Medical Device Equipment Management.

HPRA Information Day
Medical Devices
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Central Theme

The Passing of Time!

Leads To

New Medical Innovations Together With the Need for User Assurances.
Medical Technology
The Past & Present
The Challenge !!!

- In recent decades, an expanding number of new technologies and applications have been introduced into the Health Service worldwide.

- Opening up new possibilities for diagnosis and therapy.

- But also raising questions of appropriateness, safety, effectiveness and provision of assurances.

- Increasing external regulatory requirements for which there is a necessity for organisational assurance.

- Increasing amount of complex care delivered outside the acute sector.

- Recent developments in eHealth technology

- Significant cost associated with medical device technology.

- Provision of Patient Safety in the use of medical device technology.

- Litigation issues.
Assurances - Key Drivers

- EU Legislation & Standards
- Health Products Regulatory Authority (HPRA) - Competent Authority Ireland
- Health Information Quality authority (HIQA)
- HSE Policies & Guidance
EU Regulations & Standards

- To ensure the highest level of patient safety while promoting innovation and competitiveness.
- Provides a regulatory framework for market access and regulatory convergence
  - COUNCIL DIRECTIVE (90/385/EEC) of Active Implantable Medical Devices.
  - COUNCIL DIRECTIVE 93/42/EEC concerning medical devices
  - DIRECTIVE 98/79/EC on in vitro diagnostic medical devices
  - to move towards a safer, more transparent and sustainable legislation for medical devices

The revised regulatory framework is comprised of the following:
- The European Databank on Medical Devices – Eudamed
  - requirement that manufacturers register themselves and the devices in a central European database.
  - requirement to make publicly available a summary of safety and clinical performance.
- IEC & ISO International Standards.
HPRA Recommendations

- Organisation-wide policy for the management of Medical Devices / Equipment.
- Clearly defined roles of responsibility for the management of Medical Devices Equipment.
- Designated responsibility for medical devices / equipment management.
- Asset Register/tracking and record keeping.
  - Safety Alerts
  - SLA on service standards
- Acceptance testing.
  - Installation
  - Commissioning
- All professional and end users should be trained in the safe and effective use of the equipment
Standard 3.1: Service providers protect service users from the risk of harm associated with the design and delivery of healthcare services.

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

- Systems in place for the management of Medical Devices /Equipment across the HSE organisation.

- Well defined structures at local, regional and national level.

- Uniform coordinated approach across the organisation with responsibilities at local, regional and national level.
HSE
Medical Device Equipment Management
Policy & Guidance

- Policy developed under Quality & Patient Safety Directorate.
- to provide a HSE organisation wide framework for the management of Medical Devices/Equipment
- that the highest standards of device safety, risk management and financial efficiency are realised.
- to minimize related hazards and enhance patient safety.
- reporting of vigilance incidents and near incidents to HPRA
- devices are maintained in a safe and reliable condition, are quality assured and subjected to asset management that is inclusive of device history and full traceability.
HSE Policies & Guidance

- HSE Decontamination Code of Practice for RIMD.
- National Radiation Safety Committee
- Quality Assessment and Improvement Tool (QA+I tool)
- National Standards for the Prevention and Control of Healthcare Associated Infections (PHCAI)
National Medical Equipment Asset Management System

- HSE has agreed on implementation of a National Asset management system “ECRI AIMS” for implementation in both the Acute and Primary Care Services.

- To provide a coordinated standardised asset management system that is managed locally.

- To provide the supporting inventory detail for equipment replacement.

- To provide traceability of medical equipment for the management of Medical Device Alerts as issued by the HPRA.
Medical Device Equipment Management – Online Self Assessment

- HSE implementing online self assessment on compliance with standards & guidance for medical device equipment management.

- The Principal Objective is to provide evidence of assurance in that: “There is a system in place which ensures that all risks associated with acquisition and use of Medical Devices and Equipment are minimized”.

- Expected release December 2014.
To provide an organisation wide assurance in the management of medical device alerts as issued by the competent authority the Health Products Regulatory Authority (HPRA).

To develop a system that delivers notifications to the appropriate personnel for consideration of action.

Track the various stages and processes through which notifications must pass.

Respond on consideration of actions required

The system is web based.
The UDI is a series of numeric or alphanumeric characters that is created through a coding system. It allows the unambiguous identification of a specific product on the market. The UDI comprises the Device Identifier and Production Identifier.

The objective of a UDI is to enhance patient safety by:

- Facilitating traceability of devices by providing a single globally accepted source for identification of medical devices through distribution and use.
- Improving the identification of devices involved in adverse events leading to more rapid resolution of problems.
- Facilitating field service corrective actions.
- It is anticipated that a UDI System may facilitate the reduction of medical errors by simplifying integration of information on device use into medical records.

HSE UDI Preparation.

- HSE have committed to the use of GS1 standards as a form of unique identification for medical devices.

- HSE national management system adopted GS1 standards form of identification to track all existing and future medical equipment assets.

- GS1 standards form of identification adopted to track and track reusable invasive medical devices for Central Sterile Services Department (CSSD) and Endoscopy reprocessing units.

- HSE are engaging with global medical instrument providers to the HSE on the need for GS1 standards to be afforded to facilitate traceability within the service.
Why?
To enhance Diagnostic / Therapeutic treatment together with ensuring Patient Safety.
Thank You For Listening.