

MDA BULLETIN

BULLETIN



*Medical Devices
and Equipment
Management:
Repair and
Maintenance
Provision*

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The Medical Devices Agency helps safeguard public health by working with users, manufacturers and lawmakers to ensure that medical devices meet appropriate standards of safety, quality and performance and that they comply with the relevant Directives of the European Union.

Our primary responsibility is to ensure that medical devices achieve their fullest potential to help healthcare professionals give patients and other users the high standard of care they have a right to expect.

The Medical Devices Agency is an Executive Agency of the Department of Health

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EXECUTIVE SUMMARY

This bulletin builds on and provides additional guidance to that contained within MDA Device Bulletin DB 9801, but can be used as a stand-alone document.

It is aimed at those within user organisations with responsibility for device and equipment repair and maintenance. This will include managerial, technical and clinical staff.

The guidance within this bulletin covers the management of the repair and maintenance process, and sets out good practice for the organisation that carries it out.

This bulletin covers the following topics:

- the types of organisations undertaking repair and maintenance (Section 2);
- the information provided by the manufacturer on repair and maintenance methods (Section 3);
- training of repair and maintenance personnel (Section 4);
- the repair process, including the availability and specification of spare parts (Section 5);
- the handling and monitoring of repair and maintenance (Section 6);
- selecting a service provider (Section 7);
- contractual agreements with service providers (Section 8);
- the liabilities associated with device repair and maintenance (Section 9).

The bulletin provides two comprehensive questionnaires designed to assist the user organisation when evaluating a service provided.

The legal responsibilities and liabilities of both the user organisation and service provider are also considered.

This document can be used by hospital personnel who need to assess the suitability of service providers. Selecting an appropriate service provider may lead to reduced costs.

Key Points

The user organisation should ensure that:

- ◆ *the repair and maintenance of a device is considered at the purchase stage.*
- ◆ *all the information necessary to undertake a repair or to maintain a device safely is made available.*
- ◆ *they have a system in place to bring any changes to repair and maintenance methods to the attention of the repairer.*
- ◆ *the repairers are appropriately trained and up-to-date with their knowledge of repair and maintenance methods.*
- ◆ *the instructions used should be as specified by the manufacturer.*
- ◆ *replacement parts should match those specified by the manufacturer.*
- ◆ *the use of alternative instructions, methods and parts should be demonstrated to be equivalent and take into account all risks to patients and users and fully documented.*
- ◆ *all replacement spare parts and critical components used in a repair or maintenance are traceable.*
- ◆ *all associated repair and test equipment is suitable for its purpose and is appropriately maintained and calibrated.*
- ◆ *they are made aware of any changes in circumstance which may affect repair and maintenance and assess the impact of those changes to ensure that agreed specifications continue to be met.*
- ◆ *they have a system in place to manage device repair and maintenance activities.*
- ◆ *the device itself remains identifiable.*
- ◆ *all records relating to the repair and maintenance of any device are accurate, detailed and readily accessible.*

- ◆ *they undertake regular audit and review of the repair and maintenance process, taking any action as necessary.*
- ◆ *the service provider reports to it conditions that have the potential to cause a device failure or otherwise compromise the clinical outcome.*
- ◆ *they report device failures to MDA.*
- ◆ *they always have a contract with the repairer defining responsibilities for repair and maintenance.*
- ◆ *they are aware of their legal responsibilities and liabilities in respect of device repair and maintenance.*
- ◆ *all devices intended for repair or maintenance are safe to handle.*

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1. OBJECTIVES

1.1 Scope

This bulletin has been prepared by the MDA following wide consultation with relevant interested parties. It builds upon the general guidance already provided on repair and maintenance in MDA Device Bulletin DB9801, "Medical Device and Equipment Management for Hospital and Community-based Organisations". It is designed to assist anyone within a healthcare setting who has responsibility for the repair and maintenance of devices.

The information within this bulletin applies both to medical devices, as defined by the medical devices regulations, and also to other medical equipment used in the delivery of healthcare for which MDA has responsibility. The term '*device*' is used throughout this bulletin to encompass both medical devices and medical equipment.

This bulletin covers all repair and maintenance activities performed by any service organisation and extends to the activities of reconditioning, modification and refurbishment. These activities fall outside of the scope of the medical devices regulations (see glossary).

1.1.1 Exclusions

Full refurbishment

Devices that are fully refurbished and subsequently placed on the market are covered by the medical devices regulations and are therefore not covered by this bulletin (see glossary).

Purchasing

This bulletin does not cover the process of purchasing a device, whether it is new, second-hand, leased or ex-demonstration, though it does consider the provision of information on repair and maintenance at the purchase stage. Further information on purchasing is contained within MDA DB 9801.

1.2 Introduction

The main objective of the Medical Devices Agency (MDA) is to take all reasonable steps to ensure that medical devices and equipment in the UK are of safe design, of appropriate quality, perform as intended and are properly used. The repair and maintenance of a medical device or item of equipment has an influence on its safety, quality and performance. It is therefore important that any work is carried out correctly such that the device will continue to meet these criteria.

The guidance and recommendations in this bulletin supplement the duties of user organisations and service providers under health and safety legislation to ensure that equipment is adequately maintained. Failure to comply with health and safety law is a criminal offence.

The term '*repair and maintenance*' is used throughout this bulletin to cover the activities of repair, maintenance, servicing, reconditioning, modification and refurbishment (see glossary).

The manufacturer is usually the primary source for the repair and maintenance of its devices. However, not all manufacturers carry out repair and maintenance of their devices. Whoever is carrying out the repair or maintenance activity, the service provider should always use the written service documentation from the manufacturer. The onus is on the service provider to demonstrate to the satisfaction of the user organisation that they meet the general recommendations of this bulletin.

If any organisations or individuals other than the manufacturer undertake repair or maintenance work, they should ensure that it is done in accordance with the manufacturer's instructions. The user organisation should ensure that its chosen service provider has the capability to carry out the work. It is the responsibility of the user organisation to ensure, as far as possible, that equipment continues to operate in accordance with its original specification after repair.

When a device needs to be repaired the user organisation should consider whether a failure should be reported as an adverse incident, or reported to HSE under RIDDOR (Reporting Injuries, Diseases and Dangerous Occurrences Regulations 1995).

Users should ensure that they carry out both a risk-benefit as well as a cost-benefit analysis in selecting a service organisation for the repair and maintenance of a specific device. Account should be made of expertise within the user organisation in this process.

User organisations should only adopt repair and maintenance organisations which:

- ◆ *can demonstrate appropriate training, knowledge and experience of the repair or maintenance of the device;*
- ◆ *have access to appropriate equipment to undertake repair and maintenance;*
- ◆ *have a system in place to notify the user organisation of any deviation to the maintenance repair or maintenance method;*
- ◆ *take responsibility for the repair or maintenance.*

1.3 Terminology

The following terms have been defined for the purpose of this bulletin:

User organisation

A device owner, which either uses devices (e.g. a hospital trust) or loans them to end-users (e.g. a community store).

User

Professional user and/or end-user.

Professional user

The trained and qualified person who operates a device for the benefit of a patient or client.

End-user

The patient or client who uses the device.

Manufacturer

An organisation with responsibility for the design, manufacture, packaging and labelling of a device. [A more detailed definition can be found in the Medical Devices Directive 93/42/EEC].

Service provider

Any organisation or individual providing repair or maintenance on a medical device (see section 2).

Note: Duties under health and safety legislation are placed on the employer and the self-employed rather than the user organisation or the service provider and on employees rather than professional users.

Repair and maintenance

The restoration of a device, by a service provider, to its original function, in response to the failure of the device. The repair process may also include servicing, reconditioning, modification and refurbishment.

Other useful terms can be found in the glossary.

2. REPAIRERS AND SERVICE PROVIDERS

User organisations and service providers are reminded of their duties under health and safety legislation to ensure that repairs and maintenance are only done by those who are competent to do the work.

2.1 Types of Organisation

A medical device service provider may be:

Manufacturer service organisation

The service provider employed directly by the device manufacturer.

Authorised service agents

This organisation will have been authorised and supplied with the necessary spare parts to undertake repair and maintenance on behalf of the manufacturer. It should therefore operate to the same standards and have trained personnel and access to all the necessary information to carry out repair and maintenance in accordance with the manufacturer's instructions.

Multi-vendor service providers

A manufacturer who repairs and maintains devices manufactured by another manufacturer in addition to his own.

This organisation will generally repair and maintain devices of the same generic type as they manufacture, e.g. x-ray equipment. They may use the experience of their own equipment in the repair and maintenance of other manufacturer's devices, or sub-contract when they do not have the necessary expertise.

Third party service providers

A specialist organisation operating primarily in the field of repair and maintenance.

These organisations may also specialise in the repair and maintenance of one particular type of device or equipment, e.g. endoscopes. The organisation may draw on the knowledge and experiences of ex-employees of a manufacturer of this type of device. The organisation may be an intermediate or a small-scale operation, suited to repair of community based devices such as wheelchairs, where the patient cannot be without the device for significant periods of time.

Managed service providers

These organisations can provide management skills to provide appropriate repair and maintenance cover as negotiated in a contract between that organisation and the Trust. Some versions of managed service providers are insurance-based.

In-house service providers

A user organisation which undertakes repair and maintenance on its own devices, and usually on its own premises.

However, if a clinical engineering department (or similar, biomedical engineering, medical physics department, etc.) undertakes repair and maintenance activities for another organisation, such as a nearby trust or medical school (outside its own legal entity) then it does so as a third party service provider.

3. INFORMATION ON REPAIR AND MAINTENANCE

3.1 Availability of Service Documentation

The user organisation should request all necessary information on repair and maintenance during any pre-purchase enquiries. [Further information on purchasing can be found in MDA DB 9801].

Health and safety law requires designers, manufacturers, suppliers and importers to provide adequate information about the use of articles for use at work, and about any conditions necessary to ensure it will be safe and without risks to health. This may include information about proper use, testing and maintenance. Interested parties such as clinical engineering staff and the Radiation Protection Adviser will need to be involved at the contract stage.

It is likely that there is a small number of devices whose design and construction is so complex that safe and effective maintenance outside of the resources of the manufacturer is not feasible. In such cases documentation may be withheld. Purchasers need then to consider 'whole-life' costs including a service requirement from the manufacturer without realistic competition.

User organisations should consider only those service providers, which have access to up-to-date, maintenance documentation in the detail necessary to carry out the tasks safely and effectively. The provision of adequate service documentation is an important consideration at the purchase stage [see section 6].

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

- calibration of the device;
- preventative 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.

If test software is essential for fault diagnosis where such information is not available in printed form, then it should be provided to the user to enable an assessment of what repair is required. Otherwise it may be licensed to service providers independent of the manufacturer. If such written documentation is essential for fault diagnosis it should be provided to enable the user organisation to identify what repair is required.

Key Points

The user organisation should ensure that:

- ◆ *the repair and maintenance of a device is considered at the purchase stage.*
- ◆ *its chosen service provider has access to, and keeps up-to-date with, all the information necessary to undertake a repair or to maintain a device.*

3.1.1 Implications of the Medical Devices Regulations

The medical devices regulations 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 manufacturer may achieve this by providing the user organisation with either sufficient information necessary to determine when maintenance is necessary or the information required to carry out the task.

3.1.2 Possible Implications of the Competition Act

A manufacturer's refusal to supply spare parts or the information necessary to undertake a repair, or the supply of such parts at excessive prices, may constitute a breach of competition law.

Other legislation is addressed in section 9.

3.2 Changes or Amendments

The user organisation should set up and maintain a system to ensure that the service provider is made aware of any changes to repair or maintenance instructions and other essential safety information supplied by the manufacturer.

These changes should include those in the design of a device or other information, which have safety implications or could significantly change the requirements for repair or maintenance, including recalls and mandatory upgrades.

Manufacturers, designers, importers and suppliers may have a legal duty under the Health and Safety at Work Act to try to ensure that those they supplied are given revised information if it becomes known that anything gives rise to a serious risk to health or safety.

It is important that the user organisation knows the version of the device currently in use and whether it has been upgraded by the manufacturer since it was supplied. This includes devices that are software driven.

Notification of any 'non-essential' or purely functional changes (including hardware and software upgrades) by the manufacturer should form part of the purchase contract, together with a timescale for notification of any changes to the repair and maintenance by the manufacturer.

This system should also be able to take into account all other information that may affect the repair or maintenance of their devices and equipment. This includes Safety and Hazard Notices issued by MDA or other advice issued by the Department of Health.

Key Point

- ◆ *The user organisation should ensure that a system is in place to bring any changes to repair and maintenance methods to the attention of the repairer.*

4. TRAINING AND EXPERIENCE OF SERVICE PERSONNEL

The training of personnel is a key element in safe and effective repair and maintenance work. Health and Safety law requires employers to ensure their employees are adequately trained.

Inadequate training 1

Several adverse incident reports were received by MDA concerning prosthetic feet. The feet had been assembled according to the manufacturer's instructions using boxwood. However, it appeared that wood from a packaging box was used rather than wood from a box tree, which is a particularly hard wood. In one instance a foot failed whilst the wearer was engaged in a fitness activity.

Inadequate training 2

The legend in a generator control desk button was replaced in the wrong orientation when the service provider changed a bulb. The legend showed the x-ray beam orientation as horizontal rather than vertical. Following this, a patient was set up for an x-ray under automatic exposure control with the incorrect receptor module selected on the generator.

Adequate training even in simple tasks is necessary to avoid potential injury to patients

EBME repair

An EBME department reported an incident involving the servicing of an anaesthetic machine. The anaesthetist checked the machine prior to commencing an operating list and discovered that the machine oxygen and nitrous oxide pipes had been transposed. The machine had just been fully serviced by the EBME department. The EBME department engineers were trained by the manufacturers for minor servicing only when the machine was purchased.

Generic versus specific equipment training

Following a series of adjustments by a service provider, a tilting x-ray table collapsed. Whilst experienced in maintenance procedures generically, their experience and training did not cover the adjustments on the unit that were being attempted.

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

All service personnel need to understand the basic principles on which devices work (generic training) as well as how to use, repair and maintain a particular model (specific training). Both are necessary. Those without adequate training should not attempt to repair or maintain devices.

The user organisation should ensure that service personnel working on equipment owned by the user organisation have been adequately trained and have relevant work experience. If the user organisation is uncertain about the skills of any individual they should be challenged.

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 system [see 5.4]. They should also be able to demonstrate that they are being kept up-to-date on new maintenance techniques, consistent with the devices they are servicing.

Training, knowledge and work experience are all important elements to safe equipment maintenance and provide that individual with the ability to provide a professional judgement during service activities.

It is essential that personnel carrying out repair and maintenance on specialised devices, such as pressurised, electrical, radiological, gas storage, patient-invasive devices or patient transfer equipment are competent to work with this equipment. They should have the necessary training, skills and experience due to the additional hazards to the repairer, patient and users and comply with the relevant regulatory requirements.

Key Point

- ◆ *The user organisation should ensure that the repairers are appropriately trained and up-to-date with their knowledge of repair and maintenance methods.*

5. REPAIR AND MAINTENANCE PROCESS

5.1 Repair and Maintenance Specification

The main source of repair and maintenance documentation (though not the only one) is the device manufacturer. He sets out the frequency of inspection and replacement of worn parts, and whilst he has a duty to provide details of the nature and frequency of maintenance, it does not necessarily include the detailed specification needed to enable repair especially down to component level [see 3.1.1].

Baseline parameters need to be agreed at the acceptance testing stage. These pass/fail criteria can then be used by the service provider during servicing and maintenance. The frequency of planned preventive maintenance also needs to be agreed taking into account the expected workload and the working environment.

A manufacturer may be entitled to supply and maintain equipment exclusively through his own organisation. Alternatively, a manufacturer may set necessary and objective criteria on the training, equipment and resources of any third party repairer who is given access to the manufacturer's information and spare parts.

If the user organisation wishes to use a service provider which cannot gain access to information from the manufacturer it should agree a specification with that organisation for repair and maintenance before any work is carried out. The user organisation must consider the risk to the patient and users arising from contracting with this organisation, including its own liability in allowing unauthorised repair methods to be carried out on its devices.

The performance of the repaired device may be inferior if the repairer uses alternative repair or maintenance methods to those specified by the manufacturer. Inadequate testing may also degrade the safety and performance increasing the risk to patients and users.

Key Points

The user organisation should:

- ◆ *ensure that the information necessary to undertake a repair or maintain a device is made available.*
- ◆ *the use of alternative instructions should be demonstrated to be equivalent and take into account all risks to patients and users and is fully documented.*

5.2 Spare Parts and other Components

5.2.1 Sourcing of Spare Parts

5.2.2 Quality and Compatibility with the Device

There are several sources of spare parts:

- the device manufacturer;
- other manufacturers;
- second-hand;
- the user organisation;
- a service provider.

The contract between the user organisation and the service provider should clearly define the terms 'spare parts' and 'consumables' and ensure that their quality match those supplied by the manufacturer.

Flexible fibre optic and video endoscopes

Flexible endoscopes repaired and maintained by a third party organisation had been repaired using spare parts and methods not specified in the manufacturer's instructions. This led to the devices being modified. Whilst MDA is not aware of any device related incidents, the modifications undertaken had the potential to cause problems which could affect patient safety.

SEE MDA SN9818.

Unauthorised repair technique

The snap-lock pin on a surgical telescope had been replaced by a crudely made parallel-sided metal rod. This was longer than the original pin, and critically did not have a semi-spherical end. As a result when the modified telescope was combined with the resectoscope, the two devices were not locked together as intended. Consequently, relative movement occurred, such that a consistent view of the cutting loop and insulated beak were difficult to maintain in use.

Repair methods, on a device, contrary to the manufacturer's instructions, must be risk-assessed for patient and user safety.

Scooters out of control

A powered scooter malfunctioned after a non-compatible controller was fitted. The speed of the scooter was affected such that the end-user was travelling in excess of the legal speed limit for this type of device, putting the end-user and pedestrians at risk of injury.

This incident highlights the potential safety and legal implications of using parts not specified by the manufacturer.

Agreements to supply such parts from sources other than that recommended by the manufacturer should be properly risk-assessed and documented.

The supply of spare parts from sources other than that recommended by the manufacturer may carry with it questions concerning safety. Additionally there may be legal consequences for the user organisation if a device failure, associated with the fitting of such a spare part, caused an injury or incident [see section 9].

In order to ensure that replacement parts are of the correct specification they should be purchased either from the manufacturer or to the same specification. However, this may not always be possible. For example, the manufacturer may no longer be trading, or the manufacturer may legitimately refuse to supply spare parts or specifications to his components.

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 and mechanical properties.

Under normal circumstances second-hand parts should not be used to repair a device [see DB9801], and may be acceptable only under exceptional circumstances following risk assessment.

Risk of scalding

A number of failures of benchtop steam sterilizers have been reported. Door seal failure is usually noisy and accompanied by violent discharge of a large volume of steam, which could cause serious injury such as scalding to persons nearby. The failures were traced to the use of replacement door seals, made from unsuitable materials. The door seals were inferior to that specified by the manufacturer.

The use of inappropriate and inadequate spare parts could lead to device failure and be a potential hazard to the user.

Key Points

The user organisation should ensure that:

- ◆ *replacement parts match those specified by the manufacturer.*
- ◆ *the use of an alternative specification is demonstrated to be equivalent and takes into account all risks to patients and users and is fully documented.*

Battery specification

One particular type of defibrillator battery may have the same dimensions and power rating as another, but the performance specification (i.e. the way in which it can deliver power) may differ which could be critical to the functioning of the defibrillator.

See MDADB 9805 for further advice on the selection of batteries.

Re-using spare parts

The failure of a wheelchair can have severe consequences for the end-user. The wheelchair seat should not be re-used – its previous history may not be known. The stresses and strains that the seat has undergone will depend on such factors as the length of time in service, age and the weight of the previous end-user(s). However a wheelchair foot rest taken from a chair no longer in use because of a wheel failure has the potential to be re-used if it appears in good condition. The risk associated with using this second-hand part is small.

5.2.3 Traceability of spare parts

The user organisation should ensure that the service provider can:

- identify all spare parts replaced during the repair of a particular device;
- trace all critical parts ¹ back to the supplier of the part.

This will allow the identification of those devices containing spare parts that are subject to corrective action, including recalls, to be identified.

¹ Not all spare parts are critical and the extent to which they need to be identified and related to the original device will depend on a number of factors. As a guide, the user organisation may wish to consider a 'critical part' to be a component whose failure might reasonably be expected to cause the failure of a critical device or to affect its safety or effectiveness and consequently result in death or injury to a patient or user.

Key Points

The user organisation should ensure that:

- ◆ *all replacement spare parts and critical components used in a repair or maintenance are traceable.*

D.I.Y.

External prostheses are generally assembled using high quality fasteners. This is because the prostheses have to routinely withstand very high stresses in an environment known to cause severe degradation (e.g. corrosion from humidity and body fluids etc). There have been instances where the required quality of fastener has been replaced with one obtained locally, resulting in failure of the device.

The full specification of a spare part should be known before it is replaced.

5.3 Repair and Maintenance Methods and Equipment

For each type of device the user organisation should be aware of the maintenance arrangements from the contract he has with the service provider.

Even if authorised spare parts are used, the methods used to dismantle and repair the device and re-assemble it following repair could lead to device failure or potential for harm to patients and others if not performed correctly.

The service provider should have all the necessary testing, measuring and repair equipment and ensure that this equipment is adequately maintained and calibrated.

Current certificates of calibration should be made available on request 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 equipment and these records could be incorporated into the service provider's quality system.

Ultraviolet tubes used in therapeutic devices

Patients undergoing therapy were injured due to overexposure to UV radiation. This was due to:

- the fitting of incorrect UV tubes in therapy devices;
- the difference in output characteristics of different tubes within the same device [cheaper tubes had been purchased in an effort to reduce cost, and in some instances had the wrong characteristics].

SEE MDASN9805.

Spare parts should match those specified by the manufacturer.

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

Where the manufacturer's maintenance methods are not adopted, the user organisation should ensure that the service provider has identified and documented all risks, implemented a strategy to manage those risks and has put in place and implemented documented procedures detailing the repair and maintenance methods.

Prior to bringing equipment back into clinical service it should be adequately tested and the user informed of the status of test results and any changes made to the settings of the device. This should include reference, where applicable, to pass/fail criteria and work which, for example, may significantly affect radiation dose to patients.

Key Points

The user organisation should ensure that:

- ◆ *the repair or maintenance method is in accordance with manufacturer's instructions.*
- ◆ *the use of an alternative method is demonstrated to be equivalent and takes into account all risks to patients and users and is fully documented.*
- ◆ *all associated repair and test equipment is suitable for its purpose and is appropriately maintained and calibrated.*

Faulty re-assembly

An adverse incident was received involving a 4 Bar knee that had been repaired at a disability service centre. The knee had been disassembled, the bearings changed and then reassembled. On re-assembly, the rear linkages were reversed. This restricted the movement when fully flexed, causing large stresses in the knee, which eventually failed in a catastrophic manner.

The failure to re-assemble a device correctly following repair can lead to device failure and patient injury.

5.4 Quality Assurance Standards

User organisations should only use a service provider which can demonstrate compliance with relevant quality system standards, for example, BS EN 46002 or BS EN ISO 9002. Such systems provide a framework on which service providers can build the necessary structures to ensure their work is of the nature and quality intended.

5.5 Sub-contracted Repair and Maintenance

If any aspect of the repair or maintenance process is sub-contracted, the user organisation should ensure that:

- they are aware of those aspects of the repair that are being sub-contracted;
- a contract is in place between the main service provider and the sub-contractor, detailing the responsibilities of each party;
- the service provider has audited the sub-contractor to establish that it has the necessary expertise and resources;
- they are notified of any changes in these arrangements.

It is the job of the main service provider to ensure that the work of the sub-contractor is of a sufficiently high standard, is audited and reviewed regularly.

5.6 Changes in the Manufacturer's Circumstances

Where contracts are placed with the manufacturer for repair and maintenance the user organisation should ensure that they 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, it is likely that the responsibility for repair and maintenance will transfer to the new organisation.

If a device manufacturer ceases business 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, it is recognised that there may be circumstances where it is judged essential to keep a device in clinical use. In such cases the user organisation should undertake a risk assessment of its continued use with no manufacturer service backup, set against the consequences of non-availability of the device.

Key Point

- ◆ *The user organisation should ensure they are made aware of any changes in circumstance which may affect repair and maintenance and assess the impact of those changes to ensure that agreed specification continues to be met.*

6. MANAGEMENT AND MONITORING OF REPAIR AND MAINTENANCE

6.1 Delegation of Responsibility

The user should have in place a policy on service provision and a management system which implements it. This may take the form of a simple record of all service contracts covering all the equipment for which he is responsible but include a description of the range, scope and limitations of work which is carried out.

It may additionally record such useful information as:

- drawing up and agreeing contracts with the service provider;
- planned maintenance schedule, dates, range, limits and scope of work to be carried out;
- work carried out under warranty, and cost information – possibly including an indicator of cost of maintaining a device in service against cost of purchasing a replacement device;
- schedule of equipment part codes upon which work can be carried out;
- arranging despatch of devices to the repairer or arranging for equipment to be repaired or maintained on-site;
- a works progress monitor;
- ensuring devices are returned if sent away;
- checking devices are fit for purpose before putting them back into service, including any devices supplied on loan while that belonging to the user organisation is being repaired;
- obtaining feedback on the service quality and process and reviewing this against the contract;
- checking all documentation and updating records following repair or maintenance;
- recording the repair and maintenance undertaken;
- recording payment of repair, if necessary;
- identifying those responsible for implementing and maintaining the system.

To ensure the system works effectively all interested parties will need to be involved, for example, purchasers, users, Sterile Service Departments or similar, clinical engineering personnel.

Key Point

- ◆ *The user organisation should have a system in place to ensure that all aspects of repair and maintenance are effectively documented and managed.*

6.2 Record Keeping

The benefits of accurate and accessible records in effective device management are documented in MDA DB 9801. This recommends that records for any device are kept by the user organisation from the outset, enabling the user organisation to trace individual devices throughout their whole life.

In addition to being good practice in keeping a device inventory up to date, retention of such records assists the user organisation in fulfilling its responsibilities in cases of future legal action involving questions concerning both correct device function and its proper maintenance. It has the additional advantage of allowing more realistic price and manpower estimates to be made at the time of service contract renewal.

Any other databases containing relevant information such as the accounts showing running costs and incident or failure reports, may be cross-referenced to provide information on the whole life cost and reliability of each device.

6.2.1 Repair and Maintenance History

These records (which may be kept either in paper form or on a computer database) should contain the complete history of the device, including the:

- manufacturer or supplier;
- serial number or other unique identifier;
- acquisition date;
- current location;
- repair and maintenance history¹.

Provision must be made within the record system to incorporate the relevant documentation relating to each device repaired or maintained.

The user organisation should agree with the service provider the detail of the work carried out and form of information to be provided to them. It may be presented in a number of forms such as a:

- paper printout of a job-card or maintenance worksheet including signatures as required;
- computer print-out or disc.

The information should be in sufficient detail to allow the user organisation to monitor the service adequately and to determine the contribution of planned preventative maintenance to the overall management of the device. In order to allow an audit trail to be followed the repair and maintenance record for each device should detail the following:

¹DB9801 Section 7 and 8 provides guidance on the extent of record keeping and traceability of low risk items in the community.

- the person who has performed the repair [see section 4.0];
- the work which has been carried out by the service provider, in sufficient detail to determine that the work is in accordance with the agreed specification and to the level of detail agreed [see section 5.1];
- the spare parts used during the repair, to determine that only those agreed in the contract are being used and for traceability [see section 5.2];
- the successful completion of the hand-back process [see section 5.3];
- any involvement of a sub-contractor who has carried out any work, in order to verify they are an approved organisation [see section 5.5];
- any device supplied to the user organisation as a service exchange or loan device [see section 6.1];
- any decontamination of the device before repair or maintenance [see section 10].

6.2.2 Record Retention

The Department of Health has issued advice on the management of records, including periods of retention, in Health Service Circular HSC 1999/053.

The user organisation must keep adequate records to demonstrate compliance with relevant health and safety legislation.

6.2.3 Device Identification

The user organisation should ensure that any additional labels or markings placed on the device by the service provider must not:

- damage or affect the correct functioning of the device;
- obscure any other markings on the device.

A traumatic incident !

An adverse incident report was received by MDA involving an atraumatic grasper, which broke in use. The hospital sent the device directly to the manufacturer, for repair. There was evidence that the device had been previously repaired by a third-party repairer and that the repairs were not in accordance with the manufacturer's requirements. The hospital was unable to locate the service history of the grasper as it had not been uniquely identified. The investigation could therefore not be progressed any further.

Records should be maintained by the user organisation to ensure that the history of a device can be traced.

Key Points

The user organisation should ensure that:

- ◆ *all records relating to the repair and maintenance of any device is accurate, detailed and readily accessible.*
- ◆ *the device itself remains identifiable.*

Device revision

A user organisation had a contract with a third party for the repair and maintenance of dental equipment. Amongst other dental equipment for repair, which was not included in the repair and maintenance contract, they collected an electrically powered dental scaler.

When it was returned, the medical physics department noted that the status of the scaler was not known. Examination of the device revealed a number of faults relating to the electrical safety of the device.

Service providers and user organisations should keep records of the devices included in the maintenance contract. Documentation showing repair status must accompany the return of repairs.

6.3 Audit and Review

The user organisation should ensure that:

- the contract gives the user organisation access to the premises of the service provider during the period of the contract;
- the performance of the service provider is reviewed at regular intervals during the contract period.

The review will help determine whether the service provider is continuing to fulfil its obligations and to enable decisions to be made on any changes to the repair and maintenance programme.

The user organisation should ensure that there is a mechanism to obtain regular feedback on all aspects of the repair process from the end-users (patients) and professional users (operators) of the devices subject to repair and maintenance [see 6.1]. This should include the reporting of even apparently minor problems as these might lead to major failure unless remedied [see 6.4].

Those responsible for monitoring the performance of service providers may need to be trained in the assessment and auditing of quality systems [see 6.1].

KeyPoints

The user organisation should:

- ◆ *undertake an audit of the service provider.*
- ◆ *seek feedback and undertake regular review of the repair process, taking any action as necessary.*

6.4 Adverse Incidents

The user organisation is reminded to report adverse incidents in accordance with SN2000(01). The reporting method described in this notice should be brought to the attention of the service provider by the user organisation.

In the event of the service provider identifying a condition that has the potential to cause a device failure or otherwise compromise the clinical outcome, they should notify the user organisation. This should include a written report. It is then the responsibility of the user organisation to verify that the condition identified by the service provider's report constitutes an adverse incident.

Devices which become the subject of an investigation following an adverse incident report should not be repaired without prior discussion and agreement with MDA.

RIDDOR set out legal requirements for reporting to the Health and Safety Executive specified types of accident, dangerous occurrences or ill health at work.

The Ionising Radiation Regulations 1999 set out reporting requirements for incidents where patients were exposed to ionising radiation to an extent much greater than intended as a result of equipment malfunction or defect, and for incidents where any person is likely to have received an overexposure.

Key Points

The user organisation should:

- ◆ *ensure that the service provider reports to them conditions which have the potential to cause a device failure or otherwise compromise the clinical outcome.*
- ◆ *report device failures to MDA* ¹.

¹See SN 2000(01) or MDAweb site <http://www.medical-devices.gov.uk/>

7. SELECTING A REPAIRER

The user organisation needs an appropriate strategy for repair and maintenance. The choice may include one or a combination of the following:

- the device manufacturer;
- an in-house department;
- an independent service provider;
- a managed service provider.

In addition to the issues highlighted in Sections 3, 4 and 5, the user organisation should consider the following in deciding which repair and maintenance company to use:

The user organisation may wish to consider:

7.1 Track Record

- the experience that the service provider has in the repair and maintenance of a given type of equipment;
- specific equipment training policy of that organisation;
- the experiences of other user organisations with that service provider;
- the length of time that organisation has been trading in its current name.
- the frequency with which repair and maintenance is likely to be needed and the required speed of response to equipment malfunction;
- the flexibility of that organisation to effect service in a department where the working day may not be the conventional 9-to-5.

7.2 Downtime

- the receipt and return of devices;
- the use of loan equipment.

7.4 Cost

- whilst this is an important factor, it should not be the only consideration. The user organisation should carry out a risk-benefit analysis alongside a cost-benefit analysis.

Some of the advantages and disadvantages of using a third party repairer are highlighted in MDA DB 9801.

8. CONTRACT WITH THE SERVICE PROVIDER

The contractual agreement with the service provider should clearly describe the level and type of service required by the user 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 personnel;
- quality assurance systems in place;
- requirement for adequate record keeping;
- use of sub-contractors.

The user organisation should take specialist advice in drawing up contracts, such as involving the Radiation Protection Adviser in the preparation of service contracts for diagnostic x-ray equipment, as required in IRR1999.

Appendix 1 brings together some of the key points raised in this bulletin by providing a list of questions to which the user organisation should seek satisfactory responses, before entering into an agreement with any service provider. Other service provision issues that the user organisation may want to consider are included in Appendix 2. Whilst these 'service' issues are obviously important to the user organisation, they should not be set against the quality of the repair itself.

8.1 NHS Purchasing and Supply Agency

There is a range of repair and maintenance contracts available through NHS Purchasing and Supply Agency. Further information on these contracts can be found from:

- CD ROM via the Local Supplies Team in each Trust;
- NHS Supplies Help Desk on Tel: 0118 980 8841;
- the following address – www.home.supplies.nhs.uk for Trusts that have access to the NHSNET.

Key Point

- ◆ *the user organisation should always have a contract with their service provider which sets out responsibilities and repair and maintenance requirements.*

9. LIABILITY FOR DEVICE REPAIR AND MAINTENANCE

The user organisation should take all reasonable steps to ensure that a device is repaired and maintained appropriately. The degree of liability taken on by the user is likely to depend on the contract between him and the service organisation.

9.1 Manufacturer's Repair and Maintenance Instructions

In addition the liability for the repair and maintenance of a device or item of equipment will vary depending on the person who effects the service and how the repair or maintenance is undertaken.

If a device fails in use following repair or maintenance and leads to the death or serious injury of a patient or user there is a greater likelihood of the user organisation and the service provider being held liable for the injuries caused if the device was not repaired in accordance with the manufacturer's instructions.

A user organisation could be held responsible under health and safety law and civil liability in the event that a patient or member of personnel died or suffered personal injury or damage as a result of a user inappropriately repairing or maintaining a device.

Key Point

- ◆ *MDA recommends the repair or maintenance of devices in accordance with the manufacturer's instructions.*

9.1.1 Implications for the User Organisations

The Medical Devices Regulations (SI1994 No3017) describe the aspects of safety, quality and performance for which a manufacturer must assume responsibility when designing and producing medical devices bearing the CE marking. As outlined in MDA Directives Bulletin 18A, devices made solely by one legal entity (e.g. a NHS Trust) and for use solely within that legal entity on its own patients are not included within the scope of the Regulations. However, MDA considers that the Regulations outline the current state of the art concerning the various areas which Trusts should consider when manufacturing or modifying medical devices. These aspects include civil liability, product design, performance validation, sterilization validation and labelling.

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 will apply as state of art to the user organisation. This is also the case if the user organisation sub-contracts these extensive modifications. Examples of this situation are the re-coating of an orthopaedic implant following damage, or changing the optical

Hydroxyapatite coatings for orthopaedic implants

The hydroxyapatite coating of a hip replacement implant was damaged prior to implantation. The clinician concerned arranged for the implant to be re-coated by a third party organisation, without reference to the original manufacturer.

SEE MDASN 9713

Clinicians and Trusts were advised that in taking up this service they were assuming responsibility for a variety of aspects of the modified implant, including product safety such as the risk of implant loosening, and civil liability.

specification of a telescope used during endoscopic tissue resection procedures. This is irrespective of whether the 'new' device is being placed on the market.

User organisations that modify devices and subsequently place them on the market, by transferring them to another legal entity, will need to comply with the medical devices regulations. The implications of manufacture by user organisations has been explored in Medical Devices Agency Directives Bulletin 18A, which distinguishes between devices which are or are not placed on the market.

9.1.2 Implications for the Service Provider

The activities of repair and maintenance are not covered by the medical devices regulations. However, if the device failed or injured a patient or user, as a result of defective repair and maintenance, both the owner of the device and the repairer could be prosecuted under health and safety law and would probably be liable to the injured person under common law and consumer protection legislation.

9.2 Other Legal Considerations

Particular types of devices and equipment are covered by legislation, which may impact on their repair. Health and safety legislation usually refers to responsibilities of the employer, rather than 'user organisation' which is used in this bulletin.

Health and Safety at Work etc Act 1974

This Act covers the general duty of care of an employer to his employees. If the employer allows the poor repair or maintenance of a device, he may be in breach of health and safety law. The Act also refers to the responsibilities of the employer to non-employees, e.g. the patient and the general public.

Control of Substances Hazardous to Health Regulations 1999

Exposure to certain hazardous substances (including biological agents which may cause infection) is covered by these regulations. The user organisation/employer is required to undertake a risk assessment to determine, amongst other requirements, the precautions necessary to prevent or control exposure of users, patients and others to the substance. User organisations therefore need to ensure that the repairer is not exposed to these substances when carrying out repair or maintenance. For example, an endoscope washer/disinfector that uses glutaraldehyde should be fully drained and rinsed before the device is inspected for repair or maintenance.

Management of Health and Safety at Work Regulations 1999

This is an important piece of legislation requiring employers to assess the risks to workers and any others who may be affected by their work activity, and to have access to competent health and safety advice. The Regulations also require co-operation and co-ordination between employers, such as between the user organisation and the service provider, and to ensure they exchange information about health and safety risks arising out of their work.

Provision and Use of Work Equipment Regulations 1998

The definition of work equipment is very broad and will include many medical devices. The duties under these regulations are to protect those at work. Duties are placed on employers, employees, the self-employed and persons who have control of work equipment.

The Lifting Operations and Lifting Equipment Regulations 1998

These regulations cover devices such as patient hoists. A hoist is used by an employee of an organisation such as the NHS or social services as a piece of work equipment. The Provision and Use of Work Equipment Regulations is applicable to employers, self-employed or any persons who have control of work equipment. Similarly the Lifting Operations and Lifting Equipment Regulations apply.

Pressure Systems Safety Regulations 1999

There is a potential for death or serious injury from stored energy if any part of a pressure system should fail. These regulations are intended to prevent that risk. They apply to the parts of pressure systems that contain fluids (except steam) at a pressure greater than 0.5 bar above atmospheric pressure and to systems that contain steam at any pressure, because steam is particularly hazardous.

These regulations require pressure systems to be maintained in good repair, to prevent danger. The employer of a repairer (the 'competent person') is responsible for ensuring that a repair does not itself cause danger (either directly or by impairing the operation of protective devices). Repair and maintenance should be carried out by a person who is competent to do the work. It is good practice to have a device checked by a competent person before it is returned to service after any repair or maintenance.

Ionising Radiations Regulations 1999

The Ionising Radiations Regulations cover the exposure of persons to ionising radiation arising out of work activities, including industrial, nuclear and medical applications. The Regulations set out the duties of employers who have control over equipment used for medical exposures (such as diagnostic x-ray equipment and radiotherapy machines). Such employers need to implement a suitable quality assurance system for this equipment, in consultation with their Radiation Protection Adviser.

Such employers need to ensure that equipment used for medical exposure is capable of restricting exposure so far as is reasonably practicable with the intended clinical purpose. This means that it must be of a suitable design and construction and be properly installed and adequately maintained.

The Regulations also set out reporting requirements to the Health and Safety Executive in cases when patient doses are much greater than intended following equipment malfunction or defect, and for incidents where any person is likely to have received an overexposure.

Additional supporting guidance ‘Fitness of equipment used for medical exposure to ionising radiation’ is also available from HSE.

Ionising Radiation (Medical Exposures) Regulations 2000

There are additional requirements for in-house engineers who may also be defined as ‘operators’ under these regulations. Those engineers not employed by a user organisation are not likely to be covered by IR (ME)R 2000 so long as they are not contracted to carry out additional tests on top of those normally carried out as part of routine maintenance.

9.3 Liability Insurance

The user organisation should ensure that the service provider has adequate insurance in place.

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.

Insurance

The contractor shall insure against its liability under condition 28 with a minimum limit of indemnity of £5 million per incident or such other sum as may be agreed between the contractor and the authority.

Employers' Liability Compulsory Insurance

Under the Employers' Liability (Compulsory Insurance) Act 1969 you, (if you are an employer – there are some exemptions, for example the NHS), must take out and maintain an approved insurance policy against liability for bodily injury or disease sustained by your employees in the course of their employment. You must also display one or more copies of the certificate of insurance at each place of business at which you employ.

Key Point

- ◆ *The user organisation should be aware of their legal responsibilities and liabilities in respect of device repair and maintenance and ensure the service providers are aware of theirs.*

10. DECONTAMINATION OF EQUIPMENT

Devices should be safe to handle by any personnel that may come into contact with them during the course of repair or maintenance. Guidance on this issue has already been published in HSG(93)26, MDA SN 9516 'Decontamination of equipment prior to inspection service or repair' and in MDA DB 9801.

The user organisation needs to ensure that all devices are adequately decontaminated prior to repair or maintenance. In the event that the user organisation does not have ready access to decontamination facilities, the user organisation may:

- contact the service provider to determine if they have the facility to undertake decontamination; or
- arrange for the decontamination to be undertaken by another organisation, qualified to do so.

Where off-site service is required, the user organisation should make appropriate arrangements for collection or delivery of the item ensuring that relevant legal requirements are met and that the necessary documentation accompanies the equipment. **Contaminated items must not be sent through the post.**

Care should be taken to ensure decontamination is in accordance with the manufacturer's recommendations and appropriate for the device. Use of an inappropriate process or agent may lead to irrevocable damage.

Key Point

- ◆ *The user organisation should ensure that all devices intended for repair or maintenance are safe to handle.*

11. GLOSSARY

Full refurbishment

This term is used in the medical devices regulations and applies to the re-manufacture and placing on the market of an ‘as new’ device. Devices that are fully refurbished and are placed on the market are covered by the medical devices regulations. As such this is an activity that will not be covered by this bulletin.

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 re-use;
- replacement of components/sub-assemblies not suitable for re-use;
- assembly of the replacement components or sub-assemblies, testing of the assembled devices against either original or revised release criteria; and
- 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 document ‘Recommendation NB-MED/2.1/Rec5’.

Placing on the market

This means making available a device for the first time with a view to distribution and/or use – whether that device is new or fully refurbished.

Reconditioning/refurbishment

These terms are synonymous and are used to describe the replacement or substitution of parts of a device with new or reclaimed spare parts. The refurbished or reconditioned device retains its original identity.

Servicing

Routine or planned preventative maintenance often according to a schedule of work.

12. BIBLIOGRAPHY

This bibliography contains documents referred to in the bulletin, together with other documents, which provide background information relevant to the subject under discussion.

Further information on these documents, together with other useful reading, can be found in MDA DB 9801.

A list of all current MDA publications can be found on our web site:
<http://www.medical-devices.gov.uk>.

12.1 Legislation

The Control of Substances Hazardous to Health Regulations 1999 SI 1999 No. 437.

Competition Act 1998.

Consumer Protection Act 1987.

Health and Safety at Work etc. Act 1974.

Management of Health and Safety At Work Regulations 1999, SI 1999 No. 3242

General Product Safety Regulations 1994, SI 1994/2328

The Provision and Use of Work Equipment Regulations 1998, SI 1999 No. 2306

Lifting Operations and Lifting Equipment Regulations 1998, SI 1998 No. 2307

Pressure Systems Safety Regulations, 1999.

RIDDOR, Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 SI 1995 No. 3163.

Ionising Radiation Regulations, 1999 SI 1999 No. 3232.

Ionising Radiation (Medical Exposure) Regulations, 2000.

Medical Devices Regulations

Active Implantable Medical Devices Regulations 1992 (SI 1992 No 3146) as amended by SI 1995 No 1671

Medical Devices Regulations 1994 (SI 1994 No 3017)

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

Guidance

Recommendation NB-MED/2.1/Rec5. Placing on the market of fully refurbished medical devices.

Medical Devices Agency Directives Bulletin 18A. Medical Devices regulations: Implications on Healthcare and Other Related Establishments.

Guidance Note from HSE, Fitness of equipment used for medical exposure to ionising radiation (in preparation).

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HSE 31 (rev1), 06/99, ISBN 0 7176 24412.

Safe Use of Lifting Equipment, Approved Code of Practice and Guidance, L113, 1998, HSE Books.

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General Coshh Approved Code of Practice, Carcinogens Approved Code of Practice and Biological Agents Approved Code of Practice, L5, 1999, HSE Books.

12.2 MDA Publications

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MDA SN 9818, April 1998. Olympus Flexible Fibre Optic and Video Endoscopes.

MDA SN 9713, November 1997. Hydroxyapatite Coatings for Orthopaedic Implants.

MDA SN 9805, February 1998. Ultra Violet Tubes Used in Therapeutic Devices.

MDA SN1999(33), September 1999. Wheelchairs, Seating and Accessories – Inspection, Maintenance and Repair Procedures.

MDA SN 2000(01), January 2000. Medical Devices-Reporting Adverse Incidents and Disseminating Safety Warnings.

12.3 Department of Health Publications

HSG(93)26, June 1993. Decontamination of equipment prior to inspection, service or repair.

EL(98)5, January 1998, Medical Devices Directive – CE Marking.

HSC 1999/179, August 1999, Controls Assurance in Infection Control: Decontamination of Medical Devices.

HSC 1999/053, March 1999, For the Record Managing records in NHS Trusts and Health Authorities.

12.4 Further Reading

Facing Cuts & Competition in Equipment Management, SCOPE Vol.6 No. 3 September 1997, 60-63.

Trends in Medical Equipment Service, Health Devices, Vol.26, No.6, June 1997, 246-253.

The Management of Medical Equipment in NHS Acute Trust in England. Report by the Comptroller and Auditor General. 10 June 1999.

ECRI Forum, Management. Volume 4, Number 3, page 9, 1998.

Use of Maintenance Insurance to Minimize Costs. Thai G Tran. Journal of Clinical Engineering, Vol 19, No.2 March/April 1994 143-147.

The Management of Medical Equipment in NHS Acute Trusts in England, Report by the Comptroller General, NAO, 10 June 1999, ISBN 0 10 268399 9

13. APPENDICES

Appendix 1 – Questionnaire on repair methods, process and standards of operation.

The user organisation should seek satisfactory responses to the following key questions from all those being considered for maintenance and repair activities.

The responses to the questions should be supported by documentary evidence and site visits, where appropriate.

This list is not exhaustive and should be used as a guide.

If the responses received are not ideal then you must assess the response in light of potential risk to patients and users.

Note 1: Not all questions will be applicable to all devices.

Note 2: These questions should be asked for each type of device.

This questionnaire applies to the following device(s):

.....
.....

(a) Information on repair and maintenance methods

No.	QUESTION	KEY POINTS
1.	What is the source of your repair and maintenance instructions ?	<ul style="list-style-type: none">• The manufacturer of the device.
2.	What arrangements do you have for obtaining these instructions ?	<ul style="list-style-type: none">• Contract between the repairer and the manufacturer or manufacturer and user organisation.• Effective communication between the parties having taken place.
3.	How do you ensure that you are kept up-to-date with the latest instructions from the manufacturer ?	<ul style="list-style-type: none">• A documented system detailing the agreement for updates and communication between the repairer and the manufacturer or user organisation.

No.	QUESTION	KEY POINTS
4.	What level of detail is the information provided by the manufacturer and is this sufficiently detailed to enable repair and maintenance tasks to be carried out effectively ?	<ul style="list-style-type: none"> Instructions are unambiguous , comprehensive. Include diagrams and diagnostic software where relevant. Repairer can demonstrate full understanding of all repair and maintenance methods.
5.	What is the experience and training of the repair and maintenance personnel ?	<ul style="list-style-type: none"> Documented evidence of relevant work experience, training and knowledge.
6.	What evidence do you have of individual personnel training ?	<ul style="list-style-type: none"> Procedures for training. Records and certificates where relevant. For all personnel, details of which equipment they have been both trained on and are competent to repair and maintain.
7.	How do you ensure that the personnel are kept up to date with training ?	<ul style="list-style-type: none"> Training records showing regular review of training needs.
8.	How do you propose to manage advisory notices [such as Hazard and Safety Notices] sent to you by the user organisation and implement their advice where relevant ?	<ul style="list-style-type: none"> A system in place to administer any necessary changes. Proactive system to seek advisory notices from the user organisation and other sources.
9.	How do you propose to manage advisory notices received by the manufacturer and implement their advice where relevant ?	<ul style="list-style-type: none"> A system in place to administer any necessary changes. Proactive system to seek advisory notices from the manufacturer.

(b) Repair and maintenance process

No.	QUESTION	KEY POINTS
10.	What is your liability for repair and maintenance ?	<ul style="list-style-type: none"> • Liability for all repair and maintenance clearly defined and documented.
11.	What repair and maintenance instructions are used ?	<ul style="list-style-type: none"> • Manufacturer's own instructions. • Documented procedures detailing the repair and maintenance methods.
12.	If using repair and maintenance methods not specified by the manufacturer, how have you demonstrated its suitability ?	<ul style="list-style-type: none"> • Ensure the user organisation is made aware of the use of any alternative methods. • All risks identified and documented. • A strategy implemented to manage the risks. • Documented procedures detailing the repair and maintenance methods.
13.	What spare parts are being used ?	<ul style="list-style-type: none"> • Manufacturer's spare parts. • List of those items considered by the repairer to be spare parts.
14.	Where do you source your spare parts ?	<ul style="list-style-type: none"> • Supplied by the manufacturer.
15.	Where do you source your spare parts if they are not available from that specified above ?	<ul style="list-style-type: none"> • Manufacturer's spare parts and components sourced from an approved supplier or distributor.
16.	If using spare parts not specified by the manufacturer, how have you demonstrated their suitability?	<ul style="list-style-type: none"> • Ensure the user organisation is made aware of the use of any alternative methods. • All risks identified and documented. • A strategy implemented to manage the risks. • Documented procedures detailing the repair and maintenance methods.

No.	QUESTION	KEY POINTS
17.	What evidence do you have of the arrangements for obtaining spare parts ?	<ul style="list-style-type: none"> • Contract between the repairer and the organisation supplying the spare parts. • Evidence of effective communication between the parties having taken place.
18.	Do you ever use refurbished parts, if so under what circumstances ?	<ul style="list-style-type: none"> • Ensure the user organisation is made aware of the use of any second-hand parts. • All risks identified and documented, which must be acceptable to the user organisation. • A strategy implemented to manage the risks. • Documented procedures detailing the repair and maintenance methods.
19.	How do you document the repair and maintenance process ?	<ul style="list-style-type: none"> • Sufficient detail to understand what repair and maintenance has been carried out. • Details of any spare parts used.
20.	What records do you keep and for how long ?	<ul style="list-style-type: none"> • Evidence of documentation in support of all activities. • A defined retention period.
21.	How would you notify the user organisation of any changes in spare parts or repair and maintenance methods ?	<ul style="list-style-type: none"> • A system in place documenting which changes need to be notified to the customer.
22.	When would you notify the user organisation of proposed changes in spare parts or methods ?	<ul style="list-style-type: none"> • Before any repair is undertaken.
23.	When would you implement a change in spare parts or method ?	<ul style="list-style-type: none"> • Following written agreement by the user organisation of the proposed change.

No.	QUESTION	KEY POINTS
24.	Do you sub-contract any aspect of the repair or maintenance process, if so how is this controlled ?	<ul style="list-style-type: none"> Any operation sub-contracted out is to the same standards detailed for the responsible repairer. Evidence of a contract detailing the responsibilities of each party, with the repairer effectively managing the sub-contractor.
25.	What tools and test equipment do you have to undertake repair and maintenance ?	<ul style="list-style-type: none"> Specification of repair and test equipment including diagnostic software in line with that detailed by the manufacturer Knowledge and training in how to use the tools and equipment [see also training].
26.	What consumables do you use in the repair or maintenance process ?	<ul style="list-style-type: none"> List of items considered to be consumable by the repairer.
27.	Where do you source the consumables used in the repair method ?	<ul style="list-style-type: none"> From the manufacturer or approved supplier.
28.	How do you maintain the repair tools and test equipment ?	<ul style="list-style-type: none"> Procedure in place for regular maintenance, testing and calibration as appropriate.

(c) Quality systems

29.	What quality system do you operate ?	<ul style="list-style-type: none"> BS EN ISO 9002 and BS EN 46002.
30.	Has the system been independently assessed and if so by whom ?	<ul style="list-style-type: none"> Certification by an accredited certification body.
31.	How do you ensure that the service provider reports conditions which have the potential to cause a device failure or otherwise compromise the clinical outcome ?	<ul style="list-style-type: none"> The service provider should be aware of MDA's adverse incident reporting system. The service provider should have a system in place to report such conditions.

(d) Contractual agreements

No.	QUESTION	KEY POINTS
32.	Do you fully understand the requirements of the user organisation ?	<ul style="list-style-type: none"> • Signed up to the contract. • Declaration that only the work detailed in the contract will be undertaken.

Appendix 2 – Questionnaire on service provision issues

The user organisation might also consider the following service related questions, which may or may not be relevant or critical depending on the level of service required.

QUESTION	RESPONSE
Provide details of other user organisations that you provide a service to [include name of organisation, address, contact name, device type].	
What is the experience of other user organisations named above ? *	
Do you provide a loan service to replace equipment that is undergoing repair or maintenance?	
If a loan service is provided, how do you demonstrate the loan device is safe and fit for purpose ?	
Do you operate an emergency call out service for fixed installation equipment ?	
How do you handle broken devices or equipment that cannot be repaired immediately ? For example, where the fault might not be easily identifiable.	
Do you keep supplies of all spare parts on site ? If not, what is the expected delivery time for spare parts ?	
Do you operate 24-hour service, if not how would you handle out of hours repairs ?	
What is the response time for both off-site and on-site repairs ?	
What other service options can you provide ?	

QUESTION	RESPONSE
Provide a summary of the history of the repairer and the current personnel structure.	
Are any IT systems used in managing the repair process. If so, provide details.	
Do you offer a help desk facility ? What is the procedure for obtaining a repair ?	
Do you offer a remote diagnostic support service ? If so, how is this operated and supported ? Is the support via a modem link ?	
Do you provide software for fault finding ?	
What documentary information can you provide on the repair or maintenance that has been undertaken and in what format is this delivered [e.g. computer print-out, worksheet] ?	
Is there any equipment specified that you cannot repair or maintain ?	
Can the user organisation have access to your facility at any time for inspection or audit ?	
What contracts do you have with other organisations ?	
Do you supply upgrades for software-driven devices free of charge ?	

*** The response to this question should be verified independently by the user organisation.**

DISCLAIMER

The Medical Devices Agency (MDA) is willing to, and does give general guidance on questions arising under the Regulations on medical devices. User organisations should not rely on the views of the MDA in respect of legal liability but should take advice from their own lawyers or other professional advisors. Any opinion or guidance given by the MDA is not intended to and can have no legal consequences as only a court can give an authoritative ruling. The information provided in this Bulletin must be read in the light of these comments.

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This Device Bulletin should be brought to the attention of managers and staff in all hospitals, liaison officers and others who report adverse incidents.

This Device Bulletin should also be brought to the attention of medical device co-ordinators, clinical engineering staff, IT staff, medical and nursing directorate managers, general practitioners, dental practitioners, pathology laboratory managers, purchasers and staff responsible for medical equipment use in the community.

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