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Medical Device Equipment Management Policy (Incorporating Medical Device Equipment Management Best Practice)

Item Type	Policy
Authors	National Quality Improvement Division
Publisher	Health Service Executive
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Link to Item	https://hdl.handle.net/10147/641353

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Medical Device Equipment

Management Policy

(Incorporating Medical Device Equipment Management Best Practice)

Document Reference number	**OQR030**	**Document developed by**	**National Quality Improvement Division**
Revision number	**03**	**Document approved by**	**Senior Management Team**
Approval date	**August 2019**	**Responsibility for implementation**	**All Health Sector Employees**
Revision date	**May 2021**	**Responsibility for review and audit**	**National Medical Device Equipment Management Committee**

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1.0 INTRODUCTION

An increasing number of medical devices are being used to support the delivery of care in both Hospital and Primary Care settings. The availability of such devices assists greatly in the ability of healthcare organisations to effectively monitor, treat and support the care of service users in the management of their medical conditions. It also allows for the management of care in a community setting and facilitates self care for patients in many instances.

The World Health Organisation (WHO) has recognized the importance of having in place appropriate policies that address all elements related to medical devices which are supported by a system of compliance monitoring. The Commission on Patient Safety and Quality Assurance stressed the importance of adopting standards and guidelines as a key element of effective governance. In the UK it has been identified that 400 people die or are seriously injured in adverse events involving medical devices each year. Whilst comparable figures are not available in Ireland, as part of the HSE's approach to clinical governance it is critical to ensure that there are systems in place to confirm that medical devices are managed in a way which complies with the requirements of regulation and best practice.

Various professions within the health services have direct contact with medical device equipment, such as the Physiotherapist, Occupational Therapist, Medical Physicists, Lab Scientist, Nurse, Biomedical/Clinical Engineering, Pharmacist, Doctor etc.; each having varying degrees of responsibility in the care of medical device equipment. It is acknowledged that various professions deal directly with the day to day use and quality assurance of their particular equipment such as Lab scientists performing quality assurance for Lab equipment, Occupational Therapists prescribing equipment, Medical Physics performing quality assurance for ionisation equipment, Physiotherapists prescribing physiotherapy equipment, nurses and doctors performing user checks etc. With respect to the management of medical device equipment, it is acknowledged that this is the core function of the Biomedical/Clinical Engineering profession.

This policy has been developed by the HSE to ensure compliance with requirements of legislation and guidance from the European Union (EU), the Health Information and Quality Authority (HIQA), the Health Products Regulatory Authority (HPRA), the Health and Safety Authority (HSA), the National Standards Authority of Ireland (NSAI) and the Electro-Technical Council of Ireland (ETCI), including the Technical Committee 10 (TC10) of ETCI in matters related to the management of medical device equipment.

2.0 POLICY STATEMENT

It is the policy of this organisation (HSE) to ensure that a formal system to manage Medical Device Equipment is established in the HSE. The HSE is committed to ensuring that uniform policy, Best Practice and procedural guidance are implemented to support the development of a system which assures a designated coordinated approach for the management of medical device equipment throughout the organisation. This is essential to ensure patient safety through clinical and social care governance, risk management and quality assurance of medical device equipment and in achieving Value For Money (VFM) by way of effective use of resources.

The overall objective of this policy is to provide an organisation wide framework for the management of Medical device equipment and that the highest standards of device safety, risk management and financial efficiency are realised in the management of Medical Device Equipment. The policy aims to minimize related hazards, to ensure that employees are properly trained and competent in the use of medical device equipment, that devices are maintained in a safe and reliable condition, are quality assured and subjected to asset management that is inclusive of device history and tracking.

The policy promotes the use of a Best Practices based approach which will instill a safer, more efficient and high quality management of all medical device equipment. Good management will involve all aspects of the lifecycle of medical device equipment to include:

- Case of Need
- Affordability
- Case of Need Approval
- Prescription/Specification
- Trials
- Selection
- Commissioning and Installation
- User Training
- Maintenance
- Malfunction
- Capital Development Projects and Minor Capital
- Gifts and Donations
- Alert Management

- Infection Prevention and Control
- Decontamination and Cleaning
- Disposal

3.0 LINKS WITH OTHER HSE POLICIES

- Risk Management in the HSE An Information Handbook
- Risk Assessment Tool and Guidance
- Developing and populating a Risk Register Best Practice Guidance
- Safety Incident Management Policy
- Corporate Safety Statement
- Waste Management Policy
- Manual Handling Policy
- Procurement Policy
- Point of Care Testing
- Infection Control Policies
- Major Emergency Plan & Policies
- IT Security Policy
- Decontamination Policy
- National Financial Regulations

The Policy and Management Best Practice should be read in conjunction with the following:

- HSE's Medical Device Equipment Management Best Practice, Guidance for Service Areas
- HIQA National Standards For Safer Better Healthcare
- National Standards for the Prevention and Control of Healthcare Associated Infections (HIQA)
- Health Service Executive Standards and Recommended Practices for Decontamination of Reusable Invasive Medical Devices (RIMD)
- Designated Person Procedure – National Medical Device Safety Alert System
- HPRA Guide to Incident Reporting for General Medical Devices and Active

Implantable Medical Devices.

There are also national and international statutory requirements which must be adhered to regarding Medical Device Equipment (see Appendix II). The policy must also be implemented with regard to the Health Act 2004 in that implementation must be "within the limits of resources available".

4.0 PURPOSE

The purpose of this document is to set out the HSE's Policy in relation to the management of medical device equipment within its services and within agencies funded by the HSE, to ensure that medical device equipment are managed in a way which complies with the requirements of regulation and best practice.

5.0 SCOPE

This policy applies to all HSE services and services funded by the HSE. It also applies to companies who are contracted by the HSE to provide services in relation to any aspect of the management of medical device equipment.

6.0 DEFINITIONS

6.1 Definition of a Medical Device (World Health Organisation)

'Medical device' means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- investigation, replacement, modification, or support of the anatomy or of a physiological process,
- supporting or sustaining life,
- control of conception,
- disinfection of medical devices
- providing information by means of in vitro examination of specimens derived from the human body;

and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

Note: Products which may be considered to be medical devices in some jurisdictions but not in others include:

- disinfection substances,
- aids for persons with disabilities,
- devices incorporating animal and/or human tissues,
- devices for in-vitro fertilization or assisted reproduction technologies

6.2 Definition of Medical Device Equipment.

Medical devices requiring calibration, maintenance, repair, user training and decommissioning – activities usually managed by clinical engineers. Medical equipment is used for the specific purposes of diagnosis and treatment of disease or rehabilitation following disease or injury; it can be used alone or in combination with any accessory, consumable or other piece of medical equipment. Medical equipment excludes implantable, disposable or single-use medical devices.
http://www.who.int/medical_devices/definitions/en/

7.0 POLICY OBJECTIVES

- To minimize the risk of harm to service users and employees associated with the acquisition, use, and ongoing support of Medical device equipment.

- To clearly define and designate the roles and responsibilities for the management of Medical device equipment within the HSE and services funded by the HSE.

- To ensure that the HSE and services funded by the HSE complies with The HIQA National Standards 'For Safer Better Healthcare' in matters pertaining to medical device equipment.

- All relevant legislative Standards, Recommendations and Vigilance Systems of the Competent Authority i.e. the Health Products Regulatory Authority (HPRA).

- To ensure that the HSE and services funded by the HSE complies with all relevant legislative Standards, Recommendations and Vigilance Systems of the Competent Authority i.e. the Health Products Regulatory Authority (HPRA).

- To set out a statement of best practice and supporting criteria for use in managing medical device equipment within the HSE and services funded by the HSE.

8.0 ROLES AND RESPONSIBILITIES

8.1 The HSE Directorate

The HSE Directorate will hold responsibility to ensure that policies are in place for Medical Device Equipment Management.

8.3 Director General

The implementation of the Medical Device Equipment Management Policy and Best Practice Guidance is the responsibility of the Director General and the Leadership team. The Director General can delegate day-to-day operational management of Medical device equipment to the relevant National Director to ensure a national co-ordinated organisation wide approach.

8.4 National Directors

National Directors are responsible for ensuring that throughout their division that:

- Accountability for the management of medical device equipment has been defined and a clear line of accountability has been described to include roles and responsibilities.
- Providing the necessary assurances that the systems, processes and resources necessary to manage medical devices are in place, subject to total resources available.
- Seek evidence through audit of compliance with this policy and best practice guidance together in seeking compliance with the HIQA "National Standards For Safer Better Healthcare" in matters pertaining to medical device equipment and any related legislation and regulation.
- Oversees all risks within its division and will incorporate any risks relating to medical device equipment management in its Divisional Risk Register and manage them in line with the HSE Risk Management policy.

8.5 Hospital Group CEO and Community Healthcare Organisation (CHO) Chief Officer and Ambulance Service.

Each Hospital Group, CEO and Community Healthcare Organisation, Chief Officer has overall responsibility to:

- Provide assurance to the HSE Directorate in relation to the system for medical device equipment management. This assurance will be provided through an audit of self assessment compliance with this policy and best practice guidance. The outcomes generated by the medical device equipment self assessment "Quality Assessment and Improvement Tool" (QA+I tool) is to be the supporting evidence of compliance with the National Standards for Safer Better Healthcare with particular reference to Theme 3 "Safe Care and Support" standard 3.1.6

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

- Support an integrated Hospital Group / Community Healthcare Organisation Medical Device Equipment Management Committee (MDEMC).

- Ensure the establishment of local Hospital / Community Area "Medical Device Equipment Management Committees" throughout the Hospital Group / Community Healthcare Organisation.

- Have governance arrangements in place (Hospital Group Quality and Safety Committee reporting into the senior management team) to receive reports from the medical devices equipment management committees and ensure they are acted upon.

- Designate Biomedical/Clinical Engineering leads with delegated responsibility for the integrated management of medical device equipment within each Hospital Group / Community Healthcare Organisation.

8.6 Hospital CEO / General Manager and CHO Area Network Manager

Each CEO / General Manager / CHO Area Network Manager will be responsible for ensuring that there are systems and processes in place for the local management of Medical Device Equipment within their area of responsibility. This will include

supporting the establishment and operation of a local Medical Device Equipment Management Committee.

8.7 All Employees

It is the responsibility of each individual employee to ensure that they are conversant with the content of this policy and are appropriately trained and competent in the use of medical device equipment which they are required to employ as part of their duties.

All employees have a responsibility with regard to incident reporting and should follow the Incident Reporting Policy and Procedure in respect of incidents involving medical device equipment.

Under Health and Safety regulations employees must also take reasonable care for their own health and safety and also of other people who may be affected by their acts or omissions.

They should report any problem relating to use, maintenance, servicing or decontamination as contained within this policy to their line manager.

8.8 Medical Device Equipment Management Committee

The establishment of Medical device equipment Management Committees (MDEMC) are required at Hospital / Area, Group / Community Healthcare Organisation and National level. The MDEMC will facilitate policy implementation, monitor compliance and provide assurance in relation to this policy and best practice as is relevant to the organisational level at which they exist i.e. Hospital / Area, Group / Organisation and National.

The MDEMC will liaise with the appropriate organisational support services and specialist committees required to deliver on their objectives. The MDEMC will arrange for appropriate training: clinical training, appropriate clinical use of devices and consumables and facilitate "Train the Trainer" programmes.

8.9 Clinical Engineering lead

It is the responsibility of Biomedical/Clinical Engineering lead within a Hospital Group / Community Healthcare Organisation:

- To provide expert advice on all aspects of the management of medical device equipment.

- Develop and maintain the systems required to effectively and safely manage medical device equipment.

- Act as Chairperson for the Medical Device Equipment Management Committees (MDEMC). Carry out an ongoing programme of monitoring to provide assurance in relation to the effectiveness of the systems in place for the safe management of medical device equipment.

- To advise on the compliance requirements of relevant legislation.

- To provide guidance to managers and employees with regard to the implementation of best practice guidance.

- Keep up to date professionally in order to maintain an appropriate level of competence.

9.0 PROCEDURAL GUIDANCE AND SELF ASSESSMENT

Detailed procedural guidance together with an online Quality Assessment and Improvement Tool (QA+I tool) has been deployed to facilitate a standardised mechanism of self assessment against the with the HSE's "Medical Device Equipment Management Policy" and the HSE's "Medical Device Equipment Management Best Practice, Guidance for Service Areas" the HSE's " together with aiding assessment of compliance with the HIQA "National Standards For Safer Better Healthcare".

10.0 POLICY IMPLEMENTATION

Each National Director is responsible for the effective communication and implementation of this policy as it relates to his/her directorate.

11.0 EVALUATION AND AUDIT

In order to establish the effectiveness of this policy, services will be required to conduct an assessment of their system 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" and to put in place improvement plans where required.

The online Medical Device Equipment Quality Assessment and Improvement Tool (QA+I tool supports the development and implementation of quality improvement actions to address any gaps identified during the assessment process.

Services will also 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 by the relevant Directorate. When monitoring has identified underperformance additional quality improvement plans (QIPs) will be developed and systems put in place to ensure variances are addressed.

12.0 RECORD KEEPING

Good record keeping is essential for the safe management of all Medical device equipment. A standardised computerised medical device equipment management system should be in place throughout the organisation to capture all aspects pertaining to the device history throughout the management cycle and must be capable of providing a complete audit . The recommended Health Service dedicated computerised Medical Device Equipment Management software system is "ECRI AIMS" and must be used where available.

13.0 POLICY REVIEW

- This Policy will be reviewed 24 months from last review date.

14.0 MEDICAL DEVICE EQUIPMENT MANAGEMENT BEST PRACTICE Guidance.

14.1 Introduction.

This document sets out a framework for implementation of an integrated medical device equipment management system within the HSE. Robust "Best Practice" for the management of medical device equipment are required to ensure

- High quality safe care for service users
- Safety of employees
- Improved performance and effectiveness
- Less likelihood of unexpected events
- Better decision making at all levels
- Better resource planning and utilisation
- Compliance with legislation
- Assurance to the Quality & Patient Safety division and thereby assurance to the HSE Directorate and all stakeholders

14.2 STATEMENT OF BEST PRACTICE

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

The objective of "Best Practice" is to ensure implementation of an integrated medical device equipment management system within the health service. Eight central themes together with their associated essential elements have been devised to deliver the objective and to ensure that the medical device equipment management system is properly configured and working effectively to achieve the desired outcomes and overall objective. The central themes are:

1. Communication
2. Governance
3. Quality and Patient Safety
4. Capability
5. Outcome
6. Monitoring and Review
7. Internal Assurance
8. External Assurance

14.3 Assessment of Compliance with Best Practice

A self assessment tool has been developed to accompany the statement of Best Practice, i.e. the "Medical Device Equipment Quality Assessment and Improvement Tool" (QA+I tool)". All Service Areas are required to conduct a self assessment against best practice on an annual basis. The outcomes generated by the medical device equipment self assessment is to be the supporting evidence of compliance with the National Standards for Safer Better Healthcare and will also determine the areas requiring improvement. These areas will be the focus of quality improvement plan development, the implementation of such plans will be the subject of monitoring and review.

14.4 Essential Elements

There are 27 "Essential Elements" incorporated within the best practice guidance to assist overall compliance in line with the objective. In order to comply with best practice, it is necessary to comply with each of the essential elements.

15.0 Theme 1 Communication

15.1 Statement of Practice:

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

15.1.1 Essential Elements

Communication 1.	**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.	

16.0 Theme 2 Governance

16.1 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."

16.1.1 Essential Elements

Governance 1.	**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.	
Governance 2.	**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 Levels	
Governance 3.	**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.	
Governance 4.	**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.	
Governance 5.	**Essential Element 6.**
Medical Device Equipment is replaced in accordance with an agreed policy.	
Governance 6.	**Essential Element 7.**
All loaned Medical Device Equipment is collected when no longer needed.	

17.0 THEME 3 QUALITY AND PATIENT SAFETY

17.1 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."

17.1.1 Essential Elements

Quality and Patient Safety - 1. 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.
Quality and Patient Safety - 2. 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.
Quality and Patient Safety - 3. 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.
Quality and Patient Safety - 4. Essential Element 11.
All Medical Device Equipment new developments, modifications and trials are conducted in accordance with relevant legislation and guidance.
Quality and Patient Safety - 5. Essential Element 12.
Medical Device Equipment designated "Single Use" are not reused under any circumstances.
Quality and Patient Safety - 6. Essential Element 13.
All Medical Device Equipment is properly maintained and repaired.
Quality and Patient Safety - 7. Essential Element 14.
All Medical Device Equipment returned for servicing and repair is properly decontaminated. All Medical Device Equipment Field Safety Corrective Actions (recalls/software/modifications) are completed in a timely manner.

18.0 THEME 4 CAPABILITY

18.1 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."

18.1.1 Essential elements

Capability - 1.	**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.	
Capability - 2.	**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 HPRA Safety Notices/Manufacturer's Field Safety Notices. .	
Capability - 3.	**Essential Element 17.**
Professional Users and Technical Supervisors are trained in the safe operation of Medical Device Equipment.	
Capability - 4.	**Essential Element 18.**
End-Users are where relevant given appropriate instruction in the safe and effective use of Medical Device Equipment.	

19.0 THEME 5 OUTCOME

19.1 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)."

19.1.1 Essential Elements

Outcome - 1.	**Essential Element 19.**
There is demonstrable evidence of Key Performance Indicators relating to Medical Device Equipment Management within the Hospital / Community.	

Outcome - 2.	**Essential Element 20.**
The Hospital / Community participate in benchmarking its Management of Medical Devices Equipment; and Continuous Professional Development.	

20.0 THEME 6 MONITORING & REVIEW

20.1 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."

20.1.1 Essential Elements

Monitoring & Review - 1.	**Essential Element 21.**
All aspects of Medical Devices Equipment Management are monitored and reviewed by Hospital / Community management for the purposes of learning and improvement.	

21.0 THEME 7 INTERNAL ASSURANCE

21.1 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."

21.1.1 Essential Elements

Internal Assurance - 1.	**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 Assurance - 2.	**Essential Element 23.**
Medical Device Equipment is selected and acquired in accordance with the HSE'S Procurement Policy.	
Internal Assurance - 3.	**Essential Element 24.**

Pre-Use Checks are carried out on all newly delivered and recycled Medical Device Equipment.
Internal Assurance - 4. **Essential Element 25.**
All newly delivered Medical Device Equipment are properly stored after acceptance.
Internal Assurance - 5. **Essential Element 26.**
All Professional Users, Prescribers and End Users have access to Manufacturer's Instructions, and systems are in place to ensure all Users have received Instructions on the safe use of Medical Device Equipment.

22.0 THEME 8. EXTERNAL ASSURANCE

22.1 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."

22.1.1 Essential Elements

External Assurance - 1. **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.

23.0 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

24.0 APPENDICES

24.1 APPENDIX I. Common Categories of Medical Device Equipment

Note: This list is not exhaustive. It provides examples of medical devices.

Equipment used in the diagnosis or treatment of disease, or monitoring of patients, such as:

- Dental instruments, equipment .
- Endoscopes
- Intravenous (IV) pumps
- Nebulisers
- Ophthalmic equipment
- Peak flow meters
- Podiatry and Podiatric Surgery equipment
- Sphygmomanometers
- Suction equipment
- Surgical instruments
- Thermometers
- Ultrasound Doppler's
- Urinary catheters
- MRI
- CT Scanners
- PET Scanners
- Blood glucose measuring devices
- Defibrillators
- Domiciliary oxygen therapy systems
- In vitro diagnostic medical devices and their accessories
- Intensive Care ventilators
- Pulse oximeters
- Ventilators used in the home
- Vital Signs monitoring
- Equipment used in care, such as: Adjustable beds
- Lifting poles
- Patient hoists
- Pressure relief equipment
- Equipment used by people with disabilities, such as:

- Bathing equipment
- Commodes
- Communication aids
- Hearing aids
- Standing frames
- Walking aids
- Wheelchairs and special support seating

24.2 APPENDIX II. Statutory Requirements:

24.2.1 Directives:

European directives are passed into legislation by the co-decision procedure of the EU council and the EU parliament. Directives are applicable in Members states and are implemented in National Law. The relevant directives that apply to the Medical Devices are:

- Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of **biocidal products** on the market.

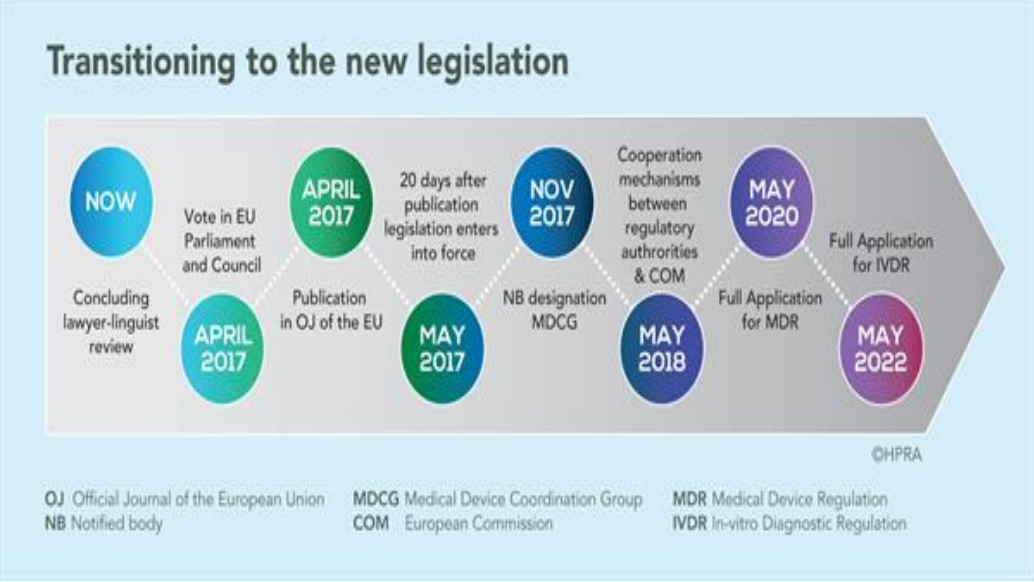
- -Directive 90/385/EEC - OJ L189/ 20.7.90

  -Directive 98/79/EC - OJ331/ 7.12.98 -consolidated version 20/11/2003

In June 2016, two new proposed Regulations on medical devices (MDR) and *in-vitro* diagnostics (IVDR) were agreed at political level between the three relevant European institutions – the European Council, the European Parliament and the European Commission. Since then these texts have been undergoing final review, translations in the different European languages and formal approval.

On 5th May 2017 the Regulations were formally published in the *Official Journal of the European Union (OJ)*. To allow time for transition to the new requirements the Regulations will become fully applicable over a period of 3 years for the MDR and 5 years for the IVDR. During this transitional period there will be a staggered application of the new requirements.

The transition period envisaged is staggered so this means that some provisions become fully applicable and legally binding earlier within the 3-5 year transition periods envisaged.



In addition in relation to **Medical Exposure from ionising radiation**, the following apply:

Medical Exposure Directive 97/43/EURATOM Council Directive of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, and repealing Directive 84/466/EURATOM. (OJ L-180 of 09/07/97 page 22)

In addition it is necessary to take into account the following **environmental** directives:

24.2.3 WEEE Directive

Council Directive 2002/96/EC[4] on waste electrical and electronic equipment as amended by Council Directive 2003/108/

24.2.4 Regulations

European Community Directives are transposed into Irish law by Statutory Instrument under the European Communities Act 1972. The following are the relevant Irish Legislation for Medical Devices

S.I. No. 252/1994 European Communities (Medical Devices) Regulations 1994 as amended

S.I. No. 253/1994 European Communities (Active Implantable Medical devices) regulations, 1994 as amended

S.I. No. 304 of 2001 European Communities (in vitro Diagnostic Medical Devices) Regulations, 2001 as amended

S.I. No. 444 of 2001 European Communities (medical devices)(Amendment) Regulations, 2001

S.I. No. 576 of 2002 European Communities (medical devices)(amendment) Regulations, 202 (Blood products)

S.I. No. 358 of 2003 European communities (medical devices)(Reclassification of Breast Implants)

(Amendment) Regulations, 2003

No. 554 of 2003 European Communities (Medical Devices) (Tissues of Animal Origin) Regulations, 2003

No 92 of 2007 European Communities (Medical Devices) (Reclassification of Hip, Knee and Shoulder Joint Replacements)(Amendment) Regulations 2007 ;

The relevant Statutory Instruments that apply to the Medical Exposures of Patients are:

Medical Exposures: SI No. 256 (2018) European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018.

Workers and Public: SI No. 30 (2019) Radiological Protection Act 1991 (Ionising Radiation) Regulations 2019.

SI 340 Waste Management (Waste Electrical and Electronic Equipment) Regulations 2005.

SI 290 Waste Management (Electrical and Electronic Equipment) Regulations 2005

S.I. No. 375 of 2008 Waste Management (Waste Electrical and Electronic Equipment) (Amendment) Regulations 2008

S.I. No. 268 of 2008 Waste Management (Batteries and Accumulators) Regulations 2008

24.2.5 EU Medical Devices MEDDEV'S

The guidelines aim at promoting a common approach by manufacturers and Notified Bodies involved in the conformity assessment procedures according to the relevant annexes of the Directives, and by the Competent Authorities charged with safeguarding Public Health.

They have been carefully drafted through a process of consultation with various interested parties during which intermediate drafts were circulated and comments were taken up in the documents. Therefore, they reflect positions taken in particular by representatives of Competent Authorities and Commission Services, Notified Bodies, industry and other interested parties in the medical devices sector.

The guidelines are not legally binding. It is recognised that under given circumstances, for example, as a result of scientific developments, an alternative approach may be possible or appropriate to comply with the legal requirements. Due to the participation of the aforementioned interested parties and of experts from Competent Authorities, it is anticipated that the guidelines will be followed within the Member States and, therefore,

ensure uniform application of relevant Directive provisions. Guidelines are subject of a regular updating process. MEDDEV's are available at:

https://ec.europa.eu/growth/sectors/medical-devices/current-directives/guidance_en

and include the following relevant guidelines:

- Clinical investigation, clinical evaluation
- Medical devices vigilance system
- Classification of MD

The relevant European Commission DG for the medical exposure directive is Directorate-General for Energy and Transport. Since 1976 the Radiation Protection unit has been responsible for publishing information covering a wide range of issues relating to ionizing radiation and radiation protection and are available on the net at:

https://ec.europa.eu/energy/en/topics/nuclear-energy/radiation-protection/scientific-seminars-and-publications/radiation-protection-publications

24.2.6 HPRA Guidance

Examples of HPRA guidance published is illustrated below, full details on web site

http://www.hpra.ie/homepage/medical-devices/safety-information/safety-notices

The following are the primary guidance documents issued by the HPRA with respect to Medical device equipment Management:

SN2003(08) Equipment Management: Guidance for the Maintenance and Timely Replacement of Medical Equipment

SN2003(09) Equipment Management: Some basic Principles of Equipment Management.

SN2006(03) The Procurement and Commissioning of Medical Equipment in Hospitals.

SN2007(06) Medical Devices Recommended by Healthcare Institutions for use in a Community Setting

SN2014(02) Medical Devices in the Home

Guide for Class I Manufacturers on compliance with European Communities (Medical Devices) Regulations, 1994

Guide for custom-made Medical Device Manufacturers on compliance with European Communities (Medical Devices) Regulations, 1994

Guide to Applications for Certificates of Free Sale for Medical Devices

Guide to Drug-Device Consultations

Guidelines for Safe and Effective Management and Use of Point of Care Testing

Guide for Ethics Committees on Clinical Investigation of Medical Devices

Categories: Medical Device-Guidance

24.2.7 STANDARDS

"Harmonised standards" are European standards, adopted by CEN, CENELEC or ETSI, following a mandate issued by the European Commission after consultation of Member States. They are developed through an open and transparent process, built on consensus between all interested parties.

Compliance with harmonised standards, of which the reference numbers have been published in the Official Journal and which have been transposed into national standards, provides presumption of conformity to the corresponding essential requirements of the EC directives. Compliance with harmonised standards remains voluntary, and manufacturers are free to choose any other technical solution that provides compliance with the essential requirements. In a number of cases compliance with harmonised standards also increases the options for conformity assessment procedures.

Where the Commission or the Member States consider that harmonised standards present shortcomings with respect to the essential requirements, the publication of the reference in the Official Journal can, in conformity with the procedures laid down in the directives, be withdrawn by the Commission. In such cases, the harmonised standard will cease to provide a presumption of conformity.

An overview of the references of harmonised standards can be found in the "List references of harmonised standards". Although it is updated regularly, it may not be complete and only publication in the Official Journal produces legal affect. Some High Level Standards are as follows:

EN ISO 13485:2003 Medical devices – Quality management systems – requirements for regulatory purposes (ISO 13485:2003).

EN ISO 14971:2007 Medical devices – Application of risk management to medical devices (ISO 14971:2007)

En 60601-1-1:2001 Medical electrical equipment – Part 1-1: General requirements for safety – collateral standard: safety requirements for medical electrical systems.

En 60601-2-xx (XXX) Series medical electrical equipment – part 2-xx: particular requirements for the safety of XXX

EN 62353, Medical Electrical Equipment, Recurrent Test and Test after Repair of Medical Electrical Equipment

ISO 9001:2008 Quality Management System

24.2.8 CE Marking

The essential objective of a conformity assessment procedure is to enable the public authorities to ensure that products placed on the market conform to the requirements expressed in the provisions of the directives, in particular with regard to the health and safety of users and consumers. CE-marking is the only marking which indicates that products conform to the relevant EC directives. The CE-marking affixed to products also provides a witness that the natural or legal person having affixed or been responsible for the affixing of the CE-marking has verified that the product conforms to all relevant EC directives which require the CE-marking applying to it, and has been the subject of the appropriate conformity evaluation procedures.

24.2.9. NSAI

NSAI aims to inspire consumer confidence and protect industry interests through setting standards and issuing certification in the quality and safety of goods and services. The NSAI benchmarks these standards against international best practice and is therefore a key facilitator of fair trade both in Ireland and in global markets. More information, such as the NSAI mission statement and its policies with regard to privacy, quality, and customers is available in strategy and policies on the NSAI website www.nsai.ie. The

NSAI provides knowledge-based services and technical support to the government, consumers and industry, through:

Consultation on standards to assist manufacturers and suppliers in meeting safety and consumer requirements; Independent certification of products, processes and services; Certification specific to the construction industry, known as 'agrément'; Regulatory control in the area of measures, or metrology; Maintenance and development of the national measurement standards.

As well as domestic activities, the NSAI also represents Ireland in European and international standards bodies, whose aim is to harmonise standards and remove technical barriers to trade.

The Electro-Technical Council of Ireland Limited (ETCI) is a voluntary body of twenty-three organisations representative of all aspects of electro-technology in the Republic of Ireland. Formally constituted in 1972, the Council is the national body responsible for the harmonisation of standards in the electro-technical field in collaboration with the National Standards Authority of Ireland

Objectives of the ETCI

1. To promote and co-ordinate standardisation in all branches of electro-technology in harmony with international agreements and in collaboration with the National Standards Authority of Ireland (NSAI).
2. To establish liaison with similar bodies in other countries and with international bodies.
3. To promote safety in electrical equipment and installations and to encourage an awareness of electrical safety among the general public
4. To advise and make recommendations on any matter pertaining to electro-technology, subject to the statutory powers, duties and functions of other bodies.

Additional information can be obtained on www.etci.ie Information is also available from:
HPRA website at www.HPRA.ie

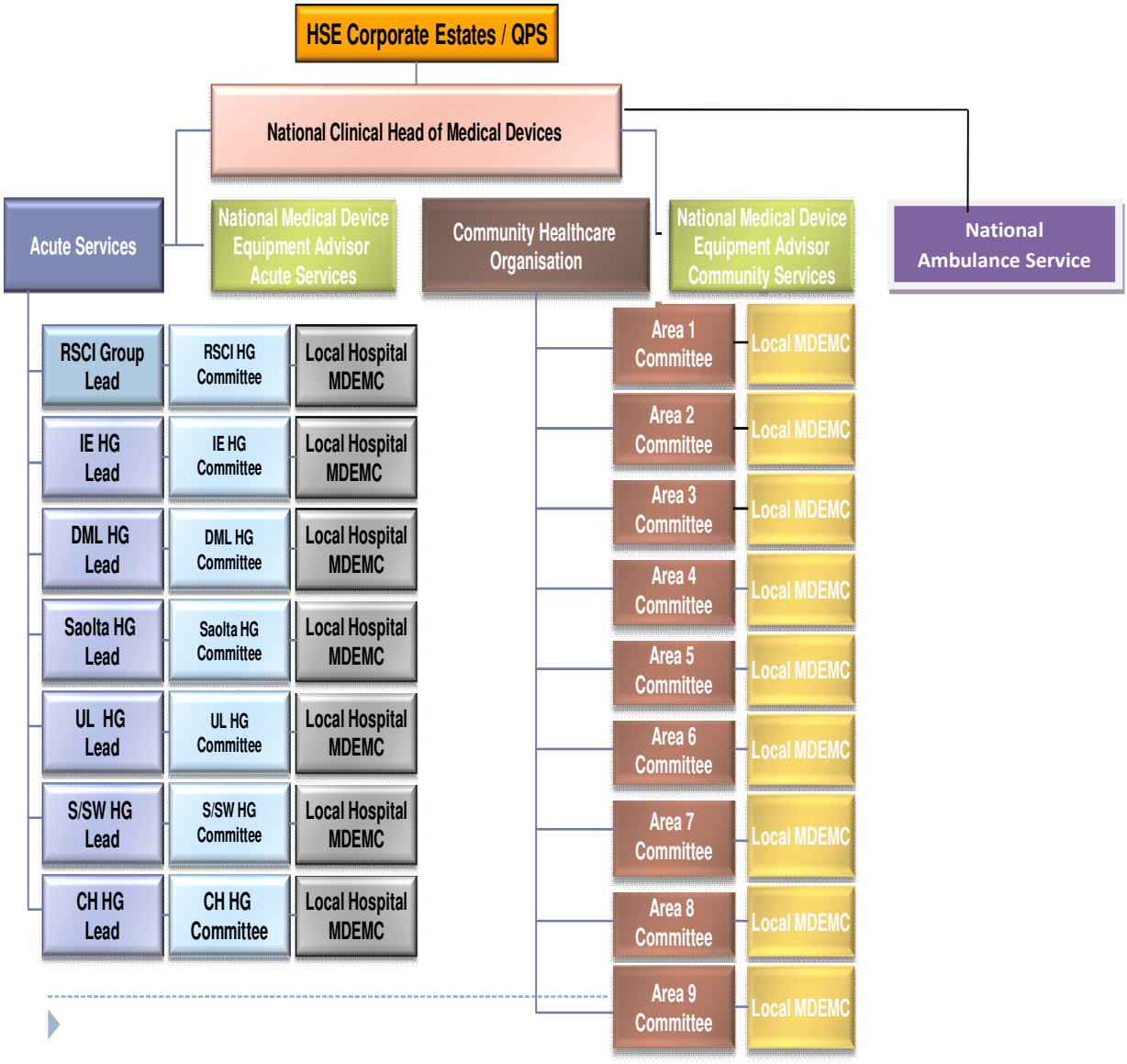
MHRA website at < http://www.mhra.gov.uk/index.htm >
FDA website at https://www.fda.gov/MEDICALDEVICES/DEFAULT.HTM

24.3 Appendix III 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

24.4 Appendix IV Acknowledgements.

The Working Group would like to thank the following individuals/groups who participated in the consultation process.

- Ms. Alice Gormley, Occupational Therapist Manager
- Dr. Angela A. O'Leary, Principal Medical Officer
- Ms. Violet Hayes, Director of Public Health Nursing
- Dr. Anne Marie Dillion, Senior Medical Officer
- Ms. Gretta Crowley, Operations Manager
- Ms. Brenda Golden, Director of Public Health Nursing
- Mr. Paddy Ryan, General Manager for Residential Services for Older People in Cork
- Ms. Ber Power, General Manager for Residential Services for Older People in Kerry
- Ms. Gabrielle O'Keeffe, General Manager, Cork South
- Ms. Ina McGrath, Risk Manager, Kerry Community Services
- Ms. Elmar Cronin, Transformation Development Officer, Primary Care
- Ms. Liz Forde, Infection Control Nurse , Community Services
- Ms. Annette Logan, Office of the Chief Officer
- Ms. Helen Cornelissen, O.T. Manager, National Therapy Co Ltd – Neurology Working Group
- Mr. Gerry Clerkin, QPS Lead, Social Care
- Sligo/Leitrim Community Services
- Galway/Roscommon Community Services

24.5 Appendix V Medical Device Equipment Management Structure.