



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Medical Devices/Equipment Management

Compliance with the HSE's Medical Devices and Equipment Management Standard

Guidance for Service Areas

Document reference number	<i>OQR031</i>	Document developed by	<i>Quality Function, Office of Quality and Risk</i>
Revision number	<i>01</i>	Document approved by	<i>Senior Management Team</i>
Approval date	<i>03.11.09</i>	Responsibility for implementation	<i>All Health sector employees</i>
Revision date	<i>03.11.10</i>	Responsibility for review and audit	<i>Office of Quality and Risk</i>

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1.0 INTRODUCTION

The purpose of this document is to supplement and provide guidance to enable service areas in complying with the HSE Medical Devices/Equipment Management Policy and Standard. This document should be used in conjunction with the Medical Devices/Equipment Management Policy and Standard.

2.0 STATEMENT OF STANDARD

The overall objective of the HSE's Medical Device and Equipment Management Policy is to provide an organisation wide framework for the management of Medical Devices/Equipment and to ensure that the highest standards of device safety, risk management and financial efficiency are realised in the management of the device.

The policy is supported by a statement of standard which sets out 26 criteria to assist overall compliance. The statement of standard states:

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

3.0 CRITERIA - GUIDANCE

The standard's 26 supporting criteria reflect the elements of a higher level management model describing a 'system of internal control'. The main elements of this model are:

- Communication and Consultation
- Accountability
- Core Processes and Programmes
- Capability
- Outcomes
- Monitoring and Review
- Independent Assurance

For a more detailed description of this model refer to the HSE's Medical Devices and Equipment Management Standard.

3.1 Communication and Consultation

Criterion 1

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

Guidance:

The Medical Devices/Equipment Management Committees (MDEMC) will enable Service Areas (local, regional and national) to:

- improve communication regarding medical devices/equipment within the organisation
- Gain the agreement of all key stakeholders in relation to any proposed changes
- Identify who is responsible for device management tasks, training and safe device operation.

Membership of the committee will need to be broad enough to address all the listed policy areas, and will most likely be the current “Decontamination Committee” with a few additions to that committee’s Terms of Reference and membership. It will need appropriate representation from among clinical, management, finance, pathology, pharmacy, Information Communication Technology (ICT), infection control, clinical engineering, users, estates and procurement. The committee should also include members of the risk management team to ensure that adverse incident reporting and Irish Medicines Board (IMB) information and advice are implemented. Clear terms of reference must be developed for the MDEMC. Specialist sub-groups may be needed to make recommendations to this committee. This committee should review the policies at least once a year and submit regular audit reports to the senior management team.

3.2 Accountability

Criterion 2

Individual responsibility for Medical Devices/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.

Guidance:

This criterion requires that Board level responsibility for Medical Devices/Equipment management is clearly defined and there are clear lines of accountability throughout the organisation leading to the Board. The HSE Medical Devices/Equipment Management Policy sets out the individual roles and responsibilities for employees at all levels in this accountability continuum. It also places emphasis on the role of the Medical Devices Equipment Management Committee in the governance of the overall system of management and the role of the Head of Clinical Engineering.

Medical Devices Equipment Management Committees (MDEMC) will be required at local, regional and national levels and shall be led by Clinical engineering in order to provide the required Board assurance in relation to the management of medical devices.

The role of the Clinical Engineering professional is critical to the successful management of medical devices/equipment. Whereas from a governance perspective it is the responsibility of the relevant MDEMC (local, regional or national) to ensure that robust systems are in place for the safe and effective management of medical devices and to provide assurance in relation to these, it is the professional and day to day responsibility of Clinical Engineering to develop and maintain the systems of management to a level that complies with professional and regulatory requirements and to advise management on areas which require improvement.

Overall accountability for medical device/equipment management should therefore be vested at an appropriate level in the organization's operational management structure (local, regional and national) and the professional accountability delegated to the head of Clinical Engineering.

From a line management perspective it is the responsibility of all line managers in areas where medical devices are used to ensure that medical devices/equipment acquired and deployed in their area of responsibility are managed in line with best practice. Their relationship with the head of Clinical Engineering who is the professional lead in this respect is critical.

The lines of management accountability should be extended, where appropriate, to include general practitioners, residential and care homes, community based services, non-statutory services that are providing services and funded by the HSE, managed care providers, Public Private Partnership (PPP) organisations and other independent contractors.

There should therefore be clear lines of both management and professional accountability throughout the organisation for medical device/equipment management.

3.3 Core Processes and Programmes

Criterion 3

There are broad-based Medical Devices/Equipment Management Committees (MDEMC) established in accordance with the recommendations of the IMB safety notice SN2006(03) at local, regional and national levels.

Guidance:

It is essential that there be Medical Devices/Equipment Management Committee (MDEMC) at all operational levels i.e. local, regional and national. The membership of these committees should be at a minimum consist of representatives of senior management, clinical engineering, relevant clinical staff (medical, health and social care professionals, nursing), clinical director, quality and risk, ICT, infection prevention and control, procurement, maintenance and finance.

The four main areas for management by this committee are:

- Management of Medical Devices within HSE facilities
- Management of Medical Devices within community settings
- Consumables and Accessories
- Management of Medical Alerts/Incidents

These areas will all be managed directly by a MDEMC who may set up specialist subcommittees which report to the MDEMC. The MDEMC in this instance will have a smaller more senior membership and adopt a governance role of oversight and assurance.

Whichever model of management is chosen each area of management will be led by Biomedical/Clinical engineering and supported by appropriate operational policies and seek the input of appropriate staff.

MDEMCs will also:

- improve communication regarding medical devices/equipment within the organisation
- Gain the agreement of all key stakeholders in relation to any proposed changes
- Identify who is responsible for device/equipment management tasks, training and safe device operation.

MDEMCs should review their procedures annually to ensure that they continue to conform with the Medical Devices/Equipment Management Policy. They will submit regular (management and monitoring) reports to management through the regional and national level MDEMCs

Criterion 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.

Guidance:

The management of medical devices/equipment should be supported by clear procedural guidance relevant to the operational area. Clear operational procedures will assist in ensuring that risks associated with the use of medical devices/equipment will be minimised.

Responsible organisations should therefore develop and regularly review device/equipment management procedures, to ensure that whenever a medical device/equipment is used, it is:

- suitable for the intended application (in the context of current equipment design and alternative technologies now available)
- used in accordance with the manufacturers' instructions that are relevant, appropriate and up-to-date
- maintained in a safe and reliable condition
- disposed of appropriately at the end of its useful life.

The device/equipment management procedures should cover the:

- selection, acquisition, acceptance and disposal of all medical devices
- training of all those who will use them
- decontamination in accordance with manufacturers instructions following use, maintenance, repair, monitoring, traceability, record keeping and replacement of reusable medical devices.

There should be a centralised group to facilitate all services areas in the development of Procedures with supporting Document Management and Document Control in the Service Area, for example Quality and Risk group, Policy and Procedure Group. These Procedures should be based on evidence based practice.

Service Areas have a responsibility to identify and develop Procedures to support all elements of Medical Device and Equipment Management to include:

- Acquisition of Medical Devices and Equipment
- Prescription of Medical Devices and Equipment
- Delivery of a new piece of Medical Device and Equipment
- Instructions for Medical Devices and Equipment
- Training on Medical Devices and Equipment
- Storage of Medical Devices and Equipment
- Installation of new Medical Device and Equipment
- Maintenance and Repair
- Incident Reporting of Medical Devices and Equipment and Alerts Management
- Decontamination
- Removal from service to inc. Disposal, decommissioning, reuse / Single use equipment.

There should be system in place to ensure effective document management and document control of Medical Devices and equipment procedures including processes to support the ongoing review and audit of procedures.

There should be system in place to train staff in appraising and developing procedures and identifying evidence based best practice.

Criterion 5

All Medical Devices and Equipment in the Service Area are selected and acquired in accordance with the HSE'S Procurement Policy.

Guidance:

The Medical Devices and Equipment Management Committee should ensure that local procedures for the sourcing and acquisition of medical devices address safety, quality, and performance as well as compliance with all applicable aspects of the HSE Procurement Policy and National Financial Regulations. Depending on the complexity of the medical device technology purchased, it is imperative that a high level of training and clinical support is provided by the manufacturer/supplier. It is important that this is quantifiably and qualitatively agreed and this is embedded in the purchase agreement between the purchaser and the supplier.

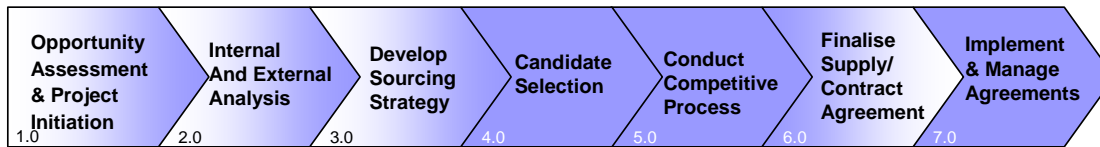
Procedures should include the need to:

- establish a multi disciplinary Product Evaluation Group to ensure that the agreed acquisition requirement takes account of the functional, technical and performance requirements of all interested parties, including those involved in use, commissioning, decontamination, maintenance and decommissioning
- Ensure that high quality evidence based clinical trial documentation is factored into the decision making process so that the best outcomes are achieved for patients.
- Ensure manufacturer/supplier performance is addressed in the decision making process.
- Ensure that the selection process complies with local and national sourcing and acquisition policies (e.g. HSE Procurement Policy, National Financial Regulations), and takes account of whole life costs, the method of acquisition and the agreed acquisition requirement.
- Prioritise each equipment requirement in the context of other requirements in any situation where funding is limited.

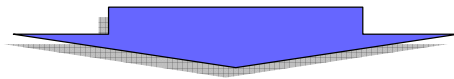
HSE Procurement has adopted a structured 7 step model for the procurement of products and services. Each step is designed to industry leading practices providing a structured and fact based approach to the procurement process.

The National Financial Regulations stipulate that HSE Procurement is accountable for and must lead all significant procurement processes.

The 7 Step Sourcing Methodology



- **Structured and rigorous process**
- **Fact based decision making process**
- **Open and fair**
- **Cyclical and repeatable**
- **Robust and proven approach**
- **Consistent with industry best practice**



Improved Sourcing Results



HSE Procurement – Portfolio And Category Management

2

Second hand medical devices

Usage and service history should always be available for prospective purchasers before sale and then supplied with the equipment at the point of sale. This information should be reviewed by an appropriate competent person prior to acceptance of the device. The input and approval from Infection Control expertise should also be sought prior to procurement.

As a minimum there should be a:

- record of any reconditioning work carried out, including a record of replacement parts
- copy of all maintenance and servicing that has been carried out including the name of maintenance/servicing organisation
- record of usage
- fault log
- Decontamination status
- CE Marking

Key points for acquiring equipment

- Local acquisition policies to be established consistent with HSE Policies and procedures.
- The MDEMC to be involved in establishing the policy and process.
- Specific Product Evaluation Groups to be established and appropriately briefed.
- Safety, quality and performance considerations to be included in all acquisition decisions.
- The recommendations of IMB, HIQA and other appropriate bodies have been followed for

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Document reference no.OQR031.Revision number 01. Approval date 03.11.09.

selection and acquisition.

- All developments, modifications and trials of devices to be carried out in accordance with the relevant legislation and guidance and under risk management policy.
- Assurances obtained from all persons involved that the device can be decontaminated by existing processes and any products used in that process are also compatible.
- Service Level Agreements (SLAs), Technical support, maintenance and repair systems and timescales to be included and managed by Clinical Engineering.
- It would be advisable that distributor performance be taken into consideration during the selection process
- Training and support services to be included where appropriate.
- The Procurement process must ensure that competent and capable suppliers are selected and that comprehensive Life Cycle Cost Models are used.
- User experience to be fed back into the policy, process, future acquisitions and advisory groups.

The **HSE Procurement Policy** is available at:

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

and

The **National Financial Regulations** is available at:

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

Criterion 6

All Medical Device and Equipment developments, modifications and trials are conducted in accordance with relevant legislation and guidance.

Guidance:

Modifying existing devices or using them for purposes not intended by the manufacturer (off-label use) has safety implications. It may also count as a manufacture of a new device under the European Regulations. The original manufacturer's liability will be limited and liability may be partly or wholly transferred to the organisation or person making the modifications if the device is implicated in an adverse incident.

It is essential that modifications in use outside of the manufacturer's intended use is only considered as part of a fully documented risk management process within the healthcare organisation's risk management policy and procedures. If a modification is made it must adhere to the IMB Guidance note 12 and have a risk assessment carried out prior to use. See Appendix 2 in the HSE Medical Devices/Equipment Management Policy for international legislation on medical devices.

Criterion 7

Delivery and pre-use checks are carried out on all newly delivered Medical Devices/Equipment

Guidance:

Responsible organisations should check that the specification of newly delivered equipment matches the purchase order detail or tender specification. It is the responsibility of clinical engineering to ensure that new equipment is subjected to an acceptance test procedure. New equipment should not be signed off for payment without acceptance test approval by clinical engineering. Performance, safety, commissioning and the SLA planned training of therapists to support the end-users should be part of the acceptance test procedure. The prescribing healthcare professional will ensure that the performance and safety checks are completed and instructions and training are provided to the end user.

Simple checks on delivery can save time and avoid trouble. Finding out that a piece of equipment is broken or inappropriate only when someone tries to use it for the first time can:

- delay or interrupt treatment
- waste staff time
- make it difficult to return the equipment
- make it harder to establish when and where the problem arose
- invalidate warranties
- Increase the risk of injury to users.

Delivery checks should include:

- checking that the correct product, complete with usage and maintenance information and any relevant accessories, has been supplied
- Ensuring that devices/equipment have been delivered in good condition and, where relevant, in good working order.

A robust procedure of asset labeling, recording and returning these details for financial purposes must be put in place. It is the responsibility of the supplier that installs the medical device/equipment to return the delivery document with install location which will then be checked (and entered on asset management database) and returned to accounts for payment. See National Financial Regulations.

The procedure for **managing new equipment** should identify:

- any training needs
- appropriate planned preventive maintenance
- technical support needs of users
- Whether risks associated with using a particular model for the first time have been minimised.

Some items, such as medical gloves, dressings, catheters and syringes are delivered in bulk packs, so it would be inappropriate to check each one on delivery. For such products key issues are:

- stock rotation/use by dates are clearly shown on packaging
- appropriate marking for tracing lots if there is a recall
- instructions and safety information are available when necessary
- packaging is appropriate for storage.

Systems for managing medical devices/equipment need to take account of the different ways that the devices/equipment can be deployed, for example:

- allocated to the particular department where they are used, which is given the responsibility for managing them: examples include fixed installations, such as large X-ray machines and smaller critical care devices in some intensive therapy units
- allocated to equipment stores, pools or libraries, from which they are issued to particular users as required

Examples include walking aids and commodes issued by community stores and infusion pumps and ventilators in many hospitals issued on long-term loan to an individual user for their use only: examples include artificial limbs and wheelchairs.

When the equipment is allocated to a department, individuals working in the department generally have primary responsibility for the way they treat the equipment and the state in which it is left. These responsibilities can also include performance checks before use and routine maintenance, such as charging batteries. It is essential that all individuals are aware of the medical device/equipment management system and the part that they play within the system to ensure that medical devices/equipment is managed correctly.

Important aspects of equipment management, such as record keeping and scheduling maintenance, are often controlled by the Clinical Engineering department. It is essential that systems and procedures ensure that the relevant records are passed on to those responsible for the management of records for a particular piece of equipment.

Some products should be risk assessed before first use (Table 1) and carried out by an adequately trained and appropriately qualified person. When a new model is first introduced, or when pre-use functional checks are complicated, technical and clinical staff should work together to ensure that:

- checks are successfully carried out and documented
- users have all the information that they need
- training needs have been identified and acted on
- users know how the device works, when functioning correctly.

Installed devices

When a piece of equipment needs to be installed, there should be a procedure for commissioning the installation, which has been agreed with the supplier and the organisation responsible for carrying it out.

This usually applies when any of the following occurs:

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- substantial assembly work will be required on-site
- there are permanent plumbing, electrical and gas pipeline connections
- the device needs to be permanently fixed in place.

As part of the Service Level Agreement (SLA), suppliers must provide instructions for installing a device and bringing it into use. Where appropriate, these instructions should include specifications for safety and performance checks.

An adequately trained and appropriately qualified person, a Clinical Engineer where available, should oversee the commissioning process, and take responsibility for deciding that it has been completed satisfactorily. The contribution of other HSE personnel might also need to be recorded in the installation/acceptance testing exercise of new equipment. These might include technical services, medical physics and infection control.

Table 1. Equipment requiring risk assessment (See HSE Risk Management Policy)

Category	Examples
Medical devices manufactured outside the scope of the Medical Devices Regulations (IMB).	<ul style="list-style-type: none"> • Purchased by an individual outside EU. • In-house manufacture.
Equipment which has, or may have, been used before.	<ul style="list-style-type: none"> • Bought second-hand. • Lent by another responsible organisation. • Equipment re-issued to second or subsequent users.
Devices within scope of Medical Devices Regulations, but not CE-marked.	<ul style="list-style-type: none"> • Custom-made for a named patient. • Under clinical investigation.

The medical device/equipment may require a unique local reference number, so that it can be recorded and traced on the local equipment management system. Any local reference number must be traceable back through to the supplier's and manufacturer's records for each device in case of future recalls or updates made by the manufacturer.

Criterion 8:

All newly delivered Medical Devices and Equipment are properly stored after acceptance.

Guidance:

In the community, routine device/equipment management may in practice transfer either to the end user or to a community healthcare worker. It is essential that all individuals are aware of the medical device/equipment management system and the part that they play within the system to ensure that medical devices are managed correctly.

The HSE must ensure that the end user is aware of their responsibility for the procedure required for scheduled maintenance and training in the use of the device. At a minimum, all medical devices/equipment in equipment stores, pools and libraries should be subjected to performance and quality assurance tests prior to reissue.

Criterion 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.

Guidance:

Good clear instructions have a crucial role in the safe and effective use of equipment. Any shortcomings in the instructions should be reported to the IMB as an adverse incident.

Where the device is reusable, information on the appropriate processes to allow reuse must be provided by the manufacturer. This information shall contain information such as instructions for disassembly and reassembly prior to cleaning, disinfection and/or sterilisation processes for that device. If appropriate, it should also include the number of times the device can be re-sterilised and any restrictions on the number of reuses.

Clear responsibilities should exist for ensuring that the manufacturer's instructions are passed on to all users and, where appropriate, carers. The manufacturer's instructions may need to be supplemented with training.

Updates

When manufacturers update their information, responsible organisations must have a protocol for: keeping track of all sets of instructions they hold or have issued to users; replacing existing instructions with revised versions; updating the content of relevant training.

Contraindications

Prescribers should refer to the manufacturer's instructions for details of how the device should be used, and for whom it is suitable. Any risks or side effects described in the manufacturer's instructions should be weighed against expected benefits.

Many community stores produce catalogues of all the equipment they supply. These should contain guidance for prescribers, including contraindications. This information should include the manufacturer's instructions and be updated as manufacturers change their content.

Instructions for end-user

All necessary information on storage, pre-use checks, use, maintenance and cleaning should be passed on to the end user, including when the device is issued to a second or subsequent user.

A failure to pass on to the end user the manufacturer's original instructions may compromise the end user's ability to use the device safely, and may leave the provider open to legal liability.

Some users or carers with particular disabilities or medical conditions may need additional instructions or training. For example, people who are visually impaired may not be able to easily read some forms of written information.

The responsible organisation may also need to supply its own information to explain any additional administrative arrangements e.g. contact details for maintenance, consumables or spare parts.

Table 2. Potential difficulties with instructions

Topic	Notes and problems
Placement	Instructions can be printed on the device itself, or its immediate packaging, or supplied as a leaflet.
Content	Instructions must be precise and clear, and should include details of who to contact for specialist problem-solving or guidance.
Print size	End users may be visually impaired.
Technical or difficult language	Instructions must be easy to understand and follow.
Translation from or into foreign language	This should be accurate and understandable.
Different versions	Manufacturers may have updated software/hardware. Need the right version to match the specific device.

Documentation

Evidence that suitable instructions and training were provided will be needed, should a legal case be brought. Users of equipment should be asked to sign statements confirming that they have received and understood written and/or oral instructions. Details of training given should also be recorded.

Key points for instructions

- All users and prescribers should have access to the manufacturer's instructions.
- Users should sign statements confirming that they have received instructions (and training) on the safe use of medical devices/equipment.
- There must be a process for recording, tracking and updating the manufacturer's instructions.
- Any updates must be distributed to all relevant users of the device/equipment.

Any manufacturer's instructions considered to be inadequate/ineffective, should be reported to the IMB.

Criterion 10:

Medical Devices designated for single use are not reused under any circumstances

Guidance:

"A device designated for 'single-use' must not be reused. It should only be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used again, even on the same patient." (MHRA, UK).

"Reuse" is defined by the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK as "another episode of use, or repeated episodes of use, of a medical device, which has undergone some form of reprocessing between each episode".



All devices designated for single use must clearly be identified with the above symbol. Any single-use device must be used on an individual patient during a single procedure and then discarded. It must not be reprocessed and used again, even on the same patient.

Criterion 11:

All necessary information required to properly manage HSE Service's range of Medical Devices/Equipment is recorded on a suitable system.

Guidance:

Good record keeping is essential for the safe management of medical devices/equipment. The prime reason for keeping good records is so that the equipment history is immediately available as an aid to any maintenance issues that may arise during the equipments useful life. This is a core function of Clinical Engineering and should include initial procurement details, all equipment repair details and routine planned preventative maintenance/safety test details etc. The detail and complexity of the

records will depend on the type of device and its usage during its lifetime. It should also include any specific guidance provided in the manufacturer's instructions and supporting information. For efficient and effective management it is essential to have in place an electronic based equipment management system that is primarily focused on medical devices/ equipment as opposed to a general asset management system. Ideally one system should be adopted nationally that can be utilised in each hospital / community setting.

Records should provide evidence of:

- a unique identifier for the device/equipment, where appropriate
- a full history, including date of purchase and where appropriate when it was put into use, deployed or installed
- any specific legal requirements and whether these have been met
- proper installation (validation records where appropriate)
- details of scheduled maintenance and repairs including planned preventative maintenance details and safety test results
- the end-of-life date.
- decommissioning details and disposal date/traceable disposal route.

Good record management is important because:

- health and safety inspectors will expect records to be available
- a defense in a negligence case based on good equipment management will only be effective if records are available for the equipment involved
- Recording the individual equipment or batch details on a database means it can subsequently be traced for maintenance or for a manufacturer's recall/field correction, if necessary.

Criterion 12:

All Medical Devices/Equipment are properly maintained and repaired

Guidance:

The organisation's Medical Device/Equipment Management policy is the responsibility of Clinical Engineering in conjunction with management and other key stakeholders and must cover the provision of maintenance and repair of all medical devices, including reconditioning and refurbishment.

This includes:

- ensuring that all equipment is routinely serviced and safety tested at the intervals

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prescribed by the equipment manufacturer (or best practice)

- how each device should be maintained and repaired, and by whom
- arrangements for maintenance and repair to be included as part of the assessment process
- arrangements for the most suitable persons/providers to carry out the work
- the timescale for planned maintenance
- the timescale for repairs to be completed.
- maintaining all associated device/repair records

The frequency and type of planned preventive maintenance should be specified, taking account of the manufacturer's instructions, the expected usage and the environment in which it is to be used.

Audit and review

Random audits should be carried out on all elements of maintenance and repair to ensure that the correct procedures are in place and being adhered to.

The responsible organisation should also ensure that there is a mechanism to obtain regular feedback from all users of the equipment on all aspects of the repair and maintenance process.

This should include the reporting of even apparently minor problems as these might lead to major failure unless remedied.

Reporting adverse incidents

Users and maintenance staff should be made aware of the need to report adverse incidents involving medical devices/equipment. These should be reported to the IMB, in addition to any internal reporting policies of the organisation.

Decontamination

Items subject to inspection, maintenance, repair or disposal should be decontaminated beforehand (see **criterion 13**).

Choosing appropriate maintenance and repair services

The HSE is ultimately responsible for ensuring that Medical Devices and Equipment are appropriately maintained and repaired. The HSE may use the services of manufacturers, outside contractors or in-house maintenance to carry out this work. A risk-benefit analysis should be undertaken by a multidisciplinary team including clinical engineering before finalising the specification for procurement of any maintenance and repair services. Cost alone should not be the determining factor. It is essential that an engineering discipline work very closely with HSE procurement to ensure appropriate maintenance and repairs are identified and agreed prior to tender.

Consider only those service providers with access to the necessary equipment and up-to-date manufacturer's instructions; otherwise they may not be able to carry out the tasks safely and effectively.

The Service Contract

The service contract should meet the criteria of the HSE Procurement Policy. Any contractual agreement with a maintenance and/or repair service provider should specify the level and type of service required by the responsible organisation and is directed by an adequately trained and appropriately qualified person, where available Clinical Engineering. It should include, where appropriate:

- reference to manufacturer's written instructions
- availability, source and traceability of spare parts
- notification of any changes, including the use of alternative spare parts or methods
- training of staff
- quality assurance systems
- requirement for adequate record keeping
- use of sub-contractors
- response times
- loan equipment (where available)
- disposal of obsolete equipment, parts and waste.

Guidance on a range of repair and maintenance contracts is available through the Clinical Engineering Departments and administered by the HSE Procurement Department.

Training and experience of repair and maintenance staff

The Safety, Health and Welfare at Work Act (2005) requires employers to ensure their employees are adequately trained.

All staff servicing equipment owned by the responsible organisation must understand the basic principles on which devices work (generic training) as well as how to use, repair and maintain a particular model (specific training). FETAC level 6 and HETAC level 7 and level 8 are the basic requirements for the maintenance and repair of medical equipment of various levels of complexity. Those without adequate training should not be allowed, nor should they attempt, to repair or maintain medical devices and equipment.

All those undertaking repair and maintenance should be able to produce written evidence of appropriate training, possibly as part of the documentation required by a quality assurance system. They should also be able to show that they are up to date on new maintenance techniques, consistent with the devices they are servicing.

Contracts with the manufacturer

Where contracts are placed with the manufacturer for repair and maintenance ensure that you are made aware of any changes in circumstances that may affect the repair or maintenance of their devices/equipment. This documentation should be issued in line with the Procurement and Contractual agreements for appropriate distribution within the organisation.

For example, if a manufacturer merges with or is taken over by another organisation, the responsibility for repair and maintenance may transfer to the new organisation.

If the manufacturer ceases trading and an alternative service provider is not able to undertake the work in accordance with the manufacturer's instructions, the device may need to be disposed of. However, there may be circumstances where it is essential to keep a device in use. If this happens, a risk assessment of its continued use with no manufacturer service backup must be completed, set against the consequences of the device not being available in the short or longer term.

Regularly review the situation to see if alternative arrangements can be made, including acquiring new

or replacement equipment and subsequent disposal of the original equipment.

Subcontracted repair and maintenance

If any aspect of the repair or maintenance process is subcontracted, the responsible organisation should ensure that:

- they are aware of those aspects of the repair that are being subcontracted
- the main service provider and the subcontractor have a contract, detailing the responsibilities of each party
- the service provider audits the subcontractor frequently to establish that it has the necessary expertise and resources, and that the work is of a sufficiently high standard
- they are notified of any changes in these arrangements.

Those without adequate training should not be allowed, nor should they attempt, to repair or maintain medical devices and equipment.

Planned preventative maintenance

The frequency of servicing should be based on the manufacturer's recommendations and managed by the Clinical Engineering department otherwise the provider will carry increased liability in any subsequent litigation. How the device will be used, and how often, must also be considered when determining service intervals.

Table 3. Planned preventive maintenance checklist

Heading	Notes
Service interval	Should be based on the manufacturer's recommendation, taking into account how much the equipment will be used.
Initial inspection	<ul style="list-style-type: none">• Is the device clean?• Does it need decontaminating?• Note settings of controls.• Inspect each element in line with manufacturer's instructions.

Parts replaced	<ul style="list-style-type: none"> • Note each item/part to be replaced. • Record each items/part replaced, including details of source manufacturer and method of fitting.
Calibration	<ul style="list-style-type: none"> • Establish if any element/part requires calibration or re-calibration. • Calibrate in line with the manufacturer's instructions.
Performance and safety checks	Carry out performance tests against the manufacturer's specifications before and after maintenance.
Decontamination	Is Decontamination Certificate completed?
Return-to-use	<ul style="list-style-type: none"> • Input all details on individual equipment record in the maintenance database. • Check the device has its accessories, where appropriate, and is properly assembled. • Return controls either to zero or to the settings noted at initial inspection. • Stick on a dated 'JUST SERVICED' label, and a note of any alterations in control settings.

Updating changes to manufacturers' instructions

Whoever provides maintenance and repair services should ensure that they are automatically alerted of any changes to repair or maintenance instructions and other essential safety information issued by the manufacturer.

There may be changes to the design, or other information, which could affect safety or change the requirements for repair or maintenance, including recalls/safety measures and mandatory upgrades.

The records of the responsible organisation and the service provider must show the version of the equipment currently in use and whether it has been upgraded, modified or repaired since it was supplied. This includes integral computer software.

This system should include all relevant guidance issued by the IMB, such as Medical Device Alerts.

Quality and compatibility with the device/equipment

The contract between the responsible organisation and the maintenance and/or repair service provider should clearly define the terms 'spare parts' and 'consumables' and ensure that their quality and compatibility match those supplied by the original equipment manufacturer.

To ensure that replacement parts are of the correct specification, purchase them either directly from the manufacturer or to the same specification.

When obtaining replacement spare parts from sources other than the manufacturer, care must be taken to ensure that all aspects of the technical specification are met, including, for example, physical dimensions, material strength, mechanical properties and compatibility.

Any agreements to supply parts from sources other than that recommended by the manufacturer **shall** be properly risk assessed, costed and documented before a decision is made to purchase them.

This should also include any effects on whole life costs: a cheaper part requiring more frequent maintenance may not be cost-effective in the longer term. There also may be legal consequences for the responsible organisation if a device failure, associated with the fitting of such a spare part, causes an injury or incident.

Reusing spare parts

Under normal circumstances pre-used parts should not be used to repair a device. They may be acceptable only in exceptional circumstances after a fully documented risk assessment.

The stresses and strains that the part has undergone will depend on many factors, such as the length of time in service, age and repair or maintenance history. Pre-used parts may therefore increase the need for maintenance checks or reduce the overall life cycle of the device.

The failure of a part can have severe consequences for the end user. The part should not be reused if its previous history is unknown.

Traceability of spare parts

The responsible organisation should ensure that the repair and maintenance service provider can:

- identify all spare parts replaced during the maintenance or repair of a particular device
- trace all critical parts back to the supplier.

This will permit ready identification of those devices containing parts that need to be repaired or recalled.

Not all spare parts are critical and the extent to which they need to be identified and related to the original piece of equipment will depend on several factors.

As a guide, a 'critical part' is a component that might reasonably be expected to cause the failure of a critical piece of equipment, or affect its safety or effectiveness and consequently result in death or injury to a user, should it stop working.

Repair and maintenance methods

Even if authorised spare parts are used, the methods used to dismantle and repair the equipment and reassemble it could cause the device to fail or potentially harm users. The maintenance and repair service provider shall therefore have all the necessary testing, measuring, and repair equipment and ensure that this is adequately maintained and calibrated:

- current certificates of calibration shall be maintained for all test and repair equipment that has a measuring function
- calibration shall be traceable to national and/or international standards
- records shall be maintained for each piece of test, repair or maintenance equipment and should be incorporated into the service provider's quality assurance system.

Test equipment, such as jigs, templates, and computer service and diagnostic software used to test devices should also be checked regularly to ensure that it can adequately demonstrate device safety.

Make sure that the service provider has identified and documented all risks, implemented a strategy to manage them, and has documented procedures detailing the repair and maintenance methods to safeguard equipment malfunctions and facilitate tracing of any subsequent parts recall.

Before bringing equipment back into service, it should be adequately tested and the user informed of the results and any changes made to the settings of the device.

Professional users should be told, where applicable, about pass/fail criteria and anything which may significantly affect the treatment of a patient-radiation dose, for example.

Routine maintenance by users

Routine maintenance by the user ensures that the device continues to function correctly

It entails regular inspection and care, as recommended in the manufacturer's user information. This should clearly show the routine tasks and how they should be carried out. These will include:

- checking that it is working correctly before use
- regular cleaning
- specific daily/weekly checks
- noting when it has stopped working properly or when obvious damage has occurred, and then discontinuing use
- for the Acute sector contact the Clinical Engineering Dept.; for Community contact the issuing healthcare professional or distribution centre.

Any problems the user finds can then be referred to a repair service. Minor changes that do not affect the safe working of the device can be recorded for attention during the preventive maintenance sessions.

Users may need to be trained to carry out routine maintenance. For example, they may require training on how to remove, change and insert batteries correctly in line with the manufacturer's instructions. They may also need to be warned about the dangers of substituting different battery types.

Breakdowns

Even with comprehensive maintenance schedules, breakdowns may still occur.

To restore function as quickly as possible, it is often easiest to substitute a similar device, although this requires increased stock levels, and is not always possible for items such as large X-ray machines and specially adapted wheelchairs.

Increased stock levels can be set against the likely costs of, for instance, paying an external service provider or providing a similar in-house service for response cover 24 hours per day.

Wherever possible, temporary repairs should be avoided. But if this is needed, because the impact of the loss is too great, the temporary repair should be carried out and all concerned should be informed of any special precautions or limitations on use until a permanent solution is available. This should be documented on the equipment records.

The equipment should be replaced or withdrawn from service as soon as possible and properly repaired before it is used again.

Legal Liabilities

The HSE should take all reasonable steps to ensure that equipment is repaired and maintained as per the manufacturer's instructions. The extent of liability will depend on the specifics of the case, and what steps are taken to ensure that adequate repair and maintenance is carried out.

If a device/equipment malfunctions after repair or maintenance and leads to the death or serious injury of a user, the HSE and the repair service provider are far more likely to be held liable for the injuries caused if the device/equipment was not repaired in accordance with the manufacturer's instructions.

If a device/equipment is not correctly repaired or maintained by an organisation (by an employee or someone acting on their behalf), then they could be held responsible under health and safety legislation should a user or member of staff die or sustain personal injury or damage as a result.

The HSE should ensure that both it and any service provider have adequate insurance in place.

See also:

SN2007(06) Medical Devices recommended by Healthcare institutions for use in a community setting

SN2003(08) Equipment Management Guidance for the Maintenance and Timely Replacement of Medical Equipment.

Key points on maintenance and repair.

- All medical devices and items of medical equipment are properly maintained and repaired.
- Where possible maintenance and repair providers are externally accredited for their quality management system.
- Audit and user feedback systems are in place to frequently review the processes, policies and contracts.
- All staff involved in maintenance and/or repair are appropriately trained and qualified.
- Spare parts are of the correct specification and their quality and compatibility match those supplied by the original equipment manufacturer.
- Manufacturer's maintenance instructions and timescales are adhered to.
- All medical devices/equipment returned for servicing and repairs are properly decontaminated.
- Organisations carrying out repairs and maintenance are fully insured.

Criterion 13:

All Medical devices/Equipment returned for servicing and repair are properly decontaminated

Guidance:

Decontamination is a series of processes to remove or destroy contamination so that infectious agents or other contaminants cannot reach a susceptible site in sufficient quantities to start infection or any other harmful response. Differing levels of decontamination are used depending on the

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device/equipment and the procedure involved.

The levels of decontamination are:

- cleaning
- cleaning followed by disinfection and or sterilization.

The choice of decontamination method should be related to the degree of infection risk associated with the intended use of the equipment (Table 9).

Table 9. Classification of infection risk associated with the decontamination of medical devices

Risk	Application of item	Recommendation
High	<ul style="list-style-type: none">• In close contact with broken skin or broken mucous membrane.• Introduced into sterile body areas.	Cleaning followed by sterilization.
Medium	<ul style="list-style-type: none">• In contact with mucous membranes.• Contaminated with particularly virulent or readily transmissible organisms.• Before use on immunocompromised patients.	Cleaning followed by sterilization or disinfection. NB: Where sterilization will damage equipment, cleaning followed by high level disinfection may be used as an alternative.
Low	<ul style="list-style-type: none">• In contact with healthy skin.• Not in contact with patient.	Cleaning.

The HSE published its Code of Practice for Decontamination of Reusable Invasive Medical Devices (RIMD) in October 2007. The HSE has published this Code of Practice as a guide to standards and recommended practices for decontamination of RIMD required in the Irish public health service.

What are Reusable Invasive Medical Devices?

Reusable invasive medical devices (RIMD) include items such as scalpels and scissors are fundamental to all surgical procedures and many medical procedures. Patients undergoing treatment have a right to expect that the RIMD used will be clean, free from infectious agents and in good working order. The decontamination processes involves working with RIMD that are potentially contaminated with infectious agents. Appropriate control and maintenance of the decontamination environment, equipment and processes is necessary to ensure the health and safety of staff. Every acute hospital in the HSE currently operates its own individual decontamination facilities. In 2006, the HSE operating as a single unified health service set about formulating these national standards in consultation with international experts, key stakeholders and also carrying out extensive literature research.

Some of the key recommendations contained in the HSE Code of Practice for RIMD include:

- Decontamination facilities should be designed, constructed, maintained and controlled to provide effective segregation of clean and dirty activities and to provide an environment that minimizes contamination of clean and disinfected RIMD
- Appropriately qualified key personnel should be in place to ensure that the decontamination service is provided effectively and efficiently
- Environmental cleaning procedures and schedules adopted must ensure that contamination from dirty areas does not contaminate the clean areas
- Cleaning should be monitored by regular documented inspection of the cleanliness of the environment and the cleaning equipment
- All decontamination equipment that does not meet the requirements of current standards is identified and upgraded or replaced in accordance with a planned replacement programme
- Appropriate Personal protective equipment (PPE) must be worn by personnel when decontaminating RIMD to reduce the risk of exposure to potentially infectious material.

The links to the Code of Practice for Decontamination of Reusable Invasive Medical Devices (RIMD) are as follows:

- [Code of Practice for Decontamination of Reusable Invasive Medical Devices 1 \(.pdf - 308 KB\)](#) HSE Published Code of Practice for Decontamination of Reusable Invasive Medical Devices, 24th October 2007
- [Code of Practice for Decontamination of Reusable Invasive Medical Devices 2 \(.pdf - 294 KB\)](#) HSE Published Code of Practice for Decontamination of Reusable Invasive Medical Devices, 24th October 2007
- [Code of Practice for Decontamination of Reusable Invasive Medical Devices 3 \(.pdf - 1427 KB\)](#) HSE Published Code of Practice for Decontamination of Reusable Invasive Medical Devices, 24th October 2007
- [Code of Practice for Decontamination of Reusable Invasive Medical Devices 4 \(.pdf - 826 KB\)](#) HSE Published Code of Practice for Decontamination of Reusable Invasive Medical Devices, 24th October 2007
- [Code of Practice for Decontamination of Reusable Invasive Medical Devices 5 \(.pdf - 980 KB\)](#) The HSE Published its Code of Practice for Decontamination of Reusable Invasive Medical Devices on 24th October 2007
- [Code of Practice for Decontamination of Reusable Invasive Medical Devices 6 \(.pdf - 549 KB\)](#) The HSE published its Code of Practice for Decontamination of Reusable Invasive Medical Devices on 24th October 2007
- [Code of Practice for Decontamination of Reusable Invasive Medical Devices 7 \(.pdf - 250 KB\)](#) The HSE published its Code of Practice for Decontamination of Reusable Invasive Medical Devices on 24th October 2007

Prior to servicing of equipment eg. suction machines, nebulisers and mattresses, i.e. items that are not covered under the Reusable Invasive Medical Devices Code of Practice, it is recommended that decontamination be undertaken as per manufacturer's instructions. The instructions provided by the manufacturer should be agreed prior to procurement. Safety data sheets should be available for the chemicals required in the decontamination process.

HSE National Cleaning Standards Manual

In February 2005 the National Hospitals Office (NHO), established a working group to evaluate the current status of infection control and cleaning services in acute hospitals. The group identified a need to develop uniform standards, guidelines and audit processes across Irish acute hospitals. The IHSAB

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Hygiene Services Standards cover the areas as audited as part of the national hygiene audits, i.e. Environment, Waste Management, Ward Kitchens, Linen, Sharps, Hand Hygiene and the Management of Patient Equipment.

The cleaning manual was designed to complement the IHSAB Hygiene Services Standards, and provide support and guidance for staff in attaining high standards of environmental cleanliness.

- [HSE National Cleaning Standards Manual \(.pdf - 532 KB\)](#)
- [HSE National Cleaning Standards Manual Appendices \(.pdf - 302 KB\)](#)

Who is responsible for decontamination?

In each responsible organisation a senior member of staff should manage all aspects of decontamination. The importance of correct decontamination needs to be clearly understood at all levels throughout the organisation to avoid cross contamination.

There should be clear lines of responsibility for decontamination matters across the organisation leading to the board. Senior managers and the board should monitor and regularly review decontamination procedures.

Figure 4 Sample form – declaration of contamination status

From (consignor): _____ Address _____ _____ _____ Reference _____ Emergency tel _____	To (consignee): _____ Address _____ _____ _____ Reference _____
---	--

Type of equipment _____ Manufacturer _____
Description of equipment _____
Other identifying marks _____
Model No. _____ Serial No. _____
Fault _____

Is the item contaminated?

Yes*

☐

No

☐

Don't know

☐

* State type of contamination: blood, body fluids, respired gases, pathological samples, chemicals (including cytotoxic drugs), radioactive material or any other hazard _____

Has the item been decontaminated?

Yes†

☐

No‡

☐

Don't know

☐

† What method of decontamination has been used? Please provide details

Cleaning _____

Disinfection _____

Sterilization _____

‡ Please explain why the item has **not** been decontaminated?

Contaminated items should not be returned without prior agreement of the recipient

This item has been prepared to ensure safe handling and transportation:

Name _____ Position _____

Signature _____

Date _____ Tel _____

Criterion 14:

Medical Devices/Equipment are replaced in accordance with an agreed policy.

Guidance:**Replacement criteria**

Feedback from routine or planned preventive maintenance along with the life cycle information from the manufacturer should inform decisions when to replace a device/equipment. Maintenance and repair services must also be informed of any removals from service. The replacement criteria and the responsibilities of the maintenance and repair provider should be specified within the contractual agreement. There should be a prioritised planned replacement programme in place to be reviewed on an annual basis.

Criterion 15:

All loaned Medical Devices/Equipment are collected when no longer needed.

Guidance:

Hospitals can loan each other equipment to avert temporary problems; manufacturers can loan products as part of an evaluation or as an incentive to purchase associated products. All Medical Devices and Equipment used in community are on a long term loan to the end user.

In all cases it must be clear at the outset whose responsibility it will be should any problems arise.

Some device/equipment management will transfer either to the individual end user or to a carer or to the prescribing healthcare professional or Clinical Engineer. Devices/equipment issued on a long term basis should be subjected to performance and quality assurance tests prior to issue. But it is essential to be clear about where responsibility lies for each aspect of management. This includes:

- decontamination procedures
- maintenance and its records
- availability of up-to-date instructions
- period and type of use
- information supplied to any discharged patients/users
- device identification
- passing on of manufacturer's instructions to end users
- contact details (users and healthcare establishment).

It is the responsibility of the end user to contact the HSE when these items are no longer required. It is

essential that all individuals are aware of the medical device/equipment management system and the part that they play within the system to ensure that medical devices/equipment are managed correctly.

Devices on loan from manufacturers should be subjected to acceptance testing by an adequately trained and appropriately qualified person. The history of the device should be taken into account. Equipment on loan from organisations with a quality assurance system for device management is likely to be safer and more reliable than from an uncontrolled system.

All equipment on loan from manufacturers should be subject to a written agreement which defines the device management requirements and responsibilities and liabilities. Delivery receipt and pre-use procedures for loan equipment should be the same as those for purchased equipment, unless otherwise specified.

Criterion 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 (IMB).

Guidance:

The HSE's Incident Management Policy and Procedure and Serious Incident Management Policy and Procedure were devised in 2008 in order to provide a standardised method for reporting and managing incidents in the organisation. These policies and procedures should be followed when reporting an adverse incident involving Medical Devices and Equipment. In addition, the Irish Medicines Board (IMB) should be notified in the case where the incident involved Medical Devices and Equipment. All incidents involving medical devices/equipment should be reported to the Clinical Indemnity Scheme (CIS) on the STARS web incident reporting system. The CIS also link with the IMB.

The role of the IMB is to protect and promote public health and patient safety. It does this by ensuring that the manufacture and use of medicines and medical devices/equipment meet appropriate standards of safety, quality, performance and effectiveness. For an up-to-date list of publications see our website www.imb.ie.

It aims to minimise the risk of new adverse incidents involving medical devices/equipment and reduce the risk of those that have already occurred from happening again.

Unless medical devices/equipment are managed proactively, the same types of adverse incidents happen repeatedly. Good medical device/equipment management will greatly assist in reducing their potential for harm.

Responsibility for minimising the risk arising from the management and use of medical devices/equipment is the responsibility of all staff in the HSE.

When should you contact the IMB?

- to report an adverse incident involving a medical device or piece of equipment before sending a medical device implicated in an adverse incident for investigation
- to obtain advice on decontamination or disposal, when the device manufacturer has ceased trading
- to seek advice on regulations affecting medical devices
- to seek advice on any other safety or quality aspects of medical device/equipment management or use.

Reporting an Adverse Incident

Manufacturers are obligated to report medical device incidents under SI No 252/1994.

The IMB provides guidance notes for health care professionals for reporting adverse incidents. The manufacturer of the device should also be notified of the incident. Information on the vigilance system for medical devices, including the responsibilities of the medical device manufacturer and the medical device adverse incident user report form, are available from the IMB medical devices department. See imb.ie

Information from adverse incident reporting indicates that the factors that have the greatest impact on the safety of devices involve the instructions issued by the manufacturer, their availability and clarity.

Other key safety factors include the design, the quality of training in the appropriate uses of devices and how well they are maintained and repaired.

The causes of incidents may include:

- inadequate instructions for use from the manufacturer
- poor training
- problems arising from the design or manufacturing process
- inappropriate local modifications or adjustments
- inadequate maintenance
- inadequate or inappropriate repairs or replacement parts
- unsuitable storage or use conditions
- use of obsolete information

In any situation where it is confirmed or suspected during normal usage of the product or equipment, that the product or equipment is defective either by design or manufacture or when an injury or near-miss has occurred during the product or equipment's use, direct adherence to the HSE policies associated with such incidents is mandatory.

Where a deficiency is either suspected or confirmed with a product or piece of equipment, full details must be notified promptly, via the MDEMC, to the Irish Medicines Board, who will advise and give guidance, as deemed necessary.

Criterion 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.

Guidance:

From time to time notices relating to the safety and/or quality of medicinal products and equipment are published by the Irish Medicines Board. (<http://www.imb.ie/EN/Safety--Quality/Advisory-Warning--Recall-Notices.aspx>)

These notices are classified under several priority related categories and may relate to human and veterinary medicines, or medical devices that may require certain action by the HSE and its facilities. The issues covered by these safety notices/alerts and notices will range from quality defect information and medicinal product safety information through to updated information on the appropriate usage of medicines or devices.

This document is designed to provide a mechanism to ensure that notices on the IMB websites or notices received from the Irish Medicines Board are dealt with appropriately and that HSE management can be satisfied that any associated patient safety risks are minimised or eliminated.

This document outlines the mechanism and indicates the designated responsible persons within the HSE facilities for:

- Receipt and recording of IMB Safety Notices/Alerts
- Distribution of IMB Safety Notices/Alerts to designated 'responsible persons' for action.
- Action by the designated 'responsible persons' within determined time frame
- Receiving and logging of actions taken.

In addition this document outlines the procedure for notifying the IMB, when products or equipment that is used within the HSE facility are suspected- or confirmed to be defective either by design or manufacture. The required actions are categorised under 4 headings namely:

- ***Immediate Action***
Used in cases where there is a risk of death or serious injury and where the recipient is expected to take immediate action on the advice.
- ***Action***
Used where the recipient is expected to take action on the advice, where it is necessary to repeat warnings on long standing problems , or to support and follow up safety information is judged to be beneficial.
- ***Update***
Used to update the recipient about previously reported incidents or series of incidents, possibly on topical or device group basis, and where further follow up safety information is judged to be beneficial.
- ***Information Request.***
Used to alert users about specific issues that may become a problem and where we are requesting feedback. These alerts may be sent out with additional questions to be completed.

Implementation of IMB Safety Notices/Alerts

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IMB will notify the Chair of the Medical Device / Equipment Management Committee (MDEMC) of the Safety Notice /Alert. NOTE: The IMB requests that the Chair of the Medical Device / Equipment Management Committee (MDEMC) notifies the IMB of any changes to contact details for the Chairperson as that person will be the main contact with the IMB.

When an IMB Safety Notice/Alert is downloaded by the Chair of MDEMC, whether electronically or in hard copy format, or when he/she has received the IMB Safety Notice/Alert via other means, the alert(s) is (are) recorded as received and assessed to determine the type of action(s) to be carried out and then forwarded by the Chairperson to the designated '**Responsible Person**' within the HSE facility for ensuring implementation of the action(s). A time frame for implementation of the advice contained in the alerts will be indicated.

Action by the designated 'Responsible Person'

The designated Responsible Person should ideally be the head of clinical engineering.

Upon receiving the IMB Safety Notice/Alert, the designated Responsible Person shall implement or arrange implementation of the IMB Safety Notice/Alert within the determined timeframe. Feedback to the Responsible Person is required in all cases within the designated timeframe. The timeframe for response will be logged and follow-up will ensue for any non-responders. The Responsible Person will advise the Chairperson, MDEMC of the following:

- acknowledgement that the IMB Safety Notice/Alert has been received by the Head of Clinical engineering/Responsible Person
- action(s)/implementation to be commenced as advised by the alert(s)
- action(s) completed.

Ideally this feedback should be entered on to a National Medical Device database such as the STARS website.

Completion timescales of actions

Immediate Action - Immediately

Action - 2 weeks from receipt of Alert.

Update – 3 weeks from receipt of Alert.

Information Request – 3 weeks from receipt of Alert.

The designated Responsible Person may be required to liaise with other clinical and non-clinical personnel and external vendors in ensuring the actions have been carried out prior to confirming to Chairperson, MDEMC of completion of action.

Criterion 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.

Guidance:

The HSE Quality, Safety and Risk framework outlines key areas that must be met in order to meet the criteria for risk management in the Quality and Risk Standard. The following questions are asked as part of the self-assessment for the Quality, Safety and Risk framework. See http://hsenet.hse.ie/HSE_Central/Office_of_the_CEO/Quality_and_Risk/Documents/HSE_companion_guide_V1_Feb_2009_.pdf for guidance on examples of verification.

1. Are arrangements in place to manage known high priority risk issues?**GUIDANCE**

Notwithstanding the need to systematically identify, assess and manage risks of all kinds, service providers should be able to demonstrate that they have systems in place to manage known high priority risk issues such as:

- Medical devices
- Waste management

High priority risk issues will typically have been previously identified from local experience and national initiatives. The risk register will also contribute to an understanding of local high priority risk issues.

2. Are staff-related occupational safety, health and welfare risks identified, assessed and managed and are arrangements in place to ensure the management of occupational health, safety and welfare?**GUIDANCE**

All staff-related occupational safety, health and welfare risks should be identified, assessed and managed in line with implementing the risk management process set out above. Appropriate systems and processes should be in place to ensure the management of occupational safety, health and welfare. The Health and Safety Authority's (HSA) Health Services Health and Safety Audit tool should be used to assist with implementing suitable systems.

3. Are environmental and fire safety risks identified, assessed and managed and are arrangements in place to ensure that environmental and fire risks are minimised through meeting legislative and mandatory requirements?

GUIDANCE

All environmental and fire safety risks should be identified, assessed and managed in line with implementing the risk management process set out above. Appropriate systems and processes should be in place to ensure that environmental and fire risks are minimised through meeting legislative and mandatory requirements. Be sure to seek the advice of competent environmental and fire safety professionals when determining risks and actions.

4. Is an ongoing programme of patient safety improvement in operation?

GUIDANCE

Achieving significant improvements in patient safety is currently seen as a major imperative for healthcare internationally. This is evidenced by the relatively recent establishment of the World Health Organisation (WHO) World Alliance for Patient Safety. All risks to patient safety should be identified, assessed and managed in line with implementing a robust risk management process defined by the above questions.

RESOURCES

- WHO World Alliance for Patient Safety - www.who.int/patientsafety/en/
- HIQA – www.higa.ie
- UK National Patient Safety Agency – www.npsa.nhs.uk
- USA Joint Commission - www.ccforpatientsafety.org/
- ECRI Institute – www.ecri.org
- Institute for Healthcare Improvement (IHI) - www.ihl.org/IHI/Topics/PatientSafety/
- US Department of Veterans Affairs National Center for Patient Safety - www.va.gov/ncps/
- US Agency for Healthcare Research and Quality - www.ahrq.gov/qual/

5. Are arrangements in place to ensure that Medical Device Alerts/Safety Notices are circulated to all relevant staff and are acted on?

GUIDANCE

A suitable policy and procedure should be in place to ensure that all alerts and safety notices are circulated to all relevant staff and, most importantly, are acted upon. Various software systems exist that enable this to be done efficiently.

6. Are incidents properly recorded and reported to management?

GUIDANCE

Refer to HSE incident management policy and procedure for detailed guidance.

7. Are incidents managed in accordance with an agreed policy?

GUIDANCE

There should be a locally agreed policy for incident management that takes cognisance of the HSE's overall incident management policy and procedure.

8. Are incidents rated according to impact and reviewed, where appropriate, to determine contributory factors, root causes and any actions required?

GUIDANCE

All reported incidents should be rated according to impact in order to determine what, if any, further action is required. The key to learning from incidents is 'root cause analysis' (sometimes termed 'systems analysis.' Refer to HSE guidance on root cause analysis for further information.

9. Are incidents subjected to periodic aggregate reviews to identify trends and further opportunities for learning, quality and safety improvement, and risk reduction?

GUIDANCE

All reported incident information should be aggregated to identify trends and further opportunities for learning, etc.

10. Are complaints, comments and appeals properly recorded and reported to management?

GUIDANCE

Refer to HSE guidance on complaints, etc.

11. Are complaints managed in accordance with an agreed policy?

GUIDANCE

This question relates to the management of the complaint subsequent to its being reported to management. There should be an agreed local policy for management of complaints that takes cognisance of HSE guidance.

In addition the following questions must be addressed in order to ensure that risks associated with Medical Devices and Equipment are being minimised:

- Are complaints associated with Medical Devices and Equipment rated according to impact and reviewed, where appropriate, to determine contributory factors, root causes and any actions required?
- Are complaints and comments associated with Medical Devices and Equipment subjected to periodic aggregate reviews to identify trends and further opportunities for learning, quality and safety improvement, and risk reduction?
- Where appropriate, are all claims associated with Medical Devices and Equipment recorded and analysed to identify opportunities for learning, quality and safety improvement, and risk reduction?

3.4 Capability

Criterion 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.

Guidance:

It is essential that the HSE ensures that the selection of medical devices for particular procedures can only be made by staff who are appropriately trained and qualified. However, the policy should not be so inflexible as to prevent any member of staff from choosing the most suitable device for the purpose.

This policy may also limit the range of devices that are allowed to be selected. This is because some devices, different models of infusion pump for example, may have a similar appearance but very different operating parameters. Serious incidents have occurred where substitution of the wrong model in error has led to dangerously inappropriate treatment.

Prescribing and fitting

Prescribing and supply or fitting of a device can take place in separate institutions and involve different people – prostheses are an example – and the fitter will sometimes need to refer patients back to the prescriber if the device proves unsuitable.

Ensuring that responsibility for choosing the most appropriate device is shared between relevant healthcare staff, the end user and the fitter can avoid these problems and reduce subsequent delays.

Administrative and technical support

Administrative and technical support can help to avoid hazards. Computer databases can build in certain safeguards in relation to safety for equipment, based on the information supplied by the manufacturers. This can assist prescribers by making limitations or restrictions in use available within the selection system. It can also monitor selection records for suitability. These medical device technologies databases should be managed by Clinical Engineering.

Criteria for choosing a device

Choose a device that best meets the requirements for the intended medical procedure and/or needs of the end user, while minimising the potential for misuse.

At times it may reduce initial delays to choose the 'best available' device from the available stock rather than the 'best' device providing that it meets the minimum required criteria and does not compromise the safety of the user. The most appropriate device can then be obtained and substituted when available.

Those responsible for selection need to have been trained and need ready access to information about the device, including:

- the manufacturer's description of the intended user, usage and the instructions for use
- safety issues and any limitations on use
- pre-use set up or testing requirements
- maintenance and cleaning or decontamination requirements.

Correct assessment

Assessment of the device and the end user are essential to ensure the correct device is issued.

In cases where a specific device would be unsuitable, because the user would not be able to operate it safely, a carer may assist the user. The device would therefore also have to meet the needs of the carer.

A department that does not employ specialist staff in all areas can request a specialist service to carry out assessments on its behalf.

Key points on prescription of devices

- All medical device and equipment prescribing decisions are made by staff who are appropriately trained and qualified, backed by appropriate administrative and technical support.
- Policies are in place to establish the range of devices available.
- Devices are chosen to best meet the requirements of the intended medical procedure or needs of the end user.
- Short-term loan/issue of a device should be considered to provide benefit to end users until the most appropriate device is available.
- The needs of the carer should be taken into account where appropriate.

Criterion 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.

Guidance:

All staff should be aware of the IMB reporting mechanisms as discussed in criterion 16 and the reporting requirements for STARS. See HSE Incident Management and Serious Incident Management Policies. Training on these policies should be in place for all staff involved in the reporting and investigation of adverse incidents involving Medical Devices and Equipment.

Criterion 21:

All professional users and technical supervisors are trained in the safe operation of Medical Devices and Equipment.

Guidance:

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Training is a key element in medical device safety. A training policy should be developed by the Medical Devices Management Committee. This will need to include:

- generic device management skills
- specific training for particular devices
- induction of new staff
- inclusion of agency and locum staff
- periodic review / retraining as required
- continuing professional development
- planned training before a new medical device is introduced to the organisation
- training for those involved in maintenance and repair services.
- Accurate and comprehensive training records pertaining to whom and when training was provided are created and maintained; this should also take into account any subsequent refresher training. This information should be retained in staff training files.

Healthcare professionals working for the organisation, as employees or contractors, have a professional duty to ensure their own skills and training are appropriate and remain up to date. The organisation's medical device/equipment training policy should take account of this and provide suitable support to its professional staff to facilitate appropriate training.

Specific training on particular medical devices/equipment should be based on the manufacturer's instructions.

Staff carrying out maintenance, repair, and/or decontamination will require additional technical information or training.

Points to consider:

- who should receive the training offered by the manufacturer or supplier?
- how will everyone else be trained, and by whom, and when?
- when is retraining indicated?
- have temporary or locum staff been trained?
- have on-call staff been trained?
- have you considered future training needs for when those trained directly by the manufacturer/supplier change jobs?
- how will training updates be managed for device/software upgrades?
- how will end users or staff in the community be trained?
- how will repair and maintenance service staff be trained (HSE employees)?

Professional users need to understand how the manufacturer intends the device/equipment to be used, and how it works normally, to be able to use it effectively and safely. Where relevant they should:

- be aware of differences between models, compatibility with other products and any contraindications or limitations on use
- be able to fit accessories and to be aware of how they may increase or limit the use of the device
- be able to use any controls appropriately
- understand any displays, indicators, alarms, etc.
- be aware of requirements for maintenance and decontamination, including cleaning, in

accordance with the manufacturer's and relevant local procedures

- be able to show end users how to use the device
- be aware of known pitfalls, including those identified in safety advice from the IMB, manufacturers and other relevant bodies
- be able to recognise device defects or when a device is not working properly and know what to do
- understand the importance of reporting device-related adverse incidents to the IMB and be familiar with the organisations' reporting procedure

Individuals providing repair and maintenance services need to be adequately trained and appropriately qualified. This applies to directly employed staff, contracted services or others. This should be reviewed by Clinical Engineering.

For simple mechanical devices a qualification at FETAC Level 6 may be appropriate. For more complex devices a qualification at HETAC Level 7 or above may be required. The level of qualifications and training required for each individual should be stipulated in all service contracts provided by external contractors or in house services. This should be reviewed by Clinical Engineering.

Documentation

Evidence that suitable instructions and training were provided will be needed for a number of reasons such as: 1. to provide assurance to management that all staff have appropriate training and 2. in the event of a legal case being brought. Users of equipment should be asked to sign statements confirming that they have received and understood written and/or oral instructions.

Details of training given should also be recorded by the head of each department. A simple test at the end of training to check that the information has been understood should also be included.

Apart from keeping records for the medical devices used by services the maintenance of training records for staff is essential. These should show that users:

- know how to use the device safely as directed by the manufacturer
- can carry out routine checks and maintenance according to the manufacturers instructions
- have been trained and had relevant refresher training.
- The line manager of the area in which the device is deployed is responsible for the maintenance and retention of these records as per the Safety Health and Welfare at Work Act 2005.

Criterion 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.

Guidance:

The need for training depends upon the specific device and can involve users, carers or staff:

- Will it be required for maintenance and repair staff, to enable them to carry out all aspects?

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- Will it be required for all anticipated users, carers or staff?
- Is the same model already in use and registered on a database for medical devices?
- If so, will refresher or update training be needed?
- If not, are new training and records needed?

End users need to understand the intended use and normal functioning of the device in order to use it effectively and safely. Where relevant, training should cover:

- any limitations on use
- how to fit accessories and to be aware of how they may increase or limit the use of the device
- how to use any controls appropriately
- the meaning of any displays, indicators, alarms etc., and how to respond to them
- requirements for maintenance and decontamination, including cleaning
- recognise when the device is not working properly and know what to do about it
- understand the known pitfalls in the use of the device, including those identified in safety advice from the IMB, manufacturers and other relevant bodies
- understand the importance of reporting device-related adverse incidents to the IMB.

3.5 Outcomes

Criterion 23:

There is demonstrable improvement in key performance indicators relating to Medical Device and Equipment Management

Guidance:

The Medical Devices/Equipment Management Policy should be audited on a yearly basis to demonstrate the criteria are met; in the event that criteria are not met, Quality Improvement Plans (QIPs) should be developed and implemented. These QIPs must then be monitored to ensure that there is demonstrable improvement in performance against the Policy.

Criterion 24:

The organisation participates in benchmarking its management of Medical Devices/Equipment.

Guidance:

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.

3.6 Monitoring and Review

Criterion 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

Guidance:

Monitoring performance on medical device management is essential to minimise or eliminate risks to patients and staff.

Services are required to conduct an assessment of their system in relation to compliance with the HSE's Medical Device and Equipment Management Standard and to put in place improvement plans where required.

Reports of audits conducted by the local Medical Device and Equipment Management Committees will be sent biannually to the Regional Medical Device and Equipment Management Committees who will aggregate the reports and send them to the National Medical Device and Equipment Management Committee on an annual basis.

The Standard contains a requirement for independent assurance 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. Independent assurance can be obtained internal to the HSE but external to the service or through an appropriate source external to the HSE, for example Health Information Quality Authority (HIQA).

When monitoring either in relation to assessment against the Standard or performance indicators have identified underperformance Quality Improvement Plans (QIPs) will be developed and systems put in place to ensure variances are addressed.

3.7 Independent Assurance

Criterion 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.

Guidance:

Independent assurance can be obtained internal to the HSE but external to the service or through an appropriate source external to the HSE. There will also be an 'external' component by organisations such as the Health Information Quality Authority (HIQA) who will set and monitor standards to ensure that robust systems are in place for the safe and effective management of Medical Devices.

4.0 References

- Safety Health and Welfare at Work Act 2005

<http://www.oireachtas.ie/documents/bills28/acts/2005/a1005.pdf>

- HSE Decontamination Standards

http://www.hse.ie/eng/Publications/services/Hospitals/HSE_Publications/Code_of_Practice_for_Decontamination_of_Reusable_Invasive_Medical_Devices_1.pdf

- National Finance Regulations

http://hsenet.hse.ie/HSE_Central/finance_Transformation_Projects/Financial%20Regulations/National_Financial_Regulations_-_PTP.pdf

- HSE Procurement

http://hsenet.hse.ie/HSE_Central/Procurement/HSE_Policies_Procedures/HSE_Procurement_Policy.pdf

- HSE Quality and Risk Standard

http://hsenet.hse.ie/HSE_Central/Office_of_the_CEO/Quality_and_Risk/Documents/OQR09_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/OOR006_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/SIMT01_Part_2_Serious_Incident_Management_Policy_and_Procedure.pdf

- HSE Medical Devices/Equipment Management Policy (incorporating the Medical Devices Management Standard)

http://hsenet.hse.ie/HSE_Central/Office_of_the_CEO/Quality_and_Risk/Documents/OOR030_HSE_Medical_Devices_Equipment_Management_Policy_and_Standard.pdf

IMB Guidance note 12, guidance for Class 1 Manufacturers regarding compliance with the requirements in accordance with SI No.252 of 1994 and directive 93/42/EEC

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

SN2003(09) Equipment Management: Some basic Principles of Equipment Management

SN2007(06) Medical Devices Recommended by Healthcare Institutions for use in a Community Setting

SN2006(03) the procurement and commissioning of Medical Equipment in Hospitals.

5.0 Appendices

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