of a robust health system, and which itself, is only as good as the policy, strategies, and action plans that constitute it.

This policy is required to create a framework through which to direct the Trusts valuable resources such as finance, human resources, information, leadership and governance to collectively address the needs of the Trust.

Within the Northern Ireland Ambulance Service Health and Social Care Trust (NIAS), Medical Devices are an essential and integral element of all aspects of pre-hospital care.

By definition, 'Medical Device' means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of diagnosis, prevention, monitoring, treatment, alleviation or compensation for an injury or disease, supporting or sustaining life<sup>1</sup>.

The Northern Ireland Ambulance Service Health and Social Care Trust (NIAS) recognises its statutory obligations under The Medical Device Regulations, MDR, and has reviewed and updated the existing policy to reflect both the structural review within NIAS and the updating of the statutory instruments in respect to Medical devices.

### 1.2 Purpose:

The purpose of this policy is to provide an up-to-date, comprehensive, Trust-wide strategy for the management of Medical Devices, from inception to disposal. This is to ensure compliance with legislation and to establish procedures for the identification, selection, procurement, integration, training, use, maintenance and ultimate replacement and disposal of Medical Devices. The Policy has been designed to protect staff and service users from risk whilst safeguarding the welfare of patients, staff and members of the public.

### 1.3 Objectives:

This Policy aims to establish a framework for statutory Medical Devices management within NIAS with due regard to the following key objectives:

- *To provide clarity and transparency for the justification and rationale for the selection, use and disposal of Medical Devices.*
- *To ensure that all Medical Devices for the Trust are identified, risk assessed, selected, procured, used, serviced and calibrated, managed, investigated and*

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<sup>1</sup> Excerpt from the WHO Medical Device Full Definition

disposed of *in compliance with statutory instruments, standards, approved codes of practice and manufacturers' recommendations.*

- *To detail the corporate responsibility to the safety of staff and patients, and set down the roles and responsibilities of all personnel.*
- *To formally record and detail the information that will be collected, collated and stored to assist in the management of Medical Devices.*

## **2.0 SCOPE:**

2.1 This Policy is applicable to all NIAS staff who are involved in the identification, selection, procurement, use, management, investigation and disposal of Medical Devices.

## **3.0 ROLES AND RESPONSIBILITIES:**

### **3.1 The Chief Executive is responsible for:**

- Ensuring that there are suitable and sufficient arrangements in place for the management of Medical Devices within the Trust, including the necessary resources, monitoring processes and oversight where appropriate.
- Ensuring the full and effective implementation of this Policy, and satisfying the Trust Board of the same.
- Ensuring there are suitable arrangements in place for the review and audit of this policy document to ensure that the policy remains fit for purpose and that full policy compliance is achieved.

### **3.2 The Medical Director is responsible for:**

- Providing the Chief Executive and Trust Board with information and assurance pertaining to the management and use of Medical Devices within the Trust.
- Ensuring that the Trust has a robust system and structure in place for Medical Devices use.
- Ensuring that systems, policies and procedures are developed and implemented on behalf of the Trust including the onward reporting of relevant incidents to external agencies for e.g., Health & Social Care Board (HSCB), Health and Safety Executive for Northern Ireland (HSENI) and the Regulation, Quality Improvement Authority (RQIA). On a daily basis, this function is delegated to the Risk Manager.
- Ensuring that the need for Medical Device familiarisation, management and use is recorded in the job descriptions of the posts concerned and in any associated recruitment documentation.
- Ensuring there is a robust mechanism for the monitoring and validation of the Medical Device training system and that measures are in place to provide statistical data on training outcomes.
- Ensuring the necessary competence and expertise of individuals' assigned specific roles and responsibilities.
- Ensuring that there is oversight and accountability with regards to the Medical Device responsibilities of all staff.

- Ensuring that employees and their representatives are kept informed at all stages of the process, encouraging participation and involvement in the development and delivery of policies and procedures.
- Chairing the Medical Equipment Group (MEG).

### 3.3 The Assistant Medical Director is responsible for:

- Representing the Trust at Contract Advisory Groups to ensure that the Trust can take advantage of regional contracts for the selection, supply, procurement, service and maintenance of Medical Devices.
- Ensuring that those appointed by the Trust for supplying, servicing and repairing Medical Equipment and Devices are competent to do so and represent the best interests of the Trust in terms of their suitability, capability, technical ability, manufacturer accreditation, quality assurance and safety, ensuring that the interests of user and patient are protected.
- Engaging with Stores and Procurement Department and play an active role in the selection of Medical Devices.
- Providing economic evaluation data to enable the provision of sufficient resources for service and maintenance contracts or where necessary provide adequate facilities and staff to ensure effective and efficient maintenance/repair/calibration of medical equipment.
- Ensuring that guidance as distributed in relation to the management and use of Medical Equipment, inclusive of but not limited to Memos, Standard Operating Procedures, Safety Alerts etc. is correct and appropriate.
- Engaging with and advising the Medical Equipment Group at the earliest opportunity if there are any changes to national guidance, services or clinical procedures, which involve the use of and which may require the review of Medical Devices.
- Advising the Medical Equipment Group of any emerging risk from the use or misuse of any Medical Equipment or Device.
- Ensuring that robust governance is embedded in all aspects of Medical Device and equipment use from inception to disposal.
- Support the Directorate in the development of clinical standards and governance plans as appropriate and providing expert advice on the application of Medical Devices to meet the clinical needs of the Trust to deliver service improvement.
- Deputise for the Medical Director where required and take a lead role in developing links between the Medical Directorate and the wider Trust in respect of clinical standards and governance.
- Support incident investigations inclusive of but not limited to clinical analysis, reviewing research and national guidelines to improve practice.

### 3.4 Directors & Assistant Directors are responsible for:

- Ensuring that this policy and any associated procedures are effectively implemented within their areas of responsibility.
- Ensuring arrangements are in place for monitoring and compliance with this Policy.
- Ensuring that there are suitable resources available for the implementation of this Policy.

- Informing the Risk Management Team where there is a significant change in circumstances.
- Ensuring line managers and supervisors have sufficient training and instruction to be competent to carry out risk assessments and to identify training needs in respect to Medical Devices.
- Ensuring that the Trust's procedure on adverse incident reporting and management is widely disseminated, promoted and implemented within their areas of responsibility.
- Ensuring that staff are appropriately trained in the reporting and management of adverse incidents.
- Promoting an open, honest and just reporting culture and ensuring that appropriate reviews are carried out.

### 3.5 The Medical Equipment Group is responsible for:

- Advising the Board, through the Safety, Quality, Experience & Performance Committee, on the management of Medical Devices, relevant to the agreement of strategic objectives and investment priorities.
- Alerting the Board, through the Safety, Quality, Experience & Performance Committee, to issues associated with the management of Medical Devices, which influence resource allocation.
- Ensure the development, implementation and audit of a Trust-wide policy and strategy for the management of Medical Devices to include procurement; training; risk assessment; maintenance, including maintenance contracts, replacement and disposal contracts.
- Organising, co-ordinating and prioritising risk management issues in relation to Medical Equipment and advising on the level of actions and resources necessary to manage those risks effectively.
- Ensuring appropriate arrangements are in place to facilitate effective cross-partnership working and to interface with other Trusts.
- Ensuring the existence and maintenance of a Trust-wide inventory of Medical Devices.
- Encouraging and fostering awareness of Medical Devices management at all levels of the organisation.
- Recommending proposals for the purchase of Medical Equipment.
- Monitoring and reviewing pharmacy provision and drug-related incidents.
- Oversight of incidents and issues pertaining to Medical Devices within NIAS.
- Ensuring lessons learned from the outcome of Medical Device investigations are used as a means of improving precautions, revising works activities and practices, including the revision of documentation or purchase of additional or alternative Medical Devices in addition to any adverse event outcomes.
- The formulation of any remedial measures that may be required and to assist with the aim of seeking continual improvement of Medical Device related tasks.
- Assessing any training requirements associated with Medical Device roles and responsibilities
- Monitoring, measuring, review and audit measures that may be required to ensure that the roles and responsibilities pertaining to Medical Devices are applied in practice and that they continue to be effective

### 3.6 The Medical Devices Lead is responsible for:

- Collaborating widely with stakeholders both internally and externally to ensure compliance with regional, national and international guidance, standards and legislation.
- Leading Medical Devices capital programmes, procurement, project and contract management, leading the Trust's actions to manage the life-cycle of medical technology efficiently and within financial limits.
- Ensuring that there are systems in place across the Trust to for planned, preventative maintenance and decontamination of Medical Devices.
- Developing and implementing asset management/ inventory systems for medical devices and equipment across the Trust.
- Developing corporate wide Medical Devices strategies, policies and procedures, including the arrangements for risk management, governance and assurance, health and safety, decontamination and training to ensure the safe and effective management of Medical Devices.
- Developing and provision of a high quality, efficient Medical Device service which is flexible and responsive to the Trust needs and demands, for example emerging risks, immediate maintenance requirements etc.
- Investigating equipment failures, completion of failure reports and when necessary escalate failures to regional or national forums.
- Managing information flows safety alerts involving medical devices and acting as the Trust's Medical Devices Liaison Officer, MDLO, to the NIAIC.
- Promoting the safe use of Medical Devices across the Trust and supporting the implementation of local and national safety initiatives and supporting actions on Field Safety Notices, acting as the Trust's Medical Devices Safety Officer, MDSO.
- Reviewing and interpreting regional, national and international legislation, health service policy, strategy standards and guidance relating to medical devices including their decontamination in-line with the Trusts Infection prevention control policies and procedures, ensuring that the Trust is compliant and informed of any changes and subsequent actions required.
- Interpreting national and regional health service policy and strategy in order to ensure safety and quality in the area of Medical Devices for the organisation.
- Responsible for reviewing and updating existing policy, procedures and developing a more robust system for all aspects of clinical equipment management in conjunction with other senior staff.
- Maintaining current knowledge of the latest scientific/technical developments/ national best practice relating to Medical Devices.
- Reacting to changes in best practice and guidance, to ensure that the Trust is at the forefront of sound Medical Devices management and ensure the safety of its staff and service users.
- Maintaining the careful use and security of all Medical Devices across the organisation.
- Ensuring that at all times the management of the Medical Devices services are patient focused.

### 3.7 The IPC Group is responsible for:

- Providing expert IPC advice in relation to the procurement of Medical Devices and Equipment.
- Being a resource for advice regarding effective decontamination of Medical Devices and Equipment.
- Advising on storage of medical devices in line with IPC best practice.
- Engaging in the audit of existing facilities and arrangements for routine cleaning and the control of infection for all Trust premises, using audit tools designed in conjunction with the Trust risk assessment process.
- Developing robust monitoring arrangements, to ensure compliance with Trust policies and procedures in relation to infection prevention & control at all times to enhance the safety and welfare of all staff, patients and visitors.
- Reviewing the Trust's policies and procedures on infection prevention & control.
- Producing regular reports to the Assurance Committee highlighting the outcome of audit reports from stations, training and management walk-around inspections, and making appropriate recommendations as required.
- As appropriate, reviewing, implementing and producing policies, procedures and practices, ensuring compliance with the Health and Safety at Work Order and COSHH Regulations making recommendations for change as appropriate.
- Developing educational programmes, delivered by the Trust's Training Department, which are to be agreed and approved by the IPCG.
- Advising on staff education in accordance to infection prevention & control standards.
- Considering emerging threats, to evaluate their relevance and consequence, and to develop and co-ordinate the Trust response as appropriate.

### 3.8 Training Officers and Clinical Support Officers are responsible for:

- Collating and interpreting training needs analysis for the purpose of developing training plans and providing training and clinical supervision as required in relation to Medical Device and Equipment use.
- Providing training and assessment to ensure staff are competent to use Medical Devices and Equipment.
- Providing advice and support to staff in the use of Medical Devices and Equipment.
- Liaising with the Medical Equipment Group for the provision of Medical Device Documentation, inclusive of but not limited to Original Equipment Manufacturers Manuals, Standard Operating Procedures, Technical Notes etc.
- Adhering to direction as provided by the Medical Device Lead and the content of this Policy, SOPs, Original Equipment Manufacturers' Manuals to ensure consistency of information and Training.

### 3.9 Line Managers are responsible for:

- Ensuring that this policy and associated procedures are effectively implemented across their area of responsibility.

- Complying fully with and distributing guidance in relation to the management and use of Medical Equipment, inclusive of but not limited to Memos, Standard Operating Procedures, Safety Alerts etc.
- Ensuring that staff using medical devices have received the appropriate training and are competent and authorised to do so.
- Ensuring appropriate support is offered to staff in the use of Medical Devices and Equipment and any training needs are addressed to the EDUCATION, LEARNING AND DEVELOPMENT.
- Maintaining a record of all Medical Devices across their area of responsibility.
- Ensuring that any risk assessments in respect to Medical Devices are carried out in line with the Risk Assessment Procedure and supported by the Risk Management Team.
- Ensuring that any issues or concerns involving Medical Devices that cannot be addressed locally, or deemed beyond their control, are escalated to a more senior manager via line management structures.
- Promoting an open, honest and just reporting culture.
- Ensuring that appropriate reviewing, approving and/ or escalating of incidents, via the Trust Incident Reporting System, is carried out in line with incident reporting procedures.
- Ensuring that any Medical Device or Equipment defective in performance or involved in an incident is immediately withdrawn from service, cleaned, decontaminated, clearly marked to ensure no inadvertent use, withheld, and returned to the Medical Device Lead. The device or equipment shall not be disposed of under any circumstances.
- Ensuring that the all respective incidents on the Trust Incident Reporting System is updated and all incidents are correctly and timeously closed, in line with incident reporting procedures.
- **Challenging any misuse or deliberate over categorisation of Medical Devices and ensuring that any stocks are at appropriate levels to reduce the potential for overstock and that all expired products are removed from stores and responsibly decommissioned, condemned or disposed.**
- Ensuring that the all Vehicular Daily Inspections, VDI, within their remit, are carried out in respect of Medical Devices and Equipment and any adverse incidents are reported via the Trust Incident Reporting System, in line with incident reporting procedures and ensuring that the content of the reports is factual and appropriate.
- Overseeing and supervising the implementation of infection control policies for the routine decontamination of Medical Devices and Equipment within their area of responsibility and to actively participate in the management of infection control related incidents and risks.

### 3.10 All Staff are responsible for:

- Adherence to this Policy and overarching arrangements.
- Attending any Medical Device training courses provided by NIAS.
- Ensuring the safety of individuals involved, service users, visitors and staff, the environment and equipment.
- Avoiding putting themselves and others in situations of danger.

- Only using medical devices if they have received the appropriate training and are competent and authorised to do so.
- Complying fully with guidance and actions required, as distributed in relation to the management and use of Medical Devices and Equipment, inclusive of but not limited to Memos, Standard Operating Procedures, Safety Alerts etc.
- Fully co-operating with any review and investigative process including the provision of witness statements, if appropriate.
- Immediately reporting Medical Device defects, faults, near misses, or any adverse incidents via the Trust Incident Reporting System, in line with incident reporting procedures, criteria and timescales, and ensuring that the content of the report is factual and appropriate.
- Where applicable, initiating, investigating or reviewing incidents, ensuring that incidents reported are in line with Trust reporting policies and procedures and the content of the report is appropriate, within agreed Trust timeframes, and closing upon completion of this process.
- Participating in adverse event investigation where applicable, the aim of which is to provide appropriate help and support at the earliest opportunity to mitigate the effects of any Medical Device related issue.
- Identifying the medical device involved in incidents, recording the type, model and serial number(s) of the equipment, clearly labelling defective devices and any consumables associated, ensuring they are taken out of use and presented for investigation.
- Ensuring that any medical device or equipment involved in incidents is held, not disposed of, and returned to the Medical Device Lead. Such devices and equipment shall not be disposed of, under any circumstances.
- Ensuring that their line manager and/or person in charge of the area is informed of any incident.
- Co-operating with any control measures implemented to protect their health.

#### **4.0 KEY PRINCIPLES:**

##### **4.1 Identification of Need**

The Trust shall take into consideration that as clinical practice and medical technology advances, so too must the Medical Devices and Equipment to support that practice and technology, especially if there are advantages to patients, to staff and to the Service.

From time to time, service developments may require new equipment, or staff may themselves consider that a new item of equipment is likely to benefit patients or the service. Staff may have witnessed the use of new or innovative Devices and Equipment in other Services, at trade fairs conference & exhibition or approached by medical equipment manufacturers / suppliers with a view to adopting new products.

Individual members of staff, Departments or Directorates wishing to identify items of medical equipment for use by NIAS shall submit an Identification of Need to the Medical Equipment Group for consideration. Copies of the Identification of Need will be available from the NIAS Intranet. The Identification of Need shall include, but not be limited to the following:

- Name of item; manufacturer, make, model
- Indications for use
- Clinical benefit or advantage over existing equipment, where applicable
- Clinical evidence to support use
- Approximate cost per item
- Dimensions; size, weight
- Power requirements; battery, vehicle charging
- Amount required e.g. per staff member, per vehicle, per department etc.
- Projected frequency of use e.g. per call, day, month etc.
- Training Requirements
- Potential supplier details, if known
- Details of potential competing products

#### 4.2 Assessment of Need

Medical Devices and Equipment shall only enter service within the Trust, through approved routes, when it has been established that the devices and equipment have been formally identified, assessed and evaluated as matching the user requirement and specification as set by the Medical Equipment Group. This is to ensure that the devices are approved and safe for use, that arrangements for, training, servicing, maintenance, calibration and decontamination, consumables and spare parts with continued supplier support are adequate and in the best interests of the Trust. New equipment requests, demonstrations or changes will be a standing item on the agenda of the Medical Equipment Group.

- All submissions that have arrived since the previous meeting shall be raised to reach an initial determination as to whether there is any merit in formal consideration.
- If the Group deems that there is no merit in further consideration, then the representative or NIAS staff member who made the submission will be notified of the decision.
- If a decision is made that the item is worthy of further consideration, then an assessment of need shall be requested and undertaken.
- The procedure for the assessment of new equipment will depend on the complexity of new Medical Devices and Equipment and the satisfaction of rationale.

For further information on equipment assessment, please see Appendix 1.

#### 4.3 Governance

The Trust shall ensure that there is an appropriate governance structure in place at all levels with clearly designated responsibilities for the oversight and management of Medical Device and Equipment.

The Trust has established and regularly reviews terms of reference for groups and committees responsible for such oversight and ensure appropriate representation and attendance.

Internal audit arrangements are in place to review that appropriate policy and procedures are in place to ensure the effective management and review of medical devices in accordance with Controls Assurance Standards (CAS) / replacement process.

Audit is a statutory requirement and the BSO Audit is an independent, objective assurance service that provides the Trust with an objective evaluation, through a systematic, disciplined approach, of the overall adequacy and effectiveness of the Trust's framework of governance, risk management and control to minimise or eliminate risks to patients and staff.

Medical Device and Equipment incident reporting is a key element of audit analysis whereby the management and performance of devices and equipment can be established through analysing the incident data as reported and establishing themes, trends, patterns etc. to provide feedback and support to the Trust, its staff and patients.

The audit shall encompass applicable criteria and key indicators capable of showing improvements in medical devices management and providing early warning of any risk. The audit shall note the criteria, detail the evidence and provide a narrative of self-assessment of compliance, including source evidence.

Any gaps in compliance shall be noted such that a post CAS assessment can be performed, and an action plan can be compiled to enable any gaps in compliance to be addressed and closed.

Any internal audit reports shall be submitted to the appropriate committees / Trust Board as necessary

The Trust shall employ additional 'external' monitoring and audit to inspect the policy and procedures against essential standards of quality and safety for the management of Medical Devices as necessary and any audit reports shall be submitted to the appropriate committees / Trust Board as necessary.

#### 4.4 Device Evaluation

Where an item of equipment has been approved for further consideration, the Medical Equipment Group shall contact the representative to arrange a demonstration of the item for members of the Group. This shall ideally be undertaken at NIAS Headquarters and will be arranged in keeping with the NIAS policy on hospitality etc. This evaluation will be undertaken by an evaluation team, a minimum of five people to include:

- The Medical Director, Assistant Medical Director, or representative,
- A member of the Regional Ambulance Clinical Training Centre Staff,
- The Stores Manager or their nominated representative,
- An Infection Prevention and Control Practitioner,
- A front-line staff member, Paramedic or Technician, who would potentially use the equipment if it was deployed,

The Director of Finance or nominated representative should ideally attend, but their consideration may be included at a later date. Where the original Identification of Need

submission has been made by a member of staff, then that staff member shall not be involved in the Initial Assessment.

The Medical Equipment Group shall develop a Medical Devices Equipment Evaluation Checklist, based on the assessment of need, to which the Device or Equipment being evaluated can be compared and assessed against.

The evaluation team shall ensure that the user requirement as defined by the Medical Equipment Group is met in the evaluation checklist.

#### 4.5 Risk Assessment

A Risk Assessment with supporting Method Statement shall be undertaken for all new Medical Devices and Equipment that are considered for implementation. The risk assessment shall take into account any potential hazards to the user, other staff, patients and the service, inclusive of but not limited to the following:

- Manual Handling: weight and orientation of the device and equipment
- Ease of use: functionality, clarity of observations, printouts, audibility
- Infection, Prevention and Control: Cleaning, disinfection, decontamination
- Deployment; impact on service delivery, downtime of vehicles
- Training element: cascading training from Trainer to End User
- Service and maintenance; impact on service delivery, downtime of vehicles

The Risk Assessment shall be carried out as part of any evaluation, with reviews and updates at each stage of the evaluation process.

The Health and Safety Team shall provide guidance and support to individuals carrying out risk assessments and method statements.

#### 4.6 Standardisation

The Trust is committed to a policy of standardisation of Medical Devices in order to:

- Reduce the range of inventory in terms of consumables held,
- Minimise risk through a common range of equipment,
- Build resiliency through available alternatives in the event of replacement or a withdrawal following the receipt of a Field Safety Notice,
- Improve the continuity of patient care,
- Minimise purchasing cost through competition and purchasing power,
- Minimise maintenance and training costs.

#### 4.7 Procurement

In the procurement of Medical Devices, be it through purchase, rental, lease, loan or transfer, the Trust shall follow the twelve agreed procurement principles, guiding public procurement in Northern Ireland as listed in Appendix 2.

The Medical Equipment Group, in assessing need, shall establish which method of procurement best suits the needs of the Trust be that outright purchase, rental or

lease, and establish for each option the ownership and responsibility for aspects such as warranty, service, maintenance, calibration, consumables, spares and changeout etc. where applicable.

The procurement of the device may take the form of a regional contract for which a region wide Contract Advisory Group, CAG, through the Centre of Procurement Expertise, COPE, will be established.

The Medical Equipment Group shall define the user requirement, the function that the item is required to perform through the preparation of a specification and the Trust will be represented at the CAG to ensure that the Trust specification can be implemented for the selection, supply, procurement, service, and maintenance of appropriate Medical Devices.

All purchases shall be in line with the Trust's policy and procedure in respect of requisitioning, ordering and receipt of goods and services.

All requisitions for Medical Devices or Equipment in terms of purchase, rental or lease, shall be placed via the electronic Procurement System, also known as eProcurement or eProc, or via the submission of a Memo of Need directly to the Stores and Procurement Department, detailing the justification of need for the new device.

All requisitions placed for Medical Devices or Equipment, shall be open to scrutiny by the Stores Department, in conjunction with the Centre of Procurement Expertise, COPE, to ensure appropriate oversight in terms of stock levels, expenditure and Trust needs.

Any order shall reflect the results of the procurement negotiations and call for delivery to an agreed location.

All requisitioners shall ensure that no requisition or order is placed, or expenditure committed for any item or items for which there is no Line Manager oversight and approval.

All requisitioners shall ensure that no requisition or order is placed, or expenditure committed for any newly approved Medical Devices or Equipment direct to suppliers for which there is no Line managers oversight or authorised by the Director of Finance on behalf of the Chief Executive.

#### 4.8 Loan Equipment

Medical Devices or Equipment shall not be supplied on loan to the Trust without an Overarching Master Indemnity Agreement being in place, detailing the Supplier, the Devices or Equipment on loan, and signed for by a representative of the Trust.

This Indemnity Agreement shall ensure clarity of responsibility for any problems, which may arise, with the equipment and detail the public liability and product liability insurance covering the Equipment together with any other information provided to the Trust is accurate and will be kept

The Medical Device Lead shall collate the identify any training elements required with the loan equipment and pass these to the Education, Learning and Development Department for implementation.

All Loan equipment shall be clearly identifiable as such, marked with a unique identifier and recorded on a database which allows for storage of loan equipment data such as:

- Type of equipment.
- Its purpose.
- Make.
- Model.
- Serial nos.
- Value.
- Purpose of loan.
- Condition as received.
- Loan period commencement date.
- Premises and location(s) at which the equipment will be kept.
- The final collection date upon return to the supplier.

The loan equipment record should also include data on maintenance, service and breakdown history, original equipment manufacturers manuals etc. and any replacement due date.

Prior to collection and return, all loan equipment shall be appropriately decontaminated, with the corresponding Decontamination Form accompanying the Equipment.

Loan equipment shall be carefully inspected for any damage and the condition recorded.

Suppliers collecting loan equipment at the end of the loan term shall complete a Collection Confirmation Receipt as part of the Indemnity Agreement, at the point of collection.

The Loan Equipment Database shall be updated to reflect the items that have been returned, the return condition and the date upon which they were collected.

Where disposable Equipment is provided to the Trust, this shall be on a transfer basis, with the same information as per loan equipment recorded and stored with the exception that a Purpose of Transfer is recorded along with the means and date of disposal.

In the event of disposal, the Trust will notify the Supplier of the disposal of any medical devices or equipment on transfer and the date upon which this occurred.

#### 4.9 Commissioning and Acceptance Procedure

All new Medical Devices or Equipment shall upon completion of the evaluation, acceptance and procurement, undergo commissioning and acceptance to ensure that they fulfil the requirements of the Trust in terms that they are:

- Undamaged.
- In Proper Working Order,
- Complete With All Necessary Accessories And User Operating Manuals and decontamination guidance,
- Allocated And Marked With An Asset Code
- Included In The Medical Devices And Equipment Management System.

All new Medical Devices or Equipment shall be delivered to the Stores Department unless otherwise arranged due to complexity, size etc., who with the Medical Equipment Group, shall ensure that they are as procured and receipted in respect of the order raised.

In the case of established Medical Devices or Equipment procured through eProcurement or Memo of Need, it shall be the responsibility of the end user who requisitioned them to inspect, confirm acceptance, and receipt the devices as procured.

#### 4.10 Asset Management

The Trust is committed to a systematic and planned approach to the management of assets from their inception to their ultimate disposal.

The Trust recognises the extensive range of Medical Devices and Equipment in terms of complexity and sophistication and the mobility that is required to take into account servicing, downtime, vehicle and facility transfer, change out, replacement etc. The Trust shall be a responsible for the management of those assets in terms of their location, use, service and maintenance, from inception to disposal, throughout their lifespan within the Trust.

The Trust shall ensure that it controls the quality and quantity of the information that it generates, can maintain that information in an effective manner and can dispose of the information efficiently when it is no longer required as set out in the Trust's Records Management Policy and Records Management Business Rules.

The Trust shall maintain an inventory of all medical devices held within it and detailed asset lists of all reusable Medical Devices and Equipment. This may be a combination of records held centrally by the Medical Directorate or by individual Departments. Depending on the type of device and the departments in which they are used, the Trust shall appoint a designated Device Manager for each device or group of devices for those departments e.g. HART, HEMS, Fleet, Medical, Education, Learning and Development Department etc. Each device manager shall be appropriately acquainted with this Policy and Procedures and clearly understands their responsibilities in the role in respect that all medical devices and equipment in their

area of responsibility are accounted for and recorded on an inventory. Device managers shall attend the Medical Equipment Group.

In addition to overarching inventory and asset lists, the Trust shall maintain asset lists of Medical Devices and Equipment under Service, Maintenance and Calibration contracts for each respective contract. All asset lists shall be named in accordance with the Trust's Records Management Policy to ensure the dating and clarity of description of each asset list with no ambiguity.

The Medical Device and Equipment asset lists and records may take different forms and formats, be that a database, spreadsheets, contractor reports in portable document formats but there shall be consistency across Device and Equipment Types to enable ease of following and information retrieval.

Medical Device and Equipment asset lists and records shall provide evidence of:

- Type of Device and Equipment,
- Make,
- Model,
- Serial Nos.,
- Unique Device Identification, UDI,
- Valid Trust asset ID tag, where appropriate,
- Deployment location,
- The purchase price of the equipment,
- Date of purchase,
- Purchase Cost,
- Date of reception into the Trust,
- Date of deployment,
- Manufacturer operating instructions and manuals,
- Any Pre-installation checks performed and completed,
- Date of installation,
- Date of installation and commissioning by manufacturer or agent,
- Trust and Contractor Emergency contacts in event of failure,
- Schedule and details of maintenance and repairs,
- Service, maintenance and calibration costs,
- Up to date Service Records,
- Dates of downtime with reasons and any actions taken,
- End-of-life date, if specified,
- Responsible Device Manager,

Medical Device records shall be protected to ensure their accuracy is maintained and that any changes are reflected and do not obscure previously recorded information. Procedures shall include the ability to store securely to enable record retrieval throughout the retention period of records to ensure that equipment is correctly serviced, maintained and calibrated, and any inconsistencies, unreliability or failures evident.

#### 4.11 Training

Medical Devices or Medical Equipment shall not be implemented into service until the end users have adequate training in its use.

The Trust shall ensure that there is commitment at all levels of management to the achievement of an adequate standard of training is essential.

All training in relation to Medical Devices shall be mandatory and shall be held during normal working hours wherever possible and so far as reasonably practicable. Where staff receive training outside their normal working hours, the Trust will ensure that they suffer no loss as a result.

The Trust shall ensure that Information, Training and Instruction (ITI) for end users be delivered by competent professionals and in a form comprehensible to the end user. The ITI shall enable end users to use the respective device safely and effectively and perform user maintenance as required.

Train the Trainer training shall be provided by the Manufacturer or their agent to members of the Education, Learning and Development Staff at Regional and Divisional level and this training shall be cascaded to end users.

This shall be inclusive of but not limited to any user decontamination, servicing, calibration and maintenance and the action to be taken in the event of a malfunction.

Medical Device documentation shall be available to Education, Learning and Development Staff and end users in the form of Original Equipment Manufacturer User Manuals, Manufacturer's Instructions, Standard Operating Procedures, and Technical Notes etc. to ensure comprehensive learning.

All training provided shall comply with any general provisions of the appropriate statutory instruments, approved codes of practice and manufacturer's instructions.

The Trust shall ensure that records are kept of training of users of medical devices. These records shall show that users:

- Know how to use the device safely.
- Can carry out routine checks, user maintenance and routine decontamination.
- Have been trained and had relevant refresher training.
- Are confident and/or competent to use devices in their areas of work.

All end users shall be assessed for competency on the respective devices with a record of assessment and competency undertaken and subsequently signed by the users that they have received and understood the instruction as provided.

The Education, Learning and Development Department, shall document and maintain records and details of training given to all personnel, inclusive of the dates, personnel trained, personnel providing the training, copies of training documentation, competency assessments and copies of certificates as issued by Training Providers.

It is the responsibility of the end users to identify any training needs that they have in their training and notify their respective line managers such that these can be addressed to the Education, Learning and Development Department and whereby new or refresher training can be provided. It is also the responsibility of the end user to attend training provided for them by line management, the Education, Learning and Development Department and the Trust.

#### 4.12 Deployment

The Medical Equipment Group shall determine the deployment rationale of Medical Devices for use throughout the Service. Medical Devices and Equipment may be issued to individual End Users, Vehicles, Departments, Stations, Divisions or Service wide. Medical Devices and Equipment may be placed on the eProcurement System or as a direct Stores Item, where they will be deployed to the requisitioner upon receipt of an eProcurement requisition or a Memo of Need.

Line managers shall take cognisance of and responsibility for the requisitioning of Medical Devices and Equipment in their Stations, Departments etc. to ensure that stores are not overstocked to the extent that devices are unnecessarily disposed of if an expiry date is reached. Where Medical Devices are issued in boxes or batches, in quantities greater than required by the requisitioner, line managers, Station Supervisors, Officers etc. shall liaise with each other for the distribution of devices across Stations and Areas so as to prevent overstocking and any unnecessary disposal. It is essential that all staff are aware of the medical device management system and the part that they play within the system to ensure that medical devices are managed correctly.

The management of Medical Devices and Equipment issued on transfer or loan shall transfer either to the individual end user or to the respective Station or Department. Responsibility for each aspect of loan device management, inclusive of the decontamination procedures, service, maintenance, calibration etc. shall be as detailed in the associated indemnity agreement. End users and line managers shall remain accountable for collecting and returning these items when they are no longer required. It is essential that all individuals are aware of the medical device management system and the part that they play within the system to ensure that medical devices are managed correctly.

Directors, Heads of Department, Area Managers, Divisional Officers, Divisional Training Officers / Station Officers shall be responsible for Medical Devices and Equipment in their areas of responsibility. End Users and Line managers shall ensure, as far as reasonably practicable, that each Medical Device or item of Medical Equipment is physically located in its respective recorded location, or list the current location such that when required, it can be easily traced.

#### 4.13 Storage

All Medical Devices and Equipment shall be stored in accordance with manufacturer's recommendations and in line with best IPC practice for the storage of equipment. Line managers shall take cognisance of and responsibility for the Medical Devices and Equipment in their Stations, Departments etc. to ensure that they are stored

appropriately, securely, cleanly, and organised, whereby stocks can be readily assessed for type, quantity and Use By dates etc., in the event of product recalls, replacement or actions required as part of Safety Alerts, Field Safety Notices etc.

#### 4.14 Infection Prevention and Control (IPC)

The Medical and Healthcare Products Regulations Agency, MHRA, defines the following terms:

- *Cleaning* 'is a process which physically removes contamination but does not necessarily destroy microorganisms. The reduction of microbial contamination cannot be defined and will depend upon many factors including the efficiency of the cleaning process and the initial bio-burden'.
- *Cleaning*, by removing organic material and reducing the number of microorganisms present, is an essential prerequisite of equipment decontamination to ensure effective disinfection or sterilisation can subsequently be carried out.
- *Disinfection* 'is a process used to reduce the number of viable microorganisms, which may not necessarily inactivate some viruses and bacterial spores. Disinfection will not achieve the same reduction in microbial contamination levels as sterilisation'. Disinfection can be achieved by the use of chemicals and sterilisation by physical methods such as the use of heat.
- *Sterilisation* 'is a process used to render the object free from viable microorganisms, including spores and viruses'.

The Trust's Guidance and Procedures for Infection Prevention and Control Policy and Strategy sets out the strategic and policy approach to the prevention and control of infection.

The NIAS Vehicle and Patient Equipment Decontamination Manual sets out the principles and process of decontamination utilised within the NIAS. This manual should be read in conjunction with the manufacturers decontamination instruction for specific medical devices.

All line managers are required to oversee and supervise the implementation of the infection control policy and procedures within their area of responsibility and actively participate in the management of infection control related incidents and risks.

The selection and implementation of Medical Devices shall comply with the Trust's Guidance and Procedures for Infection Prevention and Control Policy and Strategy such that all Medical Devices and Equipment receive an infection prevention and control evaluation as part of their assessment of need.

The whole process of decontamination shall begin prior to acquisition to ensure that device decontamination recommended by the manufacturer can be undertaken safely and effectively within the NIAS. Failure to enable effective decontamination of a device in line with accepted NIAS processes may result in a device being deemed not suitable for introduction.

Suppliers and manufacturers shall be responsible for providing information on safe decontamination methods and cleaning, disinfection and decontamination product compatibility.

All Medical Devices and Equipment shall have the ability to be cleaned, disinfected and decontaminated in accordance with the Infection Prevention and Control Policy and Procedures of the Trust. Medical Devices and Equipment that cannot be adequately and safely decontaminated shall not be considered for implementation beyond the evaluation stage.

Thorough cleaning shall always be the first step in the decontamination process. All reusable Medical Devices and Equipment shall be adequately cleaned and decontaminated in between use and in between patient use.

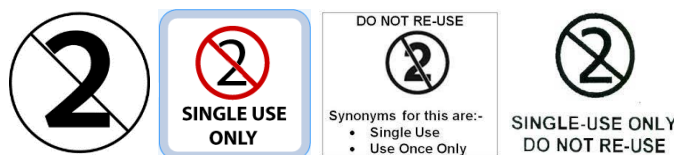
Decontamination methods shall be chosen according to the risk of infection associated with the use of a particular device or piece of equipment and shall be carried out in accordance with the Trust's guidance and the manufacturers' instructions.

Medical devices may require storage if used intermittently and this shall be undertaken in line with existing NIAS process. This will be dependent on the nature and size of the device. All devices should be decontaminated prior to storage, an indicator that cleaning has occurred should be placed on the device, Trigger tape. The device shall be placed inside a clean transparent plastic bag and sealed for the duration of storage.

Appropriate Personal Protective Equipment, PPE, shall be worn as required during the cleaning, disinfection and decontamination processes.

Single Use Disposable Medical Devices shall be suitable for one use only on an individual patient only and then discarded. They shall not be reprocessed in any way, cleaned, disinfected or sterilised, for further use.

Single Patient Use Medical Devices may be used for more than one episode on one patient only. The manufacturer shall state the number of times the item can be reused prior to disposal. Single Use items will bear the single use logo in the form of a 2 inside a circle with a line through it:



Advice shall be sought from the IPC Team in regard to compliance with the Infection Prevention and Control Policy and Procedures.

In compliance with the MHRA, all Medical Devices and Equipment requiring inspection, repair, service or calibration shall be appropriately decontaminated in order to remove or minimise the risk of infection, by the end user or other appropriately trained staff, before it is sent away.

A Decontamination Certificate must be attached to the equipment on dispatch, which states the method of decontamination used.

Copies of the Decontamination Certificate will be available from the NIAS Intranet.

Area Officers are the designated responsible managers for the routine cleaning and decontamination of equipment within their Area.

The decontamination of equipment to be used for or following use after a patient care episode is the responsibility of the member of staff who will or has used it. This principle applies across all levels of staff within NIAS without exception.

#### 4.15 Implementation

The Trust shall only implement Medical Devices and Equipment into Service once all measures in training have been completed in accordance with manufacturer's recommendations.

- All end users are appropriately trained and assessed as competent to use the devices and equipment.
- All corresponding support documentation is available to end users e.g. Original Equipment Manufacturers User Manuals, Standard Operating Procedures etc.
- Users are fully aware of servicing, maintenance and calibration procedures, where applicable.
- The Medical Equipment Group shall assign responsibility to an individual or team for the implementation process.
- Where appropriate, a risk assessment shall be developed to ascertain any risks to service provision during implementation are mitigated or controlled.
- No unauthorised Medical Devices may be used within the Trust's activities.
- Only Medical Devices and Equipment as approved by the Medical Equipment Group, implemented and issued by the Trust shall be used within the Trust.

#### 4.16 Service, Maintenance & Calibration

The Trust shall ensure that where applicable, all non-single use, reusable, Medical Devices and Equipment that can be serviced, are supported by appropriate service and maintenance contracts in compliance with the manufacturers' recommendations.

The Trust shall evaluate and allocate sufficient resources for service and maintenance contracts or where necessary provide adequate facilities and staff to ensure effective and efficient maintenance, repair and calibration of Medical Devices and Equipment.

The Trust shall maintain asset lists of Medical Devices and Equipment under Service, Maintenance and Calibration contracts for each respective contract.

Asset lists of Medical Devices and Equipment shall be named in accordance with the Service, Maintenance and Calibration contracts shall be so written as to allow for the addition and subtraction of devices to take account of expansion of need, replacement or disposal of Medical Devices and Equipment.

Any Medical Devices that are considered for decommissioning, condemnation and disposal and subject to a service, maintenance or calibration contract shall have their details removed from those respective contracts.

Trust attendance and representation at Contract Advisory Groups shall ensure that contracts for the service, maintenance and calibration of Medical Devices and Equipment represent the best interests of the Trust in terms of:

- The technical content of contracts,
- The suitability and competency of contractors,
- Provision of expert advice on the servicing, repair and calibration,
- A scheduled servicing system that takes into account the 24 hour service delivery of the trust
- Minimises impact on service delivery
- Flexibility with work patterns and continuous service provision
- Clear and unambiguous designation of serviced devices and equipment
- Frequency of servicing
- Provision of service schedules
- Provision of service reports and verification of service
- Provision of updated asset lists and inventories per contract
- Authorisation and control of work
- Quality control, assurance and safety
- Ensuring that the safety of users and patients is paramount

All Medical Devices and Equipment being presented for service, maintenance and calibration shall be appropriately cleaned, disinfected and decontaminated The Trust's Guidance and Procedures for Infection Prevention and Control Policy. A Decontamination Certificate shall accompany the equipment on dispatch, stating the method of decontamination used.

Scheduled Servicing shall be in compliance with the Original Equipment Manufacturers' recommendations, statutory instruments and approved codes of practice corresponding to the device and equipment being serviced, inclusive of but not limited to the following:

- Comprehensive inspection;
- Changing of components which require regular replacement;
- Safety checks
- Performance tests as necessary;
- Calibration;
- Final functionality checks;

User servicing shall be restricted to the following:

- Functional checks;
- Careful cleaning and, where necessary, decontamination/ sterilisation,
- Inspection of leads and ancillary devices for damage;
- Other checks as recommended in the manufacturer's User Instruction Manual.

Users shall not carry out any servicing or maintenance which is beyond their knowledge, capability, or training.

The Trust shall ensure that all respective staff are made aware of service schedules affecting Medical Devices and Equipment in their area.

It is the responsibility of all staff to ensure that equipment required for servicing is made available;

The Trust shall ensure that service history records of Medical Devices and Equipment service, maintenance and calibration shall be maintained for the lifetime of that equipment and retained for the periods as required by statutory instruments.

Service records shall detail all relevant information regarding the respective Medical device or item of Medical Equipment inclusive of but not limited to the following:

- Device details such as Make, Model, Serial Number, location;
- Identification and listing of all checks and tests carried out;
- Results of tests and checks with any recommendations;
- What components were replaced, where applicable
- Calibration;
- Verification that the device is compliant and safe for use;

Service records and updated asset lists shall be issued to Device Managers in a format amenable to them and to the Trust.

Records shall be stored where they are both secure and readily accessible to establish servicing, maintenance and calibration status along to ensure that repairs and servicing are carried out regularly and promptly and the remedial actions to be taken in the event of recommendations noted.

Any failure or breakdown of a Medical Device during servicing shall be recorded on the Trust's Incident Reporting System such that all failures and breakdowns can be recorded and used in the evaluation of new or replacement, impacting on future decisions regarding equipment procurement.

The end user and line manager shall notify the Medical Device Lead and ensure that the equipment is withdrawn from service and clearly marked to ensure that it cannot be inadvertently used.

#### 4.17 Incident reporting

The Trust Incident Reporting System, Datix, is the prime means of communicating incidents involving Medical Devices and Equipment to the Trust. It is the recognised reporting system for the escalation of incidents to the regional and national regulatory agencies and the means by which, statistical data on the performance, defects or failure can be extrapolated for use in assessments and evaluations of existing equipment and in the selection of new or replacement devices and equipment. Incidents may be shared via Datix both regionally and nationally, and as such this data

will be anonymised for data protection purposes and in a form that can be analysed to identify hazards, risks and opportunities to improve the safety of staff and patient care.

- Any Medical Device or Equipment defective in performance or involved in an incident shall be immediately withdrawn from service, cleaned, decontaminated, clearly marked to ensure no inadvertent use, withheld, and returned to the Medical Device Lead.
- It must not be interfered with or tampered with in any way until any necessary investigation has been completed.
- Any consumables used with the device or equipment in the incident shall be subject to the investigation and shall also be isolated, cleaned, decontaminated and clearly marked to ensure that they cannot be inadvertently used.
- The incident shall be reported and notified using the standard adverse incident Report on the Trust Incident Reporting System, DATIX, in line with Trust reporting policies and procedures, reporting criteria and timescales.
- In the event of identification of a defect in performance or an incident where an issue with a Medical Device has been raised, the respective line manager and the Medical Device Lead shall be included as Additional Investigating Managers, who will have access to an oversight of to this incident.
- Reporters shall make contact and agree roles before adding names to the Additional Investigating Managers part of the incident report form.

The reporter shall complete all fields of the incident report form and record specific details that will enable the identification of the Medical Device involved in the incident, to assist with any investigation, inclusive of but not limited to the following:

- Device Type.
- Model.
- Serial number(s).
- Vehicle Call Sign, if applicable.
- Station or Department, where applicable.
- Factual, clear, concise and appropriate account of the incident with key events leading up to and immediately after the event, including any relevant clinical judgement, key risks, contributory factors or causes of the incident.
- Any action taken, inclusive of logging the equipment on Contractor sites for investigation and or repair and the isolation, labelling and identification of the devices, equipment and any consumables associated for investigation and repair, ensuring they are taken out of use and presented for investigation.

The reporter shall anonymise the description of the incident with no names of patients or staff, avoiding the use of abbreviations and jargon wherever possible so that what happened in the incident is clearly understood.

#### 4.18 Medical Device Alerts

Medical Devices Alerts (MDAs) are the prime means of communicating safety information to the Trust on Medical Devices and Equipment. MDA's are prepared by the Medicines and Healthcare products Regulatory Agency (MHRA) and are distributed nationally with the same reference, content, and format.

The Northern Ireland Central Alert System (NICAS) provides access to safety alerts and information issued by the Northern Ireland Adverse Incident Centre (NIAIC), on behalf of the Department of Health, to provide safety guidance on the safe use of Medical Devices. NIAIC has direct links with the MHRA, who co-ordinate information across the adverse incident centres in England, Scotland, Wales, and Northern Ireland for issues concerning medical device safety.

NIAIC, operates as a regional centre for the voluntary reporting and investigation of adverse incidents involving medical devices, and for providing relevant safety guidance in relation to these items and alert where action is required to be taken.

NIAIC places high importance on the open reporting of adverse incidents encouraging a shift to a safety culture in the HSC, where open reporting and balanced analysis are encouraged in principle and by example to achieve continual improvement and learning in patient and staff safety.

Medical Device Alerts may be received in a number of forms, from Patient Safety Alerts to Field Safety Notices, end user feedback, incident reported via the Trust Incident Reporting System etc., and from a number of sources, inclusive of but not limited to the following:

- The Medicines and Healthcare products Regulatory Agency (MHRA).
- The National Patient Safety Alerting Committee (NatPSAC).
- The Northern Ireland Adverse Incident Centre (NIAIC).
- The Northern Ireland Central Alert System (NICAS).
- Manufacturers.
- Manufacturers Agents.
- Trust Incident Reporting System.
- Inter-Trust Communication.
- Medical Device User Forums.

The Trust shall maintain a Medical Device Register of Alerts detailing and recording all device alerts as received and applicable to the Trust and any actions undertaken. The Register shall also record all device alerts as raised within the Trust and any adverse incidents involving medical devices as reported to NIAIC, with any responses, actions undertaken and any subsequent alerts where action is required to be taken.

The Medical Device Lead is the nominated MHRA Liaison Officer and is responsible for reporting adverse incidents involving Medical Devices and Equipment to the NIAIC.

The Trust shall ensure that any Medical Device Alerts are properly scrutinised and disseminated throughout the Service appropriately to ensure that as far as reasonably practicable, all required action is taken.

#### 4.19 Replacement

The Trust shall continuously review the inventory of Medical Devices and Equipment based upon the lifespans and life stages of devices, warranties, contract periods, changes in clinical guidance and procedures etc. to best meet the needs of the Trust.

The Trust shall base any recommendation for replacement upon the priority of need.

The Medical Equipment Group shall have the authority to remove equipment from service when a specified replacement date is approaching or on safety grounds due to the receipt of Safety Alerts, equipment being worn or damaged beyond economic repair, unreliable, clinically or technically obsolete or it is deemed impossible to obtain consumables or spare parts.

The Group shall advise user departments as soon as possible, as far as reasonably practicable, when equipment needs replacing.

Reusable devices may require replacement in the advent of being lost or damaged and as such, the end user or line manager shall complete a Memo of Need, detailing the reason for the replacement e.g. lost at scene, damaged etc. and reporting the incident on the Trust Incident Reporting System, Datix, in line with Trust reporting policies and procedures, reporting criteria and timescales.

This will assist in the evaluation of the device by providing quantifiable statistical data on the performance of Medical Devices and Equipment.

The Trust shall ensure that any replacement strategy utilised shall promote the standardisation of Medical Devices and Equipment such that replacement equipment is compatible with equipment and facilities already in use. It shall also promote the continuity of service.

The recall of a device, be it by manufacturer, agent or regulatory agency shall take precedence over other considerations.

#### 4.20 Decommissioning, Condemnation & Disposal

Medical Devices shall be considered for decommissioning, condemnation and disposal when they fulfil one or more of the following criteria:

- No longer compliant with respective statutory instruments.
- No longer within their use by or expiration date.
- At the end of a life stage or lifespan.
- Obsolete.
- No longer supported by manufacturer or manufacturer's agent.
- Beyond economic repair.
- Damaged or unsafe for use.

All reusable Medical Devices and Equipment shall be regarded as assets, and when it is decided to dispose of such an asset, the Head of Department or authorised deputy will determine and advise the Director of Finance of the estimated market value of the item, taking account of professional advice where appropriate.

Any Medical Devices that are considered for decommissioning, condemnation and disposal and subject to a service, maintenance or calibration contract shall have their details removed from those respective contracts.

Asset Lists and inventories of reusable Medical Devices and Equipment shall be updated to reflect any disposals or transfers.

Decommissioning shall include the removal of all confidential data from the Medical Device, where applicable.

Any disposal of Medical Devices and Equipment shall be in accordance with the Original Equipment Manufacturers (OEM), instructions and in compliance with respective statutory instruments, policies and guidance for waste management such that devices are disposed of safely, clinically and environmentally.

Manufacturers shall also provide details of the current techniques and processes applicable to their products.

Where applicable, Medical Devices and Equipment shall be decontaminated before disposal and accompanied by a Decontamination Certificate.

Used single use disposable and single patient use Medical Devices shall be treated as clinical waste and shall be disposed of via the local, designated, controlled, secure waste storage area. All sharps, including glass, ampoules, vials, needles, syringes and medicine remnants shall be disposed of into a sharps container.

All unused single use disposable and single patient use Medical Devices shall firstly be assessed for reappropriation or if they can be treated as recyclable waste else, they shall be disposed of via the local, designated, controlled, secure waste storage area.

All electronic Medical Devices and Equipment considered for decommissioning, condemnation and disposal shall be responsibly disposed of in accordance with the Waste Electrical and Electronic Equipment, WEEE, Regulations.

All portable batteries within medical devices and equipment as considered for condemnation shall be recycled in compliance with the Waste Batteries and Accumulators Regulations 2009. Embedded batteries in sealed units shall be returned to the manufacturer or manufacturer's agent for recycling.

The Condemning Officer, and all respective line management, shall satisfy themselves as to whether or not there is evidence of negligence in use and shall report any such evidence to the Director of Finance who will take the appropriate action.

The End User or respective Condemning Officer shall complete a Trust Condemn Certificate and a Trust Condemn Spreadsheet whereby the details of the Medical Device or Equipment being condemned are fully recorded, inclusive of but not limited to the following:

- Record the Condemn Certificate number
- Budget Holder
- Location of the item(s) being condemned
- Description of the item or items being condemned.
- Asset No., where applicable

- Reasons for condemnation

The Certificate shall be signed by the user and countersigned by their Line Manager with a copy to be retained, a copy to be sent to the Procurement Department, a copy to be sent to the Finance Department and a scanned copy sent to the Medical Device Lead. Copies of the Condemn Certificate shall be available as necessary.

A Condemn Asset Spreadsheet listing the devices condemned shall accompany the Certificate and shall include the following details:

- Date.
- Device Description.
- Manufacturer.
- Model.
- Serial Number.
- UDI; Unique Device Identifier.
- REF; the Reference number of the device.
- LOT; the manufacturing Lot or Batch number of the product.
- Product Expiry or Use By Date; the date upon which the product must be used.

Copies of the Condemn Asset Spreadsheet shall be available from the NIAS Intranet. The Condemning Officer for reference shall retain a copy of the Condemn Asset Spreadsheet and a scanned copy shall be sent to the Medical Device Lead.

These details are to assist with stock control and to ensure traceability in the event of a Field Safety Notice being issued to the Trust.

Where items can be reappropriated for the purposes of training, the Condemning Officer shall firstly contact the Education, Learning and Development Team to establish capacity within Education, Learning and Development for the respective Devices.

If capacity is confirmed, the Condemning Officer shall complete a Transfer Asset Spreadsheet similar to the Condemn Asset Spreadsheet to list all the devices being transferred.

The Condemning Officer for reference shall retain a copy of the Transfer Asset Spreadsheet and a scanned copy of the Transfer Asset Spreadsheet shall be sent to the Education, Learning and Development Department accompanying the devices, and a scanned copy sent to the Medical Device Lead.

The Medical Device Lead shall notify the Medical Equipment Group of any such disposals and transfers.

## **5.0 IMPLEMENTATION OF POLICY:**

### **5.1 Dissemination:**

With regards to dissemination this Policy will be:

- Issued to all Board Members, Chair, Non-Executive Directors, Chief Executive, Directors and Assistant Directors.
- Disseminated to the required staff by Assistant Directors.
- Made available on the Internet and SharePoint so that all employees and members of the public/ stakeholders can easily have access.
- Discussed during Corporate Induction.
- Discussed during appropriate/ specific/ training sessions

## 5.2 Resources:

Information contained within this policy will be made available to new employees at the commencement of employment, at employee induction programmes, and via information leaflets.

An electronic copy of this Policy shall be available via the Trust intranet site.

For existing employees, information and training will be available through clinical updates, Clinical Training sessions, Risk Assessment Training sessions and annual mandatory training in accordance with Trust Policies.

Line managers will be responsible for ensuring compliance with the Trust / Organisation training matrix.

## 5.3 Resources:

There are no staff exempt from the operation of this Policy.

## 6.0 **MONITORING:**

It is the responsibility of the Medical Equipment Group to monitor the implementation of and assess the level of compliance with this Policy.

## 7.0 **EVIDENCE BASE/REFERENCES:**

There is a statutory requirement to under a number of pieces of legislation including the following:

- The Health and Safety at Work (NI) Order 1978
- The Management of Health and Safety at Work Regulations (NI) 2000
- Provision and Use of Work Equipment Regulations (NI) 1999
- Data Protection Act 2018, the General Data Protection Regulation (GDPR)
- Medical Device Regulations (2017/745) (MDR)
- In Vitro Diagnostic Medical Device Regulations (2017/746) (IVDR)
- The Waste Electrical and Electronic Equipment (Waste Management Licensing) Regulations (Northern Ireland) 2006
- Waste Batteries and Accumulators Regulations 2009
- The Consumer Protection (Northern Ireland) Order 1987

## 8.0 CONSULTATION PROCESS:

This updated Policy has been developed by the Medical Device Lead.

Consultation took place with the Medical Equipment Group consisting of representatives from Operations, Stores and Procurement, Fleet, Risk, Regional Ambulance Clinical Training Centre, Medical Directorate, Trade Unions, Senior Managers, Assistant Directors and Directors within the organisation. The final content of the document was agreed by the Medical Equipment Group, Senior Management Team, Safety, Quality, Experience and Performance Committee and Trust Board.

## 9.0 APPENDICES:

Appendix 1 Assessment of Need – Pertinent Questions:

Appendix 2 Procurement Principles

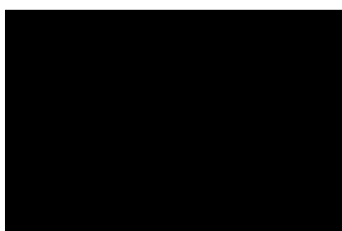
## 10.0 EQUALITY STATEMENT:

10.1 In line with duties under Section 75 of the Northern Ireland Act 1998; Targeting Social Need Initiative; Disability Discrimination Act 1995 and the Human Rights Act 1998, an initial screening exercise, to ascertain if this policy should be subject to a full impact assessment, has been carried out.

10.2 The outcome of the equality screening for this procedure undertaken on 27 May 2021 is:

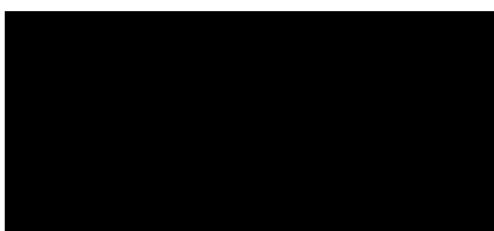
Major impact	
Minor impact	
No impact	✓

## 11.0 SIGNATORIES:



**Lead Author**

**Date: 21 October 2021**



**Lead Director**

**Date: 21 October 2021**

## APPENDIX 1 ASSESSMENT OF NEED – PERTINENT QUESTIONS:

- How long has the device/ equipment been on the market?
- What similar devices already exist?
- Has a scoping exercise been undertaken to establish what similar products are available on the market, if any, who uses them and in what context?
- Has the scoping exercise been expanded to other Trusts and Services to establish device use and any issues arising from that use that may impact on this Trust?
- Can samples be requested to enable assessment and evaluation?
- Can all similar products be made available for direct comparison?
  
- Has the user requirement, the function that the item is required to perform, been defined by the Medical Equipment Group?
- Is the equipment easy to use?
- Is the equipment more complex than needed for the task required and should it be avoided?
- Are the staff capable of using the equipment, after provision of training?
- What are the parameters of the devices and equipment in terms of dimensions, weight, portability, charging, servicing, spares and consumables?
  
- What does the device or equipment cost per unit?
- Are there discounts for bulk quantities?
- Are there consumable costs?
- What are the projected consumable costs over the lifespan of the device?
- What are the service, maintenance and calibration costs, where applicable, per service and for the lifespan of the device?
- Are there costs for call outs?
- What are the shipping costs to and from service contractor?
- Is there an energy cost associated with the device or equipment?
- Are there cleaning, disinfection and decontamination costs?
- Are there any disposal costs?
  
- Are the devices and equipment supported by appropriate service and maintenance contract?
- Is there a pre-existing service-maintenance contract already in place in Trust or can the devices and Equipment into an existing Trust or Regional contract?
- Where is the contractor located?
- Is there a time element in shipping to and from the contractor?
- Are the contracts compliant with servicing and repair schedules as recommended by the manufacturer?
- Is there satisfactory Supplier and Manufacturer Technical Support?
- Is there satisfactory Supplier User Support?
- Is the contract comprehensive or service and maintenance only?
- How does service and maintenance impact on Trust service delivery?
- Are response times applicable?
- Are loan devices available in the event of failure.
- Do the devices and equipment require supplementary testing e.g., PAT?
  
- Can the devices and equipment be stored in accordance with manufacturer's recommendations.
- Is there supporting documentation for the Device or Equipment e.g., user, service manual,
- Are User Guides and instructions suitable?
- Does the supporting documentation require additional Standard Operating Procedures?
- Is this equipment on an established PALs Framework Contract?
- Can the device procurement be openly tendered?

- Will a request for Approval of Single Tender Action, STA, as part of a Direct Award Contract, DAC, require completion and submission?
  - Do the devices and equipment bear Conformity Assessment Markings?
  - Does the device meet all the Trust's essential or desired intended functions?
  - Is the device easy to clean, disinfect, decontaminate?
  - Are any special facilities needed?
  - Does the equipment have any special requirements e.g., power, charging, mounting, assembly, accommodation, connectivity, etc.?
- What are the ICT requirements?
  - Can the device and equipment be used in adherence to Trust standards for connectivity to the Trust network and onwards to the Internet?
  - Can the device and equipment be used in adherence to the ICT technology standards
  - Can the device and equipment be used in adherence to Trust standards for information governance?
  - Is there identification of Information Assets Owners?
- Do the Medical Devices and Equipment have the ability to be cleaned, disinfected, and decontaminated in accordance with the Infection Prevention and Control Policy and Procedures of the Trust?
  - Do the manufacturer's instructions detail clear methods for the cleaning, disinfection and decontamination in accordance with the Trust's policy?
- Can Train the Trainer training be provided by the manufacturer or their agent?
  - How long will training take?
  - Is there technical support for staff training?
- Are there consumables associated with the Device or Equipment?
  - Is there a consumables and spare parts list?
  - What is the availability of consumables and spares?
  - How often will consumables be required, per use, week, year?
- Is there compatibility with devices equipment and facilities already in use?
  - Can the range of inventory in terms of consumables held be reduced to support a policy of standardisation of Medical Devices?
  - Is there an implementation plan schedule?
  - Are there any implementation and installation costs?
- Have all costs associated with the device or equipment been assessed for the duration of its economic lifespan, inclusive of device cost, service, maintenance, calibration, consumables, call outs etc?
  - Has an Economic Evaluation, be that an Economic Assessment Report or Business Case, been developed, commensurate with the size of the investment, in the format specified by the DHSSPS/ HSCB?
  - Has the Finance Directorate been communicated with to determine whether there may be a potential funding stream for acquiring the new equipment?
  - Has the Business Case been approved and sufficient resources been allocated for the procurement of the devices and to ensure effective and efficient maintenance, repair, and calibration contracts throughout the lifespan of the Medical Devices and Equipment, within the Trust?

The Medical Equipment Group may decide to provide generic copies of the Assessment of Need and make these available from the NIAS Intranet.

## APPENDIX 2 PROCUREMENT PRINCIPLES:

The letting and management of contracts for goods and services, on behalf of the Trust, is carried out by the Business Services Organisation, BSO, Procurement and Logistics Service, PaLS.

PaLS is a recognised Centre of Procurement Expertise, CoPE, established under the Northern Ireland Public Procurement Policy, to comply with the Public Contract Regulations and implement the Procurement Guidance Notes, PGNs, developed by the Procurement Policy Unit in Department of Finance, Construction Procurement Delivery, CPD.

Contracts are arranged to optimise value for money for goods and services, to ensure integrity, probity and to minimise resources used in the contracting process.

In the procurement of Medical Devices, be it through purchase, rental, lease, loan or transfer, the Trust shall follow the twelve agreed procurement principles, guiding public procurement in Northern Ireland as listed below:

1. **Accountability**; Effective mechanisms shall be in place in order to enable Accounting Officers to discharge their personal responsibility on issues of procurement risk and expenditure.
2. **Competitive supply**; Procurement shall be carried out by competition unless there are convincing reasons to the contrary.
3. **Consistency**; Suppliers should, all things being equal, be able to expect the same general procurement policy across the public sector.
4. **Effectiveness**; The Trust shall meet the commercial, regulatory and socio-economic goals of government in a balanced manner appropriate to the procurement requirement.
5. **Efficiency**; Procurement processes shall be carried out as cost effectively as possible.
6. **Fair-dealing**; Suppliers shall be treated fairly and without unfair discrimination, including protection of commercial confidentiality where required. The Trust shall not impose unnecessary burdens or constraints on suppliers or potential suppliers.
7. **Integration**; The Trust shall pay due regard to the Executive's other economic and social policies, in line with the NI Executive's policy on joined-up government.
8. **Integrity**; There should be no corruption or collusion with suppliers or others.
9. **Informed decision-making**; The Trust shall base decisions on accurate information and to monitor requirements to ensure that they are being met.
10. **Legality**; The Trust shall conform to all appropriate regional, national and international legal requirements.
11. **Responsiveness**; The Trust shall endeavour to meet the aspirations, expectations and needs of the community served by the procurement.
12. **Transparency**; The Trust shall ensure that there is openness and clarity on procurement policy and its delivery.