Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Medical Devices/Equipment Management Policy (Incorporating the Medical Devices Management Standard)

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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 organizations 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 devices/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 devices/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 devices/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 Irish Medicines Board, 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 devices / equipment.

2.0 POLICY STATEMENT

It is the policy of this organisation (HSE) to ensure that a formal system to manage medical devices is established in the HSE. The HSE is committed to ensuring that uniform policy, standards and procedural guidance are implemented to support the development of a system which assures a designated coordinated approach for the management of Medical Devices / Equipment throughout the organisation. This is essential to ensure patient safety through clinical and social care governance, risk management and quality assurance of Medical Devices/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 Devices/Equipment and that the highest standards of device safety, risk management and financial efficiency are realised in the management of the device. The policy aims to minimize related hazards, to ensure that employees are properly trained and competent in the use of Medical Devices/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 standards based approach which will instill a safer, more efficient, and high quality management of all medical devices/equipment. Good management will involve all aspects of the lifecycle of medical devices/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

- Integrated Risk Management Policy
- Incident Management Policy and Procedure
- Serious Incident Management Policy and Procedure
- 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 standard should be read in conjunction with the following:

- HSE's Quality and Risk Management Standard
- HSE's Quality, Safety and Risk Management Framework and Companion Guide
- HSE's Medical Device/Equipment Procedural Guidance
- National Standards for the Prevention and Control of Healthcare Associated Infections (HIQA)

There are also national and international statutory requirements which must be adhered to regarding Medical Devices and 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 devices/equipment within its services and within agencies funded by the HSE and to ensure that medical devices/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 devices.

6.0 DEFINITION OF A MEDICAL DEVICE

This refers to any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

— Diagnosis, prevention, monitoring, treatment or alleviation of disease,

— Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,

— Investigation, replacement or modification of the anatomy or of a physiological process,

- Control of conception

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

(EU definition)

This definition includes devices intended to administer a medicinal product, such as a syringe driver, or which incorporate a substance defined as a medicinal product, such as a drug-eluting stent.

A list of some of the products covered by the definition of medical device and prepared by the Irish Medicines Board is attached (See Appendix I).

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 Devices/Equipment
- To clearly define and designate the roles and responsibilities for the management of Medical Devices/Equipment within the HSE.

- To ensure that the HSE complies with all relevant legislative Standards, Recommendations and Vigilance Systems of the Competent Authority i.e. the Irish Medicines Board
- To set out a statement of standard and supporting criteria based on a model of internal control for use in managing medical devices/equipment within the HSE.

8.0 ROLES AND RESPONSIBILITIES

8.1 The HSE Board

The HSE Board will receive and consider the Reports of the Risk Committee and will hold responsibility for Medical Devices/Equipment Management.

8.2 The Risk Committee

The Risk Committee oversees all risks within the HSE and will incorporate any issues relating to medical devices/equipment management in its reports to the Board.

8.3 CEO

The implementation of the Medical Devices/Equipment Policy and management standard is the responsibility of the CEO and the management team. The CEO can delegate day-to-day operational management of Medical Devices/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 directorate that:

- Accountability for the management of medical devices/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 standard and any relevant legislation and regulation.

8.5 Regional Directors of Operations

Each Regional Director of Operations has overall responsibility to:

- Provide assurance to the National Operations Director in relation to the system for medical device/equipment management. This assurance will be provided through an audit of compliance with this policy and standard and any relevant legislation and regulation.
- Establish and support an integrated Regional Medical Devices /Equipment Management Committee (MDEMC).
- Designation of sub-regional areas for the integrated management of medical devices/equipment.
- Ensure the establishment of sub-regional Medical Devices/Equipment Management Committees in the region.
- Designate Biomedical/Clinical Engineering leads with delegated responsibility for the integrated management of medical devices/equipment within each sub-region.

8.6 Hospital Managers/Local Health Managers

These persons will be responsible for ensuring that there are systems and processes in place for the local management of Medical Devices / Equipment within their area of responsibility. This will include supporting the establishment and operation of a sub-regional Medical Devices/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 to use the medical devices which they are required to use 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 devices.

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 in this policy to their line manager.

8.8 Medical Devices/Equipment Management Committee

The establishment of Medical Devices/Equipment Management Committees (MDEMC) are required at local, regional and national levels. This will most likely be the current "Decontamination Committee" with a few additional members and additional Terms of Reference. The MDEMC will facilitate implementation, monitor compliance and provide assurance in relation to this policy and standard as is relevant to the organisational level at which they exist i.e. sub-regional, regional or 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 with areas such as Technical Services.

8.9 Clinical Engineering lead

It is the responsibility of Biomedical/Clinical Engineering lead within a sub region:

- To provide expert advice on all aspects of the management of medical devices/equipment
- Develop and maintain the systems required to effectively and safely manage medical devices/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 devices/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

Detailed procedural guidance to support the successful implementation of this policy and compliance with the standard has been developed.

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 Standard (see Appendix II) and to put in place improvement plans where required.

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 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 Devices/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 trail.

13.0 POLICY REVIEW

This Policy will be reviewed in October 2010.

14.0 REFERENCES

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

http://www.hse.ie/eng/Publications/services/Hospitals/HSE_Publications/Code_of_Practice_for_Decontamination_of_Reuable_Invasive_Medical_Devices_1.pdf

- **National Finance Regulations**

http://hsenet.hse.ie/HSE_Central/finance_Transformation_Projects/Financial%20Regulations/NFR_1_Purchase_to_Pay.pdf

- **HSE Procurement**

http://hsenet.hse.ie/HSE_Central/Commercial_and_Support_Services/Procurement/Policies_Procedures/HSE_Procurement_Policy.pdf

- **HSE Quality and Risk Management Standard**

http://hsenet.hse.ie/HSE_Central/Office_of_the_CEO/Quality_and_Risk/Documents/OQR009_Quality_Risk_Management_Standard.pdf

- **HSE Quality, Safety and Risk Framework**

http://hsenet.hse.ie/HSE_Central/Office_of_the_CEO/Quality_and_Risk/Documents/HSE_quality_safety_and_risk_framework_V1_Jan_2009.pdf

- **HSE Quality, Safety and Risk Framework Companion Guide**

http://hsenet.hse.ie/HSE_Central/Office_of_the_CEO/Quality_and_Risk/Documents/HSE_companion_guide_V1_Feb_2009_.pdf

- **HSE Incident Management Policy and Procedure**

http://hsenet.hse.ie/HSE_Central/Office_of_the_CEO/Quality_and_Risk/Documents/OQR006_Incident_Management_Policy_Procedure.pdf

- **HSE Serious Incident Management Policy and Procedure**

http://hsenet.hse.ie/HSE_Central/Office_of_the_CEO/Quality_and_Risk/Documents/SIMT_01_Part_2_Serious_Incident_Management_Policy_and_Procedure.pdf

- **HSE Medical Devices/Equipment Management – Compliance with the HSE's Medical Devices and Equipment Management Standard – Guidance for Service Areas**

http://hsenet.hse.ie/HSE_Central/Office_of_the_CEO/Quality_and_Risk/Documents/OQR031_HSE_Medical_Devices_Equipment_Management;_Best_Practice_Guidance.pdf

- **Framework for the Corporate and Financial Governance of the Health Service Executive. HSE Integrated Risk Management Policy**

http://hsenet.hse.ie/HSE_Central/Office_of_the_CEO/Quality_and_Risk/Documents/OQR023_HSE_Integrated_Risk_Management_Policy_Doc_2_4_.pdf

- **HSE Corporate Safety Statement**

http://hsenet.hse.ie/Intranet/Library/HSE_Publications/?importUrl=http://localhost:82/eng/Publications/corporate/HSE_Corporate_Safety_Policy_and_Corporate_Safety_Statement.pdf

- **A Framework for Major Emergency Management**

http://www.mem.ie/memdocuments/a%20framework%20for%20major%20emergency%20management.pdf

- **HSE Infection Control Policies**

http://hsenet.hse.ie/HSE_Central/Population_Health/Health_Protection/Health_Care_Associated_Infection/HCAI_publications/Local_Implementation_Team_Action_Plan.pdf

- **HSE Information Technology Acceptable Usage Policy**

http://hsenet.hse.ie/HSE_Central/Commercial_and_Support_Services/ICT/Policies_and_Procedures/Policies/HSE_Information_Technology_Acceptable_Use_Policy.pdf

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

http://www.hiqa.ie/media/pdfs/National_Standards_Prevention_Control_Infections.pdf

- **Health Act 2004**

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

15.0 Appendices

APPENDIX I

COMMON CATEGORIES OF MEDICAL DEVICE

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 and materials.
- Dressings
- Endoscopes
- Examination gloves
- Gastrostomy tubes
- Intravenous (IV) administration sets and pumps
- Nebulisers
- Ophthalmic equipment
- Peak flow meters
- Podiatry and Podiatric Surgery equipment
- Sphygmomanometers
- Suction equipment
- Surgical instruments
- Syringes and needles
- Thermometers
- Ultrasound Doppler's
- Urinary catheters

Equipment used in life support such as:

- Blood glucose measuring devices
- Cholesterol test kits
- Defibrillators
- Domiciliary oxygen therapy systems
- In vitro diagnostic medical devices and their accessories
- Intensive Care ventilators
- Insulin injectors
- Pregnancy test kits
- Pulse oximeters
- Specimen collection tubes
- Urine test strips
- Ventilators used in the home

- Vital Signs monitoring

Equipment used in care, such as:

- Adjustable beds
- Lifting poles
- Patient hoists
- Pressure relief equipment
- Stoma care equipment

Equipment used by people with disabilities, such as:

- Bathing equipment
- Commodes
- Communication aids
- External prostheses and orthoses
- Hearing aids
- Prescribable footwear
- Standing frames
- Urine drainage systems
- Walking aids
- Wheelchairs and special support seating

Items stocked by Pharmacy Departments with CEs

- Interactive Wound Dressings
- Bone Cements
- Viscoelastic Opthalmic Injections
- Inhaled Drug Delivery Devices

APPENDIX II

Statutory Requirements:

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:

- Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active **implantable** medical devices.
- Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of **biocidal products** on the market.
  Directive 2007/47EEC - OJ L247/ 21.9.07

  - Active Implantable Medical Devices (AIMDD) - consolidated version 11/10/2007
    - Directive 90/385/EEC - OJ L189/ 20.7.90

  - Medical Devices Directive (MDD) - consolidated version 11/10/2007
    - Directive 93/42/EEC - OJ 169/ 12.7.93

  - In Vitro Diagnostic Directive (IVDD)
    - Directive 98/79/EC - OJ331/ 7.12.98 - consolidated version 20/11/2003

EC Implementing Legislation

- Reclassification of breast implants:
  - Directive 2003/12/EC - OJ L028/ 4.02.2003

- Common Technical Specification on IVD:
  - Commission Decision 2002/364/EC - OJ L131/ 16.05.2002

- MD manufactured utilising tissues of animal origin:
  - Directive 2003/32/EC - OJ L105/18- 26.04.2003

- MD incorporating stable derivates of human blood or human plasma:
  - Directive 2000/70/EC - OJ L 313 , 13/12/2000

- MD incorporating stable derivates of human blood or human plasma:
  - Directive 2001/104/EC - OJ L 6/50 , 10/01/2002

- Reclassification of hip, knee and shoulder joint replacements:
  - Directive 2005/50/EC - OJ L 210 , 12/08/2005

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:

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

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.
S.I. No. 253/1994:	European Communities (Active Implantable Medical Devices) Regulations, 1994.
S.I. No. 304 of 2001	European Communities (In Vitro Diagnostic Medical Devices) Regulations, 2001)
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, 2002 (Blood Products)
S.I. No. 358 of 2003	*European Communities (Medical Devices) (Reclassification of Breast Implants)*

(Amendment) Regulations, 2003

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

S.I. 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:**

Amendment SI 303 (2007)	SI 478 /2002, European Communities (Medical Ionising Radiation Protection) Regulations 2002
SI 125/ 2000,	Radiological Protection Act, 1991 (Ionising Radiation) Order, 2000 Environmental Statutory Instruments
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

GUIDANCE:

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:

<http://ec.europa.eu/enterprise/medical_devices/meddev/meddev_index_en.htm>

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 :
(http://ec.europa.eu/energy/nuclear/radioprotection/publication_en.htm).

GUIDANCE IMB:

Examples of IMB guidance published in 2008 is illustrated below, full details on web site <http://www.imb.ie/EN/Publications/Publications.aspx?pagecategoryid=202

The following are the primary guidance documents issued by the IMB with respect to Medical Devices / 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

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

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.

High Level Standards would be:

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
ISO 9001:2008	Quality Management Series

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.

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 electrotechnical 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 electrotechnology, 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:
IMB website at www.imb.ie
MHRA website at < http://www.mhra.gov.uk/index.htm >
FDA website at < http://www.fda.gov/CDRH/ >
TGA website at < http://www.tga.gov.au/devices/devices.htm >

APPENDIX III

HSE MEDICAL DEVICES AND EQUIPMENT STANDARD

1.0 Introduction

This document sets out a framework for implementation of an integrated medical devices and equipment management system within the HSE. Robust standards for the management of medical devices and 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 Risk and Audit Committees and thereby assurance to the HSE Board and all stakeholders.

What follows in this document is a framework for an integrated medical devices and equipment management system, comprising a statement of overall standard together with supporting criteria. HSE guidance in relation to the criteria is available to support the achievement of the standard Reference. Each criterion reflects the elements of a higher level management model describing a 'system of internal control' for a healthcare organisation. This standard is aligned to the HSE's Quality and Risk Management Standard and the NHO and PCCC's Integrated Quality, Safety and Risk Framework.

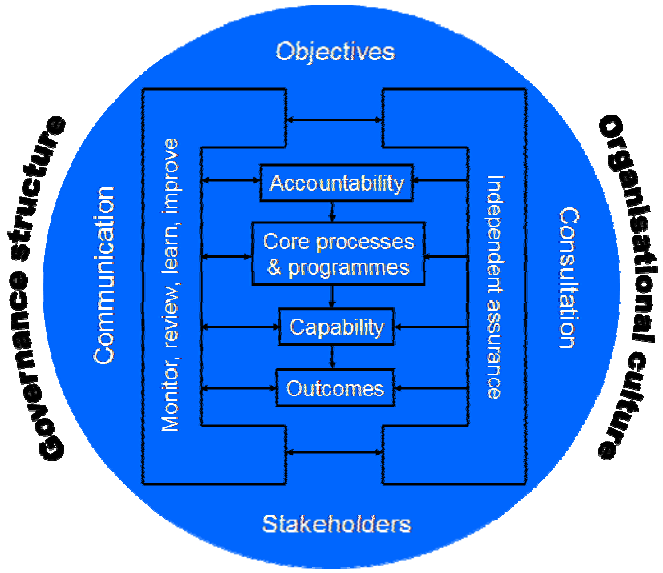

Figure 1 – Internal Control Model

The model (see above) sits within an overarching **Governance approach** and influences, and is influenced by, the **Organisational Culture**. The model specifies a generic approach to providing assurances to stakeholders that a healthcare organisation is meeting its various objectives and providing the right 'outcomes'. In this case the objective (or 'standard') is to ensure implementation of an integrated medical devices and equipment management system within the HSE. Various criteria, including outcomes criteria, have been devised in line with the elements of the model as follows:

- 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 Devices and Equipment are minimized. "This is known as the 'Statement of Standard.'
- **Stakeholders** should be identified and there should be proper **Communication and Consultation** with all relevant stakeholders within and outside the organisation.
- An appropriate **Accountability** 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 Directorate.
- The **Core Processes and Programmes** required to produce the desired outcomes should be in place – these include a range of quality and risk management processes.
- The organisation (or department, etc.) should have the necessary **Capability** (leadership, knowledgeable and skilled staff, adequate financial and physical resources, etc.) to ensure the entire system works effectively.
- Management should receive sufficient objective **Independent assurance** as to the robustness of the system defined by the model.
- 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. Overall, this process will ensure that the medical devices and equipment management system is properly configured and working effectively to achieve the desired outcomes and overall objective(s).

2.0 STANDARD

2.1 Statement of Standard

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

2.2 Assessment of Compliance with the Standard

A self assessment tool will accompany this Standard. All Service Areas are required to conduct a self assessment against this standard 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.

3.0 CRITERIA

There are 26 criteria incorporated within this standard divided in line with the internal control model above as described on page 13 of this document.

In order to comply with the standard, it is necessary to comply with each of the criteria.

3.1 Communication and Consultation

1	Appropriate and effective mechanisms are in place for communication and consultation on medical devices and equipment management matters within and outside the HSE.

3.2 Accountability

2	Individual responsibility for Medical Devices and Equipment management is clearly defined and there are clear lines of accountability for medical devices and equipment leading up to the most senior manager or director.

3.3 Core Processes and Programmes

3.	There are broad-based Medical Devices and Equipment groups established in accordance with the recommendations of the IMB safety notice SN2006(03) at local, regional and national levels.
4.	There are procedures, based on best available evidence, implemented throughout the HSE for all aspects of Medical Devices and Equipment Management which are governed by a formal document control process.
5.	All Medical Devices and Equipment are selected and acquired in accordance with the HSE'S Procurement Policy
6.	All Medical Device and Equipment developments, modifications and trials are conducted in accordance with relevant legislation and guidance.

7.	Delivery and pre-use checks are carried out on all newly delivered Medical Devices/Equipment
8.	All newly delivered Medical Devices and Equipment are properly stored after acceptance.
9.	The manufacturer is responsible for issuing clear, accurate instructions. 9.1 All professional users and end-users have access to manufacturer's instructions and all users sign statements to the effect that they have received instructions on the safe use of Medical Devices or Equipment 9.2 Where Medical Device/Equipment manufacturers automatically send copies of revised instructions to a named recipient, these are appropriately dealt with. 9.3 All instructions supplied by HSE services are evaluated for their adequacy.
10.	Medical Devices/Equipment designated for single use are not reused under any circumstances
11.	All necessary information required to properly manage HSE Service's range of Medical Devices/Equipment is recorded on a suitable system.
12.	All Medical Devices/Equipment are properly maintained and repaired.
13.	All Medical devices/Equipment returned for servicing and repair are properly decontaminated.
14.	Medical Devices/Equipment are replaced in accordance with an agreed policy.
15.	All loaned Medical Devices/Equipment are collected when no longer needed.
16.	All adverse incidents involving Medical Devices and Equipment are managed in accordance with the requirements of the HSE's Incident and Serious Incident Management Policies and the Irish Medicines Board
17.	A complete record of guidance issued by the Irish Medicines Board is maintained; warning notices are distributed to the appropriate people in the organisation; and recommendations contained in the notices are implemented.
18.	The risk management process contained within the HSE's Quality and Risk Standard is applied to the management of Medical Devices and Equipment risk.

3.4 Capability

20.	Employees are made aware of and, where necessary, trained in incident management (reporting and investigation) for the management of adverse incidents involving Medical Devices and Equipment.
19.	All Medical Devices and Equipment prescribing decisions are made by employees with appropriate professional qualifications and suitable experience, backed by appropriate administrative and technical support.
21.	All professional users and technical supervisors are trained in the safe operation of

	Medical Devices and Equipment.
22.	All end-users (employees and service users) are where relevant given appropriate training in the safe and effective use of Medical Devices and Equipment.

3.5 Outcomes

23.	There is demonstrable improvement in key performance indicators relating to Medical Device and Equipment Management
24.	The organisation participates in benchmarking its management of Medical Devices/Equipment.

3.6 Monitoring and Review

25.	All aspects of the system in place for Medical Devices and Equipment Management are monitored and reviewed by management for the purposes of learning and improvement.

3.7 Independent Assurance

26.	Senior Management receives independent assurance(s) that an appropriate and effective system of managing Medical Devices and Equipment is in place and that the necessary level of controls and monitoring are being implemented.

APPENDIX IV

Members of Working Group:

Name	Address
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APPENDIX V

Acknowledgements:

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

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27	Irish Medicines Board (IMB)	Ann O'Connor Andrea Hanson
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30	Markievicz House, Sligo, Community Medicine	Paula Gilvarry
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32	Naas General Hospital, Co. Kildare	Peter Grainger
33	Occupational Therapist Manager, Donegal Community Services	Anne Flannery
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40	Roscommon PCCC	Fiona Garvey
41	Senior Clinical Engineer, Enable Ireland Disability Services	John Tiernan
42	Senior Manager, Environmental Health, Population Health	Ciara Norton
43	St Josephs Hospital, Trim, Co. Meath	Karl Brogan
44	St Vincent's University Hospital, Dublin	Margaret Boland
45	St Vincents Hospital, Dungarvan Co Waterford	Paula French
46	St. James Hospital	Neil O Hare Fran Hegarty Sharon Glynn Miriam Kenny Betty Murphy Gail Melanophy