IRISH MEDICINES BOARD

news MEDICAL DEVICES LETTER

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Letter from the Editor

Welcome to the third edition of the medical devices newsletter of 2006.

In this edition we are providing information in relation to the type of technical documentation that is required to support medical devices that are self-declared by manufacturers to be in compliance with the medical devices legislation. This should address some of the deficiencies that are being noted when data is presented to the IMB for review. We are also providing an outline of our recent safety notice on the procurement and commissioning of medical equipment in hospitals. A series of recommendations are presented for consideration. The safety notice is available on our website at www.medicaldevices.ie.

In the last number of months there has been a deterioration in the quality of applications submitted to the IMB for certificates of free sale for medical devices. A specific article is presented which outlines how to complete the application form and what type of supporting documentation should accompany the application.

As always readers are encouraged to provide feedback particularly in relation to articles that may be of interest by contacting us at medicaldevices@imb.ie.

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The Procurement and Commissioning of Medical Equipment for Hospitals

The Irish Medicines Board (IMB) has recently published a safety notice on the procurement and commissioning of medical equipment for hospitals, SN2006(03). 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.

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 the 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:

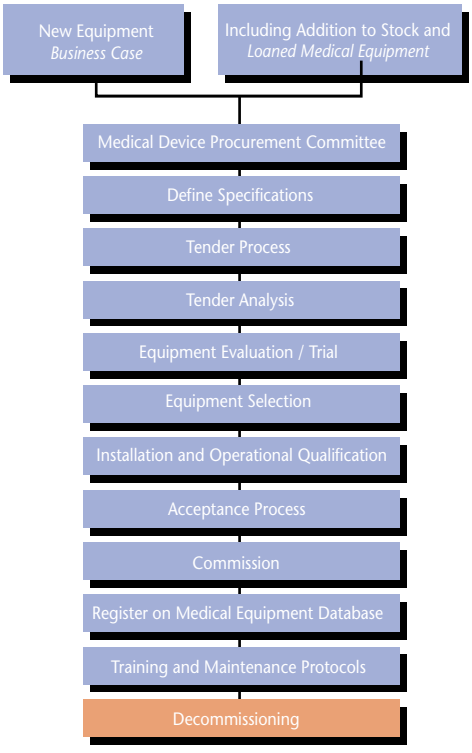
- An organisation wide policy for the procurement and commissioning of medical equipment
- A medical device procurement committee to manage the purchase of medical equipment at an organisation level. This should be a multidisciplinary committee with representation from all relevant areas
- A mechanism 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 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 the flow chart below.

There are also a number of good practice guidelines available that provide recommendations for the purchase and commissioning of medical equipment. The implementation of 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.

This safety notice, SN2006(03) can be obtained from the Medical Devices Department of the IMB or may be downloaded directly at www.medicaldevices.ie.

KEY AREAS FOR THE PURCHASE AND COMMISSIONING FOR MEDICAL EQUIPMENT



Review of Technical Documentation for Self-Declared General Medical Devices by the IMB

The IMB has the responsibility for overseeing the implementation of the Medical Devices Regulations (S.I. No. 252 of 1994), which transposed the Medical Device Directive 93/42/EEC in Ireland.

Our legal obligation, as the Competent Authority, includes confirming that manufacturers are in compliance with the requirements of S. I. No. 252 of 1994, European Communities (Medical Device) Regulations, 1994. To fulfil this obligation the IMB periodically selects manufacturers / authorised representatives of medical devices that self-declare their devices to be in compliance with the legislation as the basis for CE marking.

Should your medical device be chosen for technical documentation review by the IMB, the following is the minimum data that should be provided:

CLASS I MEDICAL DEVICES

- The EC declaration of conformity
- Product description, intended use and rational for its classification
- Final product specifications
- Test results, e.g. static and fatigue strength: BS EN ISO 11334-1:1997
- Examples of labelling used and any instructions for use,
- A summary of risk analyses performed
- Documents demonstrating compliance with the essential requirements, including a list of any standards applied to the product,
- A summary of relevant clinical data, where applicable
- Procedures in place for corrective action, post-market surveillance and vigilance notification
- For sterile and measuring products evidence would also be required that the functions necessary to retain sterility or metrology aspects of production have been verified by a Notified Body, e.g. by providing a copy of their certificate.

CUSTOM-MADE MEDICAL DEVICES

The technical documentation review for custom-made medical devices is

generally carried out at the site of manufacture. The following is the minimum technical documentation that should be available for review:

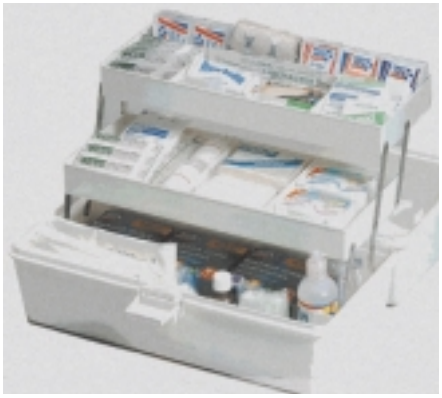
- Design verification and design validation data
- Information on manufacturing controls, including a review of the prescribed requirements and details on calibration and maintenance of critical equipment
- Risk analysis performed
- A review of product performance
- Clinical data (in most cases a compilation and review of existing clinical experience would be sufficient to cover this requirement provided equivalence to existing medical devices can be shown)
- Copies of labelling and any instructions for use
- A statement concerning devices for special purposes as per schedule 8 of S.I. No 252 of 1994

SYSTEMS AND PROCEDURE PACKS

The technical documentation review for system and procedure packs is generally carried out at the site of manufacture. The following is the minimum technical documentation that should be present:

- The declaration for systems and procedure packs if all of the devices included in the system or procedure pack bear the CE marking
- If all of the individual medical devices in the system or procedure pack do not bear the CE marking, supporting technical documentation for the system or procedure pack as a device in its own right including:
  - Product description, intended use and rational for its classification
  - Final product specifications
  - Examples of labelling used and any instructions for use
  - A summary of risk analyses performed
  - Documents demonstrating compliance with the essential requirements including a list of any standards applied to the product
  - A summary of relevant clinical data, where applicable
- Procedures in place for corrective action, post-market surveillance and vigilance notification
- For sterile devices or devices with a measuring function, evidence would also be required that the functions necessary to retain sterility or metrology aspects of production have been verified by a Notified Body, e.g. by providing a copy of their certificate.

Should you seek further clarification, please contact the IMB by email medicaldevices@imb.ie.



IMB Medical Devices Information Day – Safe Management of Infusion Devices

The IMB held an information day on the 'Safe Management of Infusion Devices', at the Education Theatre of the Adelaide & Meath Hospital incorporating the National Children's Hospital, Tallaght, Dublin 24 on Wednesday 14th June 2006.

This event was well attended by nursing staff, clinical engineers, risk managers and other healthcare professionals involved in the use and management of infusion devices. The overall attendance for the day reached approximately 145 people.

Feedback from attendees indicated that aims and objectives of the day were successfully attained, where the presentations and discussions provided participants with a good understanding of the safe management of infusion devices.

The mix of presentations from the Irish Medicines Board (IMB), the Medicines and Healthcare products Regulatory Agency (MHRA) and representatives from hospitals in Ireland and the United Kingdom provided participants with some key practical information and advise that they could take away with them.

Mr. Jim Lefever – Medicines and Healthcare products Regulatory Agency, Mr. Paul Lee – Swansea NHS Trust, Ms. Ann O'Connor – Irish Medicines Board, Mr. Wilf Higgins – Department of Health and Children, Mr. Alan Glass – Adelaide & Meath Hospital incorporating the National Children's Hospital and Mr. Pat O'Mahony – Irish Medicines Board

Some manufacturers and distributors demonstrating the safety features of their medical devices

The IMB would like to thank, the Adelaide & Meath Hospital incorporating the National Children's Hospital for hosting the event, the speakers, Alan Glass (Adelaide & Meath Hospital incorporating the National Children's Hospital), Ger Flynn (Cork University Hospital), Jim Lefever (MHRA), Mona Habib (Hammersmith Hospitals NHS Trust), John Riddle (Medical Devices Trainer at Queen's Medical Centre, Nottingham) and Paul Lee (Medical Devices Training Manager for Swansea NHS Trust) for giving up their time to prepare and present such stimulating presentations. We would also like to thank those manufacturers who provided demonstrations of the safety features of their infusion devices and all those that attended this event to help make the day such a success.

A copy of the presentations are available on request. If anyone would like to suggest ideas for future information days, please do so by emailing medicaldevices@imb.ie.

Quality of Applications Submitted to the IMB for Certificates of Free Sale for Medical Devices

The IMB Medical Devices Department are currently experiencing a number of problems with the applications submitted for certificates of free sale for medical devices.

The quality of the applications and accompanying documentation is of a poor standard. This is resulting in many emails or telephone calls between the IMB and medical device organisations, which can lead to delays in processing applications. It is the responsibility of the medical device organisation to ensure that they submit a complete application. Please note that from Monday 26th June, incomplete applications and documentation will be returned to the applicant for completion. The IMB will not be completing applications on behalf of the applicant.

Below, please find a number of issues, which need to be addressed when making an application for certificates of free sale:

1. Application Form

(a) The application form must be completed in full and emailed to the Medical Devices Department for processing.
(b) The site of manufacturer details should be provided in Section B and the authorised representative details should be provided in Section C. If you wish to have the legal manufacturer details included on the certificate, please include the legal manufacturer details in your email. Please note that the Irish Medicines Board will only issue certificates of free sale when the site of manufacture, the authorised representative or the legal manufacturer are located in Ireland.
(c) Section F of the application form regarding the device details must be COMPLETED IN FULL. This section of the form expands and will allow for a large number of devices.
(d) In section F, each product code should have a product description. One product description is insufficient for a large number of devices.
(e) CE marked devices and non-CE marked devices cannot be placed on the same application.

2. Amendments to Previously Issued Certificates

(a) If you wish to make amendments to a previously issued certificate, the application form must be completed. The application form should include the details of the previously issued certificate with all the necessary amendments made to it. A list of the changes in an email to the Medical Devices Department will not suffice.

3. Documentation accompanying applications

(a) If you are applying for a certificate for a CE marked device, you must provide a copy of the Notified Body certificate as proof of the CE mark. This certificate should have a list of product codes or product families manufactured by your organisation. If you do not have a Notified Body certificate, please supply the IMB device registration number for each product. This information is kept on file, so there is no need to send it with every application, just the first application for that product. If your Notified Body certificate expires, please send updated certificate to the Medical Devices Department.
(b) A notarised document must be supplied for each device. When an organisation makes the first request for a certificate of free sale, proof of manufacture in the form of a notarised document must accompany the application. The original notarised document must be sent to the IMB by post. The notarised document must include:

- Name and address of the manufacturer, authorised representative (if applicable) and legal manufacturer (if applicable)
- List of devices concerned by item number / product code and description produced, which should appear as follows:
  Product Code 1 Description 1
  Product Code 2 Description 2
  Product Code 3 Description 3
  Product Code 4 Description 4
- A statement that the organisation manufactures these devices.

Additions and withdrawals can be made to this original notarised document by submitting an update to your notarised document to the IMB. In this case, a designated representative within your organisation should notify the IMB of any changes to this listing such as the addition and withdrawal of device(s). It is not compulsory for these changes to the product listing to be "notarised" each time. However, the IMB must receive as hard copy of this document. A scanned copy submitted by email will be accepted in order to issue certificates but the original must follow in the post. The update to the notarised document must be on your organisation's letterhead paper and signed by the designated representative. It is not sufficient to send an email as it must be a signed letter.

4. Turnaround Time and Payment

(a) Four certificates, issued within two working days, cost €100.00. These

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Quality of Applications Submitted to the IMB for Certificates of Free Sale for Medical Devices

certificates will be issued within two working days once the correct documentation and payment have been received. Additional certificates cost €20.00 each.

(b) Four certificates, issued within one working day, cost €190.00. These certificates will be issued within one working day once the correct documentation and payment have been received. Additional certificates cost €20.00 each.

(c) If you are using a credit on account facility for your certificates of free sale, please include your account number from which the payment should be taken.

Please note that a fee increase for certificates of free sale will be implemented in due course as the fees have remained at the same level since early 2003.

5. Who to Send your Application to?

From the 10th July 2006, Karen Lord and Sinead Carty in the Medical Devices Department will also be looking after certificate of free sale applications. Please forward your email to either Karen at karen.lord@imb.ie or Sinead at sinead.carty@imb.ie or the general email address medicaldevices@imb.ie.

In summary, please ensure your certificate of free sale application form is completed in full. All incomplete application forms will be returned to you and your application will not be processed. Guidance Note 4: Guidance Note for the Application for Certificates of Free Sale gives further details on how to apply for a certificate of free sale. Guidance Note 9: Guide to Fees for Medical Devices provides details of payment and methods of payment for certificates of free sale. Both these guidance documents and the certificate of free sale application can be downloaded from the publications sec-

QUESTIONS AND ANSWERS

Mobile Phone Interference and Medical Devices FAQ

Can mobiles phones affect medical devices?

Under certain circumstances, the electromagnetic interference from a mobile phone can affect the performance of some devices. Definite reports of malfunction of infusions pumps have been reported due to the proximity of a mobile phone. In addition, alarm tones on medical equipment may be overlooked because of confusion with telephone ring tones.

Are there any specific areas in hospitals where a ban on mobile phones is recommended?

It will depend on hospital policy, however mobile phones may not be recommended for use in critical care areas such as intensive therapy units, special care baby units or where patients are attached to complex devices, as any effect on such equipment could be detrimental to patient care.

For more information, the MHRA have recently published guidance on "mobile communications interference" on their website www.mhra.gov.uk.

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