Safeguarding public health

MHRA

Device Bulletin

Managing Medical Devices

Guidance for healthcare and social services organisations

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Contents

1 Introduction

1.1 Aims of the guidance

The purpose of this document is to outline a systematic approach to the purchasing, deployment, maintenance, repair and disposal of medical devices.

This document updates and replaces previous guidelines published in DB 9801 'Medical device and equipment management for hospital and community-based organisations' (including supplements 1 and 2) and also DB 2000(02) 'Medical devices and equipment management: repair and maintenance provision'.

It is intended primarily for people in hospital and community based organisations that are responsible for the management of medical devices, to help them set up systems that minimise risks associated with the use of those medical devices.

NB: For the purposes of this document, the term 'medical device' encompasses medical devices as legally defined in the Medical Devices Regulations [1], other medical devices and assistive technologies (examples given in **Table 1**).

This guidance aims to:

- provide balanced information for groups developing local policy
- identify relevant legislation
- address the strategies for ownership and use of medical devices
- help healthcare organisations meet the Healthcare Commission's core standards for the safe use of medical devices
- identify sources of additional guidance.

The main topics covered are:

- monitoring/audit
- reporting adverse incidents
- acquiring the most appropriate device
- acceptance procedures for newly delivered devices
- maintenance and repair
- training
- adequacy of manufacturer instructions
- prescribing the best device
- decontamination
- decommissioning
- disposal
- transfer of ownership
- legal liabilities.

Table 1 Examples of medical devices

Function	Examples
Diagnosis or treatment of disease	Anaesthetic equipment, catheters, diagnostic laboratory equipment, dressings, implants, scanners, surgical instruments, surgical gloves, syringes, X-ray machines.
Monitoring of patients	ECG, pulse oximeter.
Critical care	Baby incubators, blood-gas analysis, defibrillators, ventilators, pressure relief mattresses.
Improve function and independence of people with physical impairments	Communication aids, environmental controls, hoists, orthotic and prosthetic appliances, supportive seating and pressure care, walking aids, wheelchairs.
Community-based healthcare	Catheters, dressings, domiciliary oxygen therapy systems, glucose tests, pressure care equipment, syringes, urine drainage systems.
Emergency services	Stretchers, trolleys, resuscitators.

1.2 Role of the MHRA

The MHRA was formed in April 2003 from the merger of the Medical Devices Agency (MDA) and the Medicines Control Agency (MCA). Some guidance published by these former organisations remains current. For an up-to-date list of publications see our website.

The role of the MHRA 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 meet appropriate standards of safety, quality, performance and effectiveness.

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

The MHRA:

- investigates adverse incidents involving medical devices and equipment
- issues safety warnings
- provides advice and guidance on safety and quality issues
- acts as the UK Competent Authority, the regulator for the medical devices industry.

The primary causes of incidents with medical devices include:

- inappropriate management procedures
- inadequate instructions for use
- inadequate servicing or maintenance
- shortcomings in the design or manufacture
- lack of policies for disposal and replacement
- inappropriate use (including incompatible devices)
- inadequate training (staff and users/carers)
- incompatible ancillary equipment, such as leads, infusion sets
- inadequate documentation, such as missing service history or instructions for use.

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

Northern Ireland, Scotland, Wales
Responsibility for minimising the risk arising from the management and use of medical devices is as follows:

- Northern Ireland: Department of Health, Social Services and Public Safety
- Scotland: Scottish Executive
- Wales: National Assembly for Wales

In Northern Ireland, the NI Defect and Investigation Centre conduct incident investigations; in Scotland most are carried out by Scottish Healthcare Supplies; in Wales, the MHRA carry out most investigations on behalf of the National Assembly for Wales.

All these bodies co-operate closely with the MHRA, and issue similar safety publications, although often with different reference numbers.

1.3 When you should contact the MHRA

Contact the MHRA:

- to report an adverse incident involving a medical device or piece of equipment (see **section 2.6**)
- 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 management or use.

2 Systems of management

2.1 Management responsibility and policies

Responsible organisations should appoint a director or board member with overall responsibility for medical device management. There should be clear lines of accountability throughout the organisation leading to the board. These lines of accountability should be extended, where appropriate, to include general practitioners, residential and care homes, community based services independent hospitals providing services for NHS patients, managed care providers, PFI organisations and other independent contractors. It is important to establish who is accountable, and where there is a need for joint accountability arrangements.

The board should ensure that policies address:

- decontamination
- equipment life cycle
- procurement
- records
- adverse incident reporting
- actions required on MHRA's Medical Device Alerts and manufacturers' corrective notices
- training
- technical specifications
- regulatory compliance and related issues
- rationalisation to single models, where possible
- risk management
- equipment inventory
- manufacturer's instructions
- disposal.

2.2 Device management procedure

A device management procedure will help to ensure that risks associated with the use of medical devices will be minimised.

Responsible organisations should therefore set up and regularly review a device management procedure, to ensure that whenever a medical device is used, it is:

- suitable
- used in accordance with the manufacturer's instructions
- maintained in a safe and reliable condition
- disposed of appropriately at the end of its useful life.

The device management policy should cover the:

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

2.2.1 Record keeping

Good record keeping is essential for the safe management of medical devices. 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.

Ensure that your records provide evidence of:

- a unique identifier for the device, 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
- where it was deployed
- scheduled maintenance
- maintenance and repairs
- the end-of-life date.

Your records should also show that users:

- know how to use the device safely
- can carry out routine checks and maintenance
- have been trained and had relevant refresher training.

Note: All of the aspects of medical device management covered within this guidance document will require some degree of record keeping. The records should be maintained within one system wherever possible. For non-centralised records ensure that there are suitable cross references between the various record systems.

2.3 Deployment

Systems for managing medical devices need to take account of the different ways that the devices 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 hospital trusts

- issued on long-term loan to an individual user for their use only: examples include artificial limbs and wheelchairs.

2.3.1 Department control

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 management system and the part that they play within the system to ensure that medical devices are managed correctly.

In many trusts some important aspects of equipment management, such as record keeping and scheduling maintenance, are often controlled outside of a department. It is essential that systems and procedures allow for the relevant details to be passed on to those responsible for the management records for a particular piece of equipment

2.3.2 Equipment stores, pools and libraries

In the community routine device 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 management system and the part that they play within the system to ensure that medical devices are managed correctly.

2.3.3 Devices issued individually on long-term loan

Some device management will transfer either to the individual end user or to a healthcare worker or other carer. 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).

The responsible organisation remains accountable for collecting these items when they are no longer needed. It is essential that all individuals are aware of the medical device management system and the part that they play within the system to ensure that medical devices are managed correctly.

2.4 Putting policies into practice

2.4.1 Medical devices management group

Healthcare organisations should establish a medical devices management group to develop and implement policies across the organisation. This group should review the policies at least once a year and submit regular audit reports to the board. It will also:

- improve communication about medical devices within the organisation
- gain the agreement of clinicians, technical staff and users in relation to any proposed changes
- reduce confusion about who is responsible for device management tasks, training and safe device operation.

Membership of the group will depend on the requirements of each healthcare organisation, but will need to be broad enough to address all the listed policy areas. It will need appropriate representation from among clinical, management, pathology, infection control, engineering, users, maintenance and purchasing. The group should also include the MHRA medical device liaison officer to ensure that adverse incident reporting and MHRA information and advice are implemented. Specialist sub-groups may be needed to make recommendations to this group.

2.5 Monitoring and audit

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

Much of this activity will be internal audit, as part of the organisation's governance arrangements, but there will also be an 'external' component by organisations such as the Healthcare Commission, which will include the management of medical devices as part of its assessment of organisations (see the Healthcare Commission's 'Assessment for Improvement' [2]).

Healthcare professionals working for the organisation, as employees or contractors, have a professional duty to ensure their own skills and training remain up to date (see **section 5**). The healthcare organisation should ensure that continuous professional development and training activities include the safe use of medical devices during annual staff appraisal.

2.5.1 Internal audit

Healthcare organisations will need to review their policies and systems for managing the use of medical devices regularly. This internal audit should performed by the medical devices management group on a regular basis. An audit report should be submitted to the board at least annually.

This audit should examine the organisation's policies and procedures for the safe acquisition, use, maintenance and repair, decontamination and disposal of medical devices against the checklists set out in this guidance.

2.5.2 External audit

The safe management of medical devices is an essential element of the Department of Health's performance framework for healthcare organisations. See the Department of Health's document 'Standards for Better Health' [3].

All healthcare organisations will need to comply with the three 'core standards' that relate to the safe use of medical devices, namely:

- C1b 'ensure that patient safety notices, alerts and other communications concerning patient safety which require action are acted upon within the required timescales'
- C4b 'all risks associated with the acquisition and use of medical devices are minimised'
- C4c 'all reusable medical devices are properly decontaminated prior to use and that the risks associated with decontamination facilities and processes are well managed'.

The Healthcare Commission will be undertaking regular audits and inspections of healthcare organisations and will expect that the MHRA guidance on the safe use of medical devices has been followed. Guidance on assessment can be accessed on their website (www.healthcarecommission.org.uk).

Medical Device Alerts are disseminated to healthcare organisations by the Department of Health's Safety Alert Broadcast System (SABS). SABS notices include deadlines for action by trusts. The performance against these deadlines is audited by strategic health authorities.

2.6 Reporting adverse incidents

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 prepared.

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
- inadequate end of life or scrapping information.

The first Medical Device Alert issued by the MHRA in each year (for 2006 it is MDA/2006/001 [4]) has details of how to report adverse incidents.

Key points for systems of management

- There is a system in place, which ensures that all risks associated with the acquisition, use, reprocessing, maintenance, decommissioning and disposal of medical devices are minimised.
- Board level responsibility for medical devices management is clearly defined and there are clear lines of accountability throughout the organisation leading to the board.
- There is a broad based medical devices group that includes appropriate representation from among clinical, management, pathology, infection control, engineering, users, maintenance and purchasing staff.
- There is a comprehensive organisation-wide policy on the management of medical devices including acquisition, deployment, use, monitoring, maintenance and disposal that takes into account MHRA guidance.
- There is a record of medical devices and equipment to facilitate a systematic approach to medical devices management and to help establish the relevance of any particular Medical Device Alert or manufacturer alert to the organisation.
- Key indicators capable of showing improvements in medical devices management and/or providing early warning of risk are used at all levels of the organisation, including the board.
- The effectiveness and usefulness of these indicators are reviewed regularly.
- The system in place for medical devices management, including risk management, is monitored and reviewed by management and the board to see if it can be improved.
- The board seeks independent assurance that the medical devices management policy is appropriate and effective and that the necessary level of controls and monitoring are in place.
- All loaned medical devices and items of medical equipment are collected when no longer needed by the user.
- All adverse incidents involving medical devices are reported in accordance with the first Medical Device Alert issued by the MHRA each year (for 2006 this is MDA/2006/001 [4]). A complete record of advice and recommendations issued by the MHRA and the actions taken is maintained.
- Medical Device Alerts and other MHRA safety guidance are distributed to the appropriate people in the organisation.
- The actions contained in Medical Device Alerts are implemented and other MHRA guidance is followed.
- Independent contractors using medical devices have appropriate risk management systems in place and are aware of the overall policy and systems for medical device management within the healthcare organisation.

3 Acquiring equipment – safety, quality and performance

3.1 Acquisition policies

The medical devices management group should ensure that local policies for the acquisition of medical devices address safety, quality, and performance as well as all aspects of the acquisition cycle (see **section 3.5**).
Policies should include the need to:

- establish advisory groups to ensure that the agreed acquisition requirement takes account of the needs and preferences of all interested parties, including those involved in use, commissioning, decontamination, maintenance and decommissioning
- ensure that the selection process takes account of local and national acquisition policies (e.g. PASA), whole life costs, the method of acquisition (see 3.2 below) and the agreed acquisition requirement.

3.2 Methods of acquisition

Purchasing and leasing are the most common methods of acquisition, but there are others. Examples are loaned equipment from manufacturers or other healthcare organisations and in-house manufacture.

3.2.1 Loan

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.

In all cases it must be clear at the outset whose responsibility it will be should any problems arise. Consult the medical devices management group before any device loan is arranged.

3.2.2 In-house manufacture

Many larger biomedical engineering departments design and build medical devices. If the devices are supplied to another legal entity then the Medical Devices Regulations [1] apply.

Organisations that manufacture medical devices but do not place them on the market (i.e. they are used only within the organisation or legal entity) should, as a matter of best practice, ensure that those devices are manufactured in accordance with the Medical Devices Regulations [1].

3.2.3 Modifying and changing use

Modifying existing devices or using them for purposes not intended by the manufacturer (off-label use) has safety implications. It may also count as manufacture of a new device under the Medical Devices Regulations [1]. 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 organisations risk management policy and procedures.

3.3 Factors to consider before acquisition

The selection process should consider:

- the agreed acquisition requirement (see **section 3.1**)
- fitness for intended purpose/application
- safety and performance information from the manufacturer (including detailed specifications of the medical device) compared against the performance specifications contained within the acquisition requirement
- rationalising the range of models versus diversity
- availability of manufacturers' instructions
- maintenance support services, where applicable
- availability of training
- availability of technical support and/or where applicable training for local service support
- decontamination and disposal procedures, including compatibility with the local decontamination processes already in use e.g. can it withstand the parameters used
- installation requirements and commissioning procedure (see **section 4.3**)
- support services
- reliability and previous performance
- lifetime costs
- warranty details
- other support facilities.

3.3.1 Fitness for intended purpose/application

The device chosen must meet the responsible organisation's performance specification, but unnecessary features may be a disadvantage. Points to consider are:

- whether the device is compatible with other devices and any medicinal products that it is likely to be used with
- whether the manufacturer intends the device to be used by those who will be using it
- whether the device is appropriate for the intended environment.

3.3.2 Safety and performance

- Is the device CE-marked?
- Is there any local knowledge or past history of problems with the device or type of device?

- Do MHRA safety publications, manufacturer's advisory notices or other relevant publications identify issues related to the device?

3.3.3 Rationalising the range of models versus diversity

Having a variety of models for the same purpose can increase the risk of operator confusion, leading to misuse and complicating training requirements. Restricting purchase and stock holding to one type of device will reduce these risks.

On the other hand, reliance on a single model can be problematic. The chosen model may prove unreliable, or be subject to a manufacturer's recall. Sooner or later the manufacturer is likely to withdraw the old model, as designs improve or the manufacturer may even cease trading.

There is a particular risk of operator confusion with devices that are superficially similar but have different applications and limitations. If there is a need for different facilities or functions (e.g. between infusion pumps for theatre and ITU) it may be better to choose completely different models.

3.3.4 Maintenance support services

Points to consider:

- can the desired service provider maintain the device?
- how will the proposed contract or service level agreement deal with continuity of care? e.g. on site repair if needed
- is alternative equipment available to cover periods when a device is being repaired or serviced?
- are response times appropriate and guaranteed?
- what are the proposed intervals between service, frequency and complexity of checks and calibrations needed during operation?
- are spares readily available and for how long?
- is service support guaranteed, and for how long?
- what information is available e.g. circuit diagrams, preventive maintenance schedules, trouble shooting, repair procedures, parts list, special tools list?

3.3.5 Training

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

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

3.3.6 Technical support

- Does the manufacturer give free access to technical advice?
- Is there a 24-hour helpline?

3.3.7 Support services

- Is the installation to be carried out by manufacturer/supplier?
- If so, what building and utility services are required?
- Is special decontamination, calibration or other associated equipment needed?

3.3.8 Reliability and previous performance

- Have other users experienced problems and failures?
- Can the manufacturer provide evidence of reliability from other responsible organisations?

3.3.9 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.

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.

3.3.10 Clinical investigations involving non-CE-marked medical devices

The organisation's medical device management policy should include situations where that organisation agrees with a medical device manufacturer to take part in a pre-CE marking Clinical Investigation of a new medical device. That policy should include consideration of the following factors:

- has the MHRA issued the manufacturer with a letter of no objection?
- has the relevant ethics committee given approval for the study?
- have the relevant healthcare professionals received adequate training?
- are there arrangements in place to segregate the investigational devices from other CE-marked medical devices and to ensure that the only healthcare professionals to use the investigational device are those named as clinical investigators in the application to the MHRA?

- have patients who agreed to take part in the investigation only done so after providing fully informed consent?
- has provision been made, where relevant, for decontamination, reprocessing, servicing, maintenance and disposal in conjunction with the sponsoring manufacturer?

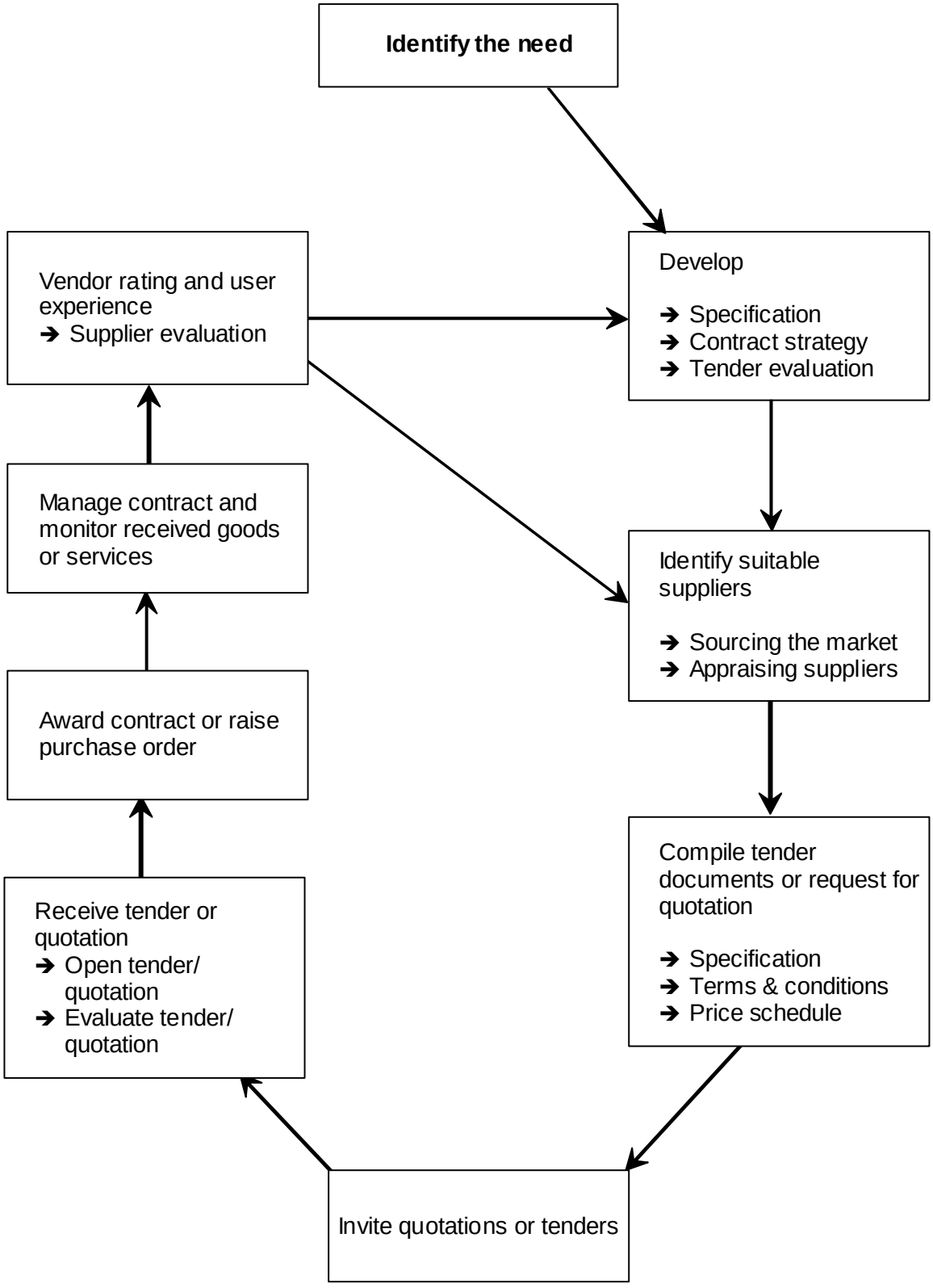
3.4 Documentation and monitoring

Once the selection process has identified the most suitable medical device, then the final terms and conditions covering all aspects of the acquisition should be agreed by all interested parties and documented. Only then should the contract be awarded, the purchase order raised or the acquisition otherwise be cleared to proceed.

The acquisition should then be managed in accordance with the terms and conditions agreed and the results of the acquisition and usage experience fed back into any subsequent acquisitions.

3.5 The acquisition cycle

Figure 1 Flow chart of the acquisition cycle



Key points for acquiring equipment

- Local acquisition policies to be established.
- The medical devices group to be involved in establishing the policy and process.
- The relevant advisory groups to be established and consulted.
- Safety, quality and performance considerations to be included in all acquisition decisions.
- The recommendations of the MHRA and other appropriate bodies have been followed for 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.
- Model ranges to be rationalised where possible.
- Technical support, maintenance and repair systems and timescales to be included.
- Training and support services to be included where appropriate.
- User experience to be fed back into the policy, process, future acquisitions and advisory groups.

4 Delivery of a new piece of equipment

4.1 Importance of acceptance checks

Responsible organisations should check that the specification of newly delivered equipment matches the purchase order detail or tender specification.

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 have been delivered in good condition and, where relevant, in good working order.

The procedure for managing new equipment should also 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.

4.1.1 Record keeping

The responsible organisation should keep records of the order, the results of the delivery inspection, the individual equipment or batch identifier and any safety or functional tests.

It should always be possible to find out who carried these out, when and how, because:

- health and safety inspectors will expect records to be available
- a defence 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.

4.1.2 Skills required for checks and tests

Table 2 and Table 3 give basic guidance on what checks and tests should cover, and the skills required to carry them out. Checks and tests can only be effective if everyone carrying them out has appropriate training.

Table 2 Basic guidance on delivery checks

	Delivery check	**Skills required**
Paperwork/ database	• Is the device compatible with specification set out in the purchase order? • Have the user, repair and maintenance information, compliance and calibration certificates, test results been included, where relevant? • Add device details and serial number on to device management records • Does the device (or any component part or accessory) need decontaminating before first use? • are the instructions for use appropriate?	Familiarity with: • Ordering system • Inventory system • Names and appearances of common medical devices • Medical device documentation (instructions for use, certificates etc.) • Serial numbers and model identification codes.
Visual inspection	• Is the outer packaging intact and undamaged? • Is there any damage apparent to the device on inspection? • Are there case markings, CE marking, notified body number, electrical class, quantity in pack, storage information for unopened pack etc.?	• Knowledge of areas to check for damage. • Familiarity with: > the appearance of product in good condition > common defects.

Additionally, the manufacturer's instructions may specify particular testing, calibration or adjustment before a medical device is used for the first time. It may also be desirable to generate baseline data for comparisons during subsequent maintenance.

Table 3 Basic guidance on safety and calibration checks

	Safety and calibration checks	Skills required
Functional check Note: this may require more extensive checks by specialist staff for complex or specialist equipment.	• Does the device function in line with the manufacturer's information? • Are accessories/parts included and compatible? • Do indicators and displays function correctly in line with the manufacturer's information when powered up?* • When powered up, does the device start when it should and do the dials and switches do what they say?*	For some devices the skills required will be little more than basic training to allow the manufacturer's information to be followed. In cases where the manufacturer's instructions specify specialist assembly or manipulation, familiarity with the functions of the device and its components and accessories will be required.
Electric (basic safety)	Are the mains leads, plugs and other connectors undamaged?	Training in visual electrical safety inspection techniques.
Calibration and measurement	Where appropriate, use test device to check: • Accuracy of physiological measurements. • Dose delivery.* • Energy delivery.* • Accuracy of other outputs.*	Tests should be carried out by an adequately trained and appropriately qualified person.

*only for active devices

4.1.3 Safety test limits

Pre-use tests should not exceed the bounds of normal use:

- disassembly should be restricted to what is necessary for normal use and cleaning
- currents or voltages applied during tests should not exceed those occurring in normal use.

Any test in addition to those intended by the manufacturer and involving an abnormal stress, such as loading a hoist above its stated maximum working load, carries an unacceptable risk of causing permanent damage. It should not be carried out.

4.1.4 Manufacturer's own testing

Some responsible organisations may wish to use data generated by the manufacturer rather than do their own tests. The manufacturer must give them adequate documentation of the tests and their results.

Before relying on the tests and results provided by a manufacturer ensure that any tests were carried out on the actual product in question, and are not just sample data.

4.2 Special considerations

4.2.1 Risk assessment before first use

Some products should be risk assessed before first use (Table 4).

Table 4 Equipment requiring risk assessment before first use

Category	Examples
Medical devices manufactured outside the scope of the Medical Devices Regulations.	• Purchased by an individual outside EU. • In-house manufacture.
Equipment which has, or may have, been used before.	• 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.	• Custom-made for a named patient. • Under clinical investigation.

Risk assessment may mean local testing and the issue of a local safety certificate. A local safety certificate is intended to:

- confirm that a device is safe and effective
- set any necessary limits on its use.

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.

The medical device 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.

4.2.2 Devices on loan from manufacturers

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 in this written agreement.

4.2.3 Home use

Where the ownership and management of the device remain with the supplier, such as enteral feeding pumps, the manufacturer's pre-dispatch tests combined with simple pre-use checks by those responsible for the care of the end user in the community (e.g. community nurse) should provide adequate safety assurance. In this situation, record-keeping is the supplier's responsibility with input from the end user as appropriate. For

devices owned by healthcare services and loaned to end users in the community for use at home the responsibility for ensuring that the device is delivered and is safe to use is the responsibility of the healthcare service. However, this may include an agreement for the end user to carry out basic assembly or safety checks before use.

4.3 Using equipment for the first time

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.

4.3.1 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:

- 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.

Under the Medical Devices Regulations [1], 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.

A designated member of staff should oversee the commissioning process, and take responsibility for deciding that it has been completed satisfactorily.

4.4 Legal requirement for electrical safety testing

The Electricity at Work Regulations (EWR) [5] (under the Health and Safety at Work etc Act 1974 (HASAWA) [6]) came into force in April 1990. They form the basis of programmes used by hospital estates departments for the regular electrical testing of portable electrical equipment.

HASAWA imposes a duty on employers to provide:

- ‘plant and systems of work that are, so far as is reasonably possible safe and without risks to health’
- ‘such information, instruction, training and supervision as is necessary’.

The EWR state that ‘no electrical equipment shall be put into use when its strength and capability may be exceeded...’ and that ‘all systems shall be maintained so as to prevent, so far as is reasonably practicable, danger’.

There is no specific legal obligation, or even guidance, requiring responsible organisations to carry out any particular test, but there is a general duty to take necessary steps to protect staff from danger.

Responsible organisations should ensure that they have implemented electrical safety testing procedures to comply with this legislation. These include pre-use testing of new devices in addition to subsequent maintenance tests. Note: the tests listed in product safety standards, such as IEC 60601-1 [7], are designed for type-testing and may damage the device under test hence they are not suitable for pre-use or maintenance tests.

For less complex equipment bought with an adequately specified purchase order or tender system, pre-use testing may not be appropriate. Organisations may, however, wish to carry out random testing of samples at the delivery stage, as well as subsequent periodic checks.

Key points for delivery of a new piece of equipment

- Newly acquired equipment matches the acquisition specification and is undamaged, and accompanied by all the necessary information and documentation.
- The appropriate acceptance checks and tests have been carried out in accordance with risk assessment and legal requirements.
- Where required medical devices have been appropriately installed.
- Details of the equipment and the manufacturer’s instructions have been entered into the appropriate equipment monitoring and tracking systems.
- Training needs have been identified and acted on.
- For reusable devices, maintenance has been scheduled.

5 Training

5.1 Policy on training

Training is a key element in medical device safety. A training policy should be developed by the medical devices management group. This will need to include:

- generic device management skills
- specific training for particular devices
- induction of new staff
- inclusion of agency and locum staff and contractors
- 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.

Note: Interactive training on the general principles of using medical devices safely is also available from the MHRA website.

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 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 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?

5.2 Training for professional users

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 MHRA, 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 MHRA and be familiar with the organisations' reporting procedure (see **section 2.6**).

5.3 Training for end users

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 MHRA, manufacturers and other relevant bodies
- Understand the importance of reporting device-related adverse incidents to the MHRA (see **section 2.6**).

5.4 Training for repair and maintenance service providers

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

For simple mechanical devices a qualification at NVQ level 2 may be appropriate. For more complex devices a qualification at NVQ level 3 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.

5.5 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. A simple test at the end of training to check that the information has been understood should also be included.

Key points for training

- There is an organisation wide policy on training about the safe use of medical devices.
- Staff and users are made aware of, and where necessary, trained in adverse incident reporting requirements for medical devices.
- All professional users are trained in the safe operation of medical devices.
- All end users are given appropriate training in the safe and effective use of medical devices.
- All professionals and contractors are trained in the safe use of medical equipment.
- Staff and contractors involved in providing maintenance and repairs are adequately trained and appropriately qualified.
- Independent contractors using medical devices have appropriate risk management systems in place.

6 Instructions

6.1 The importance of effective instructions

Good clear instructions have a crucial role in the safe and effective use of equipment. The Medical Devices Regulations [1] stipulate that the manufacturer is responsible for supplying appropriate instructions, taking into account the knowledge and training of the intended user(s).

Any shortcomings in the instructions should be reported to the MHRA as an adverse incident (see **section 2.6**).

It also is a requirement of the Medical Devices Regulations [1] that, where the device is reusable, information on the appropriate processes to allow reuse must be provided by the manufacturer. This information shall contain information on cleaning, disinfection and/or sterilization processes for that device. If appropriate, it should also include the number of times the device can be re-sterilized 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.

Example 1 Problems with a near-patient testing device
A known diabetic was admitted to a hospital A&E department with signs and symptoms of diabetic keto-acidosis. The patient's blood glucose was measured at the point of care using a blood glucose meter. A separate sample sent to the hospital laboratory gave a very different result. The hospital reported the inadequate performance of the ward-based meter to the MHRA.

A review of the manufacturer's instructions for the meter revealed several contra-indications for use, including keto-acidosis of which the professional users were unaware.

Blood glucose meters may be used for the sole diagnosis and treatment of certain clinical conditions. In all cases professional users should be aware of the manufacturer's instructions and any contraindications. Such information should be incorporated into training for all staff involved in blood glucose measurement outside the laboratory – this is a case when instructions need supplementing with training.

6.1.1 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.

6.1.2 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.

6.2 Instructions for the 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 lay the provider open to legal liability under:

- the Consumer Protection Act 1987 [8] (in the case of a medical device)
- the General Product Safety Regulations 2005 [9] (in the case of a consumer product not covered by other specific legislation)
- the common law of negligence.

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.

Instructions may need to be written locally to cover whole systems where devices are used together with other equipment such as connecting a blood analyser to a computer to permit automatic updating of patient records.

If responsible organisations draft their own instructions to supplement the manufacturer's instructions, consider obtaining feedback on their accuracy and suitability from the manufacturer before issue.

Table 5 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.

Example 2 Home dialysis
Patients using peritoneal dialysis equipment at home need more comprehensive backup than can be provided by written instructions. A 24-hour helpline gives access to expert advice, and home dialysis nurses can be called out to help in the patient's home.

6.2.1 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. A simple test at the end of training to check that the information has been understood should also be included.

Example 3 Attempt to attach instructions permanently to a device
A community store produced instructions on printed plastic cards which were clipped to hoists with a key ring. They were, however, generally missing when the hoists were returned. Ask end users not to remove the instructions, or make them very hard to remove.

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.
- 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.
- Any manufacturer's instructions considered to be inadequate/ineffective, should be reported to the MHRA (see **section 2.6**).

7 Appropriate prescription of devices

7.1 Policies

It is essential that the healthcare organisation 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.

Example 4 Selection of wheelchairs
Some departments may have guidelines indicating that people who are visually impaired or who have severe epilepsy may be unable to use powered wheelchairs safely. But guidelines need to take account of the benefits, the individual circumstances, diagnosis and prognosis, so that particular end users, who could in fact use the powered wheelchair safely, are not unfairly denied.

7.1.1 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.

Example 5 Therapist and technician jointly decide on the best chair raiser
The therapist recommends chair raising blocks for somebody assessed in a day centre. But she has not visited the person's home, so does not specify the particular make of block. A technician visits the persons home with two or three different types of block, and can therefore decide exactly which make of block can be used safely with the particular chair in question.

7.1.2 Administrative and technical support

Administrative and technical support can help 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.

Example 6 Computer system picks up mistakes
The computer tracking system in a community store logs the manufacturer's maximum weight capacity for particular types of equipment, such as hoists or commodes. When an equipment request is input by the prescribing professional directly or via an administrative officer, the system asks for the proposed user's weight. The request will not be accepted if the user's weight exceeds the stated maximum.

7.2 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.

7.2.1 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.

Example 7 Support seating for severely disabled children
The prescription of the wrong equipment for severely disabled children can have permanently detrimental effects on the child, causing or worsening postural problems, skeletal deformity, etc.

Transfers of the user to and from the seating, adjusting the seat and transport are all major points that may require input from the user's carer(s).

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.

8 Maintenance and repair

8.1 Management policy for medical devices

The organisation's medical device management policy must cover the provision of maintenance and repair of all medical devices, including reconditioning and refurbishment.

This includes:

- 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.

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.

8.1.1 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.

8.1.2 Reporting adverse incidents

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

Information on adverse incidents and how to report them to the MHRA can be found in **section 2.6** and on the MHRA website (www.mhra.gov.uk).

8.1.3 Decontamination

Items subject to inspection, maintenance, repair or disposal should be decontaminated beforehand (see **section 9**).

8.2 Choosing appropriate maintenance and repair services

The Medical Devices Regulations [1] require a manufacturer to provide:

> 'all the information needed to verify whether the device can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the device operates properly and safely at all times'.

The following organisations and individuals can have a role in ensuring that medical devices are adequately maintained and repaired:

- manufacturer service organisation
- authorised service agents
- generic service providers
- third party service providers
- in-house maintenance departments
- end users.

The responsible organisation should carry out a risk-benefit analysis before finalising the specification of any maintenance and repair services. Cost alone should not be the determining factor.

Where available use a service provider who complies with relevant quality system standards, such as BS EN ISO 13485:2003 [10] or BS EN ISO 9001:2000 [11]. These standards ensure their work is consistently of the nature and quality intended. (Also see **section 8.3.1**).

A manufacturer may wish to supply and maintain equipment exclusively to guarantee the standard of repair. Alternatively, a manufacturer may stipulate strict criteria on the training, equipment and resources of any third party repairer.

Consider only those service providers with access to the necessary equipment and up-to-date and detailed maintenance records, otherwise they may not be able to carry out the tasks safely and effectively.

The type and detail required will vary with the type of equipment and may include:

- calibration
- preventive maintenance
- trouble-shooting
- full details of the repair and maintenance procedures and spare parts
- consumable materials, such as adhesives or thread locking compounds
- special tools and methods, together with details of the equipment calibration, where necessary
- availability of diagnostic software.

Consider the track record of the service provider. How quickly can they provide a service? Will they loan equipment whilst maintenance or repair is being carried out?

Table 6 Comparison of in-house maintenance with an external provider

Maintenance/ repair organisation	Possible advantages	Possible disadvantages
Outside organisations	• Predictable costs. • Possible to specify response times. • Possible to specify equipment down times.	• Possibly hard to maintain fast response cover for critical care or high dependency breakdowns. • Equipment may need to be sent away for repair and servicing. • Equipment loans may be required.
In-house	• Fast response possible for breakdowns. • On site repairs can lead to short down times. • May be less costly for a given level of service.	• Hard to maintain adequate stocks of spare parts across a wide range of devices. • Special tools and test equipment may not be available. • Specialist training costs can be high. • Manufacturers sometimes reluctant to provide training.

Table 7 Comparison of third party with a manufacturer's servicing organisation

Maintenance/ repair organisation	Advantages	Disadvantages
Manufacturer	• Same build standard as original device, with modifications and updates incorporated. • Assured access to spares. • Remote diagnostics via computer network sometimes available. • No problems with warranty/liability. • Availability of training for professional users.	• Contracts with many separate manufacturers need to be negotiated and updated. • Quality control must be monitored. • Response times may be long, depending on the contract. • Users may need long lists of helpline numbers.
Independent third party	• Often cheaper than manufacturer. • Possible to have an on-site engineer to cope with breakdowns. • Fewer external organisations to deal with.	• May only be able to cover certain devices. • Some devices may be excluded due to lack of commercial advantage. • Manufacturers may be reluctant to train staff. • Possible lack of manufacturer's information.

8.3 The service contract

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 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.

Take specialist advice in drawing up contracts, where specific legislation covers the process e.g. the radiation protection adviser in the preparation of

service contracts for diagnostic X-ray equipment, as required by the Ionising Radiation Regulations 1999 [12] and for hoists or lifting equipment the Lifting Operations and Lifting Equipment Regulations 1998 [13]. (See **section 11** for other examples of legislation).

Guidance on a range of repair and maintenance contracts is available through the NHS Purchasing and Supply Agency (PASA).

8.3.1 Training and experience of repair and maintenance staff

Health and Safety law 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). NVQ level 3 for the maintenance and repair of medical equipment are already available and NVQ level 2 are being compiled during 2006. NVQs should be considered when establishing minimum training requirements.

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.

Example 8 Hazards of inadequate training

Adequate training, even in simple tasks, avoids potential injury to patients. The legend in a generator control desk button was replaced in the wrong direction when the service provider changed a bulb. The legend showed the X-ray beam orientation as horizontal rather than vertical. A patient was subsequently set up for an X-ray under automatic exposure control with the incorrect receptor module selected on the generator.

An anaesthetist checked an anaesthetic machine that had just been serviced before starting an operating list and discovered that the machine's oxygen and nitrous oxide pipes had been transposed. The service engineers who carried out the service had not been sufficiently trained.

After a series of adjustments by a service provider, a tilting X-ray table collapsed. Although experienced in maintenance procedures generically, experience and training did not cover the adjustments being attempted.

All service staff should be adequately trained and have sufficient work experience of the devices they repair and maintain.

8.3.2 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.

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.

8.3.3 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.

8.4 Planned preventive maintenance

The frequency of servicing should be based on the manufacturer's recommendations 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 8 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	• Is the device clean? • Does it need decontaminating? • Note settings of controls. • Inspect each element in line with manufacturer's instructions.
Parts replaced	• Note each item/part to be replaced. • Record each items/part replaced, including details of source manufacturer and method of fitting.
Calibration	• 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.
Return-to-use	• 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.

Example 9 Wheelchair maintenance requires particular consideration

There must be a policy for wheelchair maintenance used for those used in hospitals (e.g. porters or wards) and on loan to people in the community. Recommended periodic servicing and testing will not only vary between different types of wheelchair (e.g. manual or electric), but also on the type of usage and the user. A policy of checking every wheelchair at the same fixed interval is therefore unlikely to be appropriate. Some users spend 18 hours a day in their wheelchair, but only ever move a short distance, whilst others use their wheelchairs very frequently in different environments and others only use them occasionally for short periods.

8.4.1 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 MHRA, such as Medical Device Alerts.

8.5 Spare parts and other components

There are several sources of spare parts:

- device manufacturer
- other manufacturers
- responsible organisation
- service provider
- pre-used.

8.5.1 Quality and compatibility with the device

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 should 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.

8.5.2 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.

8.5.3 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.

8.5.4 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 should therefore have all the necessary testing, measuring, and repair equipment and ensure that this is adequately maintained and calibrated:

- current certificates of calibration should be maintained for all test and repair equipment that has a measuring function
- calibration should be traceable to national and/or international standards
- records should 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.

8.6 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
- contacting the relevant servicing organisation.

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.

8.7 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. Decisions will also depend on the level of service the NHS service wishes to provide for its patients and any associated costs for re-arranging clinic appointments, etc.

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.

8.7.1 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. 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.

8.8 Legal liabilities

The responsible organisation should take all reasonable steps to ensure that equipment is repaired and maintained appropriately. 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 malfunctions after repair or maintenance and leads to the death or serious injury of a user, the responsible organisation and the repair service provider are far more likely to be held liable for the injuries caused if the device was not repaired in accordance with the manufacturer's instructions.

If a device 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 law and civil liability should a user or member of staff die or sustain personal injury or damage as a result.

Where the repair is extensive and modifies the device in a way not intended by the manufacturer, the responsibilities of the 'manufacturer,' as defined in the Medical Devices Regulations [1], may apply to the responsible organisation. This is also the case if the responsible organisation subcontracts extensive modifications.

Responsible organisations that modify devices and subsequently transfer them to another legal entity, such as another NHS trust, will also need to comply with the Medical Devices Regulations [1].

8.8.1 Pertinent legislation

Particular types of devices and equipment are covered by legislation, and this may affect their repair. Health and safety legislation usually refers to the responsibilities of the employer, rather than the term 'responsible organisation' used throughout this bulletin. See **section 11** for a list of relevant legislation.

8.9 Insurance

The responsible organisation should ensure that both it and any subsequent service provider has adequate insurance in place.

8.9.1 Indemnity

Without prejudice to its liability for breach of any of its obligations under the contract the contractor shall be liable for and shall indemnify the authority, any health authority and the Secretary of State for Health against any liability, loss, costs, expenses, claims or proceedings whatsoever arising under any statute or at common law in respect of:

- any loss of or damage to property (whether real or personal)
- any injury to any person, including injury resulting in death.

The contractor shall insure against its liability with a minimum limit of indemnity per incident agreed between the contractor and the authority.

8.9.2 Employers' liability compulsory insurance

Under the Employers' Liability (Compulsory Insurance) Act 1969 [14] a contractor must take out and maintain an approved insurance policy against liability for bodily injury or disease sustained by employees in the course of their employment.

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 returned for servicing and repair are properly decontaminated.
- Organisations carrying out repairs and maintenance are fully insured.

9 Decontamination

9.1 Correct procedure

Responsible organisations should keep patients, staff and visitors safe by having systems to ensure that all reusable medical devices are properly decontaminated prior to use or repair and that the risks associated with decontamination facilities and processes are well managed.
See Standards for Better Health, Core Standard C4 (c) [15].

Staff handling used medical equipment should assume that it is contaminated and take precautions to reduce the risk to themselves and others. The use of personal protective equipment/clothing should be considered.

Medical devices should be decontaminated and stored in accordance with legislative and best practice requirements. Where appropriate decontamination should always be carried out in dedicated facilities, for example:

- endoscopes – endoscopy suite
- surgical instruments – sterile services
- home loans – home loans decontamination facility.

There should be a local policy for the management and transport of medical equipment from the point of use to the decontamination facility.

If the manufacturer's instructions appear inappropriate or incomplete, report this to the MHRA as an adverse incident (see **section 2.6**).

Decontamination requirements should be considered before reusable medical devices are acquired to ensure they are compatible with the decontamination equipment available.

Set up local protocols for decontamination activities, seeking advice from the following:

- manufacturer of the medical device
- manufacturer of equipment used for decontamination/reprocessing
- infection control staff
- sterile services manager
- consultant microbiologist or consultant in communicable disease control or a public health doctor
- risk assessment officer
- device and equipment users
- advice from appropriate government bodies such as the MHRA and NHS Estates
- advice from appropriate professional bodies such as IDSc, ICNA, HIS, NAEP.

9.1.1 Choice of method

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 device 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	• In close contact with broken skin or broken mucous membrane. • Introduced into sterile body areas.	Cleaning followed by sterilization.
Medium	• 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	• In contact with healthy skin. • Not in contact with patient.	Cleaning.

Other factors to consider when choosing a method of decontamination include the:

- nature of the contamination
- time required for processing
- heat, pressure, moisture and chemical tolerance of the object
- availability of the processing equipment
- quality and risks associated with the decontamination method.

All medical devices, decontamination equipment, and surfaces should be appropriately dealt with after use on patients known to have, or who are in a risk category for, CJD.

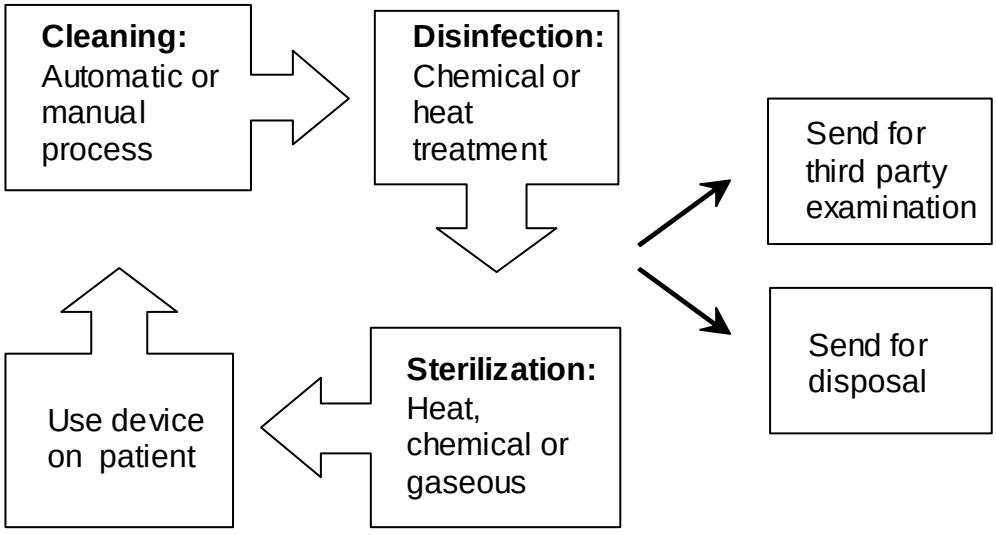
‘Advances in decontamination of prion protein contaminated equipment is proceeding at a rapid pace. This work is to be encouraged. It is important that until the efficacy of those products and technologies is established fully against human prions, that clinicians ensure that the current ACDP-TSE guidelines remain extant.’ - Comment from the Engineering and Science Advisory Committee on the decontamination of surgical instruments including prion removal.

9.2 When to decontaminate

Items subject to inspection, maintenance, repair or disposal, either on site or at the manufacturer's or agent's premises, should be decontaminated beforehand.

Any loaned items being returned to a manufacturer or supplier should also be decontaminated (Figure 2).

Figure 2 Decontamination process chart for reusable device or for third party examination



Once decontamination has been completed the items should be labelled accordingly, and a declaration of contamination status form completed (see Figure 4). This should be readily accessible to the recipient of the equipment.

Devices intended for single-use only do not require decontamination, except where they are implicated in an adverse incident and may need to be sent to the MHRA or the manufacturer for investigation.

In this situation, contact the manufacturer to find out the most appropriate method of decontamination.

9.2.1 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.

9.2.2 How should decontamination be carried out?

All decontamination processes should be operated and carried out in accordance with the equipment manufacturer's instructions and the process be able to decontaminate all contaminated areas of the device.

Assurances shall be obtained from the medical device manufacturer that the decontamination process chosen is appropriate and not harmful to the device.

Use only chemicals compatible with the device and at the correct concentration as recommended by the various manufacturers involved.

Decontamination equipment should be properly:

- commissioned
- validated and revalidated
- subject to planned maintenance by properly trained and competent staff.

Only appropriately trained staff, provided with suitable equipment/clothing should carry out decontamination.

Staff involved in decontamination should be aware of legal requirements and best practice and be up to date in these areas.

Training in appropriate aspects of decontamination practice should be provided to relevant healthcare staff, including those working in a clinical environment.

Figure 3 Decontamination flow chart for devices being sent for investigation/repair or service

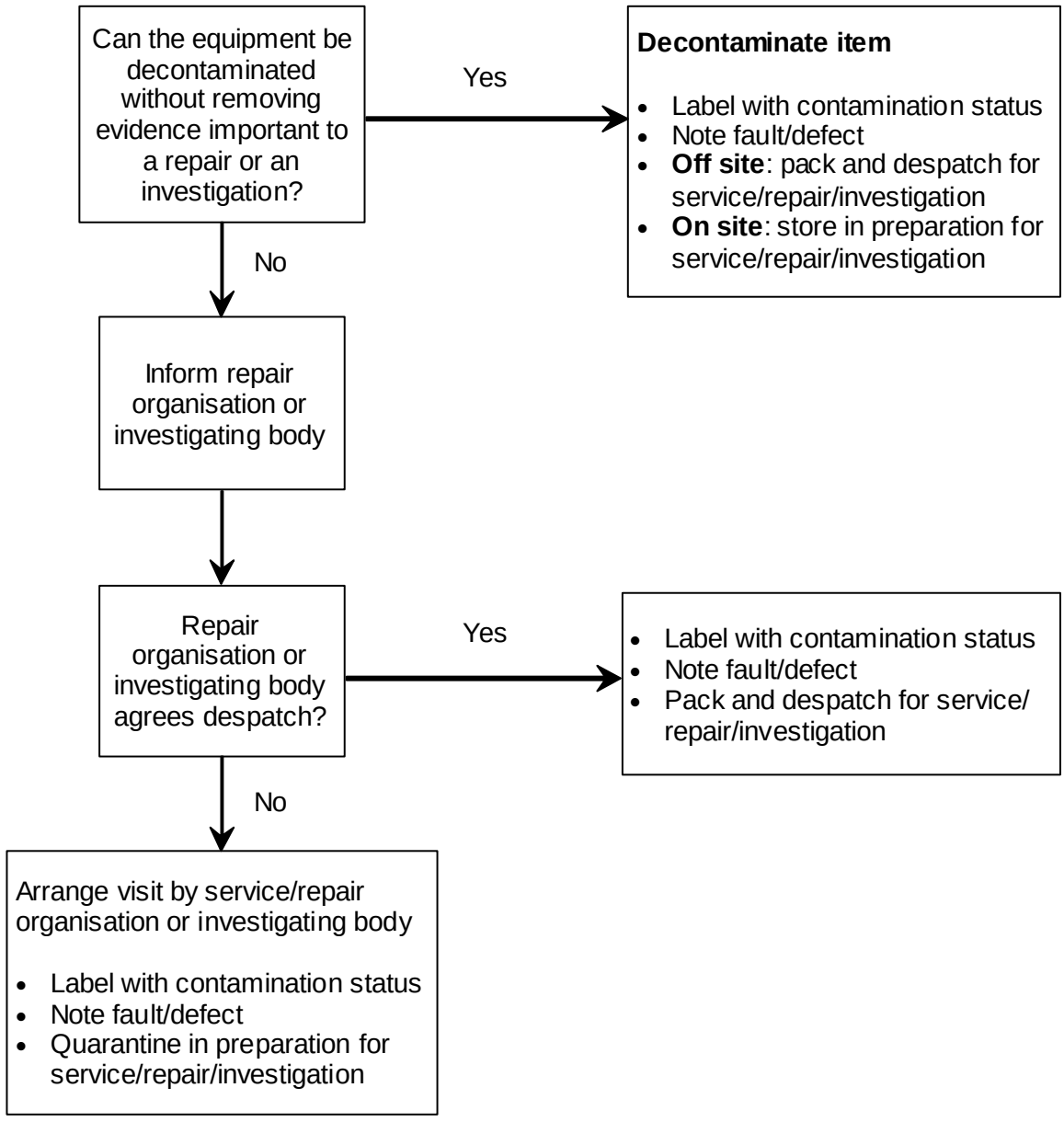


Figure 4 Sample form – declaration of contamination status

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 .....

Key points on decontamination

- A local policy sets out the management and transport of medical devices from the point of use to the decontamination facility.
- The method of decontamination selected takes account of the degree of infection risk associated with the use of the equipment.
- All items subject to inspection, service, repair, or disposal should be decontaminated beforehand.
- A senior member of staff is managing all aspects of decontamination.
- Decontamination has been carried out in accordance with the manufacturer's instructions.
- All relevant staff have been fully trained in decontamination protocols.
- It is illegal to send contaminated items through the post.

10 Removal from service

10.1 Planning for replacement

A removal from service policy is an essential part of equipment management. At some point, all equipment will need to be replaced.

The expected life cycle of a device/piece of equipment should be held in the inventory record and regularly reviewed against the usage, maintenance and repair record to see if the end date needs to be adjusted. Heavy use or irregular maintenance may reduce the life cycle; limited use may extend it.

Manufacturer recall of a device will take precedence over other considerations.

10.1.1 Replacement criteria

Factors to consider include:

- whether the device is damaged or worn out beyond economic repair
- its reliability (check service history)
- clinical or technical obsolescence
- changes in local policies for device use
- absence of manufacturer/supplier support
- non-availability of correct replacement parts
- non-availability of specialist repair knowledge
- users' opinions
- possible benefits of new model (features, usability, more clinically effective, lower running costs)
- lifecycle of the medical device.

10.2 Disposal

Consult the manufacturer for the best methods of waste disposal. They should be able to provide details of the current techniques and processes applicable to their products.

The Waste Electrical and Electronic Equipment Regulations [16] (currently in draft format – see the DTI website) will primarily impose duties on ‘producers’, i.e. manufacturers and importers.

10.2.1 Examples of special waste

Some waste products need specialised disposal. Examples include:

- wastes containing certain metals (e.g. mercury above 3%, some batteries)
- oil wastes (including polychlorinated biphenyls – PCBs)
- wastes from coolants
- radioactive waste
- healthcare wastes from human or animal origin

- human waste from natal care, diagnosis, treatment or prevention of disease.

Where applicable, equipment should be decontaminated before disposal or transfer to a third party and supplied with a certificate of decontamination.

10.2.2 Transport of equipment before disposal

When returning medical devices to the manufacturer at end of life, or when transporting equipment, ensure that it is appropriately packaged and secured.

Legislation applies to the transport of goods by road and rail:

- The Carriage of Dangerous Goods by Road Regulations 1996 [17]
- The Carriage of Dangerous Goods by Rail Regulations 1994 [18]
- Chemicals (Hazard Information and Packaging for supply) Regulations 1999. [19]

10.3 Decommissioning

Decommissioning aims to make equipment safe and unusable, while minimising damage to the environment. Any equipment deemed unfit for reuse should be decommissioned.

Decommissioning should include decontamination, making safe, and making unusable. This is to ensure that an inappropriate person does not use the equipment and expose themselves to potential hazards.

It is advisable to contact the manufacturer at this stage for information on decommissioning. The manufacturer should be able to provide details of any environmental, disposal, recycling or structural requirements.

If the manufacturer has ceased trading, contact the MHRA for further guidance.

Decommissioning larger installations often involves removal from a purpose-built room or surroundings. Decommissioning of equipment incorporating radioactive sources must be carried out in accordance with the Ionising Radiations Regulations 1999 [12].

For other equipment that is mobile or housed in general facilities, safety checks, such as power disconnection and cooling system disconnection, should be carried out.

10.3.1 Erasing stored data

If a device stores identifiable patient information, this should be securely deleted when the device is taken out of service. There is no need to delete event logs that cannot be related to identifiable patients.

10.4 Sale or donation for reuse

The Medical Devices Regulations [1] apply to medical devices being sold for the first time. There is no legislation which specifically covers the resale or reuse of medical devices or equipment.

However, used medical devices are still required to be safe under other national provisions, including:

- Consumer Protection Act 1987 (Consumer Safety and Product Liability) [8]
- Sale and Supply of Goods Act 1994 [20]
- Health and Safety at Work Act 1974 [6]
- Trade Descriptions Act 1968 [21]
- The Electrical Equipment (Safety) Regulations 1994 [22]
- Unfair Contract Terms Act 1977 [23].

10.4.1 Liability issues

Before sale or transfer of ownership of medical devices, both parties should be clear about their legal liabilities. Legal advice should be obtained concerning general device types such as walking frames or wheelchairs and more specific advice on an individual larger devices such as x-ray machines.

- The purchaser may inherit the liability for previous incidents or unpaid hire purchase costs if appropriate contracts are not used.
- A vendor may request the purchaser to sign a disclaimer, to the effect that the vendor has no future responsibility for the equipment.
- The product may be 'sold as seen' or 'buyer beware', in which case liability is usually transferred to the purchaser.
- The vendor may retain contributory negligence.
- In general, the more comprehensive the information supplied by the vendor, the lower will be the inherited liability.

Essential requirement 13b of the Medical Devices Regulations [1] requires the manufacturer to provide:

> 'all the information needed to verify whether the medical device can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the device operates properly and safely at all times'.

It is good practice to apply this principle to the sale of used equipment or transfer of ownership, to ensure safety.

This information should be available for a prospective purchaser to view before sale and be supplied with the equipment on its completion.

On selling or donating used equipment the following should be supplied with the equipment to the purchaser:

- a clear statement that the equipment is being resold/donated
- certificate of decontamination
- user manuals and training requirements
- full details of maintenance and servicing requirements
- service history and manual
- usage history
- quality assurance test details
- safety updates, including MHRA and manufacturer documents that have been released since the medical device was first supplied.

If instructions, training and maintenance/repair information are not available, it may not be appropriate to pass the equipment to a new user.

10.4.2 Refurbishment

A medical device supplied to a new owner after full refurbishment is covered by the Medical Devices Regulations [1]. A new CE marking has to be affixed by the person or organisation that carries out the refurbishment. The term 'reconditioning/refurbishment' is often used for the process of routine cleaning and maintenance, which precedes the re-issue of an item. This process is not generally 'full' refurbishment.

Full refurbishment

This term is used in the Medical Devices Regulations [1] and applies to the re-manufacture and placing on the market of a device 'as new'. Devices that are fully refurbished and placed on the market are covered by the Medical Devices Regulations [1].

Full refurbishment will vary for a given device, but is generally considered to consist of:

- stripping into component parts or sub-assemblies
- checking their suitability for reuse
- replacement of components/sub-assemblies not suitable for reuse
- assembly of the replacement components or sub-assemblies, testing of the assembled devices against either original or revised release criteria
- the identification of the fully refurbished device by appropriate means.

Additional guidance on what constitutes 'full refurbishment' of medical devices can be found in the European Association of Notified Bodies for Medical Devices document Recommendation NB-MED/2.1/Rec5 [24].

Key points for removal from service

- Medical devices and items of medical equipment are replaced, decommissioned and disposed of in accordance with an agreed policy.
- Before the sale or donation of medical equipment for reuse the potential for future liability against the responsible organisation should be considered.
- Disposal of waste should meet the applicable requirements for UK legislation.

11 Legislation

This section gives examples of legislation that might apply to your organisation; it is not an exhaustive list.

Consumer Protection Act 1987 (Consumer Safety and Product Liability) [8].

Control of Substances Hazardous to Health Regulations 1999 [25]

Electricity at Work Regulations 1989 [5].

Electrical Equipment (Safety) Regulations 1994 [22].

Employers' Liability (Compulsory Insurance) Act 1969 [14].

General Product Safety Regulations 2005 [9].

Health and Safety at Work etc. Act (HASAWA) 1974 [6].

In Vitro Diagnostic Medical Devices Regulations [26].

Ionising Radiation (Medical Exposures) Regulations 2000 [27].

Ionising Radiations Regulations 1999 [12].

Lifting Operations and Lifting Equipment Regulations 1998 [13].

Management of Health and Safety at Work Regulations 1999 [28].

Medical Devices Regulations 2002 (Amended 2003) [1].

Pressure Systems Safety Regulations 1999 [29].

Provision and Use of Work Equipment Regulations 1998 [30].

Sale and Supply of Goods Act 1994 [20].

Trade Descriptions Act 1968 [21].

Unfair Contract Terms Act 1977 [23].

Waste Electrical and Electronic Equipment Regulations [16].

12 References and further information

References

1 The Medical Devices Regulations 2002. Statutory Instrument 2002 No. 618. ISBN 0110423178.
http://www.opsi.gov.uk/SI/si2002/20020618.htm

2 Healthcare Commission. Assessment for Improvement: annual health check. 2005.
http://www.healthcarecommission.org.uk

3 Department of Health. Standards for Better Health, 2004.
http://www.dh.gov.uk

4 MHRA. Medical Device Alert MDA/2006/001 'Reporting adverse incidents and disseminating Medical Device Alerts'. 2006.
http://www.mhra.gov.uk

5 The Electricity at Work Regulations. Statutory Instrument 1989 No. 635. ISBN 011096635X.
http://www.opsi.gov.uk/si/si1989/Uksi_19890635_en_1.htm

6 Health and Safety at Work etc. Act 1974. London: HMSO, 1974. ISBN 0105437743.

7 IEC 60601-1 Edition 3 2005 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance. BSI 2005.
http://www.bsonline.bsi-global.com/server/index.jsp

8 The Consumer Protection Act 1987 (Commencement No. 1) Order 1987. Statutory Instrument 1987 No. 1680 (C.51). ISBN 0 11 077680 1.
http://www.opsi.gov.uk/si/si1987/Uksi_19871680_en_1.htm

9 The General Product Safety Regulations 2005. Statutory Instrument 2005 No 1803. ISBN 0110730542.
http://www.opsi.gov.uk/si/si2005/20051803.htm

10 BS EN ISO 13485:2003 Medical devices. Quality management systems. Requirements for regulatory purposes. BSI 2003.
http://www.bsonline.bsi-global.com/server/index.jsp

11 BS EN ISO 9001:2000 Quality management systems. Requirements
http://www.bsonline.bsi-global.com/server/index.jsp

12 Ionising Radiation Regulations 1999. Statutory Instrument 1999 No. 3232. ISBN 0 11 085614 7.
http://www.opsi.gov.uk/si/si1999/19993232.htm

13 Lifting Operations and Lifting Equipment Regulations 1998. Statutory Instrument 1998 No. 2307. ISBN 0 11 079598 9.
http://www.opsi.gov.uk/si/si1998/19982307.htm

14 Employers' Liability (Compulsory Insurance) Act 1969. HMSO 1969. ISBN 0105457698

15 Department of Health. Standards for Better Health, July 2004
http://www.dh.gov.uk

16 Waste Electrical and Electronic Equipment Regulations (draft).
http://www.dti.gov.uk/innovation/sustainability/weee/page30269.html

17 The Carriage of Dangerous Goods by Road Regulations 1996. Statutory Instrument 1996 No. 2095. ISBN 0110629264.
http://www.opsi.gov.uk/si/si1996/Uksi_19962095_en_1.htm

18 The Carriage of Dangerous Goods by Rail Regulations 1994. Statutory Instrument 1994 No. 670. ISBN 0110436709. ISBN 0110436709.
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19 Chemicals (Hazard Information and Packaging for supply) Regulations 1999. Statutory Instrument 2002 No. 1689. ISBN ISBN 0 11 042419 0.
http://www.opsi.gov.uk/si/si2002/20021689.htm

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http://www.opsi.gov.uk/acts/acts1994/Ukpga_19940035_en_1.htm

21 Trade Descriptions Act 1968. HMSO 1968. ISBN 0105429686.

22 The Electrical Equipment (Safety) Regulations Statutory Instrument 1994 No. 3260
http://www.opsi.gov.uk/si/si1994/Uksi_19943260_en_1.htm

23 Unfair Contract Terms Act 1977. HMSO 1977. ISBN 0105450774

24 European Association of Notified Bodies for Medical Devices. Recommendation NB-MED/2.1/Rec5
http://www.team-nb.org/Documents/R2_1-5_rev5.pdf

25 Control of Substances Hazardous to Health Regulations 2002. Statutory Instrument 2002 No. 2677. ISBN 0 11 042919 2.
http://www.opsi.gov.uk/SI/si2002/20022677.htm

26 The In Vitro Diagnostic Medical Devices Regulations 2000. Statutory Instrument 2000 No. 1315. ISBN 0 11 099260 1.
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27 Ionising Radiation (Medical Exposures) Regulations 2000. Statutory Instrument 2000 No. 1059. ISBN 0 11 099131 1.
http://www.opsi.gov.uk/si/si2000/20001059.htm

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http://www.opsi.gov.uk/SI/si1999/19993242.htm

29 Pressure Systems Safety Regulations 2000. Statutory Instrument 2000 No. 128. ISBN 0 11 085836 0.
http://www.opsi.gov.uk/SI/si2000/20000128.htm

30 Provision and Use of Work Equipment Regulations 1998. Statutory Instrument 1998 No. 2306. ISBN 0 11 079599 7.
http://www.opsi.gov.uk/SI/si1998/19982306.htm

Sources of further information:

MHRA publications:

Devices in Practice: A Guide for Health and Social Care Professionals. 2001.
http://www.mhra.gov.uk

DB 2003(05) Management of medical devices prior to repair, service or investigation. 2003.
http://www.mhra.gov.uk

DB 2006 (01) Reporting Adverse Incidents and Disseminating Medical Device Alerts. 2006.
http://www.mhra.gov.uk

Leaving hospital with a medical device
http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=256

Sterilization, Disinfection and Cleaning of Medical Equipment: Guidance on Decontamination from the Microbiological Advisory Committee to Department of Health (MAC manual).
http://www.mhra.gov.uk

Other:

Health and Safety Executive
http://www.hse.gov.uk/

NHS Purchasing and Supply Agency (PASA)
http://www.pasa.nhs.uk/

European Association of Notified Bodies for Medical Devices
http://www.team-nb.org

Note: website links last accessed November 2006.

13 Glossary

Cleaning
A process which physically removes infectious agents and the organic matter on which they thrive, but does not necessarily destroy infectious agents. The reduction of microbial contamination depends on many factors, including the effectiveness of the cleaning process and the initial bioburden. Cleaning is an essential prerequisite to ensure effective disinfection or sterilization.

Contamination
The soiling or pollution of inanimate objects or living material with harmful, potentially infectious, or other unwanted matter. In the clinical situation, this is most likely to be organic matter and infectious agents but may also include chemical residues, radioactive material, degradation products, packaging materials, etc. Such contamination may have an adverse effect on the function of a medical device and may be transferred to a person during use or subsequent processing and storage.

Decontamination
A series of processes to enable a device to be safe for use on a patient or to be safely handled after being used on a patient. The reprocessed device then made available to either:

- reuse it on another patient
- send for repair, servicing or further examination
- disposal.

Disinfection
A process used to reduce the number of viable infectious agents but which may not necessarily inactivate certain viruses and bacterial spores. Disinfection does not achieve the same reduction in microbial contamination levels as sterilization. Under certain defined conditions moist heat will also disinfect.

End user
A person who uses the device on or for him/herself, as distinct from a professional user.

Legal entity
Trust or other responsible organisation.

Maintenance
The correction or prevention of faults by a programme of inspection and replacement of parts in order to keep the medical device performing as intended by the manufacturer.

Manufacturer
An organisation with responsibility for the design, manufacture, packaging and labelling of a device. See Medical Devices Regulations [1].

Medical device
This refers to an instrument, apparatus, appliance, material or other article, whether used alone or in combination, together with any software necessary for its proper application, which is intended by the manufacturer to be used for the purposes of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or physical impairment
- investigation, replacement, or modification of the anatomy or of a physiological process
- control of conception.

A medical device does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means.

This definition includes devices intended to administer a medicinal product, such as a syringe driver, or which incorporate a substance defined as a medicinal product, such as a drug-eluting stent.

Planned preventive maintenance
Maintenance carried out at fixed intervals by appropriately trained and qualified staff.

Professional user
A trained and qualified person who uses a medical device(s) on or for a person during the provision of healthcare on behalf of the responsible organisation.

Repair
The restoration of a device to correct working order, after it has either broken down or stopped working properly. The repair process may also include **maintenance** or reconditioning.

Responsible organisation
An organisation that either uses devices or loans them to end users.

Single-use medical device
A device that is intended to be used on an individual patient during a single procedure and then discarded. It must not be used on another patient.

Sterilization
A process used to render an object free from viable infectious agents, including viruses and bacterial spores.

User
Professional user and/or end-user.

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