Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Medical Device Equipment Management

Self Assessment Tool

Document Development	Document Reference No	Version	Description
Feb 2010	SG PG01	1.0	Review by National Clinical Engineering Consultancy Group 24/02/2010
Sept 2015	NMDEMC WG01	2.0	Redraft in line with new prompts and QA&I IT Tool
Nov 2015	SAT WG01	3.0	Circulation to NMDEMC for comment, cut off 20/11/2015
Dec 2015	SAT WG01	4.0	Signed off by NMDEMC with Working Group Upgrades to be included 18/12/2015
April 2016	SATWG01	5.0	04/04/16 Working Group Upgrades complete

Revision Date	April 2017	National Medical Device Equipment Management Committee WG01

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1.0 INTRODUCTION.

The **Purpose** of this document is to outline the Self Assessment Tool that is associated with the Health Service Medical Device Equipment Management Policy, Best Practice and Guidance Document. This Self Assessment Tool should be used in conjunction with the Health Service "Medical Device Equipment Management Policy & Best Practice and to comply with the Health Service "Medical Device Equipment Management Best Practice – Guidance for Service Areas".

2.0 OVERALL OBJECTIVE.

The **Overall Objective** of the 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 Medical Device Equipment.

3.0 PRINCIPAL OBJECTIVE – STATEMENT OF BEST PRACTICE.

The **Principal Objective** is to ensure that:

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

This is known as the **'Statement of Best Practice.'**

4.0 THEMES AND DEFINITIONS.

There are 8 THEMES which reflect a higher level management model describing a 'system of internal control' for a healthcare organisation. The 8 THEMES of this model are outlined and defined below:

 # 1. Communication

 # 2. Governance

 # 3. Quality & Patient Safety

 # 4. Capability

 # 5. Outcome

 # 6. Monitoring and Review

 # 7. Internal Assurance

 # 8. External Assurance

4.1 Communication *(Statement of Practice #1)*

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

4.2 Governance: *(Statement of Practice #2)*

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.

4.3 Quality & Patient Safety: *(Statement of Practice #3)*

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.

4.4 Capability: *(Statement of Practice #4)*

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.

4.5 Outcome: *(Statement of Practice #5)*

Overall, this process will ensure that the medical device equipment management system is properly configured and working effectively to achieve the desired **Outcomes** and overall **Objective(s).**

4.6 Monitoring and Review: *(Statement of Practice #6)*

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

4.7 Internal Assurance: *(Statement of Practice #7)*

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.

4.8 External Assurance: *(Statement of Practice #8)*

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.

5.0 ESSENTIAL ELEMENTS

There are 27 ESSENTIAL ELEMENTS incorporated within this Statement of Best Practice to assist overall compliance. The Statement of Best Practice 27 supporting Essential Elements reflect a higher level management model describing a 'system of internal control' for a healthcare organisation.

In order to comply with the Statement of Best Practice, it is necessary to comply with each of the Essential Elements.

5.1 MEDICAL DEVICE EQUIPMENT QA&I TOOL

The Medical Device Equipment QA+I tool is centred on the 8 central themes together with the 27 "Essential Elements" associated with the various themes within the Medical Device Equipment Management Policy and Best Practice Guidance documents. The "Essential Elements" represent those key aspects of quality you would expect to have in place for the management of Medical Device Equipment.

A total of 284 quality level guides are incorporated within the tool to assist in the determination of assessment on the quality level status for each "Theme" and their associated Essential Elements. The quality level guides represent guiding prompts that describe what a service should have in place for each level of quality.

Theme		Number Essential Elements	Number of Quality level Guides
Theme 1	Communication	1	15
Theme 2	Governance	6	79
Theme 3	Quality & Patient Safety	7	66
Theme 4	Capability	4	40
Theme 5	Outcome	2	11
Theme 6	Monitoring & Review	1	6
Theme 7	Internal Assurance	5	63
Theme 8	External Assurance	1	4
Total		**27**	**284**

Fig 1. Assessment Structure

5.1.1 Levels of Quality.

For each Essential Element there are four incremental levels of quality. These levels of quality are foundation blocks which build on each other and allow services to objectively select the level of quality and maturity that most accurately reflects their service for each Essential Element. The content within each level should be viewed as guiding prompts that describe what a service should have in place for each level of quality.

LEVELS OF QUALITY	
Emerging Improvement (EI)	There is progress with a strong recognition of the need to further develop and improve existing governing structures and processes.
Continuous Improvement (CI)	There is significant progress in the development, implementation and monitoring of improved quality systems.
Sustained Improvement (SI)	Well established quality systems are evaluated, consistently achieve quality outcomes and support sustainable good practice.
Excellence (E)	The service is an innovative leader in consistently delivering good patient experience and excellent quality care.

Fig 2. Levels of Quality

A guiding principle of the assessment is to create a process of continuous quality improvement progressing towards full compliance with the Medical Device Equipment Management Policy and Best Practice Guidance. Progression through the levels assumes that the main aspects within the previous levels have been achieved. Progression along this continuum also indicates that the service is maturing, becoming more sustainable and demonstrating strong leadership and innovation.

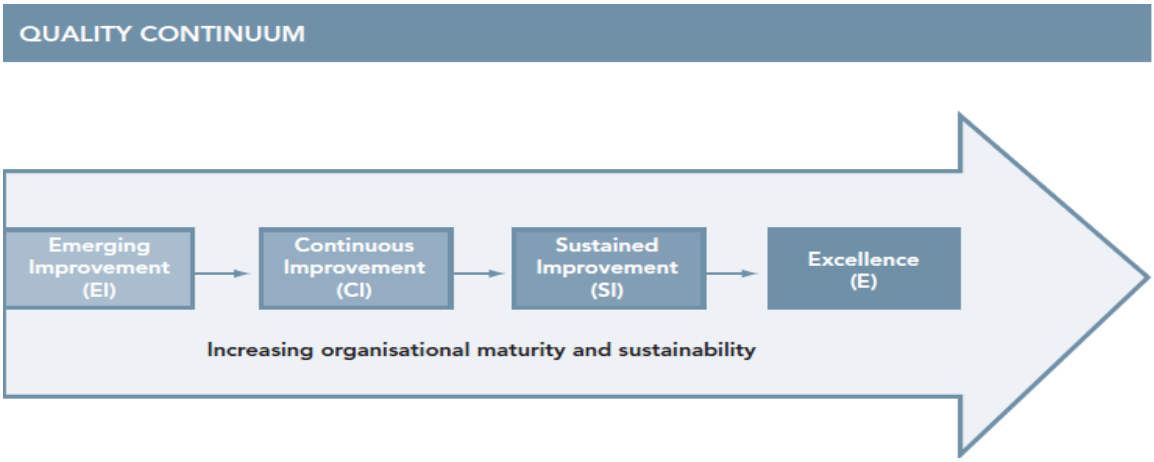

Fig 3. Quality Continuum

5.2 27 ESSENTIAL ELEMENTS.

5.2.1 #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.

5.2.2 #2 Governance:

Essential Element 2

Individual accountability for Medical Device Equipment Management is clearly defined leading up to the most senior manager in the hospital/community.

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.

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.

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 where available.

Essential Element 6

Medical Device Equipment is replaced in accordance with an agreed Policy, Procedure & Guideline (PPG).

Essential Element 7

The management of all Medical Device Equipment on loan is governed by appropriate PPG's.

5.2.3 #3 Quality & 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 auctioned internally using closed loop processes, recorded, and fed back externally utilizing the National Medical Device Safety Alert System.

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.

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.

Essential Element 11

All Medical Device Equipment developments, modifications and trials are conducted in accordance with relevant legislation and guidance.

Essential Element 12

Medical Device Equipment designated "Single Use" are not reused under any circumstances.

Essential Element 13.

All Medical Device Equipment is properly maintained and repaired.

Essential Element 14

All Medical Device Equipment returned for servicing and repair is properly decontaminated.

5.2.4 #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.

Essential Element 16

Employees are made aware of and, where necessary, trained in incident management (reporting and investigation) for the management of adverse events involving Medical Device Equipment; and similarly so, vigilance for Safety Bulletins.

Essential Element 17

Professional Users and Technical Supervisors are trained in the safe operation of Medical Device Equipment.

Essential Element 18

End-Users are where relevant given appropriate instruction in safe and effective use of Medical Device Equipment.

5.2.5 #5 Outcome:

Essential Element 19

There is demonstrable evidence of Key Performance Indicators relating to Medical Device Equipment Management within the hospital/community.

Essential Element 20

The hospital/community participates in benchmarking its Management of Medical Device Equipment; and Continuous Professional Development (CPD).

5.2.6 #6 Monitoring and 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.

5.2.7 #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.

Essential Element 23

Medical Device Equipment is selected and acquired in accordance with the HSE's Procurement Policy.

Essential Element 24

Pre-Use Checks are carried out on all newly delivered and recycled Medical Device Equipment.

Essential Element 25

All Medical Device Equipment is properly stored.

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.

5.2.8 #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.

6.0 SELF ASSESSMENT OF COMPLIANCE WITH THE STATEMENT OF BEST PRACTICE

The self-assessment process allows the organization 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.

In order to establish the effectiveness of this policy, services are required to conduct a Self Assessment of their system in relation to compliance with the Medical Device Equipment Management Statement of Best Practice on an annual basis.

The outcome of this self assessment will 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.

7.0 SELF ASSESSMENT TOOL COMPOSITION.

In order to comply with the Statement of Best Practice, it is necessary to comply with each of the Essential Elements. For each Essential Element there are a number of “Attainment Goals” that should be complied with in order to achieve compliance with the respective Essential Element. These “Attainment Goals” are measured in relation to individual supporting prompts for each Essential Element.

The Number of Themes in the overall Self Assessment Tool together with the number of associated Essential Elements and supporting prompts per individual Essential Element are outlined in *Table #1* below.

Table #1 No. of Self Assessment Themes/ Essential Elements/ Supporting Prompts

Number of Themes	Number of Essential Elements	Element Number	Self Assessment Supporting Prompts
1 Communication	#1	1	15
2 Governance	#6	2	9
		3	10
		4	18
		5	19
		6	11
		7	12
3 Quality & Patient Safety	#7	8	9
		9	11
		10	6
		11	5
		12	7
		13	19
		14	9
4 Capability	#4	15	9
		16	6
		17	17
		18	8
5 Outcome	#2	19	7
		20	4
6 Monitoring and Review	#1	21	6
7 Internal Assurance	#5	22	5
		23	20
		24	15
		25	7
		26	16
8 External Assurance	#1	27	4
TOTAL's	**#27**	**#27**	**284**

Theme		Number Essential Elements	Number of Quality level Guides
Theme 1	Communication	1	15
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Theme 3	Quality & Patient Safety	7	66
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Total		**27**	**284**

This Self Assessment will ensure that there are robust Standards for the Management of Medical Device Equipment which ensures:

- 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 Risk and Audit Committees and thereby assurance to the Health Service and all stakeholders.

8.0 General Self Assessment Tool Instruction

Each organisation shall conduct a Self Assessment of their system in relation to compliance with the HSE's Medical Device Equipment Management Policy on an annual basis.

The time scales for completion shall be outlined by the National Medical Devices Equipment Management Committee.

The Self Assessment Excel Tool shall be returned complete inclusive of Quality Improvement Plans and Good Practices.

8.1 Assessment Preparation and Process

The HSE QA+I tool outlines **six** practical steps that services can take to prepare their service for assessment. The Assessment Process can be repeated on an annual basis following commencement of initial assessments. This provides for quality improvement plans to be implemented with progress being regularly monitored to ensure progression along the continuum quality levels.

Step 1	Clarify governance for the implementation of the HSE National Medical Device Equipment Management Policy & Best Practice Guidance
Step 2	Identify a Designated Lead for the implementation of HSE National Medical Device Equipment Management Policy & Best Practice Guidance
Step 3	Agree a team based approach to assessing against the HSE National Medical Device Equipment Management Policy & Best Practice Guidance
Step 4	Agree scope of assessment within a service
Step 5	Plan a schedule for undertaking the assessment.
Step 6	Convene Medical Device Equipment Management Policy & Best Practice Guidance assessment team(s)

Fig 6. Assessment Preparation

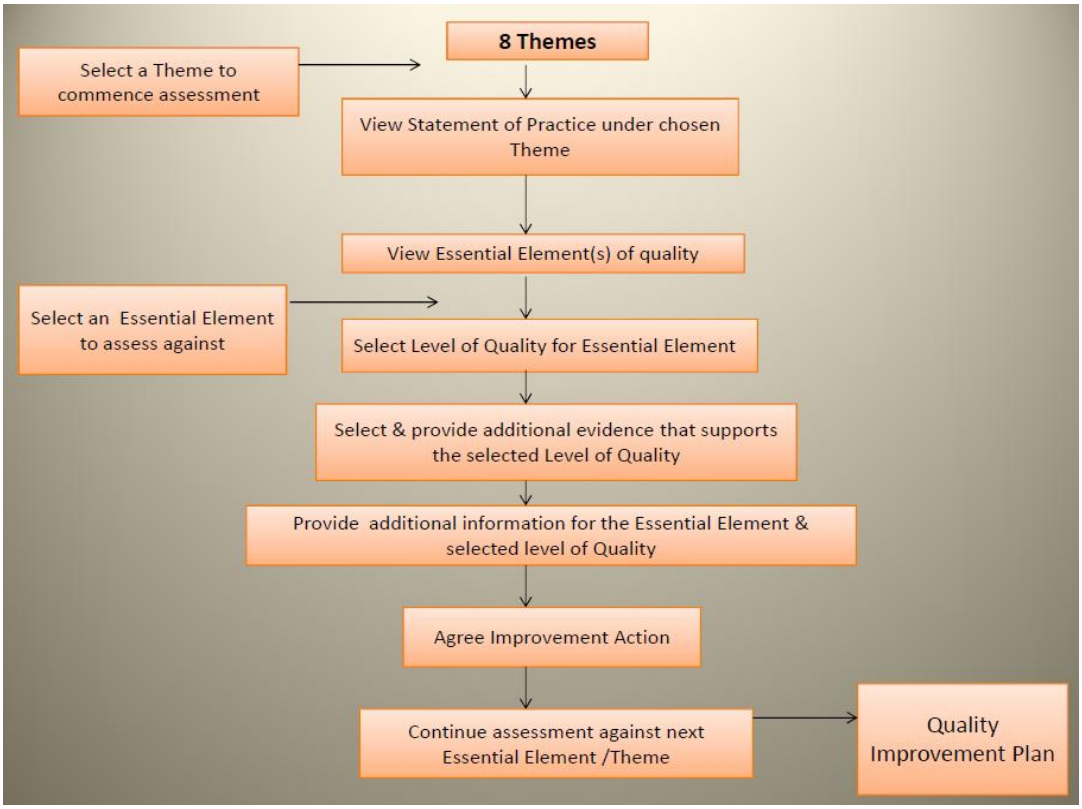

Fig 7. Assessment Process Overview

9.0 SPECIFIC SELF ASSESSMENT TOOL INSTRUCTION

Each identified user will self assess their discipline/service/department against each of the 27 Essential Elements. Once complete, assign a level of quality that best meets where the discipline/service/department currently sits for each of the 27 applicable Essential Elements.

All user information is collated by the MDEMC for input into the National Medical Device Equipment Assessment Tool. This tool will calculate an overall score for the hospital with respect to each element.

Example: Essential Element 1

10. SELF ASSESSMENT TOOL DETAIL

Essential Element 1 **Communication # 1**

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

Emerging Improvement (EI)

1.1 There is a National Communication Strategy in place to ensure all service providers, professional users, prescribers, carers, and staff are made aware of the importance of the Management of Medical Device Equipment.

1.2 There are policies and procedures in place to ensure effective communication and consultation occurs throughout the hospital / community in the Management of Medical Device Equipment, the implementation of the HSE Policy and Guidance, and use of Self Assessment Tool.

Continuous Improvement (CI)

1.3 The hospital / community has ongoing education programmes on the Management of Medical Device Equipment.

1.4 There is evidence that there are appropriate and reliable channels of communications within all areas of the hospital / community for the purpose of the efficient and safe Management of Medical Device Equipment.

1.5 There are mechanisms in place for the communication, consultation and interaction between the hospital / community and the National Medical Devices Equipment Management Committee.

1.6 There is evidence that each member of staff in the hospital / community are aware of their respective role and responsibilities pertaining to the care, safe-use and Management of Medical Device Equipment.

1.7 The Medical Device Equipment Management Policy is included as part of the induction programmes for new or temporary employees.

1.8 All equipment suppliers, distributors and contractors are aware of the mechanisms and acknowledged procedures in each hospital / community pertaining to the Management of Medical Device Equipment and there is evidence of same.

Sustained Improvement (SI)

1.9 There are mechanisms in place to facilitate staff and key stakeholders to provide feedback on the effectiveness of the Medical Device Equipment Management Policy and Best Practice Guideline.

1.10 There is evidence of proactive communications / education within the hospital / community for the purpose of Management of Medical Device Equipment, its clinical use and associated safety.

1.11 Hospital / community Medical Device Equipment Management communication channels and mechanisms are reviewed on a scheduled basis for effectiveness.

1.12 There is evidence of knowledge among all medical device technical staff and medical equipment managers of the roles that the Health Products Regulatory Authority (HPRA - IMB), The Electro Technical Council of Ireland (ETCI) and the National Standards Association of Ireland (NSAI) play in the Governance of Medical Device/Equipment in Ireland.

Excellence (E)

1.13 The hospital / community has evidence of management led communication in work areas such as team briefings and meetings for recognition of achievement awards, notice boards, in-house journals/magazines/pamphlets, audio-visual and electronic media such as email and websites, or employee surveys and suggestion schemes in relation to Medical Device Equipment Management.

1.14 There is evidence of hospital / community inclusion of International Best Practice, Legislation, Recommendations, Best Practice and Common Norms in their Management of Medical Device Equipment.

1.15 Communication channels with regard to the Management of Medical Device Equipment are well established within the hospital / community and information is shared across the service and externally where appropriate.

Essential Element 2 **Governance # 1**

2 Individual accountability for Medical Device Equipment Management is clearly defined leading up to the most senior manager in the hospital / community.

Emerging Improvement (EI)

2.1 The hospital / community has defined clear lines of accountability for Medical Device Equipment Management.

2.2 Clear lines of accountability for medical device equipment are documented and communicated throughout the hospital / community at all levels.

2.3 Overall accountability for Medical Device Equipment Management is vested at an appropriate level in the hospital / community's operational management structure.

2.4 Management of Medical Device Equipment is delegated to the Head of Clinical Engineering where ever possible.

Continuous Improvement (CI)

2.5 There is evidence that the hospital / community executive committee has approved and implemented the clearly defined lines of accountability throughout the hospital / community for Medical Device Equipment Management.

Sustained Improvement (SI)

2.6 Within the hospital / community, all line managers have the responsibility to ensure that Medical Device Equipment acquired and deployed in their area of responsibility is managed in line with the National Medical Device Equipment Management Policy and Guidance.

2.7 Accountability arrangements are reviewed periodically to strengthen governance.

Excellence (E)

2.8 Lines of Medical Device Equipment Management accountability are extended to include other equipment providers, prescribers, practitioners and users, where appropriate.

2.9 The hospital / community implements learning from the wider system, and also national and international recommendations arising from investigations to further improve their accountability structure, for the management of medical device equipment.

Essential Element 3 **Governance # 2**

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.

Emerging Improvement (EI)

3.1 The hospital / community has established a Medical Device Equipment Management Committee (MDEMC) whose terms of reference holds general responsibility for all aspects of Medical Device Equipment Governance.

3.2 Membership of the hospital / community's MDEMC is appropriately multi disciplinary in nature and consistent with best practice recommendations.

3.3 The MDEMC, or a reporting sub group such as a Medical Device Vigilance Group (MDVG), has responsibility for the Management of Medical Device Equipment Alerts within the hospital / community. Alert governance is conducted in accordance with HPRA Guidelines and utilises the HSE National Medical Device Alert feedback computerised reporting system.

3.4 The hospital /community Incident Committee liaises with the MDEMC for investigation of Medical Device Equipment incidents, utilises specialist Medical Device Equipment Management expertise as appropriate, and communicates with MDEMC regarding outcome.

Continuous Improvement

3.5 The MDEMC has developed adequate communication awareness systems regarding its Medical Device Equipment Management within the hospital / community.

3.6 The MDEMC, and other relevant associated committees or groups are led by Clinical Engineering as per Guidelines where ever possible.

3.7 The hospital / community management provide adequate resources for the safe effective Management of all Medical Device Equipment.

Sustained Improvement (SI)

3.8 The MDEMC, or a reporting sub group, has policy and governance knowledge of the Management of Medical Device Equipment that is prescribed or placed within the Community; in accordance with HPRA Safety Notice SN2007(06).

3.9 The MDEMC has identified the person who in line management who is responsible within the hospital / community for training to ensure all users of Medical Device Equipment are appropriately trained and competent in the safe use of medical device equipment.

Excellence (E)

3.10 The MDEMC, or a reporting sub group, has policy and governance knowledge of the Management of Medical Device Equipment Consumables and Accessories within the hospital / community.

Essential Element 4 **Governance # 3**

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.**

Emerging Improvement (EI)

4.1 The hospital / community's Policy for Management of Medical Device Equipment is governed by a formal document control process.

4.2 The hospital / community's Medical Device Equipment Management policies /procedures / guidelines (PPG's) cover the delivery, acceptance, testing, installation, commissioning and validation of all Medical Device Equipment.

4.3 The hospital / community's Medical Device Equipment Management PPG's cover the instructions and storage of all Medical Device Equipment.

4.4 The hospital / community's Medical Device Equipment Management PPG's cover training for all those who will use the Medical Device Equipment.

4.5 The hospital / community's Medical Device Equipment Management PPG's cover the maintenance, repair, monitoring, traceability and record keeping of all Medical Device Equipment.

4.6 The hospital / community's Medical Device Equipment Management PPG's cover the decontamination of Medical Device Equipment in accordance with manufacturer's instructions pre and post usage.

4.7 The hospital / community's Medical Device Equipment Management PPG's cover the decontamination of Reusable Invasive Medical Devices in accordance with HSE Standards and Recommended Practices.

4.8 The hospital / community's Medical Device Equipment Management PPG's cover the replacement of reusable Medical Device Equipment.

4.9 The hospital / community's Medical Device Equipment Management PPG's cover the Incident Reporting of Medical Devices and Equipment and Alerts Management of all Medical Device Equipment.

4.10 The hospital / community's Medical Device Equipment Management PPG's cover the disposal and decommissioning of all Medical Device Equipment.

Continuous Improvement (CI)

4.11 The Management of Medical Device Equipment throughout its life cycle is governed by formal document control process/es and recorded within the hospital / community's computerised Medical Device Equipment Management System.

4.12 There is clear Medical Device Equipment Management procedural guidance for relevant clinical speciality operational areas.

4.13 The hospital / community's MDEMC regularly review and revise Medical Device Equipment Management PPG's.

4.14 The hospital / community is aware of its obligations with respect to "Software as a Medical Device", and has associated PPG's in place.

4.15 The hospital / community's Medical Device Equipment Management PPG's cover the prescribing of Medical Device Equipment.

4.16 The hospital / community has ensured that the clinical engineering services and MDEMC have adequate resources to manage and administer their responsibilities with respect to the Medical Device Equipment Management Policy & Guidance Documents, subsequent Self Assessment and recommendations arising there from.

Excellence (E)

4.17 Medical Device Equipment Management PPG's are shared across the service.

4.18 The PPG's developed within the hospital / community also take cognisance of best available evidence and recommendations from the HPRA, ETCI and NSAI for all aspects of Medical Device Equipment Management.

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 where available.

Emerging Improvement (EI)

5.1 The hospital / community has in place a dedicated electronic based Medical Equipment Management System - where available that system is to be ECRI AIMS. Where not available pending implementation of ECRI AIMS, a comprehensive record system shall be in place.

5.2 The Medical Device Equipment history record is available as an aid to any maintenance issues that may arise during the equipment's useful life.

5.3 Clear records are kept from the outset, enabling the hospital / community to trace individual products (e.g. by serial number, hardware version, software revision etc.), or at least particular types/batches of devices throughout their whole life cycle.

5.4 Records provide evidence of installation and acceptance details (validation records where appropriate).

Continuous Improvement (CI)

5.5 The record includes specific guidance provided in the manufacturer's instructions and supporting information.

5.6 The electronic based system is a dedicated Medical Device Equipment Management system as opposed to a general asset management system.

5.7 Records document all equipment support provided by in-house and external providers for scheduled / unscheduled maintenance, repairs, replacement parts, safety, function and quality test results for the life of the equipment.

5.8 Where information is stored on a computer, the hospital / community ensures a back-up system is in operation. If a national or multi site system is in use, then evidence of information back up is evident.

5.9 Records of second hand Medical Device Equipment procured for a hospital or community shall be accompanied with full history of Medical Device Equipment documentation and records.

5.10 Records include manufacturers recommended planned preventative maintenance details including frequency and pro forma service, test procedures and documentation.

5.11 The records identify the stock of Medical Device Equipment currently available for use, or in use, together with their present location.

5.12 Records provide evidence of being updated when equipment is removed from clinical service, together with the end-of-use date and decommissioning details.

5.13 Records provide evidence of a unique universal identifier for the Medical Device Equipment, where appropriate.

Sustained Improvement (SI)

5.14 The hospital / community reviews the accuracy and consistency of record keeping and record systems for Medical Device Equipment.

5.15 Medical Device Equipment records provide evidence of any specific legal requirements and whether these have been met.

Excellence (E)

5.16 Audit Reports are provided on the accuracy and consistency of detail of Medical Device Equipment assets within the hospital / community.

5.17 ECRI AIMS is used to provide Medical Device Equipment identity detail and support evidence for consideration of replacement of equipment under the National Medical Equipment replacement programme.

5.18 Records are kept for at least 7 years post decommissioning of equipment.

5.19 Records provide evidence of disposal date and traceable disposal route.

Essential Element 6 **Governance # 5**

6 Medical Device Equipment is replaced in accordance with an agreed Policy, Procedure & Guideline (PPG).

Emerging Improvement (EI)

6.1 The hospital / community ensures that Medical Device Equipment is replaced in accordance with an agreed policy.

6.2 The Medical Device Equipment replacement programme is reviewed on an annual basis.

6.3 The Medical Device Equipment replacement programme is submitted to the National Clinical Head of Medical Devices for consideration of funding approval. The route to submission shall be documented.

Continuous Improvement (CI)

6.4 The Medical Equipment Management System is updated when Medical Device Equipment is replaced.

6.5 The Medical Device Equipment replacement recommendation governance is the responsibility of the Medical Device Equipment Management Committee.

6.6 The Medical Device Equipment replacement programme is planned and prioritised in accordance with documented criteria.

Sustained Improvement (SI)

6.7 Processes and templates are in use for departmental submissions of equipment replacement needs for consideration by the Medical Device Equipment Management Committee.

6.8 The national decision support tool "Prioritising Medical Device Equipment, Guidance for Services" is referenced to aid the prioritisation of a planned replacement programme.

6.9 Waste, Electrical and Electronic Equipment (WEEE) facilities are available and employed to safely remove and traceably dispose of redundant equipment and there is documented evidence, and policy pertaining to same.

Excellence (E)

6.10 There is evidence that the hospital / community participates in a systematic process in the identification of medical equipment replacement needs that takes account of developing clinical service delivery strategy within the wider system.

6.11 Identification of medical equipment replacement needs is evidence based, prioritised and that takes account of mitigation of risk within the hospital / Community.

Essential Element 7 **Governance # 6**

7 The management of all Medical Device Equipment on loan is governed by appropriate PPG's.

Emerging Improvement (EI)

7.1 Clear responsibility for each aspect of the management of Medical Device Equipment on loan is identified.

7.2 Medical Device Equipment issued is subject to performance, safety and quality assurance testing prior to issue, in accordance with manufacturer's instruction; or agreed local policy.

7.3 Medical Device Equipment on loan from a manufacturer is subject to acceptance testing by an adequately trained and competent person.

7.4 There are systems in place to ensure the appropriate collection/return of Medical Device Equipment.

Continuous Improvement (CI)

7.5 Medical Device Equipment on loan from a manufacturer is assigned to the electronic Medical Device Equipment Management system.

7.6 Delivery, receipt, acceptance and pre-use procedures for Medical Device Equipment on loan are the same as those for purchased Medical Device Equipment, unless otherwise specified.

7.7 Medical Device Equipment on loan from manufacturers are reviewed regularly to ensure that they are subject to appropriate maintenance schedules.

Sustained Improvement (SI)

7.8 There are local policies for the handling, management and transport of Medical Device Equipment on loan.

7.9 There are well-organised and understood procedures in place for cleaning/decontamination, checking, performance, quality assurance testing and preparing Medical Device Equipment before reissue.

7. 10 The technical history of the Medical Device Equipment on loan is taken into account prior to reissue, if possible.

Excellence (E)

7.12 Medical Device Equipment on loan from a manufacturer is subject to a written agreement which defines the device management requirements and responsibilities

and liabilities.

The hospital / community's MDEMC, or Sub Group, ensures that all Medical Device Equipment on loan in the community are in accordance with the “Medical Devices Recommended by Healthcare Institutions for Use in a Community Setting”, *(HPRA - Safety Notices)*.

Essential Element 8. Quality and Patient Safety # 1

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, recorded, and fed back externally utilising the National Medical Device Safety Alert System.

Emerging Improvement (EI)

8.1 The hospital / community employs the use of the on-line National Medical Device Safety Alert System, where accessible, for the centralised governance of Guidance and Safety Notifications issued by the Health Products Regulatory Authority (HPRA).

8.2 The hospital / community has identified and documented appropriate "Designated Person/s" for the receipt of Medical Device Equipment Alerts from the National Medical Device Safety Alert System.

8.3 The hospital / community has identified and documented appropriate "Designated Persons" for the receipt of Guidance Notices and Safety Alerts from the regulatory authority HPRA, Field Safety Notices from manufacturers and other notices/alerts from within the system.

8.4 All Safety Bulletins received are tabled and managed as a standing agenda item of the Medical Device Vigilance Group or its hospital / community equivalent.

Continuous Improvement (CI)

8.5 The MDEMC, or a reporting sub group such as a Medical Device Vigilance Group (MDVG), has responsibility for the Management of Medical Device Equipment Safety Bulletins within hospital / community. Safety Bulletins usually are in the format of Alerts or Guideline Notices (HPRA), or Field Safety Notices from the manufacturer.

8.6 HPRA Guidance and Safety Notification received are reviewed for action by the hospital / community within the due date timeframe assigned by the National Medical Device Safety Alert System; or the HPRA assigned action date whichever is sooner.

8.7 A hospital / community internal system is in place to ensure the recommended actions within any Safety Bulletin received is implemented, where applicable.

Sustained Improvement (SI)

8.8 A hospital / community internal process is in place and documented for assignment of the appropriate responsible person for implementation, and verification of completion, on any Safety Bulletin's recommended actions, as appropriate.

Excellence (E)

8.9 KPI's are maintained in regard to completed sign off of HPRA Guidance and Safety Notification within the priority timeframe assigned by National Medical Device Safety Alert System; and also manufacturers Field Safety Notices.

Essential Element 9. Quality and Patient Safety # 2

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.

Emerging Improvement (EI)

9.1 The hospital / community ensures that all adverse incidents involving Medical Device Equipment are managed in accordance with the requirements of the HSE's Safety Incident Management Policy (2014).

9.2 The hospital / community ensure that all adverse incidents involving Medical Device Equipment are managed and reported in accordance with the requirements of the HPRA.

9.3 The hospital / community has a Medical Device Vigilance Liaison Officer appointed with the necessary authority to take responsibility for the reporting of device related adverse incidents to the HPRA, *(typically Clinical Engineering Manager).*

9.4 The hospital / community's Incident Reporting Committee always consults with the Medical Device Vigilance Liaison Officer when an adverse incident regarding a Medical Device Equipment is discussed.

9.5 Where a deficiency is either suspected or confirmed with a product or piece of equipment, full details are notified promptly, via the Medical Device Vigilance Liaison Officer, to the HPRA.

Continuous Improvement (CI)

9.6 The Medical Device Vigilance Liaison Officer has received formal Incident reporting training/education on HPRA incident reporting processes.

9.7 Medical Device Equipment involved in an adverse incident together with other material evidence (e.g. packaging of a single use device) is clearly identified and kept in quarantine, where practicable, until the Medical Device Vigilance Liaison Officer has conducted their investigation.

9.8 Where quarantine is not practicable there are known systems so that the state of the Medical Device(s) at the time of the incident is recorded for use in any subsequent investigation, and the Medical Device is clearly labelled.

Sustained Improvement (SI)

9.9 The hospital / community ensures that all adverse incidents involving Medical Device Equipment are managed in accordance with the requirements of the Clinical Indemnity Scheme (CIS) on the NIMS web incident reporting system, or respective hospital / community equivalence.

Excellence (E)

9.10 The system that is in place for recording and reporting incidents within the hospital / community is self assessed for effectiveness in ensuring that adverse incidents occurring within the hospital / community are not repeated.

9.11 Patient learning outcomes from Medical Device Equipment incidents is shared throughout the wider system.

Essential Element 10. Quality and Patient Safety # 3

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.

Emerging Improvement (EI)

10.1 The hospital / community ensures that 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.

10.2 The hospital / community is compliant with the key areas that must be met in order to meet the criteria for risk management in the HSE's Safety and Incident Management Policy (2014).

10.3 Risk Analysis Methods are used to systematically identify Medical Device Equipment risks, and also adherence to the Medical Device Equipment Management Policy and Guideline documents.

Continuous Improvement (CI)

10.4 Adverse events associated with Medical Device Equipment are rated according to impact, and reviewed where appropriate, to determine contributory factors, root causes and any actions required.

Sustained Improvement (SI)

10.5 Adverse events associated with Medical Device Equipment are rated according to impact, subjected to periodic aggregate reviews to identify trends and further opportunities for learning, quality and safety improvement, and risk reduction.

Excellence (E)

10.6 Where appropriate, all claims associated with Medical Device Equipment are recorded and analysed to identify opportunities for learning, quality and safety improvement and risk reduction.

Essential Element 11. Quality and Patient Safety # 4

11 All Medical Device Equipment new developments, modifications and trials are conducted in accordance with relevant legislation and guidance.

Emerging Improvement (EI)

11.1 The hospital / community has a policy that ensures that all Medical Device Equipment developments, modifications and trials are conducted in accordance with relevant legislation and guidance.

11.2 Medical Device Equipment trials for the purpose of evaluation are subject to acceptance testing prior to clinical use and validated by clinical engineering.

Continuous Improvement (CI)

11.3 Medical Device Equipment modifications in use outside of the manufacturer's intended use are only considered as part of a fully documented hospital / community's risk management process.

Sustained Improvement (SI)

11.4 If a modification is made to a Medical Device Equipment, the process should adhere to the HPRA Guidance Note 12.

Excellence (E)

11.5 Results of Medical Device Equipment new developments, trials and successful modifications should be shared throughout the wider healthcare system.

Essential Element 12. Quality and Patient Safety # 5

12 Medical Device Equipment designated "Single Use" are not reused under any circumstances.

Emerging Improvement (EI)

12.1 The hospital / community has a procedure in place to ensure that any Single Use Medical Device Equipment used on an individual patient during a procedure is then appropriately discarded.

12.2 The understanding of "Single Use" versus Reusable Medical Device Equipment is clearly covered in staff induction programs.

12.3 The hospital / community has a system in place to create awareness of the Single Use symbol for all relevant staff.

12.4 A checking system is in place to ensure all Medical Device Equipment designated for Single Use are clearly identified with the “Single Use Symbol”.

Continuous Improvement (CI)

12.5 The hospital / community ensures that Single Use Medical Device Equipment is not reprocessed and used again.

Sustained Improvement (SI)

12.6 The hospital / community has a comprehensive tracking system and associated policy governing the use of Single Use Medical Device Equipment.

Excellence (E)

12.7 Audits for compliance with "Single Use" policy are conducted and benchmarked on a periodic basis.

Essential Element 13 Quality and Patient Safety # 6

13 All Medical Device Equipment is properly maintained and repaired.

Emerging Improvement (EI)

13.1 The hospital / community ensures that all Medical Device Equipment is properly maintained and repaired.

13.2 The key stakeholders associated with Medical Device Equipment are identified in the hospital / community's Medical Device Equipment Management Policy.

13.3 There is a documentation / computerised system for the reporting of Medical Device Equipment issues and assistance requisitioning by users.

13.4 There is Service Level Agreements (SLA) in place for all Medical Device Equipment being serviced externally. The SLA is appropriately detailed and contractual.

13.5 Medical Device Equipment SLA's meet the criteria of the HSE Procurement Policy.

13.6 The hospital / community maintains appropriate manufacturers / suppliers / agents details.

13.7 Internal staff servicing Medical Device Equipment owned by the hospital / community are appropriately qualified; and understand the basic principles on which devices work i.e. have generic training.

13.8 Documented evidence exists that external staff involved in servicing and clinical support of Medical Device Equipment are appropriately trained and qualified.

13.9 The hospital / community has proof that manufacturers / suppliers / agents carrying out Medical Device Equipment repairs are fully insured.

Continuous Improvement (CI)

13.10 The hospital / community's Medical Device Equipment Management policy covers the provision of support of all Medical Device Equipment, including training, education, clinical support, and multidisciplinary contribution by key stakeholders.

13.11 The hospital / community ensures that Manufacturer's service instructions are adhered to, or a scientific peer reviewed documented risk analysis is conducted.

13.12 The frequency and type of planned preventive maintenance specified per device considers: the manufacturer's instructions; the expected Medical Device Equipment usage; the environment in which the Medical Device Equipment is to be used; and best practice.

13.13 A risk-benefit analysis is undertaken should manufacturers maintenance recommendations not be adhered to.

13.14 The hospital / community communicates with each external Medical Device Equipment service provider at least yearly to review performance.

13.15 The hospital / community monitors external Medical Device Equipment external servicer providers for quality management accreditation and associated supporting documentation.

Sustained Improvement (SI)

13.16 The hospital / community seek feedback from its Medical Device Equipment users on all aspects of the repair and maintenance process, and their experience.

13.17 The hospital / community has an agreement with the manufacturers / suppliers / agents ensuring timely notification of any change in manufacturers / suppliers / agents circumstances that may affect the support, functionality, safety, operation, repair or maintenance of the Medical Device Equipment they have provided to the hospital / community.

13.18 The organization has a system to ensure medical device equipment spare parts are of the correct specification, and if generic their quality and compatibility match those supplied by the original equipment manufacturer.

Excellence (E)

13.19 Audits are carried out on all elements of Medical Device Equipment maintenance and repair systems.

Essential Element 14. Quality and Patient Safety # 7

All Medical Device Equipment returned for servicing and repair is properly decontaminated.

14 All Medical Device Equipment returned for servicing and repair is properly decontaminated.

Emerging Improvement (EI)

14.1 The organisation is compliant with the HSE's published "HSE Standards and Recommended Practices" QPSD-D-003-2. V2.0, QPSD-D-005-2. V 2.0 and QPSD-D-004-2. V2.0, 2011.

14.2 Medical Device Equipment for service/repair in client's home/community are, where appropriate, subject to cleaning/decontamination in acordance with manufacturer's guidelines.

14.3 For items of Medical Device Equipment that are not covered under the Reusable Invasive Medical Devices HSE Standards and Recommended Practices, the organisation adheres to the manufacturer's decontamination/cleaning instructions.

14.4 The Medical Device Equipment maintenance facilities comply with the hospital / communities infection control recommendations.

14.5 There is evidence of Personal Protective Equipment being used by staff who handle and repair Medical Device Equipment.

Continuous Improvement (CI)

14.6 Where Medical Device Equipment is recycled or loaned out to the End User, documented procedures are in place to ensure adequate decontamination/cleaning has been performed.

14.7 The hospital / community has tracking documentation certifying status of decontamination/cleaning when equipment is returned from clinical use by the End User.

Sustained Improvement (SI)

14.8 The hospital / community has procedures and tracking documentation certifying status of decontamination/cleaning when Medical Device Equipment is returned to/from manufacturer/supplier/agents.

Excellence (E)

14.9 All Clinical Engineering or Maintenance facilities for Medical Device Equipment repair are audited by infection control and/or the decontamination coordinator.

Essential Element 15. **Capability # 1**

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.

Emerging Improvement (EI)

15.1 There is knowledge and awareness of HPRA Safety Notice: SN2007(06) Medical Devices Recommended by Healthcare Institutions for use in a Community Setting.

15.2 Procedures and policies are in place which ensure that suitably qualified and experienced staff undertake the prescription of appropriate types of Medical Device Equipment.

15.3 All Medical Device Equipment prescribing decisions are made by employees with access to appropriate administrative and technical support systems.

15.4 Systems are in place to establish the range of Medical Device Equipment available for use by the Professional User.

Continuous Improvement (CI)

15.5 There is evidence that Medical Device Equipment is chosen to best meet the requirements of the intended medical procedure or needs of the End User.

15.6 Evidence exists that all Medical Device Equipment prescribing decisions are made by employees with appropriate professional qualifications and suitable training and experience.

Sustained Improvement (SI)

15.7 Short-term loan/issue of a Medical Device Equipment which is considered to provide benefit to end users is governed by policy, until a more appropriate device is available for the End User.

15.8 There is evidence that the needs of the carer who supports a Medical Device Equipment End User is taken into account, where appropriate.

Excellence (E)

15.9 All Medical Device Equipment being prescribed, or provided, is in accordance with the "Medical Devices Recommended by Healthcare Institutions for Use in a Community Setting", Safety Notice: SN2007(06) -HPRA.

Essential Element 16. **Capability # 2**

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

Emerging Improvement (EI)

16.1 There is evidence that employees are made aware of the HSE's Safety Incident Management Policy (2014) and, where necessary, trained in incident management (reporting and investigation) for the management of adverse events involving Medical Device Equipment.

16.2 There is appropriate education material and education sessions available to all staff in relation to adverse event reporting processes, and incident investigation methodology involving Medical Device Equipment.

Continuous Improvement (CI)

16.3 There is appropriate education material and education sessions available to all staff in relation to HPRA and Manufacturer Safety Bulletin systems for the management of adverse events involving Medical Device Equipment.

16.4 There is evidence that employees are made aware of and, where necessary, trained in HPRA and Manufacturer Safety Bulletin systems for the management of adverse events involving Medical Device Equipment.

Sustained Improvement (SI)

16.5 Relevant staff are audited on their knowledge of the various reporting mechanisms for adverse events involving Medical Device Equipment.

Excellence (E)

16.6 Relevant staff are audited on their knowledge of the various HPRA and Manufacturer Safety Bulletin systems for the management of adverse events involving Medical Device Equipment.

Essential Element 17. **Capability # 3**

17 Professional Users and Technical Supervisors are trained in the safe operation of Medical Device Equipment.

Emerging Improvement (EI)

17.1 All training and instructions for Medical Device Equipment as outlined in the Corporate Safety Statement (2014), section 4.9, shall be provided for all Professional Users and Technical Supervisors.

17.2 All training and instructions for Medical Device Equipment should be governed by local policy and documented accordingly.

17.3 All training and instructions as outlined in the Corporate Safety Statement (2014), section 4.9, takes into account any subsequent refresher training needs on Medical Device Equipment.

17.4 Specific training on particular Medical Device Equipment is based on the manufacturer's documentation.

17.5 Technical Supervisors who are providing repair and maintenance services of Medical Device Equipment are generically or specifically trained and qualified.

17.6 Individuals who are providing decontamination services of Medical Device Equipment are adequately trained and appropriately qualified.

17.7 There is evidence that Professional Users have received suitable instructions and training on the use of Medical Device Equipment, to enable them to use Medical Device Equipment effectively and safely.

17.8 There is evidence that Professional Users understand when a Medical Device Equipment malfunctions.

17.9 There is evidence that relevant Professional Users understand how to clean medical device equipment and to perform decontamination.

Continuous Improvement (CI)

17.10 Training for Professional Users is monitored and audited for its suitability and effectiveness within the hospital / community.

17.11 Details of training received are recorded in an individuals training log and/or centrally archived.

17.12 Technical Supervisors have access to scientific and technical training and education that allow them conduct specialist Medical Device Equipment Management roles within the hospital / community, for example: laser safety officer, UV exposure specialist, medical gases approved and competent person, decontamination authorised person, electrical safety competent and approved person, medivac technical specialist, technology project management, medical device regulatory compliance person, etc.

17.13 Technical Supervisors have access to scientific and technical training and education by the manufacturers or appointed agents on specific Medical Device Equipment technologies used within the hospital / community.

Sustained Improvement (SI)

17.14 Specific and adequate funding is available to ensure the adequate training of staff in all aspects of equipment use and related support.

Excellence (E)

17.15 There is documented training needs analysis conducted covering all levels of Professional Users on a regular basis.

17.16 Technical Supervisors exchange Medical Device Equipment Management ideas with other hospital / communities by networking.

17.17 The hospital / community ensures that all Professional Users and Technical Supervisors are trained in the safe operation of Medical Device Equipment.

Essential Element 18. **Capability # 4**

18 End-Users are where relevant given appropriate instruction in the safe and effective use of Medical Device Equipment.

Emerging Improvement (EI)

18.1 The hospital / community ensures that all End Users are where relevant given appropriate instruction in the safe and effective use of Medical Device Equipment.

18.2 The instruction requirements for specific Medical Device Equipment are subject to a needs assessment which may involve End Users, Carers or Clinical Staff.

18.3 End Users are provided with appropriate information contained in Manufacturer's Instructions.

18.4 There is documented evidence of instruction with End Users whereby End Users demonstrate understanding of the intended use and normal functioning of the Medical Device Equipment in order to use it effectively and safely.

Continuous Improvement (CI)

18.5 There is evidence that Professional Users make sure that instruction for End Users enables them to perform any necessary routine maintenance on their Medical Device Equipment.

Sustained Improvement (SI)

18.6 The hospital / community has an instruction policy for End Users needs in accordance with HPRA guidelines.

18.7 End User instruction governance of Medical Device Equipment is contained within the hospital / community's Medical Device Equipment Management's (MDEM's) Policy.

Excellence (E)

18.8 Medical Device Equipment instruction content and quality for End Users is monitored and regularly audited for its effectiveness.

Essential Element 19. **Outcomes # 1**

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

Emerging Improvement (EI)

19.1 The hospital / community's Medical Device Equipment Management Committee has developed Key Performance Indicators (KPI's) with respect to the Essential Elements contained within the Medical Device Equipment Management Policy; they are monitored for compliance and reported at MDEMC meetings.

19.2 There is a mechanism for ongoing revision and development of Medical Device Equipment Key Performance Indicators.

19.3 KPI'S relating to Medical Device Equipment are also reported up through the hospital / community, and reporting lines are documented.

Continuous Improvement (CI)

19.4 The hospital / community has developed KPI's relating to the HPRA Vigilance Systems and Alerts that demonstrate "sign off" in all aspects.

Sustained Improvement (SI)

19.5 Medical Device Equipment assets are audited for accuracy with the computerised Medical Device Equipment Management System's database assigned locations.

19.6 There is a mechanism ensuring that the MDEM Self Assessment Quality Improvement Plans (QIPs) are monitored for progress in performance against the Policy.

Excellence (E)

19.7 There are Medical Device Equipment KPI's which are capable of highlighting Medical Devices Equipment risk trends. These risk trends are shared throughout the wider system for learning purposes.

Essential Element. 20 **Outcomes # 2**

20 The hospital / community participates in benchmarking its Management of Medical Device Equipment; and Continuous Professional Development (CPD).

Emerging Improvement (EI)

20.1 Hospital / community KPI's are developed with respect to the NMDEMC Policy. The first set of consistent data is used as a benchmark for monitoring of future improvement.

Continuous Improvement (CI)

20.2 The hospital / communities Medical Device Equipment Management supports Clinical Engineering Staff's CPD requirements, when relevant.

Sustained Improvement (SI)

20.3 Staff who practice Clinical Engineering, at all levels, graduate and technical, are facilitated with CPD opportunity with respect to their Professional Organisation's requirement i.e. Engineers Ireland (EI), Biomedical Engineering Association of Ireland (BEAI) and others as appropriate.

Excellence (E)

20.4 CPD knowledge acquired in the management of Medical Device Equipment is shared throughout the organisation for learning purposes.

Essential Element 21. Monitoring and Review # 1

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

Emerging Improvement (EI)

21.1 The hospital / community conducts an annual Self Assessment with respect to the Medical Device Equipment Management Policy and Guidance Document using the National Self Assessment Tool.

21.2 An assessment of the hospital / community Medical Device Equipment Management System/Structure is conducted in relation to compliance with the HSE's Medical Device Equipment Management Policy and Guidance Documents recommendations, and appropriate changes made where necessary.

Continuous Improvement (CI)

21.3 Hospital / community Annual Self Assessment Tool report synopsis is made available to the National MDEMC upon request.

21.4 There is evidence that internal Medical Device Equipment Management self assessment outcomes are presented to the hospital / community's QPS Committee and Health and Safety Committee.

Sustained Improvement (SI)

21.5 There is evidence that an annual report approved by the MDEMC, based on the KPI's is submitted to the hospital / community's management, demonstrating monitoring and review of aspects of the Medical Device Equipment Management System and Standard.

Excellence (E)

21.6 Key Medical Device Equipment Management examples and methods of achieving self excellence - "E award" in self assessments criteria are shared throughout the system for learning purposes.

Essential Element 22. **Internal Assurance # 1**

22 The hospital / community has effective systems in place for the determination of assurance in the Safe Management of Medical Device Equipment.

Emerging Improvement (EI)

22.1 The hospital / community's Medical Device Equipment Management Committee (MDEMC) conduct an annual Self Assessment using the National MDEMC's Self Assessment Tool and report level of compliance and Quality Improvement Plan's (QIP's) to hospital / community management for consideration of assurance in the Management of Medical Device Equipment.

Continuous Improvement (CI)

22.2 The MDEMC self assessment generates QIP's which are reviewed on a quarterly basis for successful implementation.

22.3 The MDEMC review their PPG's periodically to ensure that they continue to conform with its, and the national, Medical Device Equipment Management Policy.

Sustained Improvement (SI)

22.4 A strategic plan supports the safe Management of Medical Device Equipment within the Hospital / Community.

Excellence (E)

22.5 The hospital / community MDEMC demonstrates yearly improvement in Medical Device Equipment Management.

Essential Element 23. **Internal Assurance # 2**

23 Medical Device Equipment is selected and acquired in accordance with the HSE'S Procurement Policy.

Emerging Improvement (EI)

23.1 The hospital / community's Medical Device Equipment procurement is compliant with the National Financial Regulations and HSE Procurement Process.

23.2 The process of Medical Device Equipment Requisitioning and Procurement is traceable from user presentation of a business case to appropriate management signoff.

23.3 The hospital / community Medical Device Equipment Management Committee (MDEMC) is involved in establishing policy process and procedure for Medical Device Equipment acquisition.

23.4 The MDEMC ensures that PPG's for the sourcing and acquisition of Medical Device Equipment address safety, quality, and performance of Medical Device Equipment.

23.5 Medical Device Equipment Product Evaluation Groups are appropriately multidisciplinary in composition.

23.6 The hospital / community has evidence of adherence to the Risk Based Matrix Element of the Prioritization Guidance document developed by the National MDEMC for Medical Device Equipment replacement.

23.7 Manufacturer/supplier/distributor performance is taken into consideration during selection and decision making process concerning acquisition of Medical Device Equipment.

23.8 Manufacturer/supplier/distributor performance is taken into consideration during selection and decision making process to award a Medical Device Equipment Contract and prior to the signing of the Service Level Agreement (SLA).

23.9 Adherence to recognised good practice of standardisation of model and type of Medical Device Equipment throughout shall be maintained in replacement of Medical Device Equipment.

23.10 Detailed Medical Device Equipment life cycle costs are considered in acquiring Medical Device Equipment.

23.11 Decontamination processes, and current compatibility of any products used with existing procedures is considered when acquiring Medical Device Equipment.

23.12 The interests of infection control and decontamination are included in hospital / community Medical Device Equipment selection and replacement processes.

Continuous Improvement (CI)

23.13 When Medical Device Equipment technology is purchased, there is evidence that the hospital / community ensures that an appropriate level of training and clinical support is provided by the manufacturer/supplier.

23.14 Medical Device Equipment Service Level Agreements (SLAs) are evaluated, managed and signed off by the technical supervisor and appropriate clinical staff.

23.15 User and advisory groups experience is fed back into the MDEMC requisitioning and procurement process for Medical Device Equipment.

23.16 There is a clearly defined Agreement (e.g. Service Level Agreement, SLA) covering all aspects of Contract for any Medical Device Equipment left within the hospital / community that it does not own e.g. loan or trial Medical Device Equipment.

Sustained Improvement (SI)

23.17 The interests and requirements of Infection Control are included and adhered to in all aspects of Medical Device Equipment loan, demonstration, and evaluation exercises; and supporting documentation exist.

Excellence (E)

23.18 The recommendations of HPRA, ETCI, NSAI, HIQA and other appropriate bodies are considered and followed for selection and acquisition of Medical Device Equipment.

23.19 When considering new Medical Device Equipment technology, supporting scientific documentation from the manufacturer and other evidence based clinical trials are reviewed in accordance with the relevant legislation, recommendations, and guidance, all of which are factored into decision making processes so that the best outcomes in the selection of Medical Device Equipment are achieved for patients.

23.20 There is a policy in place for other methods of acquiring devices, including loans, donations, in-house manufacture, and modification of in-house devices, and refurbishment.

Essential Element 24. **Internal Assurance # 3**

24 Pre-Use Checks are carried out on all newly delivered and recycled Medical Device Equipment.

Emerging Improvement (EI)

24.1 The hospital / community has a procedure that governs the delivery and pre-use checks for all newly delivered Medical Device Equipment.

24.2 There is evidence that the hospital / community checks the specification of newly delivered equipment; that it matches the purchase order detail; the purchase support requisition; business case detail; and tender specification if tendered for in house.

24.3 Appropriately qualified and trained Technical Supervisors in the practice of Clinical Engineering shall oversee the installation, acceptance testing process and commissioning for Medical Device Equipment introduced into the hospital / community. This person shall take responsibility for final sign off on satisfactory completion of testing.

24.4 The hospital / community ensures that Medical Device Equipment is subjected to acceptance test procedure.

24.5 Acceptance testing of each item of equipment shall be carried out by the Technical Supervisor assigned to the installation before the first use of the Medical Device Equipment. The Medical Device Equipment may not be used without testing satisfying the criteria of acceptability. The outcomes of these tests shall be recorded by the Technical Supervisor.

24.6 There are mechanisms in place to ensure that Medical Device Equipment is not signed off for payment without acceptance test validation by the Technical Supervisor.

24.7 Medical Device Equipment is assigned an asset tag uniquely labelled at delivery / commissioning or acceptance stage.

24.8 The Medical Device Equipment is assigned to the Medical Device Equipment Computerised Management System following successful completion of acceptance test procedures. The recommended Health Service dedicated computerised Medical Device Equipment Management software system is “ECRI AIMS” and must be used if available.

24.9 Prior to Medical Device Equipment being first put into service, staff are trained and staff training is documented.

24.10 There is a reliable mechanism in place to manage Medical Device Equipment warranty period and related support of that equipment during and after the warranty period.

Continuous Improvement (CI)

24.11 All Medical Device Equipment coming into the hospital / community are pre use checked whether they are newly purchased, leased/rented, on loan, on trial, gifted, or otherwise presented.

24.12 Planned training of relevant Prescribers and Professional Users to support all Medical Device Equipment Users is part of the acceptance procedures for new Medical Device Equipment.

Sustained Improvement (SI)

24.13 Where the Medial Device Directive allows exceptions to the CE marking requirement, there is an additional documented risk assessment carried out in accordance with HPRA protocol at the time any such device is brought into the organisation.

Excellence (E)

24.14 An audit of all new assets introduced into the organisation is conduced on a yearly basis to ensure appropriate Pre-Use Check Sign off.

24.15 Prior to Medical Device Equipment being first put into service a planned preventative maintenance programme is scheduled on record.

Essential Element 25. **Internal Assurance # 4**

25 **All Medical Device Equipment is properly stored.**

Emerging Improvement (EI)

25.1 The hospital / community has developed a policy that ensures all Medical Device Equipment are properly stored.

25.2 In the community, where Medical Device Equipment Management transfers to a community healthcare worker; the hospital / community ensures that the healthcare worker is aware of their responsibility for appropriate Medical Device Equipment storage, as recommended by the Manufacturer and/or hospital/community guidelines.

25.3 In the community, where Medical Device Equipment may transfer to the End User; the hospital / community ensures that the End User is aware of their responsibility for appropriate Medical Device Equipment storage.

25.4 All relevent staff are made aware of their responsibilities for appropriate Medical Device Equipment storage as recommended by the Manufacturer.

Continuous Improvement (CI)

25.5 For all Medical Device Equipment, there are stock rotation system's in place in storage locations.

Sustained Improvement (SI)

25.6 All Medical Device Equipment in equipment stores and libraries are subjected to documented performance and safety and quality assurance tests prior to reissue.

Excellence (E)

25.7 The hospital / community provides suitable facility, e.g. space, power, ventilation, for the storage of Medical Device Equipment. This facility shall be subject to continual review/audit.

Essential Element 26. **Internal Assurance # 5**

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.**

Emerging Improvement (EI)

26.1 Professional Users and Prescribers have access to Manufacturer's Medical Device Equipment Instructions.

26.2 Professional Users confirm they have received instructions on the safe use of all relevant Medical Device Equipment and are aware of their importance.

26.3 Professional Users and Prescribers have access to the Manufacturers cleaning and decontamination instructions.

26.4 Prescribers are aware of the Manufacturer's Instructions for details of how the Medical Device Equipment should be used, and for whom it is suitable.

26.5 Manufacturer Instructions for use are provided with loan Medical Device Equipment each time the Equipment is reissued.

26.6 When Manufacturer's update their Medical Device Equipment Instructions for use, the hospital / community has an agreed process with the manufacturer (or agent) for recording, tracking and updating Instruction versions.

26.7 The Manufacturer Instructions for Use, including infection control, decontamination and relevant service instructions, are provided as a necessity for Medical Device Equipment acceptance into the hospital / community.

Continuous Improvement (CI)

26.8 All Professional Users sign confirmation that they have received training on the safe use of Medical Device Equipment.

26.9 There is a policy that advocates "In cases of doubt", the End User checks the Manufacturer Instructions.

26.10 Community stores that provide Medical Device Equipment for use, ensure Medical Device Equipment dispatched contains Manufacturer's Instructions.

26.11 Where some End Users require additional instructions or training with the use of Medical Device Equipment, there is evidence that the hospital / community have mechanisms in place to facilitate.

26.12 There is documentation signed by the End User verifying that they have received the Medical Device Equipment Manufacturer's End Users Guide.

26.13 Any Medical Device Equipment "complementary" instructions drafted by the hospital / community are submitted to the Manufacturer for comment and approval before use.

Sustained Improvement (SI)

26.14 Within the hospital / community clear lines of responsibility exist for ensuring that the Manufacturer's Instructions are afforded to all Users of Medical Device Equipment and, where appropriate, carers.

26.15 A satisfaction survey/audit is conducted of End Users knowledge and understanding of manufacturers instructions in support of 'patient centred care'.

Excellence (E)

26.16 Where there are identified deficiencies in the Manufacturer Instructions, they are reported to the manufacturer and/or HPRA.

Essential Element 27. **External Assurance # 1**

27 The hospital / community has effective systems in place for the determination of external assessment in the safe Management of Medical Device Equipment.

Emerging Improvement (EI)

27.1 The hospital/community completes an assessment of the HIQA Standards in matters pertaining to Medical Device Equipment.

Continuous Improvement (CI)

27.2 Recommendations from any HIQA report regarding the Management of Medical Device Equipment are implemented.

Sustained Improvement (SI)

27.3 Hospital / community management, and the National Quality and Patient Safety Office, where appropriate, are provided with annual reports with respect to the status of, and future planning of Medical Device Equipment.

Excellence (E)

27.4 Best practice of Medical Device Equipment Management is shared throughout the system for learning purposes.

Any suggestions or ideas generated as a result of using the Self Assessment Tool should be fed back via MDEMC members for discussion at the National MDEMC. Ie. additional prompts considered important, prompts considered unsuitable.

11.0 REFERENCES

Medical Device Equipment Management Policy (Incorporating Medical Device Equipment Management Best Practice) 2015

HSE Medical Device Equipment Management Best Practice, Guidance for Service Areas, 2015

12.0 APPENDICES

Appendix I Abbreviations

AIMS	Asset Information Management System
BEAI	Biomedical Engineering Association of Ireland
CIS	Clinical Indemnity System
CPD	Continuous Professional Development
EI	Engineers Ireland
ETCI	Electro Technical Council of Ireland
HIQA	Health Information and Quality Authority
HPRA	Health Products Regulatory Authority
HSE	Health Service Executive
KPIs	Key Performance Indicators
MDEMC	Medical Device Equipment Management Committee
MDVG	Medical Device Vigilance Group
NIMS	National Incident Management System
NSAI	National Standards Association of Ireland
PPGs	Policies, Procedures and Guidelines
QIPs	Quality Improvement Plans
QPS	Quality and Patient Safety
SLA	Service Legal Agreement
WEEE	Waste, Electrical and Electronic Equipment

Appendix II Definitions

E-Award:

- To be able to mark yourself as excellent against any of the Essential Elements in the Self Assessment Tool.

End – User:

- A patient or client who uses a medical device or item of equipment within a healthcare facility (eg. Telemetry device or PCA pump etc.) or in the home (eg. wheelchair, chair lift, diabetic infusion pump etc.).

On Loan:

- Medical Device Equipment on loan from the HSE to an End-User, or Medical Device Equipment on loan from a supplier to either a hospital or End-User provided that this loan was organised with the approval of the HSE.

Professional User:

- A trained and qualified person who operates a Medical Device Equipment for the benefit of a patient or client (e.g. doctor, dentist, surgeon, nurse etc.).

Record:

- For the purpose of this document, a record is intended to mean all documentation and information associated with the Medical Device Equipment's lifecycle history.

Technical Supervisor:

- People with technical or managerial roles in Medical Device Equipment Management, typically qualified and trained in the practice of Clinical Engineering ("competent person/clinical engineer").

Prescriber:

- The person who decides the appropriate Medical Device Equipment for a given patient or client (e.g. nurse, occupational therapist etc.).

User:

- A Professional User and/or End-User.