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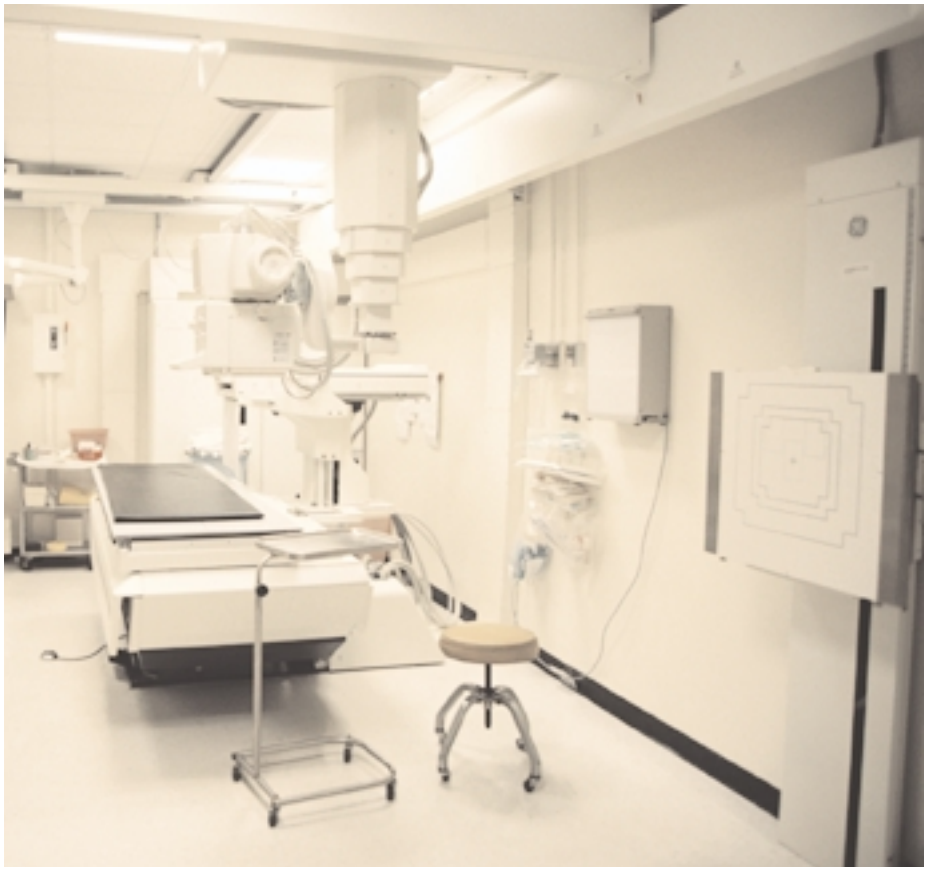
Letter from the Editor

Welcome to the first edition of the medical devices newsletter for 2007.

This year promises to be an interesting year for medical devices. One of the main activities is the finalisation of the amendments to the Medical Device Directive 93/42/EEC. The opportunity is being taken to align Directive 90/385/EEC on active implantable medical devices with the other two framework Directives on medical devices. In this edition of the newsletter we seek to clarify when the manufacture/adaption of splinting material by professionals falls within the scope of the medical devices legislation. There have been many queries on this topic and we hope the article will provide answers to the questions that are being continually raised. We have also included an article regarding the review of decontamination of invasive medical devices in publicly funded hospitals.

The area of e-labelling of medical devices is topical and a review is provided of the recently published MED.DEV guidance on the supply of instructions for use and other information for IVD medical devices – a guide for manufacturers and Notified Bodies.

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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Review of Decontamination of Invasive Medical Devices in Publicly Funded Hospitals

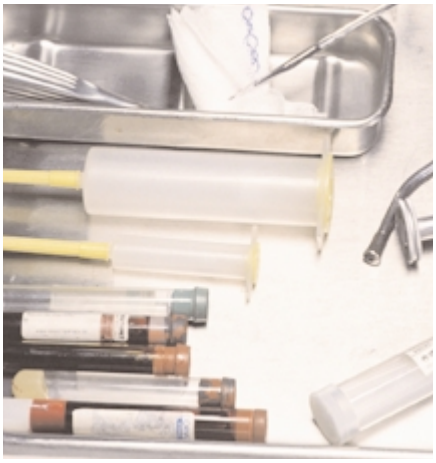
In June 2006 the Health Service Executive (HSE) invited tenders for suppliers to undertake a review of decontamination services for reusable invasive medical devices (as defined in EU Council Directive 93/42/EEC) in fifty-four publicly funded acute hospitals throughout the country.

Although the review could have been carried out in-house it was felt that the independence of an external body was important to ensure the credibility of the results.

The review was required to have a broad focus and include all related processes, facilities and equipment. The specific terms of reference for the review were:

- To establish current levels of decontamination services in publicly funded hospitals
- To advise on standards for decontamination services
- To make recommendations on the future development of decontamination services with reference to best practice and standards

The tender was won by Healthcare Science Limited, Hitchin Herts, United Kingdom. The company had extensive experience of auditing decontamination facilities in England and Scotland and of developing appropriate audit tools for the purpose. It was agreed that this company would develop a dedicated electronic audit tool - the Electronic Audit of Decontamination Ireland (EADI). This would provide a standard reporting format and would avoid the transcription errors that occur when transferring data from paper based recording systems to a database. The review would be based on the essential requirements of the Medical Device Directive (93/42/EC) and the European and International standards that may be used to provide a presumption of compliance with the essential requirements of the Directive.

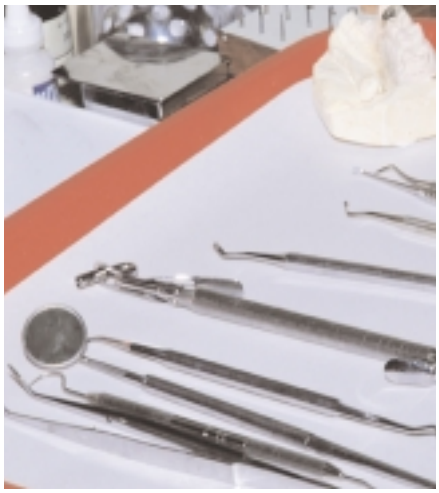


The tool has been developed for use by trained auditors not as a questionnaire for general use. It requires auditors with relevant experience of both decontamination and auditing. Four members of the team who will carry out the audits are qualified lead auditors to IS ISO EN 13485. The contract with Healthcare Science Limited also includes training of auditors from each of the hospitals at the end of the project so that follow-up reviews can be conducted in-house

The audit will include a detailed review of the management controls that are in place within hospital. It will investigate the extent to which these controls provide the assurance that all the necessary procedures and resources for safe and effective decontamination of re-usable invasive medical devices (RIMDs) are in place.

The audit will include also a review of each and every clinical unit to establish whether they use invasive medical devices; if so, how these are stored and disposed of after use will be reviewed. Where these are RIMDs, where and how they are decontaminated will also be investigated.

Decontamination is taken to include all the activities required between one clinical use of an RIMD and it being available for use on the next patient. It, thus, includes transport between point of use and the decontamination facility, cleaning, disinfection, drying, inspection, assembly, packaging and labelling, sterilization, transport to the clinical area and storage prior to use. For each of these activities, consideration will be given to the facilities and equipment used and their validation and maintenance, details of the individual processes, management and training of staff.



In addition, the impact of the choice of RIMD and the choice of decontamination equipment on securing satisfactory decontamination is recognised by detailed investigation of the procurement process.

The reports from the review will be in several formats:

1. for each individual hospital
   - a comprehensive listing of all the non-compliances against the criteria based on the relevant standards
   - a list of the 'key performance

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E-LABELLING MED.DEV:

Supply of Instructions For Use (IFU) and other information for in-vitro Diagnostic (IVD) Medical Devices

The IVD Directive 98/79/EC (Annex I, 8.1) has not specified the format required for the supply of the instructions for use (IFU).

This has led to much discussion regarding the most appropriate format that can be used to supply the information required for the safe and proper use of an IVD medical device. At present, the manufacturer supplies the IFU for IVDs in paper format. However, these documents have become lengthy due to the need to include multiple printed versions in the required languages of the EU. In addition, the cost of using paper and the impact on the environment can be significant. Given that most IVDs are used by professionals in a hospital environment with relatively common access to computers and Internet facilities the possibility of issuing the IFU for professional users in a format other than paper for example, CD-Rom or an Internet website has been raised.

The IMB led a sub-group of the European Electronic Labelling Working Group to consider this issue. This resulted in the development of a MED.DEV guidance document outlining the requirements for manufacturers to provide IFUs and other information for the safe and effective use of IVDs for professional use in a format other than paper. This guidance document was endorsed by the Medical Devices Expert Group (MDEG) in December 2007 and is now published by the European Commission on their website. The document reference is MED.DEV 2.14/3 rev 1 IVD Guidance: Supply of instructions for use and other information for *in-vitro* diagnostic (IVD) medical devices - a guide for Manufacturers and Notified Bodies

In developing this guidance, the stakeholder consensus has been that the appropriate media and means of supply of the IFU is dependant on the category of users. There are two main categories of IVDs with respect to their user population i.e. IVDs for self-testing and IVDs for professional use.

IVDS FOR SELF-TESTING

IVDs for self-testing are intended by the manufacturer for use by laypersons in a home environment. The IFU for IVDs for self testing shall always be provided in a paper format with the device. This is because the user needs ready access to the IFU, but cannot be assumed to have access to the necessary information technology systems to access an electronic format or to obtain the IFU by other means.

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indicators' against which improvements in the provision of decontamination services can be measured.

2. for HSE
   - a copy of the reports sent to each hospital
   - an anonymised statistical review of all the hospitals audited
   - an option appraisal for remedial action where necessary

The anonymised statistical review will be produced in two stages. A review of a stratified random sample of twelve hospitals (to be reported by February 2007) and the full review of fifty-four hospitals (to be reported by July 2007). The early reporting of a statistical sample should allow development of a strategic remedial action plan and funding requirements to be in place identified when the review is complete.

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IVDS FOR PROFESSIONAL USE

In general, these IVDs are used in a healthcare institution e.g. medical laboratory, by professionals who have a formal education and expertise in performing IVD tests and using IVD instrumentation.

The IFU for IVDs intended for professional use can be provided in either paper or non paper form or can be supplied by different means such as:

- providing a free of charge **telephone** number that can be contacted to have the IFU faxed, mailed or e-mailed
- making the IFU available at a fax call in number: **fax polling**
- making it available through a designated **internet** website
- or distribution through local **sales organisation**

Where the manufacturer decides to supply the IFU in a format other than paper, he shall provide a 'free of charge' contact number that can be used in order to have the IFU faxed, mailed or e-mailed to the user.

IFUs for IVDs that are specifically intended by the manufacturer for use at point of care shall be provided with each device in paper format. This is because there may not be ready access to information technology systems at the point of use of the IVD.

THE CONDITIONS FOR THE PROVISION OF THE IFU FOR REAGENTS, REAGENT KITS, AND SPECIMEN RECEPTACLES FOR PROFESSIONAL USE

The following section outlines the conditions for the provision of the IFU in a format other than paper.

1. The device must be intended for professional use only.

2. The manufacturer must ensure the proper design and function of the IFU for all media and means of supply and document the verification and validation of same as part of the quality system. This should be reviewed by a Notified Body, if applicable, as part of the conformity assessment process.

3. The manufacturer, informed by the views of healthcare professionals, must have carefully considered as part of his risk management, the risks associated with the provision of the IFU by other media and means of supply especially in light of the product usage and the professional users' need. This should be reviewed by a Notified Body, if applicable, as part of the conformity assessment process.

4. The user should be informed via the catalogue and / or the device labeling and / or any other appropriate communication that the IFU for the device will be supplied by other means to ensure that the user will have the IFU at the moment of use including any necessary equipment to read the IFU.

5. Where IFUs are posted on an Internet website, manufacturer must comply with the additional requirements as defined in the MED.DEV under section 6 below.

6. The manufacturer must have a system in place to provide in a timely manner a paper version of the IFU on request by the user at no additional cost.

7. The manufacturer must comply with the information requirements as defined in this guidance when the IFU is provided by different means of supply.

8. For revisions to the IFU there shall be a clear indication on the device label to indicate to the user that the IFU has been changed by reference to the latest revision.

9. If a revision to the IFU is necessary due to a field safety corrective action the manufacturer must ensure that each user of the device, that is already placed on the market, is informed about the change and provided with either the information on how to obtain the latest version of the IFU by other means or be provided with the IFU as a paper copy or other appropriate media.

This guidance also outlines the minimum information to be supplied with an IVD when the IFU is provided by different means of supply. In addition, the requirements for provision of IFU via Internet website are outlined. It is hoped that manufacturers will adopt these guidelines to ensure that there is a uniform approach for the provision of the IFU by different media and means of supply across Europe.

Manufacturing / Adaption of Splints and Splinting Material by Professional Users

BACKGROUND:

This article has been written to assist in clarifying whether the activities carried out by professional users in relation to splinting are covered by the provisions of the medical devices legislation in Ireland. Splints are usually manufactured or adapted within healthcare institutions by professional users such as physiotherapists and occupational therapists.

The manufacture of splints is regulated by the Medical Devices Directive 93/42/EEC, (MDD) and the related Irish Statutory Instrument, S.I. No. 252 of 1994. This legislation places specific obligations on manufacturers who intend to place medical devices on the market in Ireland or elsewhere in the European Union.

The activities of adapting and manufacturing splints have different consequences, with respect to the classification of the splints, depending upon the level of adaptation and manufacturing undertaken.

SPLINTS AS CLASS I MEDICAL DEVICES:

Off-the-shelf mass produced splints placed on the market are deemed to be class I medical devices.

Class I medical devices are regarded as low risk medical devices and must bear the CE marking.

It should be noted that if CE-marked splints / splinting materials which are already on the market are assembled or adapted within their intended purpose, i.e. the purpose specified by the manufacturer on the label or instructions for use, for an individual patient that this activity falls outside the scope of the Medical Devices legislation. Adapting such splints / splinting material to suit an individual patient by following the manufacturer's guidance, does not involve any change of use of the splint and is therefore outside the scope of the medical devices legislation.

If a professional user / healthcare institution is regarded as a manufacturer of class I medical devices, the manufacturer is required to comply with the legislation, in particular Schedule 1 (Essential Requirements) and Schedule 7 of the Statutory Instrument. In this regard, reference should be made to the IMB's Guidance Note 12 which provides guidance for class I medical device manufacturers. This guidance note also includes checklists and templates to assist with the preparation of the technical documentation.

SPLINTS AS CUSTOM-MADE MEDICAL DEVICES:

A custom-made medical device is a device that is made for an individual patient to a prescription. If a splint is manufactured for an individual patient from material which is not intended to be used for the purpose of splinting, the finished splint is regarded as being a new product and falls within the definition of a custom-made medical device.

It is important to note that significantly modifying existing splints, or using them for purposes not intended by the manufacturer, is regarded as manufacture of a new splint under the legislation and may have safety implications. Such splints can no longer be used under the original CE marking and are considered as new medical devices. Significantly modifying splints includes the addition of non-CE marked accessories (e.g. non-CE marked straps / strap material) to the splint or carrying out a processing step outside the scope of the original manufacturer's guidance.

If a professional user / healthcare institution is regarded as a manufacturer of custom-made medical devices they need to comply with the legislation, in particular Schedule 1: Essential Requirements and Schedule 8 of the Statutory Instrument: Statement Concerning Devices for Special Purposes. Reference should be made to the IMB's Guidance Note 14, which provides guidance for manufacturers of custom-made medical devices. That guidance note also includes checklists and templates to assist with the preparation of the technical documentation for these devices.

CONCLUSION

There are certain activities carried out in healthcare institutions that are outside the scope of the legislation, and which do not require the institution to meet the obligations of a manufacturer. These activities include:

- Using mass produced off-the shelf splints
- Assembly, following the guidance of the original manufacturer, of splints from CE marked material that is intended to be used for the manufacturing of splints
- Adaption of CE marked splints / materials to suit the needs of an individual patient

However, there are certain other activities that bring the healthcare institution within the scope of the legislation, in particular:

- Manufacture of splints by healthcare professionals from material that is not CE marked and not intended to be used for splinting
- Significant modification of splints

In these two instances, the healthcare institution must register with the Irish Medicines Board and meet all of the obligations of a medical devices manufacturer as outlined in the legislation.

Regulatory Update

A Medical Devices Expert Group (MDEG) meeting took place in December 2006. It consisted of a closed session for Competent Authorities (CAs) and an open session for all stakeholders. Items discussed included the implementation of Directive 2005/50/EC on the reclassification of hip, knee and shoulder joints replacements from medium to high risk category, impact of changes to the New Approach legislation particularly regarding accreditation, progress in relation to the proposed amendments to Directive 93/42/EEC and the use of mercury in medical devices. MDEG also discussed the revision of the Common Technical Specification for IVD medical devices and the extension of the scope of the Active Implantable Medical Devices Directive 90/385/EEC to include TSE requirements. The European Commission outlined its plan for 2007 and stated that the key priority is the amendment to the Medical Devices Directive 93/42/EEC.

A number of documents were approved for publication by MDEG as follows:

- MED.DEV's 2.14/3 rev 1 IVD Guidance: Supply of instructions for use and other information for *in-vitro* diagnostic (IVD) medical devices - a guide for Manufacturers and Notified Bodies
- Guidance document on Directive 2005/50/EC on reclassification of hip, knee and shoulder joint replacements.
- Consensus statement on requirements for *in-vitro* diagnostic kits measuring parameters which can be used for evaluating the risk of Trisomy 21.

With regard to Trisomy 21, the consensus statement clarifies the position in relation to this test. The manufacturer may choose to put the kits for the detection of AFP, hCG, hCG-beta, estriol and PAPP-A on the market without the intended use of risk evaluation of trisomy 21. In that case, the manufacturer should include a statement advising that "this kit is NOT intended to be used for the risk evaluation of trisomy 21" in the instructions for use (IFU) or on the package. Also, no information concerning the measured parameter in the risk evaluation of trisomy 21 can be included in the IFU. If IVD kits detecting AFP, hCG, hCG-beta, estriol and PAPP-A are specifically designed for evaluating the risk of trisomy 21, it implicates the use of a risk analysis software. Indeed, these IVD kits on their own are not able to provide any risk evaluation of trisomy 21. At least one software tool designated specifically for evaluating the risk of trisomy 21 should be identified as a safe and proper combination tool.

All of these documents may be downloaded from the medical devices section of the European Commission website at http://ec.europa.eu/enterprise/medical_devices/index_en.htm

The proposed changes to MED.DEV 2.12-1 rev 4 April 2001 on the medical device vigilance system have been finalised and it is expected that the final text will be discussed at the next MDEG meeting in May 07 with a view to subsequent publication.

A meeting took place under the German presidency of the EU. The impact on implementation of the proposed changes to the Medical Devices Directive 93/42/EEC was considered as well as market surveillance issues. A workshop titled "Future 2014" took place and considered what challenges may lie ahead regarding the regulation of medical devices.

The Clinical Evaluation Task Force (CETF) met in January 2007. A number of documents are under preparation as follows:

1. guidance for drug eluting stents
2. development of a clinical investigation checklist for Competent Authorities.

The need for a European database of clinical investigations was also discussed. The work programme and the terms of reference for the CETF were discussed and consideration is being given as the most effective way to move forward.

The Notified Body Operation Group (NBOG) currently has included in its work programme peer review in relation to designation of Notified Bodies and the notification of the scope of designation to the Directives. The chair of NBOG Mr Steve Owen, MHRA, UK retired from the chair after a very successful chairmanship. A new chair and vice-chair were elected at the recent CA meeting in Bonn, Germany. Mr Rainer Edelhauser, ZLG Germany was elected chair and Ms. Maria Carleton of the IMB was elected as vice-chair of NBOG.

In Ireland Directive 2005/50/EC on Reclassification of hip, knee and shoulder joint replacements was transposed into Irish law by way of S.I. 92 of 2007 and comes into force on 1st September 2007. Transitional arrangements are allowed and manufacturers should make themselves familiar with the requirements