Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

HSE

Medical Device Equipment Management

Best Practice,

Guidance for Service Areas.

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1.0 INTRODUCTION

The purpose of this document is to supplement and provide self assessment guidance to enable service areas in complying with the HSE Medical Device Equipment Management Policy. This document should be used in conjunction with the Medical Device Equipment Management Policy (Incorporating Medical Device Equipment Management Best Practice).

2.0 STATEMENT OF BEST PRACTICE.

The overall objective of the HSE's Medical Device Equipment Management Policy is to provide an organisation wide framework for the management of Medical Device Equipment and to ensure that the highest standards of device safety, risk management and financial efficiency are realised in the management of the device.

The policy is supported by a statement of Best Practice which sets out central themes together with their associated Essential Elements to assist overall compliance. The themes together with 27 supporting essential elements reflect the eight themes of HIQA National Standards *For Safer Better Healthcare*.

The statement of "Best Practice states":

> **"There is a system in place which ensures that all risks associated with acquisition and use of Medical Device Equipment are minimized."**

3.0 THEME 1 COMMUNICATION

3.1 Statement of Practice:

"Stakeholders should be identified and there should be proper Communication with all relevant stakeholders within and outside the organisation."

3.1.1 Essential element 1

Theme 1	**Communication.**	**Essential Element 1.**
Appropriate and effective mechanisms are in place for communications and consultation on Medical Device Equipment Management matters within and outside the Hospital / Community.		

The establishment of Medical Device Equipment Management Committees (MDEMC) will enable Service Areas (local, group/organisation and national) to:

- Improve communication regarding medical device equipment within the organisation
- Gain the agreement of all key stakeholders in relation to any proposed changes
- Identify who is responsible for device management tasks, training and safe device operation.

Membership of the committee should be multidisciplinary to address all the listed policy areas. The committee should include representation from quality and patient safety to ensure that adverse incident reporting and Health Products Regulatory Authority (HPRA) information and advice are implemented. Clear terms of reference must be developed for the MDEMC. Specialist sub-groups may be needed to make recommendations to this committee. This committee should review the policies at least once a year and submit regular audit reports to the senior management team.

4.0 THEME 2 GOVERNANCE

4.1 Statement of Practice:

"An appropriate Governance framework to meet the objective should be developed by relevant Directorates, encompassing suitable management structures and practices (leadership, committees, reporting arrangements, policies and strategies, etc.) at all levels in the organisation."

4.1.1 Essential Element 2

Theme 2	**Governance.**	**Essential Element 2.**
Individual responsibility for Medical Device Equipment Management is clearly defined and there are clear lines of accountability for Medical Device Equipment leading up to the most senior manager in the hospital / community.		

This element requires that Board level responsibility for Medical Device Equipment management is clearly defined and there are clear lines of accountability throughout the organisation leading to the Board. The HSE Medical Device Equipment Management Policy sets out the individual roles and responsibilities for employees at all levels in this accountability continuum. It also places emphasis on the role of the Medical Device Equipment Management Committee in the governance of the overall system of management and the role of the Head of Clinical Engineering.

Medical Device Equipment Management Committees (MDEMC) will be required at local, group / organisation and national levels and shall be led by Clinical engineering in order to provide the required Board assurance in relation to the management of medical device equipment.

The role of the Clinical Engineering professional is critical to the successful management of medical device equipment. From a governance perspective it is the responsibility of the relevant MDEMC (local, group / organisation or national) to ensure that robust systems are in place for the safe and effective management of medical device equipment and to provide assurance in relation to these, it is the professional and day to day responsibility of Clinical Engineering to develop and maintain the systems of management to a level that complies with professional and regulatory requirements and to advise management on areas which require improvement.

Overall accountability for medical device equipment management should therefore be vested at an appropriate level in the organization's operational management structure (local, group / organisation and national) and the professional accountability delegated to the head of Clinical Engineering where possible.

From a line management perspective it is the responsibility of all line managers in areas where medical device equipment are used to ensure that medical device equipment acquired and deployed in their area of responsibility are managed in line with best practice. Their relationship with the head of Clinical Engineering who is the professional lead in this respect is critical.

The lines of management accountability should be extended, where appropriate, to include general practitioners, residential and care homes, community based services, non-statutory services that are providing services and funded by the HSE, managed care providers, Public Private Partnership (PPP) organisations and other independent contractors.

There should therefore be clear lines of both management and professional accountability throughout the organisation for medical device equipment management.

4.2.2 Essential Element 3

Theme 2 Governance. Essential Element 3.
There are broad based Medical Device Equipment Management Committees established in accordance with the recommendations of the National Medical Device Equipment Management Policy; & the Health Products Regulatory Authority (HPRA) Safety Notice SN2006 (03) at Hospital / Community and National Level.

It is essential that there be Medical Device Equipment Management Committee (MDEMC) at all operational levels i.e. local, group/organisation and national. The membership of these committees should be at a minimum consist of representatives of senior management, clinical engineering, relevant clinical staff (medical, health and social care professionals, nursing), clinical director, quality and risk, ICT, infection prevention and control, procurement, maintenance and finance.

The four main areas for management by this committee are:

- Management of Medical Device Equipment within HSE facilities

  Management of Medical Device Equipment within Community Healthcare Organisations
- Consumables and Accessories
- Management of HPRA Safety Notices/Manufacturers FSN's/Incidents

These areas will all be managed directly by a MDEMC who may set up specialist subcommittees which report to the MDEMC. The MDEMC in this instance will have a smaller more senior membership and adopt a governance role of oversight and assurance.

Whichever model of management is chosen each area of management will be led by Biomedical/Clinical engineering and supported by appropriate operational policies and

seek the input of appropriate staff.

MDEMCs will also:

- Improve communication regarding Medical Device Equipment within the organisation
- Gain the agreement of all key stakeholders in relation to any proposed changes
- Identify who is responsible for device/equipment management tasks, training and safe device operation.

MDEMCs should review their procedures annually to ensure that they continue to conform to the Medical Device Equipment Management Policy. They will submit regular (management and monitoring) reports to management through the regional and national level MDEMCs.

4.2.3 Essential Element 4

Theme 2 Governance. Essential Element 4.
There are Policies, Procedures & Guidelines (PPG's), based on best available evidence, implemented throughout the Hospital / Community for all aspects of Medical Device Equipment Management. These PPG's are governed by a formal document control policy.

The management of Medical Device Equipment should be supported by clear procedural guidance relevant to the operational area. Clear operational procedures will assist in ensuring that risks associated with the use of Medical Device Equipment will be minimised.

Responsible organisations should therefore develop and regularly review device/equipment management procedures, to ensure that whenever medical device equipment is used, it is:

- suitable for the intended application (in the context of current equipment design and alternative technologies now available)
- used in accordance with the manufacturer's instructions that are relevant, appropriate and up-to-date
- maintained in a safe and reliable condition
- disposed of appropriately at the end of its useful life.

The device/equipment management procedures should cover the:

- selection, acquisition, acceptance and disposal of all medical devices
- training of all those who will use them
- decontamination in accordance with manufacturer's instructions following use, maintenance, repair, monitoring, traceability, record keeping and replacement of reusable medical devices.

There should be a centralised group to facilitate all services areas in the development of Procedures with supporting Document Management and Document Control in the Service Area, for example Quality and Risk group, Policy and Procedure Group. These Procedures should be based on evidence based practice.

Service Areas have a responsibility to identify and develop Procedures to support all elements of Medical Device and Equipment Management to include:

- Acquisition of Medical Device Equipment
- Prescription of Medical Device Equipment
- Delivery of a new piece of Medical Device Equipment
- Instructions for Medical Device Equipment
- Training on Medical Device Equipment
- Storage of Medical Device Equipment
- Installation of new Medical Device Equipment
- Maintenance and Repair
- Incident Reporting
- Safety Communications
- FSCA's
- Decontamination in accordance with HSE policy guidance
- Removal from service to inc. Disposal, decommissioning, reuse / Single use equipment.

There should be systems in place to ensure effective document management and document control of Medical Device equipment procedures including processes to support the ongoing review and audit of procedures.

There should be systems in place to train staff in appraising and developing procedures and identifying evidence based best practice.

4.2.4 Essential Element 5

Theme 2 Governance. Essential Element 5.
All necessary information required to properly manage the Hospital / Community Service's range of Medical Device Equipment is recorded on a dedicated Medical Device Equipment Management documentation system. This documentation system is to be computerised / digital wherever possible. The recommended Health Service dedicated computerised Medical Device Equipment Management software system is "ECRI AIMS" and must be used if available.

Good record keeping is essential for the safe management of Medical Device Equipment. The prime reason for keeping good records is so that the equipment is subject to track and trace for the provision of device history as an aid to any maintenance issues /recalls/regulatory safety notices/ field safety notices that may arise during the equipments useful life. This is a core function of Clinical Engineering and should include initial procurement details, all equipment repair details and routine planned preventative

maintenance/safety test details etc. The detail and complexity of the records will depend on the type of device and its usage during its lifetime. It should also include any specific guidance provided in the manufacturer's instructions and supporting information. For efficient and effective management it is essential to have in place an electronic based equipment management system that is primarily focused on medical device equipment as opposed to a general asset management system. Ideally one system should be adopted nationally that can be utilised in each hospital / community setting. **The recommended Health Service dedicated computerised Medical Device Equipment Management software system is "ECRI AIMS" and must be used if available.**

Records should provide

- Operator Manual Instructions
- Manufacturers Manual
- a unique identifier for the device equipment, where appropriate
- a full history, including date of purchase and where appropriate when it was put into use, deployed or installed
- any specific legal requirements and whether these have been met
- proper installation (validation records where applicable)
- details of scheduled maintenance and repairs including planned preventative maintenance details and safety test results
- the end-of-life date.
- decommissioning details and disposal date/traceable disposal route.

4.2.5 Essential Element 6

Theme 2	**Governance.**	**Essential Element 6.**
Medical Device Equipment is replaced in accordance with an agreed policy.		

The failure to replace essential medical device equipment is a risk to both patient safety and business continuity. Given the finite nature of funding, especially in today's economic climate, these decisions can be particularly challenging. The challenges include balancing the impact of replacing/not replacing against a number of other potential impacts e.g. on patient safety, service continuity, regulatory compliance and hospital revenue. To support the mitigation of risk there is a need to have in place a systematic process for the identification of equipment which requires replacement due to age, obsolesce or existing service need along with a process to support risk based decision making where it is not possible to replace all equipment.

Equipment replacement should be part of a planned and funded replacement programme subject to prioritisation criteria for submission to the National Clinical Head of Medical Devices for consideration of funding. The National decision support tool "Prioritising Medical Device Equipment, Guidance for Services" should be referenced to aid the prioritisation of a planned replacement programme. The purpose of this tool is to provide support to decision makers in prioritising requests for replacement of medical equipment and devices received within a service delivery setting.

Examination of the resulting identified equipment replacement needs should take place

to ensure consistency with the scope of the developing service delivery strategy required throughout the group or healthcare organisation. There will be a need to balance appropriately the impact of replacing/not replacing against a number of potential impacts e.g. on patient safety, service continuity, regulatory compliance and revenue.

4.2.6 Essential Element 7

Theme 2	**Governance.**	**Essential Element 7.**
All loaned Medical Device Equipment is collected when no longer needed.		

Hospitals can loan each other equipment to avert temporary problems; manufacturers can loan products as part of an evaluation or as an incentive to purchase associated products. All Medical Device Equipment used in community are on a short/long term loan to the end user.

In all cases it must be clear at the outset whose responsibility it will be should any problems arise.

Some device/equipment management will transfer either to the individual end user or to a carer or to the prescribing healthcare professional or Clinical Engineer. Devices/equipment issued on loan for a short/long term basis should be subjected to performance and quality assurance tests prior to issue/reissue. It is essential to be clear about where responsibility rests for each aspect of management. This includes:

- decontamination procedures
- maintenance and its records
- Track and Trace
- electrical Safety Testing (EST)where applicable
- availability of up-to-date instructions
- period and type of use
- information supplied to any discharged patients/users
- device identification
- passing on of manufacturer's instructions to end users
- contact details (users and healthcare establishment)
- Relevant training as required

It is the responsibility of the end user to contact the HSE when the short/long term loan items are no longer required. It is essential that all individuals are aware of the medical

device/equipment management system and the part that they play within the system to ensure that Medical Device Equipment is managed correctly and safe to use.

Devices on loan from manufacturers should be subjected to acceptance testing by an adequately trained and appropriately qualified person. The history of the device should be taken into account. Equipment on loan from organisations with a quality assurance system for device management is likely to be safer and more reliable than from an uncontrolled system.

All equipment on loan from manufacturers should be subject to a written agreement which defines the device management requirements and responsibilities and liabilities. Delivery receipt and pre-use procedures for loan equipment should be the same as those for purchased equipment, unless otherwise specified.

All loan medical device equipment is to be recorded on an electronic based medical equipment management system and is subject to track and trace for the provision of device history as an aid to any maintenance issues /recalls/regulatory safety notices/ field safety notices that may arise during the equipments useful life.
The recommended Health Service dedicated computerised Medical Device Equipment Management software system is "ECRI AIMS" and must be used where available.

5.0 THEME 3 QUALITY AND PATIENT SAFETY

5.1 Statement of Practice:

"The Core Processes and Programmes required to produce the desired outcomes should be in place to deliver a safe effective service in the management of medical device equipment that are inclusive of a range of quality and risk management processes in the delivery of quality patient care."

5.1.1 Essential Element 8

Theme 3.	**Quality and Patient Safety.**	**Essential Element 8.**
Medical Device Equipment Guidance and Safety Notifications issued by the Health Products Regulatory Authority (HPRA) and Manufacturer Field Safety Notices are distributed to designated persons within the hospital / community. These recommendations are actioned internally using closed loop processes and recorded, and then fed back externally utilising the National Medical Device Safety Alert System.		

From time to time notices relating to the safety and/or quality of medical device equipment are published by the statuary body for medical devices within Ireland, "The Health Products Regulatory Authority" (HPRA). The issues covered by these notices will range from quality defect information to product recalls, to updated information on the appropriate usage of the medical devices. Such notifications can be accessed at the following web address (https://www.hpra.ie/homepage/medical-devices/safety-information/safety-notices)

A key part of the HPRA medical device vigilance system is the dissemination of

information, which may be used to prevent recurrence of the incident or to alleviate the consequences of such incidents. The aim of HPRA safety notices is to advise the user of the device, whether that is at home, in a hospital or in a community setting, of important information regarding the safe use of their medical device.
The HPRA circulates safety notices in many instances. Some examples are included below:

- To highlight a serious public health issue.
- To draw attention to field safety corrective actions which, following an HPRA risk assessment, are deemed to be related to medium or high risk safety issues.
- To highlight an issue that has already been communicated by a manufacturer via a field safety notice but where the manufacturer has indicated to the HPRA that they have experienced difficulty reaching all customers or obtaining feedback from all customers
- To highlight an issue when either the device manufacturer or distributor to the Irish market no longer exists. For example, where the manufacturer has gone into liquidation or where the manufacturer is not known e.g. counterfeit devices.
- To communicate concerning trends identified by the HPRA in relation to particular product families.
- To communicate safety concerns identified by the HPRA in monitoring vigilance issues e.g. equipment management issues and traceability issues.

Due to the varying nature of these safety notices, the HPRA prioritise the communications. A traffic light system of red, amber and green is used to aid in dissemination of safety information. The system is risk based and all safety notices are assigned a priority number (1-3) and are categorised as outlined in the table 1:

Priority	Category	Examples
Priority 1	For Immediate Action	• Urgent product removal • Urgent information
Priority 2	Warning	• Action required • Caution in use
Priority 3	Advisory	• Traceability issue • Generic information regarding medical devices

Table 1.

The HSE is responsible to ensure that a process is operational to assure management of Medical Device Safety notices as issued by the HPRA an. On receipt of the above notifications it is the responsibility of the HSE to ascertain if the safety notice or alert pertains to any of the locations within the HSE or HSE funded voluntary services.

The HSE developed and implemented a national standard processes together with the supporting ICT application to provide corporate assurance in the management of medical device alerts as distributed by the competent authority in Ireland, the HPRA. The national ICT system is operational to provide Local, Area, Regional and corporate assurance both in the Acute and Community Healthcare Organisations for the management of medical device alerts as distributed by the HPRA and others.

The assurance is delivered by way of assigning to the national web based ICT system a nominated "Designated Persons" within each service facility to take responsibility for the receipt of the medical device notifications together with assuring the further internal facility distribution to the relevant personnel for implementation of the recommended actions where applicable. In general a nominated "Designated Person" may come from clinical engineering, vigilance officer, local medical device committee, local Q&PS committee, head of discipline or others.

The general outline structure of the National web ICT system is as follows:

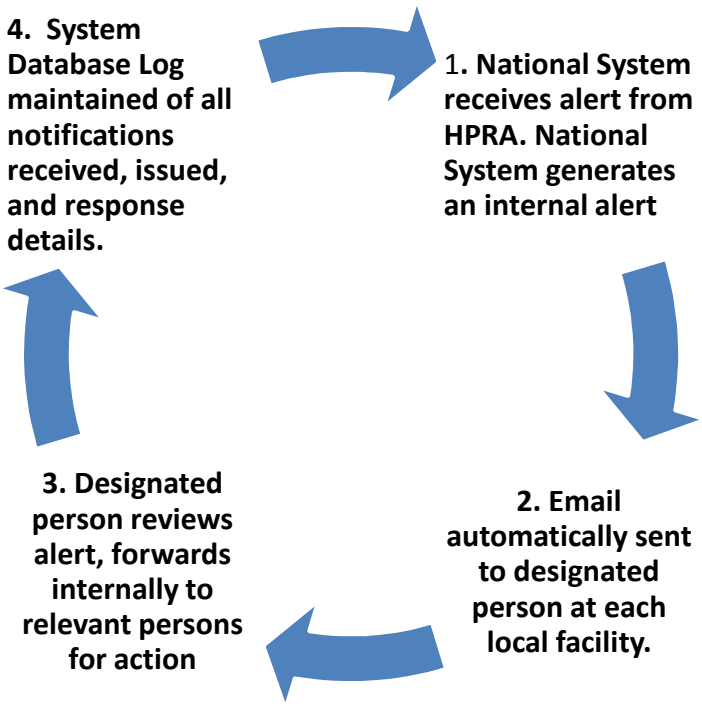


FIG. 1.

- The national ICT system will receive notification directly from the HPRA of all Medical Device Safety / Hazard notifications or any internal generated HSE safety notifications for distribution.

- The National system notifies the relevant designated persons via their HSE email account of an alert for processing within an appropriate timescale.

- The Designated Person will log into the system and review the relevant notification for processing.

- The Designated Person will process and if applicable forward the notifications to the relevant person/s within their organisation for action.

- The Designated person will choose one of the predetermined options listed on the system to close off the alert response details for the national system.

- Automated reminders will be issued from the national system to designated persons who have not closed off alerts received from the national system.

- The National System Business Administrator will generate and issue quarterly Hospital Group specific performance reports for the consideration of each CEO Hospital Group / Community Healthcare Organisation.

5.1.2 Essential Element 9

Theme 3. Quality and Patient Safety . Essential Element 9.
All adverse incidents involving Medical Device Equipment are managed in accordance with the requirements of the HSE's Safety Incident Management Policy (2014); and the Health Products Regulatory Agency (HPRA) Requirements.

The HIQA National Standards *'For Safer Better Healthcare'* outlines that service users are protected from risk of harm associated with the design and delivery of healthcare services through an appropriate risk management process. Standard 3.1 states the following together with a specific focus on Medical Devices in standard 3.1.6

Standard 3.1: Service providers protect service users from the risk of harm associated with the design and delivery of healthcare services.

3.1.6: Safe and effective management of medical devices and other equipment in accordance with legislative requirements, national policy, national guidelines where they exist, and best available national and international evidence.

Proactive identification, evaluation and management of immediate and potential risks and actions to reduce or eliminate these risks is carried out. A process for monitoring and analysis of the following information associated with Medical Device Equipment is in place:

- Patient safety incidents,
- Complaints,
- Findings from risk assessments,

- Legal claims,
- Audits,
- Satisfaction surveys,
- Findings from national reviews,
- Activity and performance data.

In addition the following questions must be addressed in order to ensure that risks associated with Medical Device Equipment are being minimised:

- Are complaints associated with Medical Device Equipment rated according to impact and reviewed, where appropriate, to determine contributory factors, root causes and any actions required?
- Are complaints and comments associated with Medical Device Equipment subjected to periodic aggregate reviews to identify trends and further opportunities for learning, quality and safety improvement, and risk reduction?
- Where appropriate, are all claims associated with Medical Device Equipment recorded and analysed to identify opportunities for learning, quality and safety improvement, and risk reduction?

5.1.3 Essential Element 10

Theme 3.	**Quality and Patient Safety.**	**Essential Element 10.**
The risk management process contained within the HSE's Safety and Incident Management Policy (2014) is applied to the management of Medical Device Equipment risk.		

The HSE's Safety Incident Management Policy provides a standardised method for reporting and managing incidents within the organisation. This policy should be followed when reporting an adverse incident involving Medical Device Equipment. In addition, the manufacturers and HPRA should be notified in the case where the incident involved Medical Device Equipment. All incidents involving medical device equipment should be reported to the Clinical Indemnity Scheme (CIS) on the NAEMS (National Adverse Event Management System) web incident reporting system. The CIS also link with the HPRA.

The role of the HPRA is to protect and promote public health and patient safety. It does this by ensuring that the manufacture and use of medicines and medical devices meet appropriate standards of safety, quality, performance and effectiveness. For an up-to-date list of publications see https://www.hpra.ie

It aims to minimise the risk of new adverse incidents involving medical devices and reduce the risk of those that have already occurred from happening again.

Unless medical device equipment are managed proactively, the same types of adverse incidents happen repeatedly. Good medical device equipment management will greatly assist in reducing their potential for harm.

Responsibility for minimising the risk arising from the management and use of medical device equipment is the responsibility of all staff in the HSE.

When should you contact the HPRA?

Medical device safety issues can be identified through manufacturer or healthcare professional reporting, through identification and reporting of issues by members of the public or through information sharing with other regulators (competent authorities).

The HPRA strongly encourages those who have experienced a safety issue with a medical device to report that issue. The HPRA currently operate a voluntary reporting system for users of medical devices, healthcare professionals or any other person who identifies a medical device safety issue.

Increased levels of reporting from healthcare professionals and other device users may help in the early detection of adverse trends or safety issues. When the HPRA receives reports of safety issues from users or the public, they are obliged by the medical devices directives to ensure that the manufacturer of the device concerned, or his authorised representative, is also informed of the report. The source of the report will not be disclosed without prior permission.

Definition of an incident (HPRA)
An incident is an event that causes, or has the potential to cause, unexpected or unwanted effects involving the health and safety of patient's, users or other persons.
Incidents in medical devices may arise due to:

- shortcomings in the design or manufacture of the device itself
- inadequate instructions for use
- inadequate servicing and maintenance
- locally initiated modifications or adjustments
- inappropriate user practice
- inappropriate management procedures
- inappropriate environment in which a device is used or stored
- selection of the incorrect device for the purpose

This list does not purport to be definitive and each case should be handled individually

Reporting an Adverse Incident

Manufactures are obligated to report medical device incidents under SI No 252/1994.

The HPRA provides guidance notes for health care professionals for reporting adverse incidents. The manufacturer of the device should also be notified of the incident. Information on the vigilance system for medical devices, including the responsibilities of the medical device manufacturer and the medical device adverse incident user report form, are available from the HPRA medical devices department.

Issues or concerns about a medical device can be submitted through the HPRA's online reporting system or by downloading and completing our incident report form. Users may also report medical devices safety issues to the HPRA by:

- post (Medical Devices Vigilance, HPRA, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2);
- email (devicesafety@hpra.ie);
- telephone (01 676 4971).

Information from adverse incident reporting indicates that the factors that have the greatest impact on the safety of devices involve the instructions issued by the manufacturer, their availability and clarity.

Other key safety factors include the design, the quality of training in the appropriate uses of devices and how well they are maintained and repaired.

In any situation where it is confirmed or suspected during normal usage of the product or equipment, that the product or equipment is defective either by design or manufacture or when an injury or near-miss has occurred during the product or equipment's use, direct adherence to the HSE policies associated with such incidents is mandatory.

Where a deficiency is either suspected or confirmed with a product or piece of equipment, full details must be notified promptly, via the MDEMC, to the HPRA, who will advise and give guidance, as deemed necessary.

5.1.4 Essential Element 11

Theme 3.	**Quality and Patient Safety.**	**Essential Element 11.**
All Medical Device Equipment new developments, modifications and trials are conducted in accordance with relevant legislation and guidance.		

Modifying Medical Device Equipment or using them for purposes not intended by the manufacturer (off-label use) has safety implications. It may also count as a manufacture of a new device under the European Regulations. The original manufacturer's liability will be limited and liability may be partly or wholly transferred to the organisation or person making the modifications if the device is implicated in an adverse incident.

It is essential that modifications in use outside of the manufacturer's intended use is only considered as part of a fully documented risk assessment process within the healthcare organisation's risk management policy and procedures.

If a modification is made it must adhere to the HPRA Guidance note 12 *"Manufacture of Medical Devices within Healthcare Institutions".* This guidance note has been written to help clarify whether the activities carried out in or by healthcare establishments and other related organisations are covered by the provisions of the medical devices legislation in Ireland.
The guidance note does not purport to be the definitive interpretation of the law and/or Regulations and is for guidance purposes only.

5.1.5 Essential Element 12

Theme 3.	Quality and Patient Safety.	Essential Element 12.
Medical Device Equipment designated "Single Use" are not reused under any circumstances.		

The general Medical Device Directive (93/42/EEC) distinguishes between devices that are intended by the device manufacturer for single use only and those which are intended for reuse i.e. following suitable reprocessing as recommended by the manufacturer.

A single use device (SUD) is a medical device that is intended to be used on an individual patient during a single procedure and then discarded. Medical devices that are for single use must be clearly labelled with the words "do not reuse". The synonymous terms for "do not reuse" are "single use" or "use only once". This wording can be replaced by the symbol:

A 'single use device' is defined under Directive 2007/47/EC, the amendment to the Medical Device Directive 93/42/EEC, where it states that: "single use device" means a device intended to be used once only for a single patient. Examples include stents, orthopaedic implants, catheters, needles and lancets.

A medical device labelled as single use indicates that the device has only been validated and designed for use for a single occasion. It is not intended to be reprocessed and/or used on another patient. The term 'Single Use' means that the manufacturer intends the device to be used once and then discarded and considers that the device is not suitable for use on more than one occasion.

The following recommendation are provided by the HPRA Safety Notice SN2010(14)

1. Be aware of the difference between medical devices intended by the manufacturer for single use and medical devices intended for single patient use.

2. Become familiar with the legislation in this area, in particular the implications for reprocessing of single use devices.

3. Ensure the risks associated with the reuse of single use medical devices are considered at local level, in light of the update to the medical devices legislation and regulatory developments as outlined by the European Commission. Further information can be found on European Commission website under Reprocessing of Medical Devices.

All devices designated for single use must clearly be identified with the above symbol. Any single-use device must be used on an individual patient during a single procedure

and then discarded. It must not be reprocessed and used again, even on the same patient.

5.1.6 Essential Element 13

Theme 3.	**Quality and Patient Safety.**	**Essential Element 13.**
All Medical Device Equipment is properly maintained and repaired.		

The organisation's Medical Device Equipment Management policy outlines the responsibility of Clinical Engineering in conjunction with management and other key stakeholders and must cover the provision of maintenance and repair of all medical devices, including reconditioning and refurbishment.

This includes:

- ensuring that all equipment is routinely serviced and safety tested at the intervals prescribed by the equipment manufacturer (or best practice)
- how each device should be maintained and repaired, and by whom
- arrangements for maintenance and repair to be included as part of the assessment process
- arrangements for the most suitable persons/providers to carry out the work
- the timescale for planned maintenance
- the timescale for repairs to be completed.
- maintaining all associated device/repair records

The frequency and type of planned preventive maintenance should be specified, taking account of the manufacturer's recommendations, the expected usage and the environment in which it is to be used.

Audit and review

Random audits should be carried out on all elements of maintenance and repair to ensure that the correct procedures are in place and being adhered to.

The responsible organisation should also ensure that there is a mechanism to obtain regular feedback from all users of the equipment on all aspects of the repair and maintenance process.

This should include the reporting of even apparently minor problems as these might lead to major failure unless remedied.

Choosing appropriate maintenance and repair services

The HSE is ultimately responsible for ensuring that Medical Device Equipment are appropriately maintained and repaired. The HSE may use the services of manufacturers, outside contractors or in-house maintenance to carry out this work. A risk-benefit analysis should be undertaken by a multidisciplinary team including clinical engineering before finalising the specification for procurement of any maintenance and repair

services. Cost alone should not be the determining factor. It is essential that an engineering discipline work very closely with HSE procurement to ensure appropriate maintenance and repairs are identified and agreed prior to tender.

Consider only those service providers with access to the necessary equipment and up-to-date manufacturer's instructions and safety information (FSN/Recalls); otherwise they may not be able to carry out the tasks safely and effectively.

The Service Contract

The service contract should meet the criteria of the HSE Procurement Policy. Any contractual agreement with a maintenance and/or repair service provider should specify the level and type of service required by the responsible organisation and is directed by an adequately trained and appropriately qualified person, where applicable, Clinical Engineering. It should include, where appropriate:

- reference to manufacturer's written instructions
- availability, source and traceability of spare parts
- notification of any changes, including the use of alternative spare parts or methods
- training of staff
- quality assurance systems
- requirement for adequate record keeping
- use of sub-contractors
- response times
- loan equipment (where available)
- disposal of obsolete equipment, parts and waste.

Guidance on a range of repair and maintenance contracts is available through the Clinical Engineering Departments and administered by the HSE Procurement Department.

Training and experience of repair and maintenance staff

The Safety, Health and Welfare at Work Act (2005) requires employers to ensure their employees are adequately trained.

All staff servicing equipment owned by the responsible organisation must understand the basic principles on which devices work (generic training) as well as how to use, repair and maintain a particular model (specific training). QQI level 6, QQI level 7 and level 8 are the basic requirements for the maintenance and repair of medical equipment of various levels of complexity. Those without adequate training should not be allowed, nor should they attempt, to repair or maintain medical devices and equipment.

All those undertaking repair and maintenance should be able to produce written evidence of appropriate training, preferably manufacturer certified, as part of the documentation required by a quality assurance system. They should also be manufactured, certified and device specific and be able to show that they are up to date on new maintenance techniques, consistent with the devices they are servicing.

Contracts with the manufacturer

Where contracts are placed with external provider such as the manufacturer or manufacturer agent for repair and maintenance, the organisation should be made aware of any changes in circumstances that may affect the repair or maintenance of their devices/equipment. This documentation should be issued in line with the Procurement and Contractual agreements for appropriate distribution within the organisation.

For example, if a manufacturer merges with or is taken over by another organisation, the responsibility for repair and maintenance may transfer to the new organisation.

If the manufacturer ceases trading and an alternative service provider is not able to undertake the work in accordance with the manufacturer's instructions, the device may need to be disposed of. However, there may be circumstances where it is essential to keep a device in use. If this happens, a risk assessment of its continued use with no manufacturer service backup must be completed, set against the consequences of the device not being available in the short or longer term.

Regularly review the situation to see if alternative arrangements can be made, including acquiring new or replacement equipment and subsequent disposal of the original equipment.

Subcontracted repair and maintenance

If any aspect of the repair or maintenance process is subcontracted, the responsible organisation should ensure that:

- they have access to all upgrades and FSN's
- they are aware of those aspects of the repair that are being subcontracted
- subcontractor is competent in the provision of the respective repair and maintenance need together with documented evidence of same.
- the main service provider and the subcontractor have a contract, detailing the responsibilities of each party
- the service provider audits the subcontractor frequently to establish that it has the necessary expertise and resources, and that the work is of a sufficiently high standard
- they are notified of any changes in these arrangements.

Those without adequate training should not be allowed, nor should they attempt, to repair or maintain medical devices and equipment.

Planned preventative maintenance

The frequency of servicing should be based on the manufacturer's recommendations and managed by the Clinical Engineering department otherwise the provider will carry increased liability in any subsequent litigation. How the device will be used and how often, must also be considered when determining service intervals.

Table 3. Planned preventive maintenance checklist

Heading	Notes
Service Interval	Should be based on the manufacturer's recommendation, taking into account how much the equipment will be used.
Initial Inspection	Is the device clean? Does it need decontaminating? Note settings of controls Inspect each element in line with manufacturers' instructions
Parts replaced	Note each item/part to be replaced Record each items/part replaced, including details of source manufacturer and method of fitting.
Calibration	Establish if any element/part requires calibration or re-calibration Calibrate in line with the manufacturers' instructions
Performance and Safety checks	Carry out performance tests against the manufacturers specifications before and after maintenance
Decontamination	Is decontamination certificate completed
Return to use	Input all details on individual equipment record in the maintenance database Check the device has its accessories, where appropriate and is properly assembled. Return controls either to zero or to the settings noted at initial inspection Stick on a dated 'JUST SERVICED' label and a note of any alterations in control settings.

Updating changes to manufacturers' instructions

The provider of maintenance and repair services should ensure that they are automatically alerted of any changes to repair or maintenance instructions and other essential safety information as issued by the Original equipment Manufacturer (OEM).

There may be changes to the design, or other information, which may affect safety or change the requirements for repair or maintenance, including recalls/safety measures and mandatory upgrades.

The records of the organisation and the service provider must show the version of the equipment currently in use and whether it has been upgraded, modified or repaired since it was supplied. This includes integral computer software.

This system should include all relevant guidance issued by the HPRA, such as Medical Device Alerts.

Quality and compatibility with the device/equipment

The Service Level Agreement (SLA) between organisation and the maintenance service provider should clearly define the terms 'spare parts' and 'consumables' and ensure that their quality and compatibility match those supplied by the Original Equipment manufacturer(OEM).

To ensure that replacement parts are of the correct specification, purchase either directly from the manufacturer or any considered alternatives that are the same specification.

If obtaining replacement spare parts from sources other than the OEM, care must be taken to ensure that all aspects of the technical specification are met, including, for example, physical dimensions, material strength, mechanical properties and compatibility. An assessment should be part of a risk based analysis approach to ensure patient safety is not compromised.

Any agreements to supply parts from sources other than that recommended by the manufacturer shall be properly risk assessed, costed and documented before a decision is made to purchase them.

This should also include any effects on whole life costs: a cheaper part requiring more frequent maintenance may not be cost-effective in the longer term. There may also be legal consequences for the responsible organisation a device failure, associated with the fitting of such a spare part, causes an injury or incident.

Reusing spare parts

Under normal circumstances pre-used parts should not be used to repair a device. They may be acceptable only in exceptional circumstances after a fully documented risk assessment.

The stresses and strains that the part has undergone will depend on many factors, such as the length of time in service, age and repair or maintenance history. Pre-used parts may therefore increase the need for maintenance checks or reduce the overall life cycle of the device.

The failure of a part can have severe consequences for the end user. The part should not be reused if its previous history is unknown.

Traceability of spare parts

The organisation should ensure that the repair and maintenance service provider can:

- identify all spare parts replaced during the maintenance or repair of a particular device
- trace all critical parts back to the supplier.

This will permit ready identification of those devices containing parts that need to be repaired or recalled.

Not all spare parts are critical and the extent to which they need to be identified and related to the original piece of equipment will depend on several factors.

As a guide, a 'critical part' is a component that might reasonably be expected to cause the failure of a critical piece of equipment, or affect its safety or effectiveness and consequently result in death or injury to a user, should it stop working.

Repair and maintenance methods

Even if authorised spare parts are used, the methods used to dismantle and repair the equipment and reassemble it could cause the device to fail or potentially harm users. The maintenance and repair service provider shall therefore have all the necessary testing, measuring, and repair equipment and ensure that this is adequately maintained and calibrated:

- current certificates of calibration shall be maintained for all test and repair equipment that has a measuring function
- calibration shall be traceable to national and/or international standards
- records shall be maintained for each piece of test, repair or maintenance equipment and should be incorporated into the service provider's quality assurance system.

Test equipment, such as jigs, templates, and computer service and diagnostic software used to test devices should also be checked regularly to ensure that it can adequately demonstrate device safety.

The service provider has identified and documented all risks, implemented a strategy to manage them, and has documented procedures detailing the repair and maintenance methods to safeguard equipment malfunctions and facilitate tracing of any subsequent parts recall.

Before to releasing equipment back into service, the equipment should subjected to the manufacturer operational function test, to IEC 62353 - Medical Electrical Equipment, Recurrent Test and Test after Repair of Medical Electrical Equipment and the user informed of the results and any changes made to the settings of the device.

Professional users should be told, where applicable, about pass/fail criteria and anything which may significantly affect the treatment of a patient-radiation dose, for example.

Routine Maintenance by Users

Routine maintenance by the user ensures that the device continues to function in accordance with manufacturer specifications.

It entails regular inspection and care, as recommended in the manufacturer user instructions. The user instructions should clearly show the routine tasks and how they should be carried out. These may include:

- checking that it is working correctly before use
- regular cleaning
- specific daily/weekly checks
- noting when it has stopped working properly or when obvious damage has occurred, and then discontinuing use

Any problems the user identifies should then be referred to a repair service. Minor changes that do not affect the safe working of the device can be recorded for attention during the preventive maintenance sessions.

Users may need to be trained to carry out routine maintenance. For example, they may require training on how to remove, change and insert batteries correctly in line with the manufacturer's instructions. They may also need to be warned about the dangers of substituting different battery types.

Breakdowns

Even with comprehensive maintenance schedules, breakdowns may still occur.

To restore function as quickly as possible, it is often easiest to substitute a similar device, although this requires increased stock levels, and is not always possible for items such as large X-ray machines and specially adapted wheelchairs.

Increased stock levels can be set against the likely costs of, for instance, paying an external service provider or providing a similar in-house service for response cover 24 hours per day.

Wherever possible, temporary repairs should be avoided. But if this is needed, because the impact of the loss is too great, the temporary repair should be carried out and all concerned should be informed of any special precautions or limitations on use until a permanent solution is available. This should be documented on the equipment records.

Equipment malfunction should be replaced or withdrawn from service as soon as possible and the necessary repair actions completed before been reissued for use. The repaired equipment should subjected to the manufacturer operational function test, to IEC 62353 - Medical Electrical Equipment, Recurrent Test and Test after Repair of Medical Electrical Equipment.

Under no circumstance should the user attempt to repair equipment.

Legal Liabilities

The HSE should take all reasonable steps to ensure that equipment is repaired and maintained as per the manufacturer's instructions. The extent of liability will depend on the specifics of the case, and what steps are taken to ensure that adequate repair and maintenance is carried out.

If a device/equipment malfunctions after repair or maintenance and leads to the death or serious injury of a user, the HSE and the repair service provider are far more likely to be held liable for the injuries caused if the device/equipment was not repaired in accordance with the manufacturer's instructions.

If a device/equipment is not correctly repaired or maintained by an organisation (by an employee or someone acting on their behalf), then they could be held responsible under health and safety legislation should a user or member of staff die or sustain personal injury or damage as a result.

The HSE should ensure that both itself and any service provider have adequate insurance in place.

The following Safety Notification were issued by the HPRA in the provision of key recommendations

> *SN2007(06) Medical Devices recommended by Healthcare institutions for use in a community setting*
>
> *SN2003(08) Equipment Management Guidance for the Maintenance and Timely Replacement of Medical Equipment.*

Some of the Key points contained within are:

- All medical devices and items of medical equipment are properly maintained and repaired.
- Where possible maintenance and repair providers are externally accredited for their quality management system.
- Audit and user feedback systems are in place to frequently review the processes, policies and contracts.
- All staff involved in maintenance and/or repair are appropriately trained and qualified.
- Spare parts are of the correct specification and their quality and compatibility match those supplied by the original equipment manufacturer.

- Manufacturer's maintenance instructions and timescales are adhered to.
- All medical devices/equipment returned for servicing and repairs are properly decontaminated.
- Organisations carrying out repairs and maintenance are fully insured.

5.1.7 Essential Element 14

Theme 3. Quality and Patient Safety. Essential Element 14.
All Medical Device Equipment returned for servicing and repair is properly decontaminated.

Classification of infection risk
Failure to adequately decontaminate Reusable Invasive Medical Devices (RIMD) / Medical Devices will increase the risk of transmission of infection between patients. Effective decontamination of RIMD / Medical Devices is necessary to maintain the functionality of devices, maintain integrity of biopsy specimens, and protect the patient and healthcare worker from adverse consequences of non-sterile contaminants.

The choice of decontamination method should be related to the degree of infection risk associated with the intended use of the equipment.
Spaulding (1968) devised a classification system for infection risk associated with the decontamination of RIMD. The following risk categorisation table uses this model with the appropriate level of decontamination dependant on the procedure for which the RIMD is used. It should be noted that examples are for illustrative purposes only; the manufacturers' recommendations for reprocessing must be followed, some devices may not withstand the sterilization process.

Risk	**Application of item**	**Recommendation**	**Examples**
Critical	Items that enter sterile tissues/ sterile body areas or the vascular system	Cleaning and disinfection followed by sterilisation.	Surgical reusable invasive medical devices, biopsy forceps, laparoscopes', arthroscopes Surgical dental RIMD's e.g. forceps, elevators, luxators, scalers
Semi- Critical (Not applicable to dental decontamination services)	Items in contact with mucous membranes or non-intact skin.	Sterilisation preferred but at a minimum requires high level disinfection.	Flexible endoscopes Specula Respiratory therapy equipment.

Non -critical	Items in contact with intact skin but not mucous membranes or items not in direct contact with the patient	Can be processed by cleaning(and low level disinfection where necessary)	Blood pressure cuffs, oximeters, ECG Leads, denture fabrication equipment, apex locators impression material dispensers

NOTE *'Specific procedures apply to RIMD used in high or medium risk procedures on Patients with, or "at increased risk" of, Creutzfeldt - Jakob disease or other transmissible spongiform encephalopathies.*

Decontamination process
Decontamination is the combination of processes (including cleaning, disinfection and sterilisation) used to render RIMD/ medical devices safe for handling by staff and for use on service users. Effective decontamination of RIMD / medical devices is an essential component in the prevention of healthcare associated infection.

Cleaning is the process that physically removes soiling including large numbers of microorganisms and the organic material on which they thrive.

Disinfection describes a process that eliminates many or all pathogenic microorganisms on inanimate objects, with the exception of bacterial spores.

High level disinfection refers to complete inactivation of all infectious microorganisms (vegative bacteria, mycobacteria, enveloped and non-enveloped viruses) in or on a device, but not necessarily bacterial spores. High level disinfection requires the use of specific disinfectants, specialist equipment and trained staff (e.g., endoscope reprocessing units).

Sterilisation refers to a physical or chemical process that completely kills or destroys all forms of viable microorganisms from an object, including spores. Sterility is an absolute condition - an item is either sterile or not sterile. When describing a sterilisation process, it is impossible to say that the chance of an organism surviving a process is zero. For medical equipment, it is acceptable to achieve a sterility assurance level of one in a million chances of a single organism surviving the process.

In May 2009, The Health Information & Quality Authority (HIQA) published the **National Standards for the Prevention and Control of Healthcare Associated Infections.** These national standards provide a framework for health and social care providers to prevent or minimise the occurrence of healthcare associated infections, such as MRSA and C Difficile, in Ireland.

There are 12 national standards setting out a range of Criteria including

- *prevention and reduction of invasive medical devices related infections*

Criteria 3.6 in particular includes medical devices

' The cleanliness of the physical environment is effectively managed and maintained according to relevant national guidelines and legislation; to protect service – user dignity and privacy and to reduce the risk of the spread of HCAI s . This includes but is not limited to

- *All equipment, medical and non-medical, including cleaning devices, are effectively managed, decontaminated and maintained.*

In addition to daily medical device equipment cleaning protocols within organisations, all medical device equipment removed from service or sent for repair should undergo cleaning and decontamination. A "Decontamination Certificate" should be completed to indicate the contamination status of the device and that the equipment is safe/unsafe to handle. (See Appendix for certificate example)

Non invasive medical device equipment is to be cleaned / decontaminated in accordance with the manufacturer guidelines and the locally implemented infection control guidelines. All end users should be provided with the manufacturer instructions and the locally implemented infection control guidelines to safely clean the medical device equipment.

Who is responsible for decontamination?

All staff and end users should take responsibility to ensure all aspects of cleaning /decontamination are adhered too. The importance of correct decontamination needs to be clearly understood at all levels throughout the organisation to avoid cross contamination via the use of medical device equipment.

There should be clear lines of responsibility for decontamination matters across the organisation leading to the board. Senior managers and the board should monitor and regularly review decontamination procedures.

RIMD / Medical Devices transferred between organisations whether for loan, trial, borrowing or repair are required to be accompanied by their manufacturers' "Instructions for Decontamination and Reprocessing" and a signed decontamination certificate identifying the decontamination status of the device that is transferred.

Reusable Invasive Medical Devices (RIMD).

Reusable invasive medical devices (RIMD) include items such as scalpels and scissors are fundamental to all surgical procedures and many medical procedures. Patients undergoing treatment have a right to expect that the RIMD used will be clean, free from infectious agents and in good working order. The decontamination processes involves working with RIMD that are potentially contaminated with infectious agents. Appropriate control and maintenance of the decontamination environment, equipment and processes is necessary to ensure the health and safety of staff.

The Health Service Executive Code of Practice for Decontamination of Reusable Invasive Medical Devices was first published in August 2007. A review of this document was completed in September 2011 resulting in the publishing of the HSE Standards and Recommended Practices for Endosocpy, Central Decontamination, Dental and Local

Dental Decontamination Units. These documents provide guidance on current legal requirements and best practice relating to decontamination of RIMD.

The HSE Standards and Recommended Practices for Decontamination of RIMD provide:

1. A framework for the management of RIMD decontamination in the Health Service Executive to maximise patient and user safety

2. A reference point against which continuous quality improvement in decontamination services can take place.

Standards and Recommended Practices for Decontamination of RIMD applies to all relevant staff in the public health service. This is an evolving document as standards and practices in relation to decontamination will change over time.

A requirement of the HSE Standards and Recommended Practices for RIMD is the establishment of a Decontamination Committee with responsibility for overseeing the implementation of the Standards and Best Practice Recommendations identified in the HSE document and associated self-assessment tools.

6.0 THEME 4 CAPABILITY

6.1 Statement of Practice:

"The organisation (or department, etc) should have the necessary Capability (leadership, knowledge and skilled staff, adequate financial and physical resources, etc) to ensure the entire system works effectively."

6.1.1 Essential Element 15

Theme 4.	**Capability.**	**Essential Element 15.**
All Medical Device Equipment Prescribing decisions are made by employees with appropriate professional qualifications and suitable experience, backed by appropriate administrative and technical support.		

Medical device equipment prescribed for use in the community have become more sophisticated and complex ranging from hearing aids and nebulisers to more complex infusion pumps and continuous positive airway pressure (CPAP) units. *In vitro* diagnostic medical devices such as blood glucose meters and INR self testing devices are also routinely used.

There are risks and challenges in ensuring that medical device equipment are both prescribed and used effectively and safely in the community setting. It is fundamental that good medical device management is adhered to in order to reduce the potential for harm associated with the use of medical devices in this environment

For effective management of medical device equipment in the home setting the HPRA

recommends that each facility has a policy on the management of medical devices to include: acquisition, deployment, use, monitoring, maintenance, tracking decontamination disposal and training.

It is essential that the HSE ensures that the selection of medical devices for particular needs can only be made by staff who are appropriately trained and qualified. However, the policy should not be so inflexible as to prevent any member of staff from choosing the most suitable device for the purpose.

Prescribing and fitting

Prescribing and supply or fitting of a device can take place in separate institutions and involve different professionals – prostheses are an example – and the fitter will sometimes need to refer patients back to the prescriber if the device proves unsuitable.

Ensuring that responsibility for choosing the most appropriate device is shared between relevant healthcare professional, the end user and the fitter can avoid these problems and reduce subsequent delays.

Individuals responsible for the placement / prescribing of medical devices to users in should maintain up-to-date systems to ensure that devices are readily traceable in the event of a safety notices or product recall.

Medical Device Equipment reissued for reuse must be appropriately cleaned, decontaminated, sterilised and serviced, as applicable, prior to distribution to the next device user. The IFU should be provided with the device. Appropriate device user records should be updated accordingly to ensure continued traceability. Prior to reissue medical device equipment should subjected to the manufacturer operational function test, where applicable subjected to IEC 62353 - Medical Electrical Equipment, Recurrent Test and Test after Repair of Medical Electrical Equipment.

Administrative and technical support

Administrative and technical support can help to avoid hazards. Computer databases can build in certain safeguards in relation to safety for equipment, based on the information supplied by the manufacturers. This can assist prescribers by making limitations or restrictions in use available within the selection system. It can also monitor selection records for suitability.

A system should be in place to ensure that prescribed medical device equipment which require routine maintenance and regular servicing are managed in accordance with the manufacturer's recommended schedule. Maintenance, servicing and repair should be undertaken by authorised and suitably qualified individuals. Specific individuals should be identified at each local community level whose responsibility is to ensure routine device maintenance is performed and records are kept of device servicing and repair.

For efficient and effective management it is essential to have in place an electronic based equipment management system that is primarily focused on medical device equipment as opposed to a general asset management system. **The recommended Health Service**

dedicated computerised Medical Device Equipment Management software system is "ECRI AIMS" and must be used if available.

Criteria for choosing a device

Choose a device that best meets the requirements for the intended medical procedure and/or needs of the end user, while minimising the potential for misuse.

At times it may reduce initial delays to choose the 'best available' device from the available stock rather than the 'best' device providing that it meets the minimum required criteria and does not compromise the safety of the user. The most appropriate device can then be obtained and substituted when available.

Those responsible for selection are required to be appropriately trained and require ready access to information about the device, including:

- the manufacturer's description of the intended user, usage and the instructions for use
- safety issues and any limitations on use
- pre-use set up or testing requirements
- maintenance and cleaning or decontamination requirements.

Correct assessment

Assessment of the device and the end user are essential to ensure the correct device is issued.

In cases where a specific device would be unsuitable, because the user would not be able to operate it safely, a carer may assist the user. The device would therefore also have to meet the needs of the carer.

A department that does not employ specialist staff in all areas can request a specialist service to carry out assessments on its behalf.

6.1.2 Essential Element 16

Theme 4.	**Capability.**	**Essential Element 16.**
Employees are made aware of and, where necessary, trained in incident management (reporting and investigation) for the management of adverse incidents involving Medical Device Equipment; and similarly so vigilance for Safety Bulletins.		

All staff should be aware of the HPRA reporting mechanisms and the reporting requirements for NAEMS (National Adverse Event Management System). See HSE Incident Management and Serious Incident Management Policies. Training on these policies should be in place for all staff involved in the reporting and investigation of adverse incidents involving Medical Devices and Equipment.

The HPRA provides guidance notes for health care professionals for reporting adverse incidents. The manufacturer of the device should also be notified of the incident. Information on the vigilance system for medical devices, including the responsibilities of the medical device manufacturer and the medical device adverse incident user report form, are available from the HPRA medical devices department. Additional guidance can be sourced from https://www.hpra.ie/homepage/medical-devices/safety-information/vigilance-reporting

6.1.3 Essential Element 17

Theme 4.	Capability.	Essential Element 17.
Professional Users and Technical Supervisors are trained in the safe operation of Medical Device Equipment.		

It is necessary to ensure that the relevant professional users are trained in the safe operation of Medical Device Equipment. The department should coordinate and ensure that there are adequate arrangements for training of relevant staff on the use equipment. The department head should ensure that they are in receipt of the equipment user manual together with the infection control guidelines when accepting new equipment and to ensure that new or additional staff are afforded user training. All training courses are to be documented with records of attendees. All users have a professional responsibility to ensure that they are trained in the safe use of the equipment. The department head is to ensure that staff are aware of the infection control and decontamination guidelines for the equipment. All training courses to be planned with the relevant department/wards.

The following criteria to apply to Professional User Training: -

- Documented user training to be provided.
- New or additional staff to be afforded user training.
- HOD to ensure user manual is available in the department.
- Infection Prevention & Control and Decontamination guidelines to be provided with equipment.
- Users to ensure competency is attained in the use of the equipment
- Refresher training to be provided at a frequency deemed necessary

A training policy should be developed by the Medical Device Equipment Management Committee. This will need to include:

- generic device management skills
- specific training for particular devices
- induction of new staff
- inclusion of agency and locum staff
- periodic review / retraining as required

- continuing professional development
- planned training before a new medical device is introduced to the organisation
- training for those involved in maintenance and repair services.
- Accurate and comprehensive training records pertaining to whom and when training was provided are created and maintained; this should also take into account any subsequent refresher training. This information should be retained in staff training files.

Healthcare professionals working for the organisation, as employees or contractors, have a professional duty to ensure their own skills and training are appropriate and remain up to date. The organisation's medical device equipment training policy should take account of same and provide suitable support to its professional staff to facilitate appropriate training.

Specific training on particular medical device equipment should be based on the manufacturer's instructions.

Staff carrying out maintenance, repair, and/or decontamination will require additional technical information or training. Manufacturer Technical manuals should be made available for the respective medical device equipment.

Points to consider:

- who should receive the training offered by the manufacturer or supplier?
- how will everyone else be trained, and by whom, and when?
- when is retraining indicated?
- have temporary or locum staff been trained?
- have on-call staff been trained?
- have you considered future training needs for when those trained directly by the manufacturer/supplier change jobs?
- how will training updates be managed for device/software upgrades?
- how will end users or staff in the community be trained?
- how will repair and maintenance service staff be trained (HSE employees)?

Professional users need to understand how the manufacturer intends the device/equipment to be used, and how it works normally, to be able to use it effectively and safely. Where relevant they should:

- be aware of differences between models, compatibility with other products and any contraindications or limitations on use
- be able to fit accessories and to be aware of how they may increase or limit the use of the device

- be able to use any controls appropriately
- understand any displays, indicators, alarms, etc.
- be aware of requirements for maintenance and decontamination, including cleaning, in accordance with the manufacturer's and relevant local procedures
- be able to show end users how to use the device
- be aware of known pitfalls, including those identified in safety advice from the HPRA, manufacturers and other relevant bodies
- be able to recognise device defects or when a device is not working properly and know what to do
- understand the importance of reporting device-related adverse incidents to the HPRA and be familiar with the organisations' reporting procedure

Individuals providing repair and maintenance services are required to be adequately trained and appropriately qualified. This applies to directly employed staff, contracted services or others. This should be reviewed by Clinical Engineering.

For simple mechanical devices a qualification at QQI Level 6 may be appropriate. For more complex devices a qualification at HETAC Level 7 or above may be required. The level of qualifications and training required for each individual should be stipulated in all service contracts provided by external contractors or in house services. This should be reviewed by Clinical Engineering.

Documentation

Evidence that suitable instructions and training were provided will be needed for a number of reasons such as:

1. to provide assurance to management that all staff have appropriate training
2. in the event of a legal case being brought. Users of equipment should be asked to sign statements confirming that they have received and understood written and/or oral instructions.

Details of training given should also be recorded by the head of each department. A simple test at the end of training to check that the information has been understood should also be included.

The maintenance of professional user and technical training records for staff is essential. These should show that users:

- know how to use the device safely as directed by the manufacturer
- can carry out routine checks and maintenance according to the manufacturers instructions
- have been adequately trained

- received refresher training at a frequency deemed necessary.

The Head of Department of the area in which the medical device equipment is deployed is responsible for the maintenance and retention of these records as per the Safety Health and Welfare at Work Act 2005.

6.1.4 Essential Element 18

Theme 4.	**Capability.**	**Essential Element 18.**
End-Users are where relevant given appropriate instruction in the safe and effective use of Medical Device Equipment.		

Appropriate training should be directed to device end users and other designated individuals e.g. family members, carers etc, to ensure correct and safe device use. This would be particularly relevant for more complex medical devices such as hoists, infusion pumps and CPAP units. Training should be provided by appropriately qualified individuals with refresher courses / updates offered when applicable. Records should be kept of all user training courses provided. The user instruction manual should be provided with the medical device equipment.

End users are required to understand the intended use and normal functioning of the device in order to use it effectively and safely. Where relevant, training should cover:

- any limitations on use
- how to fit accessories and to be aware of how they may increase or limit the use of the device
- how to use any controls appropriately
- the meaning of any displays, indicators, alarms etc., and how to respond to them
- requirements for maintenance and decontamination, including cleaning
- recognise when the device is not working properly and know what to do about it
- understand the known pitfalls in the use of the device, including those identified in safety advice from the HPRA, manufacturers and other relevant bodies
- understand the importance of reporting device-related adverse incidents to the HPRA.

End users should ensure that they receive and follow the instructions for use that are provided with the medical device equipment, if applicable. Appropriate training if required, should be sought from the medical device supplier / manufacturer / Healthcare professional or prescriber.

7.0 THEME 5 OUTCOME

7.1 Statement of Practice:

"To ensure that the medical device equipment management system is properly configured and working effectively to achieve the desired Outcomes and overall Objective(s)."

7.1.1 Essential Element 19

Theme 5.	Outcome.	Essential Element 19.
There is demonstrable evidence of Key Performance Indicators relating to Medical Device Equipment Management within the hospital / community.		

Services will be required to agree, implement and monitor relevant performance indicators at an operational and national level, and that these will be the subject of monitoring and review by the relevant Directorate.

7.1.2 Essential Element 20

Theme 5.	Outcome.	Essential Element 20.
The hospital / community participate in benchmarking its Management of Medical Devices Equipment; and Continuous Professional Development.		

The Medical Devices/Equipment Management Policy should be audited on a yearly basis to demonstrate that criteria are met; in the event that criteria are not met, Quality Improvement Plans (QIPs) should be developed and implemented. These QIPs must then be monitored to ensure that there is demonstrable improvement in performance against the Policy.

8.0 THEME 6 MONITORING AND REVIEW

8.1 Statement of Practice:

"Management should continuously Monitor, review, learn and improve all aspects of the system defined by the model. Such monitoring etc. will necessarily include taking on-board any independent assurances received."

8.1.1 Essential Element 21

Theme 6.	Monitoring & Review.	Essential Element 21.

All aspects of Medical Device Equipment Management are monitored and reviewed by hospital / community management for the purposes of learning and improvement.

Monitoring performance on medical device equipment management systems is essential to minimise or eliminate risks to patients and staff.

Medical Device Equipment Management should form part of a comprehensive quality management system of the Governing Board and governing committees throughout the organisation. The locally established medical device equipment management committee should provide monitoring reports to the designated governance committee on all matters pertaining to the safe management of medical device equipment.

The Quality management systems should support the analysis and monitoring of information relating to Medical Device Equipment Management.

There should be regular evaluation of the quality management systems and the information reported. The systems should be updated in line with local and national requirements.

Regular monitoring and reporting of Medical Device Equipment Management should be a standing agenda item on the designated governing committee.

Progress against quality improvement plans should be regularly monitored and reported to the designated Governing committee with relevant information communicated throughout the Organisation.

Reports of audits conducted by the local Medical Device Equipment Management Committees should be provided the designated Governing

9.0 THEME 7 INTERNAL ASSURANCE

9.1 Statement of Practice:

"Senior Management receive sufficient objective Internal Assurance that an appropriate and effective system for the management of Medical Device Equipment is in place and that the necessary level of controls and monitoring are being implemented."

9.1.1 Essential Element 22

Theme 7.	**Internal Assurance.**	**Essential Element 22.**
The hospital / community has effective systems in place for the determination of assurance in the Safe Management of Medical Device Equipment.		

Internal provision of assurances in the management of Medical Device Equipment is to be provided by a self assessment process against the HSE's "Medical Device Equipment Management Policy" and the accompanying HSE "Medical Device Equipment Management Best Practice, Guidance for Service Areas"

A self-assessment process allows the organisation to discern clearly its strengths and areas in which improvements can be made and culminates in planned improvement actions which are then prioritised and monitored for progress.

Services are required to conduct a self assessment of their systems in relation to compliance with the HSE's Medical Device Equipment Management Policy together with the HSE's "Medical Device Equipment Management Best Practice, Guidance for Service Areas" on an annual basis.

A Quality Assessment and Improvement Tool (QA+I tool) has been developed by the National Medical Device Committee and the QPS Directorate to facilitate a standardised mechanism of self assessment against the HSE's Medical Device Equipment Management Policy and Best Practice Guidance. This web enabled tool supports the development and implementation of quality improvement actions to address any gaps identified during the assessment process.

Use of the tool supports the creation of momentum in improving quality across the organisation. It provides opportunities for organisations to gain an informed picture of the quality of services and practices within their organisation in relation to Medical Device Equipment Management.

The assessment process allows services to identify gaps in current service provision, develop quality improvement plans (QIP's) to address these gaps and demonstrate accomplishments achieved in improving services and improving patients' experience of these services.

Reports generated from the Quality Assessment and Improvement Tool (QA+I tool) are to be collated by the local Medical Device Equipment Management Committees and provided biannually to local senior management, to Group/Healthcare Organisation CEO and to the Group Medical Device Equipment Management Committees who will aggregate the reports for provision to the National Medical Device Equipment Management Committee on an annual basis.

The outcomes the Quality Assessment and Improvement Tool (QA+I tool) is to be the supporting evidence of compliance with the National Standards for Safer Better Healthcare standards with particular reference to Theme 3 "Safe Care and Support" standard 3.1.6

3.1.6: Safe and effective management of medical devices and other equipment in accordance with legislative requirements, national policy, national guidelines where they exist, and best available national and international evidence.

9.1.2 Essential Element 23

Theme 7. Internal Assurance. Essential Element 23.
Medical Device Equipment is selected and acquired in accordance with the HSE'S Procurement Policy

The Medical Device Equipment Management Committee should ensure that local procedures for the sourcing and acquisition of medical devices address safety, quality, and performance as well as compliance with all applicable aspects of the HSE Procurement Policy and National Financial Regulations. Depending on the complexity of the medical device technology purchased, it is imperative that a high level of training and clinical support is provided by the manufacturer/supplier. It is important that this is quantifiably and qualitatively agreed and this is embedded in the purchase agreement between the purchaser and the supplier.

Procedures should include the need to:

- establish a multi disciplinary Product Evaluation Group to ensure that the agreed acquisition requirement takes account of the functional, technical and performance requirements of all interested parties, including those involved in use, commissioning, decontamination, maintenance and decommissioning

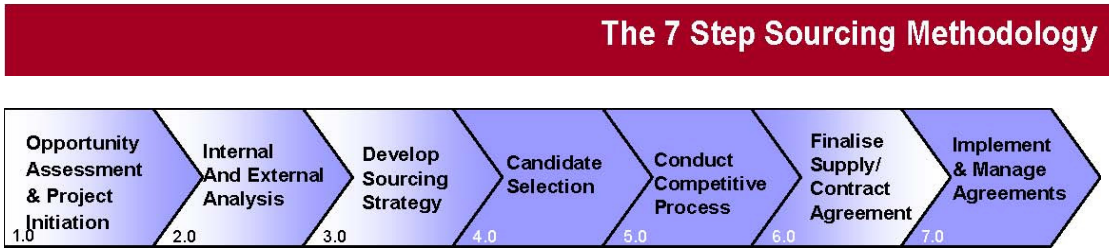
- Ensure that all available high quality evidence based clinical trial documentation is factored into the decision making process so that the best outcomes are achieved for patients.

- Ensure manufacturer/supplier performance is addressed in the decision making process.

- Ensure that the selection process complies with local and national sourcing and acquisition policies (e.g. HSE Procurement Policy, National Financial Regulations), and takes account of whole life costs, the method of acquisition and the agreed acquisition requirement.

- Prioritise each equipment requirement in the context of other requirements in any situation where funding is limited.

HSE Procurement has adopted a structured 7 step model for the procurement of products and services. Each step is designed to industry leading practices providing a structured and fact based approach to the procurement process. The National Financial Regulations stipulate that HSE Procurement is accountable for and must lead all significant procurement processes.


The 7 Step Sourcing Methodology
Opportunity Assessment & Project Initiation
1.0
Internal And External Analysis
2.0
Develop Sourcing Strategy
3.0
Candidate Selection
4.0
Conduct Competitive Process
5.0
Finalise Supply/ Contract Agreement
6.0
Implement & Manage Agreements
7.0

Second hand medical devices

It is essential that the procurement of used medical device equipment is considered as part of a fully documented risk assessment process within the healthcare organisation's risk management policy and procedures.

Usage and service history should always be available for prospective purchasers before sale and then supplied with the equipment at the point of sale. This information should be reviewed by an appropriate competent person prior to acceptance of the device. The input and approval from Infection Control expertise should also be sought prior to procurement.

As a minimum there should be a:

- Record of previous FSN's and FSCA's associated with the device
- record of any reconditioning work carried out, including a record of replacement parts
- copy of all maintenance and servicing that has been carried out including the name of maintenance/servicing organisation
- record of usage
- fault log
- Decontamination status
- CE Marking

Key points for acquiring equipment

- Local acquisition policies to be established consistent with HSE Policies and procedures.
- The MDEMC to be involved in establishing the policy and process.
- Specific Product Evaluation Groups to be established and appropriately briefed.
- Safety, quality and performance considerations to be included in all acquisition decisions.
- The recommendations of HPRA, HIQA and other appropriate bodies have been followed for selection and acquisition.
- All developments, modifications and trials of devices to be carried out in accordance with the relevant legislation and guidance and under risk management policy.
- Assurances obtained from all persons involved that the device can be decontaminated by existing processes and any products used in that process are also compatible.
- Service Level Agreements (SLAs), Technical support, maintenance and repair systems and timescales to be included and managed by Clinical Engineering.
- It would be advisable that distributor performance be taken into consideration during the selection process
- Training and support services to be included where appropriate.

- The Procurement process must ensure that competent and capable suppliers are selected and that comprehensive Life Cycle Cost Models are used.
- User experience to be fed back into the policy, process, future acquisitions and advisory groups.

The HSE Procurement Policy is available at:

https://hbspass.ie/hse-procurement-policy.pdf

and

The **National Financial Regulations** is available at:

https://www.hse.ie/eng/staff/resources/financial%20regulations/

9.1.3 Essential Element 24

Theme 7.	**Internal Assurance.**	**Essential Element 24.**
Pre-Use Checks are carried out on all newly delivered and recycled Medical Device Equipment.		

Responsible organisations should check that the specification of newly delivered equipment matches the purchase order detail together with the relevant tender award specification. It is the responsibility of clinical engineering to ensure that new equipment is subjected to an acceptance test procedure. New equipment should not be signed off for payment without acceptance test approval by clinical engineering or in the absence of this service by the relevant Healthcare Professional. Performance, electrical safety, commissioning, agreed maintenance service level agreement (SLA) and user training including therapists to support the end-users should be part of the acceptance test procedure. The prescribing healthcare professional should ensure that the performance and safety checks are completed and instructions together with training are provided to the end user.

Delivery checks should include:

- checking that the correct device/equipment, complete with user and technical manuals and any relevant accessories, has been supplied as per order number
- Ensuring that devices/equipment have been delivered in good condition
- Deliver matched the Purchase Order detail

The receipt of equipment information such as location, owner, procurement details, maintenance schedules, breakdown records and general equipment history should be received on the National Asset Management System "ECRI AIMS".

The following are the minimum requirements for commissioning:

- Clinical Engineering department and relevant leads of departments to agree installation dates
- Acceptance tests to be performed by Clinical Engineering Department according to local procedures.
- Commissioning to be performed by supplier and accepted by Clinical Engineering Department.
- Manufacturer performance test to be carried out by provider and documentation to be provided.
- Acceptance tests to be performed as per local procedures, electro-safety certificates to be provided where applicable.
- Calibration certificates to be provided where applicable
- Cleaning and decontamination recommendations to be provided
- User and technical manuals to be provided

9.1.4 Essential Element 25

Theme 7.	**Internal Assurance.**	**Essential Element 25.**
All newly delivered Medical Device Equipment are properly stored after acceptance.		

In the community, routine medical device equipment management may in practice transfer either to the end user or to a community healthcare worker. It is essential that all individuals are aware of the medical device equipment management system and the part that they play within the system to ensure that medical devices are managed correctly.

The HSE must ensure that the end user is aware of their responsibility for the procedure required for scheduled maintenance and training in the use of the device. At a minimum, all medical devices/equipment in equipment stores, pools and libraries should be subjected to performance and quality assurance tests prior to reissue.

The storage of medical Device Equipment should be incorporated within policies and procedures that ensure all newly delivered Medical Device Equipment are properly stored after acceptance.

Medical Device Equipment in storage must be subject to manufacturer performance testing and electrical safety testing prior to issue for use.

9.1.5 Essential Element 26

Theme 7.	**Internal Assurance.**	**Essential Element 26.**
All Professional Users, Prescribers and End Users have access to Manufacturer's Instructions, and systems are in place that ensure all Users have received Instructions on the safe use of Medical Device Equipment.		

Good clear instructions have a crucial role in the safe and effective use of equipment. Any shortcomings in the instructions should be reported to the HPRA as an adverse incident.

Where the device is reusable, information on the appropriate processes to allow reuse must be provided by the manufacturer. This information shall contain information such as instructions for disassembly and reassembly prior to cleaning, disinfection and/or sterilisation processes for that device. If appropriate, it should also include the number of times the device can be re-sterilised and any restrictions on the number of reuses.

Clear responsibilities should exist for ensuring that the manufacturer's instructions are passed on to all users and, where appropriate, carers. The manufacturer's instructions may need to be supplemented with training.

Updates

When manufacturers update their information, responsible organisations must have a protocol for: keeping track of all sets of instructions they hold or have issued to users; replacing existing instructions with revised versions; updating the content of relevant training.

Contraindications

Prescribers should refer to the manufacturer's instructions for details of how the device should be used, and for whom it is suitable. Any risks or side effects described in the manufacturer's instructions should be weighed against expected benefits.

Many community stores produce catalogues of all the equipment they supply. These should contain guidance for prescribers, including contraindications. This information should include the manufacturer's instructions and be updated as manufacturers change their content.

Instructions for end-user

All necessary information on storage, pre-use checks, use, maintenance and cleaning should be passed on to the end user, including when the device is issued to a second or subsequent user.

A failure to pass on to the end user the manufacturer's original instructions may compromise the end user's ability to use the device safely, and may leave the provider open to legal liability.

Some users or carers with particular disabilities or medical conditions may need additional instructions or training. For example, people who are visually impaired may not be able to easily read some forms of written information.

The responsible organisation may also need to supply its own information to explain any additional administrative arrangements e.g. contact details for maintenance, consumables or spare parts.

Table 2: Potential difficulties with instructions

Topic	Notes and problems
Placement	Instructions can be printed on the device itself, or its immediate packaging, or supplied as a leaflet.
Content	Instructions must be precise and clear, and should include details of who to contact for specialist problem-solving or guidance.
Print size	End users may be visually impaired
Technical or difficult language	Instructions must be easy to understand and follow.
Translation from or into foreign language	This should be accurate and understandable.
Different versions	Manufacturers may have updated software/hardware. Need the right version to match the specific device.

Documentation

Evidence that suitable instructions and training were provided will be needed, should a legal case be brought. Users of equipment should be asked to sign statements confirming that they have received and understood written and/or oral instructions. Details of training given should also be recorded.

Key points for instructions

- All users and prescribers should have access to the manufacturer's instructions.
- Users should sign statements confirming that they have received instructions (and training) on the safe use of medical devices/equipment.
- There must be a process for recording, tracking and updating the manufacturer's instructions.
- Any updates must be distributed to all relevant users of the device/equipment.

Any manufacturer's instructions considered to be inadequate/ineffective, should be reported to the HPRA.

10.0 THEME 8. EXTERNAL ASSURANCE

10.1 Statement of Practice:

"The Organisation receive sufficient objective Independent Assurance that an appropriate and effective system for the management of Medical Device Equipment is in place and that the necessary level of controls and monitoring are being implemented."

10.1.1 Essential Element 27

Theme 8. **External Assurance.** **Essential Element 27.**
The hospital / community has effective systems in place for the determination of external assessment in the safe Management of Medical Device Equipment.

Best practice contains a requirement for independent assurance that an appropriate and effective system of managing Medical Device Equipment is in place and that the necessary level of controls and monitoring are being implemented. Independent assurance can be obtained internal to the HSE but external to the service through the Health Information Quality Authority (HIQA).

HIQA implemented the *National Standards for Safer Better Healthcare* (the National Standards). The **National Standards** have been designed so that they can be used in all healthcare services, settings and locations and so that a variety of healthcare service providers can use them to improve the quality and safety of the care they provide.

Under current law, all healthcare services provided by or on behalf of the HSE (excluding mental health) will be monitored to make sure they are following these standards. This includes, but is not limited to, hospital care, ambulance services, community care and primary care.

The Quality Assessment and Improvement Tool (QA+I tool) for assessment of compliance with the National Standards for Safer Better Healthcare standards contributes to the provision of external assessment with particular reference to medical device equipment within Theme 3 "Safe Care and Support" standard 3.1.6

3.1.6: Safe and effective management of medical devices and other equipment in accordance with legislative requirements, national policy, national guidelines where they exist, and best available national and international evidence.

11.0 REFERENCES

- HSE Code of Practice for Decontamination of Reusable Invasive Medical Devices

  - **Ultrasound Probes**
    Health Service Executive Guidance for Decontamination of Semi-critical Ultrasound Probes; Semi-invasive and Non-invasive Ultrasound Probes 2017.

https://www.hse.ie/eng/about/who/qid/nationalsafetyprogrammes/decontamination/ultrasound-probe-decontamination-guidance-feb-17.pdf

  - **Endoscopes**

Health Service Executive Standards and Recommended Practices for Endoscope Reprocessing Units 2012

https://www.hse.ie/eng/about/who/qid/nationalsafetyprogrammes/decontamination/hse-standards-for-recommended-practices-for-endoscopy-reprocessing-units.pdf.

Health Service Executive Standards and Recommended Practices for Facility Design and Equipping of Endoscope Decontamination Units 2017

https://www.hse.ie/eng/about/who/qid/nationalsafetyprogrammes/decontamination/hse-standards-and-recommended-practices-for-facility-design-and-equipping-of-edus-qpsdd022.pdf

Health Service Executive Standards and Recommended Practices for Commissioning, Validation and Testing in Endoscope Decontamination Facilities 2018

https://www.hse.ie/eng/about/who/qid/nationalsafetyprogrammes/decontamination/standard-and-recommended-practices-for-commissioning-validation-and-testing-in-endoscope-decontamination-facilities.pdf

  - **Central Decontamination Units**

Health Service Executive Standards and Recommended Practices for Central Decontamination Units

2011https://www.hse.ie/eng/about/who/qid/nationalsafetyprogrammes/decontamination/standards%20for%20cdu's.pdf

Primary Care

Health Service Executive Guidance for the Application of Standards and Recommended Practices for Local Decontamination Units (LDUs) in Primary Care, Dental, Podiatry and GP Practice 2016.

https://www.hse.ie/eng/about/who/qid/nationalsafetyprogrammes/decontamination/guidance-for-application-of-standards-and-recommended-practices-in-primary-care-local-decontamination-units.pdf

- **Loaning and Borrowing Document**

  Voluntary Healthcare Agencies Risk Management Forum Recommended Best Practice for Use of Reusable Invasive Medical Devices (RIMDs) on trial / or on loan to/from other Hospitals and/or Companies / Suppliers 2019

https://www.hse.ie/eng/about/who/qid/nationalsafetyprogrammes/decontamination/vharmf-framework-for-loaning-and-borrowing-of-rimd.pdf

- National Finance Regulations.
  https://www.hse.ie/eng/staff/resources/financial%20regulations/
- HSE Procurement

  https://hbspass.ie/hse-procurement-policy.pdf
- HSE Incident Management

  https://www.hse.ie/eng/about/qavd/incident-management/
- HSE Medical device equipment Management – Compliance with the HSE's Medical Devices and Equipment Management Standard – Guidance for Service Areas http://www.hse.ie/eng/services/Publications/corporate/HSE%20Medical%20Devices%20Equipment%20Management%20Best%20Practice%20Guidance.pdf
- Framework for the Corporate and Financial Governance of the Health Service Executive. HSE Integrated Risk Management Policy

  https://www.hse.ie/eng/about/who/directoratemembers/codeofgovernance/hsecodeofgovernance2015.pdf
- HSE Corporate Safety Statement

  https://www.hse.ie/eng/services/publications/corporate/corporate-safety-statement-2017.pdf

- A Framework for Major Emergency Management

https://www.hse.ie/eng/services/list/3/emergencymanangement/area-mep/

- HSE Infection Control Policies

  http://www.hpsc.ie/A-Z/MicrobiologyAntimicrobialResistance/InfectionControlandHAI/

- **HSE National I.T. Policies & Standards**

  https://www.hse.ie/eng/services/publications/pp/ict/?pageNumber=326

- National Standards for the Prevention and Control of Healthcare Associated Infections (HIQA)

  https://www.hiqa.ie/reports-and-publications/standard/2017-national-standards-prevention-and-control-healthcare

- Health Act 2004

  http://www.irishstatutebook.ie/2004/en/act/pub/0042/index.html

- National Standards 'For Safer Better Healthcare' (HIQA 2012).

  https://www.hiqa.ie/reports-and-publications/standard/national-standards-safer-better-healthcare

- EU Medical Device Regulation (MDR) 2017/745

  https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745&from=EN

- EU Regulation i*n-Vitro* Diagnostic Devices (IVDR) 2017/746

  https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0746&from=EN

12.0 APPENDICES

Appendix I Current Members, National Medical Device Committee

- Ger Flynn — National Clinical Head of Medical Devices
- Alison McGuinness — CNM3, Infection Prevention & Control, St Michael's Hospital
- Bernard Ryan — ULHG Group Clinical Engineering Manager
- Caroline Conneely — National Decontamination Quality Lead, QID
- Declan Murray — Medical Devices Equipment Management Lead, IE HG
- Lorna Cannon — National Reform Programme Manager - Community Funded Schemes
- James Gorman — Finance Manager , HSE PPPA & Fair Deal Finance Unit
- John Browner — Assistant National Director, Capital & Property, HSE Estates
- Liam Hackett — National Medical Equipment Advisor Community Services
- Mary O'Kelly — Occupational Therapist Manager, HSE DSW, Primary Care Services
- Mary Ormsby — Assistant National Oral Health Lead/Primary Care
- Paddy McGowan — Medical Devices Equipment Management Lead, Saolta HG
- Pat Cooney — Chief Physicist, Medical Physics & Clinical Engineering Department, Beaumont Hospital
- Peter Grainger — Medical Devices Equipment Management Lead, DML HG
- Ronnie McDermott — Medical Devices Equipment Management Lead, RCSI HG/National Medical Devices Equipment Advisor Acute Services
- Sandra Phelan — Occupational Therapist Manager, Dublin North Central
- Colm Holland — Medical Devices Equipment Management Lead, S/SW HG
- Vincent O Sullivan — Asst. Head of Sourcing & Contracts, HBS Procurement
- Ms Niamh Galvin — Assistant National Oral Health Lead Quality
- *M*áiread Twohig — QPS, Acute Operations Risk & Incident Officer

Appendix II Acknowledgements

The working group would like to thank the following individuals/groups who participated in the feedback process.

Location	Name
Association of Occupational Therapists of Ireland	Helen Cornelissen
Infection Prevention and Control Society	Cathy Barrett
Social Care QPS Lead	Gerry Clerkin
OT Manager	Alice Gormley
Galway Mayo Roscommon community services	Marie Prendergast
Sligo Leitrim Community Services	John Hayes
CHO 4	Ger Reaney
HPRA	Anne Tobin
CHO 9	Des O Flynn

Appendix III Sample Form – Declaration of Contamination Status

From (consignor):_____ To (Consignee):_____
Address: _____ Address: _____
_____ _____
Reference: _____ Reference: _____
Emergency tel:_____

Type of equipment:_____ Manufacturer:_____

Description of equipment:_____

Other Identifying marks:_____

Model no._____ Serial no._____

Fault:_____

Is the item decontaminated? Yes ❑ No ❑ Don't know ❑

*State type of contamination: blood, body fluids, respired gases, pathological samples, chemicals (including cytoxic drugs) radioactive material or any other hazard)_____

Has the item been decontaminated? Yes ❑ No ❑ Don't know ❑

What method of decontamination has been used? Please provide details
Cleaning:_____
Disinfection:_____
Sterlisation:_____

Please explain why the item has **NOT** been decontaminated
_____
_____

Contaminated items should not be returned without prior agreement of the recipient

This items has been prepared to ensure safe handling and transportation:

Name: _____ Position:_____

Signature:_____

Date:_____ tel:_____