IRISH MEDICINES BOARD

MEDICAL DEVICE
# SAFETY NOTICE

# The Procurement and Commissioning of Medical Equipment for Hospitals
## IMB Safety Notice: SN2006(03)

S A F E T Y NOTICE

### MANUFACTURER / SUPPLIER

Various general medical device (GMD) and *in-vitro* diagnostic medical device (IVD) manufacturers and / or suppliers.

### TARGET GROUPS

This safety notice has been written as a guide for those people who are responsible for the procurement and commissioning of medical equipment for hospitals. It is targeted specifically at:

Chief Executive Officers
Clinical Engineering Department
Medical Physics Department
Laboratory Managers
Chief Medical Scientists
Theatre Managers
Purchasing / Material Managers
Risk Managers
Building Service Managers
Technical Service Managers
Hospital Pharmacists

### ISSUE

Effective medical equipment management systems, which include policies and procedures for the purchase and commissioning of medical devices, can help to ensure the safety of professional users, patients and third parties.

### BACKGROUND

Medical equipment includes such devices as diagnostic imaging equipment, life support equipment, infusion pumps, endoscopes,

nebulisers, laboratory analysers and point of care IVDs, which are used for the treatment, management and diagnosis of patients in hospitals. The way in which medical equipment is purchased, managed and used can have a significant impact on the quality of care that is delivered to patients. It is important therefore that hospitals have a clearly defined and well-structured approach to the purchase and commissioning of medical equipment. Inadequate attention to detail at the purchasing and commissioning stage can result in safety implications at a later date e.g.

- Poor, inadequate or unstable power supplies can have an impact on the results provided by diagnostic imaging equipment
- Poor water supplies can compromise sterilisation systems
- Lack of adequate or poor storage facilities can result in inappropriate storage of a device and / or device damage prior to use
- Inadequate space provision in theatres or laboratories to accommodate one or more pieces of medical equipment can result in equipment not performing as intended due to unsuitable environmental conditions.
- Incompatibility with other existing medical devices, equipment or consumables.

As part of the vigilance system, the IMB has seen evidence of issues arising for medical equipment in some of the above areas.

The aim of this safety notice is to highlight some of the key areas in this process and to provide recommendations to ensure that best practice is adopted for the acquisition of medical equipment.

**RECOMMENDATIONS**

Given that serious problems can arise over the operational lifetime of medical equipment the IMB recommend that healthcare institutions consider the implementation of a comprehensive management system for the purchase and commissioning of medical equipment in order to ensure that all aspects are considered at or before the time of purchase of the device. Such a system should encompass the following areas:

- An organisation wide policy for the procurement and commissioning of medical equipment
- A medical device procurement committee to manage the purchase of medical equipment at an organisation level. This should be a multidisciplinary committee with representation from all relevant areas (see Appendix 1).
- A mechanism for linking with other hospital staff involved in the purchase of consumables, e.g. purchasing managers who independently purchase consumables for use with medical equipment.
- A mechanism for linking with other existing medical equipment to ensure compatibility / consistency in the type of equipment used throughout the hospital.
- A mechanism for identifying medical equipment needs and a method of outlining the equipment requirement e.g. formal business

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case with relevant supporting documentation
- A standard / transparent tender process
- A contractual agreement with the manufacturer / supplier
- A system to ensure that installation and operational qualification are addressed
- A medical device acceptance process
- A medical equipment management system e.g. computerised database
- A training protocol
- A cleaning and / or decontamination protocol
- A maintenance protocol
- A procedure for re-qualification
- A de-commissioning protocol

A schematic representation of the key areas in the process is illustrated in Appendix 2.

**NOTE**: ***The focus of this notice is on medical equipment and does not consider the purchase of smaller consumable medical devices or implantable medical devices. A similar purchasing and commissioning management philosophy can be applied to these areas.***

***However when consumables are required in order for the medical equipment to function both the consumables and medical device should be considered as part of the formal business case by the*** **procurement committee.**

## REPORTING OF ADVERSE INCIDENTS

All adverse incidents relating to a medical device should be reported to the Medical Devices Department at the Irish Medicines Board.

Adverse incidents may be reported via the **on-line vigilance reporting system,** which can be accessed in the medical devices section of the IMB website www.medicaldevices.ie, or by completing a **User Adverse Incident Report Form (DSF-4-01-01/4),** which is available on request from the IMB or may be downloaded from the IMB website.

## ENQUIRIES

If you have any enquiries, you may contact the Medical Devices Department at:

Irish Medicines Board
Medical Devices Department
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971

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Fax: +353-1-6344033
Email: medicaldevices@imb.ie
Website: www.imb.ie

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## **Appendix 1:** Good Practice Guidelines

There are a number of good practice guidelines available that provide recommendations for the purchase and commissioning of medical equipment, some of which are listed in Appendix 3. The following list summarises some of the key areas in the process for the establishment of such a system.

A **comprehensive organisation-wide policy** for the procurement and commissioning of medical equipment should be in place in hospitals. The responsibility for this process should be clearly defined within the organisation.

The procurement and commissioning of medical equipment should be conducted in accordance with the relevant European and national legislation and guidance. Please refer to Appendix 3 for a list of the relevant legislation for medical equipment.

A **medical equipment procurement committee** should be established for the purchasing and commissioning of all medical equipment within a hospital. This committee should be multidisciplinary and include representation from healthcare management, finance management clinical engineering, medical physics, pharmacy, information technology, infection control, CSSD, nursing and relevant clinical or laboratory personnel as appropriate. This will ensure that a consistent approach is adopted for the acquisition of all medical equipment for the hospital.

A formal **business case** should be prepared to define the requirements for the tender documentation and is particularly important for the acquisition of significant medical equipment such as larger diagnostic imaging systems. A well-prepared business plan will ensure that the tender process is comprehensive and consistent across manufacturers / suppliers. Some of the following should be considered in the preparation of a business case:

- Define user specifications
- Identification of a range of potential medical devices
- Development of a pre-purchase questionnaire or checklist which includes a list of standard questions for the medical device being purchased
- Include complete lifetime costing, for example consumables, training, operation costs, maintenance and availability of spare parts
- Risk assessment / management strategies should be applied where appropriate

Once appropriate specifications are identified for the medical equipment being purchased **tenders** are invited through a formal procedure based on the tender documentation developed from the business case.

The committee should conduct an **analysis of the tenders** received to select the appropriate medical equipment for purchase based on defined

criteria. The pre-purchase questionnaire is useful in this selection process as manufacturers / suppliers can be compared across key areas such as, compliance with the legislation, the presence of a certified quality system, where appropriate, compliance with safety standards, support for maintenance and service, provision of spare parts, training and lifetime costing for the medical equipment.

At this stage it is also important to establish a **contractual agreement** with the manufacturer and supplier defining the responsibilities for the medical equipment over the complete operational lifetime. This should include, for example:

- Ownership
- Installation
- Operation qualification
- Consumables
- Servicing / maintenance
- Training
- Spare parts / add ons
- Infection control
- Sterilisation
- Health and safety

Once the specific medical equipment has been chosen by the Committee **installation and operational qualification** protocols should be prepared and agreed by the Committee and the manufacturer prior to acceptance and commissioning of the medical equipment.

The **installation qualification** is used to verify that the medical equipment is installed according to the manufacturer's recommendations. As part of this process the manufacturer or supplier's representative should visit the site to ensure that the environmental conditions are suitable for the installation and operation of the medical equipment based on the product specifications.

Some of the following may need to be considered as part of this assessment procedure:

- Access e.g. door and lifts
- Physical connections
- Storage of ancillary
- Power supply
- Ventilation
- Humidity and temperature
- Electrical safety
- Radiation protection
- Space planning – to evaluate the space available and the number of medical devices that will be in operation in a given area. For example a large laboratory analyser may be placed in a small operating area alongside another large analyzer, whereby their close proximity to each other may have an impact on the operation of both devices

- System configuration
  Interfacing of the medical device with a patient management system and / or other medical device
- Waste disposal
- Disinfection room

An **operational qualification** is conducted to ensure that the medical equipment operates as intended by the manufacturer and in accordance with the product specifications.

The user should arrange for the medical equipment to be tested independent of the manufacturer's testing as part of the **performance qualification** procedure to ensure that the medical equipment achieves the performance claims specified by the manufacturer. A validation report is prepared once this process is complete.

As part of the **medical equipment acceptance process** the manufacturer / supplier should provide documented evidence that the medical equipment is in compliance with the procurement specifications and the performance claims for that equipment. This should be signed off by the relevant hospital staff prior to acceptance of the medical equipment.

A **training protocol** should be developed for the medical equipment to ensure that all appropriate hospital staff are trained in the use of the equipment and are familiar with the instructions for use. It is important that all users are adequately trained in the operation of medical equipment because it can reduce the potential for adverse incidents that occur due to user error.

A **maintenance protocol** should be prepared for the management of medical equipment in hospitals. The manufacturer's recommendations should be adhered to for the maintenance of all medical equipment. Please refer to the following IMB safety notices on medical device equipment management for further information on the maintenance of medical devices:

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

***IMB Safety Notice SN2003(09):*** Equipment Management: Some Basic Principals of Equipment Management

Once the medical equipment has been accepted it should be registered in the **medical equipment management system**. The establishment of medical equipment management system is important for the effective and efficient management of medical equipment within a hospital and can be used in particular to record maintenance and servicing, to indicate what medical equipment is on loan and to indicate what medical equipment is in use.

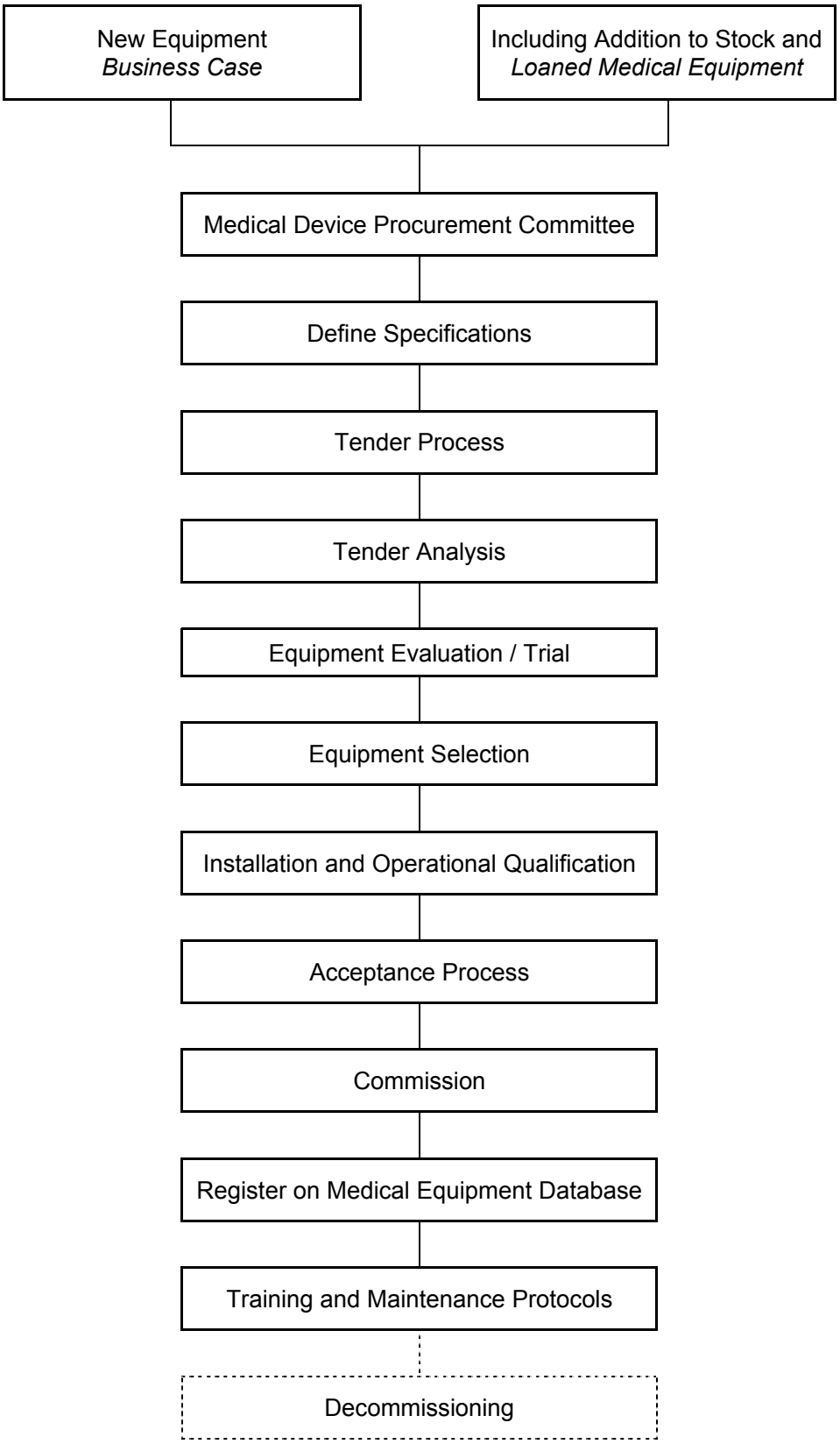
A protocol should be developed for the **re-qualification** of medical

equipment following a significant change, for example the movement and relocation of non-portable medical equipment or the replacement of a major part.

A procedure should also be developed for the **de-commissioning** of medical devices that are no longer in use once, for example the device has reached the end of its service life or has been taken out of service for safety related or other reasons.

**The above recommendations should also be considered for medical equipment that is donated or given to a healthcare institution on long-term loan.**

**Appendix 2:** Key Areas for the Purchase and Commissioning for Medical Equipment

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## **Appendix 3:** Bibliography


Health Service Procurement Policy, 2000

Medical Device and Equipment Management for Hospital and Community-based Organisations. Medical Devices Agency Device Bulletin 9801, January 1998

Management of *In-vitro* Diagnostic Medical Devices. Medical Devices Agency Device Bulletin 2002(02), March 2002.

The Management of Medical Equipment in NHS Acute Trusts in England. NAO Report HC 475 1998/99, 10 June 1999.

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

IMB Safety Notice SN2003(09): Equipment Management: Some Basic Principals of Equipment Management

Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in-vitro* diagnostic medical devices

Statutory Instrument No. 252 of 1994, European Communities (Medical Devices) Regulations, 1994

Statutory Instrument No. 253 of 1994, European Communities (Active Implantable Medical Devices) Regulations, 1994

Statutory Instrument No. 304 of 2001, European Communities (*In-vitro* Diagnostic Medical Devices) Regulations, 2001

Statutory Instrument No. 444 of 2001, European Communities (Medical Devices) (Amendment) Regulations, 2001

Statutory Instrument No. 576 of 2002, European Communities (Medical Devices) (Amendment) Regulations, 2002.


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