



AAGBI SAFETY GUIDELINE

Safe Management of Anaesthetic Related Equipment

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1. Summary

- 1.1 Safety, quality and performance considerations must be included in all equipment acquisition decisions.
- 1.2 Each directorate should nominate one consultant with responsibility for equipment management. This Nominated Consultant should be a member of a Medical Devices Management Group, which reports directly to the Trust Board, and he or she should liaise closely with the Technical Servicing Manager.
- 1.3 An inventory of all equipment, including donated equipment, must be held by the technical department for maintenance and replacement purposes.
- 1.4 A planned preventative maintenance programme must be in place.
- 1.5 There should be a policy to cope with equipment breakdown.
- 1.6 A replacement programme which defines equipment life and correct disposal procedures should be in place.
- 1.7 Purchase of new equipment should include wide consultation (especially involving users), and technical advice to ensure practicality, cost effectiveness and suitability for purpose.
- 1.8 There must be a commissioning or acceptance procedure before any new equipment is put into use.
- 1.9 All users must be trained in the use of all equipment that they may use.
- 1.10 All adverse incidents arising from the use of equipment must be reported.

2. Introduction

The Association of Anaesthetists of Great Britain and Ireland has long been committed to improving patient safety. The majority of critical incidents in anaesthesia arise from human error and, although about 20% of incidents are due to equipment failure, many incidents that are initially thought to be equipment failure turn out to be user error or inappropriate use, both of which indicate a lack of training in the correct use of equipment. The Association has produced a number of guidelines with the intention of improving patient safety by reducing human error and detecting potential equipment failure. These include *Checking Anaesthetic Equipment 3 (2004)* and *Standards of Monitoring during Anaesthesia and Recovery Edition 4 (2007)* [1,2]. The Department of Health, through the MHRA, regularly produces Medical Device Alerts concerning problems with equipment, and it is essential that all anaesthetists are aware of relevant publications.

This document gives guidance on choosing, purchasing, maintaining, replacing and disposing of equipment. It also emphasises the need to ensure that anaesthetists are trained in the use of their equipment and that technicians are trained to maintain the equipment. The MHRA publications, *Managing Medical Devices DB 2006(05)* and *Devices in Practice – a guide for health and social care professionals (2008)*, are written from a technical point of view and should be used as an adjunct to the information in this booklet [3,4].

In addition, the MHRA, or their local or national counterpart, is usually willing and able to give detailed advice on the safe management of equipment, and their contact details are given in the appendix.

Throughout this document, the term 'Trust' refers to NHS Trusts, Health Boards, and any other hospital where anaesthetics are given.

3. Responsibility of anaesthetists and Trust or other healthcare providing organisation

3.1 The individual anaesthetist

All anaesthetists must be adequately trained in the use of, and familiar with, all equipment which they use routinely. This training should be recorded, and individual anaesthetists should keep their own record of training for appraisal purposes. They should also be aware of Medical Device Alerts relevant to such equipment. They should all participate in selection of new equipment, training in the use of equipment, and reporting equipment associated incidents.

3.2 The directorate – the nominated consultant or equipment officer/controller

Anaesthetic directorates should nominate one consultant with responsibility for equipment (the 'equipment officer'). The equipment officer will develop specific expertise with respect to equipment and be responsible for a co-ordinated approach to its management (including maintenance and training), replacement and purchase. He or she may wish to enlist the support of other colleagues or suitable operating department personnel to assist with the duties as well as consulting regularly with all members of the anaesthetic directorate. Identification of the departmental equipment officer is the responsibility of the clinical director who should ensure that the individual is identified to the various heads of the technical department.

Large Trusts will need more than one consultant to fulfil this role, and an 'equipment or technical team', answerable to the Directorate Management Team, may be required.

3.3 Duties of the equipment officer

The equipment officer will represent the directorate on the Medical Devices Management Group and liaise closely with the head of the technical department. Their responsibilities include:

- Co-ordinating user input into the choice and procurement of equipment and ensuring its suitability for the purposes intended.
- Ensuring that training is available for staff in the use and care of the equipment and ensuring that appropriate training records are maintained.
- Acceptance of equipment into service.
- Ensuring that procedures for the use of equipment are followed.
- Verification of service arrangements and effectiveness.
- Supervision of user servicing tasks.
- Ensuring there are documented contingency arrangements for patient care in the event of equipment failure.
- Maintaining appropriate records.
- Ensuring that the Trust's policy applies to all equipment brought into the Trust irrespective of the source of funding, e.g. university purchased equipment, loaned and donated equipment.
- Ensuring that all adverse incidents involving medical devices are reported in accordance with the instructions contained in the first Medical Device Alert of each year (titled 'All Medical Devices') issued by the MHRA and that all MHRA and NPSA safety guidance is distributed appropriately.

Adequate sessional time to fulfil these duties should be made available by the Trust.

3.4 The Trust - Medical Devices Management Group and Manager of Technical Servicing

Trusts should establish a Medical Devices Management Group to develop and implement policies across their organisations. This group should report directly to the Trust Board, where a named director should have overall responsibility for medical equipment.

The responsibility for the technical management of each item of equipment must be assigned to one department (the 'technical department'). Most hospitals have a Manager of Technical Servicing in post although their title and the department to which they belong may vary, e.g. department of electronic and biomedical engineering, department of medical physics or estates department.

3.5 Inventory of equipment

Technical departments must maintain an 'inventory of equipment' which should include the following information:

- Unique identifier of equipment – item labelled where possible (if not possible, e.g. endoscope, serial number recorded).
- Date of purchase and when it was put into service.
- Any specific legal requirements needed and whether they have been complied with.
- Where it is located, and record of satisfactory commissioning/installation.
- Recommended service schedule documentation.
- Service arrangements – in-house, supplier, or external contractor details and service level agreement.
- Service reports.
- Records of incident investigations and product complaints.
- Manual or 'Instructions For Use' (IFU) readily available, and record of where kept.
- End-of-life date.

In addition to items for which the technical department has continuing responsibility, the inventory should also include items such as laryngoscopes and non-clinical items such as computers and printers. Although these may not need regular maintenance they should be included in the replacement programme.

Every item of equipment, including consumables, must be identified by a unique number or batch number, and its location must be recorded. This is particularly important in the case of equipment recall due to a subsequent fault. All equipment records should be held on one central record keeping system where possible, e.g. software database managed by medical engineering department. If this is not possible, adequate cross referencing between record systems must be in place. This is particularly important where equipment may be moved between sites.

4. Standards

4.1 Medical Devices Directive and CE marking

The Medical Devices Directive of the European Union prohibits the sale of medical devices within the EU that are not CE (Conformité Européene) marked. A CE mark indicates that devices meet all essential requirements of the Medical Devices Directive and are safe and fit for their intended purpose. However, the CE mark does not indicate clinical efficacy in all circumstances, therefore user assessment is vital for any purchase.

4.2 Standards

To ensure suitability for a given task, most devices are manufactured to one or more verified standards. Standards are produced by CEN, the Comité Européen de Normalisation, or European Committee for Standardization, for mechanical devices, and CENELEC for electrical devices. Many devices used by anaesthetists use electricity to get mechanical results, and have to meet standards of both organisations. ISO, the International Organization for Standardization, and IEC the International Electrotechnical Commission, produce standards for the international market. The British Standards Institution is a national member of the European Organization, and its standards have gradually been integrated with their European equivalents.

4.3 CE marking and non-medical equipment

CE marks for medical devices are awarded in four categories of differing stringency. However, devices intended for non-medical use may also bear a CE mark that is indistinguishable from those on medical devices, but they may not be suitable for use as medical devices. An example is computer equipment, including display units and recording devices, which may have electrical leakage currents which far exceed the safe levels for use near patients with external pacemakers or central lines

that can conduct electricity directly to the heart. A formal risk assessment by an appropriate expert should be performed, followed by suitable modification, before such equipment is used close to patients.

4.4 Non-EU equipment

Equipment purchased outside the European Union may not carry CE marks. For advice concerning such equipment, see Medical Devices Regulations 2002 [5]. Use of non-CE marked medical devices may leave the clinician, and their employer, open to liability that would otherwise be assumed by the manufacturer.

4.5 Permissible devices supplied without CE marking

There are three exceptions permissible for a device to be supplied without a CE mark:

- Custom Made – this is a single device designed and manufactured specifically for a specific patient as prescribed by a healthcare professional.
- Device undergoing clinical investigations – the device must be labelled as such and have the necessary approval (see CA. ISO 14155).
- Exceptional use on humane grounds.

For both Custom Made and Clinical Trial devices the manufacturer must adhere to all other requirements for compliance.

5. Responsibility of manufacturers and suppliers

5.1 The Consumer Protection Act, Liability for Defective Products Act, and the Medical Devices Regulations

The Consumer Protection Act 1988 (CPA) in Britain, the Liability for Defective Products Act 1991 (LDPA) in Ireland, and the Medical Devices Regulations in Great Britain and Ireland which implement the EC Medical Devices Directives into law, embody the current legislation which describes the manufacturer's responsibility with regard to equipment.

5.2 General responsibilities

The CPA, LDPA and Medical Devices Regulations place absolute responsibility for the safety of products on the manufacturer. In the event of a defect causing injury, the manufacturer can be sued by any injured party, i.e. the patient or the purchaser. This is provided that the device has been used for its intended purpose, and in accordance with the manufacturer's instructions. Negligence need not be proved and it is not possible for the seller to escape liability by exclusion clauses in the contract of sale. The manufacturer's responsibility, as described in the CPA and LDPA, ends ten years after delivery of the equipment.

After ten years, the purchaser, but not the patient, could still sue the manufacturer under the Sale of Goods Act in Britain or the Sale of Goods and Supply of Services Act in Ireland but it would probably be difficult to convince the court that the equipment was still 'as supplied'.

5.3 Compliance with the regulations and the competent authority

To place a device on the market a medical device manufacturer must be in compliance with the applicable European

Regulations, including those transposed in each of the member states, e.g. language requirements. With full compliance a manufacturer is then able, where applicable, to affix a CE mark demonstrating compliance with the essential requirements of the Directive. The Medical Devices Directive and the application of the CE mark was a legal requirement for all manufacturers with effect from 14th June 1998, following a 5-year transition period.

Within the United Kingdom and Northern Ireland responsibility for the enactment and compliance with the Medical Devices Directives has been assigned to the Medicines and Healthcare products Regulatory Agency {(MHRA) (Competent Authority – CA)}, working in conjunction with the respective devolved administrations of Northern Ireland, Scotland and Wales. The CA for Ireland is the Irish Medicines Board, Medical Devices Department.

6. Choosing and trialling equipment

6.1 General principles

Choosing anaesthetic equipment should address the requirements of safety, quality, performance and affordability (value for money). The selection process should take into account local and national acquisition policies. The choice of equipment should incorporate plans for standardisation and rationalisation to meet existing and future needs. The Medical Devices Management Group should ensure that acquisition requirement takes into account the needs and preferences of all interested parties including the user, the commissioning, decontamination, maintenance and de-commissioning parties.

6.2 Criteria for choosing

There are many different categories of equipment used in anaesthesia, ranging from low cost items purchased in large volumes to high cost items purchased in small numbers. Purchasers are encouraged to establish a list of available manufacturers and suppliers. The choice can then be made on evidence supplied on the following criteria:

- Fitness for intended purpose/application, including ease of use.
- Safety, quality and performance information from the manufacturer.
- Rationalising the range of models versus diversity.
- Requirement and availability of training and support services.
- Single use where appropriate.
- Maintenance, repair support services and availability of technical support.
- Decontamination and disposal procedures, including recycling, compatible with local processes.
- Previous performance, reliability and warranty details.
- Lifetime costs.

6.3 Assessing equipment and the final choice

Equipment under consideration can be assessed by various means. A literature review can be carried out to provide the best evidence. Organisations such as the Centre for Evidence-based Purchasing (CEP, which was part of the NHS Purchasing and Supply Agency) and Emergency Care Research Institute (a US-based organisation) publish reports on various categories of equipment. For up-to-date information, purchasers should contact and visit other users, trade exhibitors and sometimes factories. In particular, previous performance by the manufacturer in terms of delivery, stock held, training provided and response to problems are rarely published, but details could be obtained from users in other Trusts.

The Medical Devices Management Group, including the anaesthetic equipment officer, should then carefully consider the options from the information available. Once a choice is made, a trial should be carried out on the selected equipment by users. As many users as possible should be encouraged to participate and to feedback to the equipment officer on an agreed form. Such forms are often a compulsory part of the purchasing procedure.

The outcomes from trials of some equipment can be assessed against the known outcomes from 'gold standard' equipment, for example first time insertion success of laryngeal mask airways. The manufacturer will usually provide a free loan of equipment or samples if the products are disposable. It is important to remember that NHS contract terms impose full responsibility on the suppliers for equipment on loan. All staff using loan equipment must be trained by the supplier or an authorised agent. It is the Trust's responsibility to ensure that loan equipment is decontaminated before return to prevent cross-infection.

To avoid unnecessary duplication of trials, the anaesthetic

equipment officer is encouraged to collect all feedback from the trial and publish the outcome in an appropriate format, for example at a local or national meeting. The equipment officer will then recommend the choice of equipment to purchase.

An editorial in *Anaesthesia* in June 2008 recommended establishing a Device Evaluation Centre with a panel of experts to critically appraise available evidence and publish the results on a website [6]. Individual groups of anaesthetists would be encouraged to undertake studies with support from the Device Evaluation Centre in terms of pro formas for ethical approval and protocols, and statistical help and advice. This would avoid duplication of trials by individual Trusts and researchers, and enable rapid removal of inferior products.

6.4 'One size suits all'

Having a variety of models for the same purpose can increase the risk of operator confusion, leading to misuse and complicating training requirements. In particular, having both single-use and re-usable equipment intended for the same purpose could result in re-usable equipment being discarded and vice versa, resulting in increased costs or potential harm to the patient and exposing the Trust to risk. Restricting purchase and stockholding to one type of device reduces these risks and may reduce maintenance costs. On the other hand, restriction to one product will increase vulnerability to product faults, and remove a degree of clinical freedom from individual practitioners.

6.5 Leasing or purchasing

Consideration should be given whether equipment should be purchased outright, leased or rented. For example, it may be more cost effective to rent an expensive item for occasional use when required.

7. Public sector procurement regulations and directives and the process of purchasing

7.1 Standing orders and standing financial instructions (SFIs)

The process of procurement of goods and services in the NHS is governed by SFIs. There is a financial value for an order or contract above which a competitive process should be used; often this is in the region of £15,000 to £30,000.

7.2 Procurement directives

All public sector procurement is subject to the principles of the Treaty of Rome (transparency and fairness) and the significant majority (including all medical equipment) is also subject to the EU Procurement Directives. The Directives were updated in 2006 to account for the use of eEnablement technologies in public sector procurement and enable greater flexibility for complex procurements.

The relevant Directive for medical equipment is the Procurement Directive 2004/18/EC, 31 March 2004 for Public Contracts for which the UK Regulation that enforces the Directive is Public Contracts Regulations SI 2006 No 5 [7,8].

7.3 EU procurement thresholds

The EU Procurement Directives apply to all orders and contracts for any given organisation (or groups of organisations when collaborative procurement is undertaken). Splitting lots to avoid the thresholds contravenes the Directives. A notice of intent (indicative notice) of known future expenditure should be placed.

EU procurement thresholds

Thresholds applicable from 1 January 2008 are given below. Thresholds are net of VAT. Public contracts regulations 2006 - from 1 January 2008

| | SUPPLIES | SERVICES | WORKS |
|---|------------------------|------------------------|----------------------------|
| Other public sector contracting authorities | £139,893 (€206,000) | £139,893 (€206,000) | £3,497,313 (€5,150,000) |
| Indicative notices | £509,317 (€750,000) | £509,317 (€750,000) | £3,497,313 (€5,150,000) |

(NB. The Euro values are the reference quantities. The conversion rate to pounds was based on a exchange rate of 0.68 which may vary).

7.4 Process of purchasing

Most Trusts will use the following process for the purchase of medical equipment unless it is part of a more complex procurement. The basic steps involved in this process are:

- Indicative notice (if relevant)
- Advert in the Official Journal of the European Union (OJEU)
- Suppliers express an interest
- Suppliers provide prequalification information (should be via the NHS supplier information database, SID)
- Short listing and suppliers notified
- Issue of tender
- Presentations by suppliers, visits to suppliers
- Return of completed tender by suppliers
- Evaluation of tenders
- Award notified
- Standstill period (see 7.6)
- Award of contract

More guidance on the application can be found on the Office of Government Commerce and NHS PaSA websites [9,10].

7.5 Purchasing and Supply Agency (PaSA) and 'Buying Solutions'

By 2010 the function of PaSA will be taken over by 'Buying Solutions' – the national procurement partner for UK public services. It is planned that a series of regional support units, owned by the NHS, will provide a single point of contact for suppliers in each region.

7.6 Mandatory standstill period

The 2006 UK Regulations also brought into force a mandatory 10-day standstill period between the notification of award decision and the date of contract conclusion for all procurements that are subject to the full scope of the EU public procurement directives. This is not part of the EU Directives but follows the Alcatel court case [11].

7.7 Pre-purchase questionnaires

Medical equipment will often be subject to the completion of a pre-purchase questionnaire (PPQ) by the supplier for the Trust's EBME Department. The PPQ is usually completed by the supplier before or with the order.

7.8 Funding

Major items of equipment (e.g. workstations, monitors) are funded by the Trust Capital Equipment Committee or similar. Consumables and items below a threshold figure (usually about £5000) come out of the directorate or theatre budget.

There should be a planned process of replacement for major equipment, such as anaesthetic workstations and monitors, so that each year a proportion of these are replaced in order to spread the cost. It should be presumed that such equipment will last about eight years, and the whole life cost taken into consideration.

When negotiating a purchasing agreement for major equipment, a training package should be included and consideration given to awarding a servicing agreement. It is often advantageous to bundle extras into the initial deal rather than pay for expensive software upgrades at a later date. It is advisable to compare the complete purchasing agreement from more than one manufacturer, and in return for notifying the intention to purchase future equipment from the same company it may be possible to fix the price for a few years (plus inflation). This allows the company to plan ahead and the hospital to standardise equipment.

Advances in technology inevitably give rise to new equipment, and justification of need through a business case may have to be submitted to the Trust for approval. In some cases additional funding has been made available from central sources for 'essential' new equipment, such as NICE funding for ultrasound guided CVC placement. Charitable sources of funding also exist, e.g. League of Friends, but such organisations prefer not to fund items which should be bought by the Trust. A personal approach to such organisations with details of how patient care will be enhanced is recommended.

8. Commissioning new equipment

The MHRA Device Bulletin 'DB2006(05) Managing Medical Devices. Guidance for healthcare and social services organisations' gives comprehensive advice on commissioning new equipment [3]. Key major points are summarised below:

- It is important that deliveries of new equipment are recorded, and go to the right place.
- New anaesthetic equipment, which may not all come at the same time, has to be unpacked, assembled, recorded on an inventory, have identifying labels attached, and safety checks performed. Medical engineering departments will usually perform these tasks, although sometimes it is the responsibility of the manufacturer or supplier.
- It should also be noted that Portable Appliance Testing (PAT) applies to all equipment used in hospitals including, for example, the coffee machine in the anaesthetic dept.
- Co-ordination between several departments may be necessary, especially if permanent installation work or additional services are required.
- Before equipment is used for the first time, full functional checks must be performed, and staff trained in its use.
- If the equipment uses specialised consumable items, arrangements to purchase them should be set up well before the initial stock runs out.
- Loan equipment has to go through a similar process, and should be subject to a written agreement defining responsibilities and liabilities.

9. Shared equipment

Many types of equipment used by anaesthetists are also used by other specialties in a variety of locations throughout a hospital or unit. There are many safety, efficiency and cost advantages in standardisation. In terms of the patient journey, for example from admission through accident and emergency, to radiology, operating theatre, intensive care unit and ward, the process is considerably simpler and safer if the devices the patient is attached to all use the same connections to monitoring devices and infusion systems. It aids staff training and mobility if similar devices are in use in most areas of a hospital, important examples being defibrillators and infusion pumps. This may be facilitated if the equipment officer and the Medical Devices Management Group liaise closely with the departments using similar equipment, e.g. intensive care, accident and emergency, radiology, cardiology and respiratory medicine.

Although departments may wish to compile their own inventory of equipment for which they have managerial and financial responsibility, it is a requirement that a database of all such equipment is maintained by the technical department.

Areas of uncertainty over ownership of equipment should be clarified. Examples include infusion pumps, patient controlled analgesia equipment, and blood warmers. It may be appropriate for some high value items to be shared, and for commonly used equipment like infusion pumps to be located in a central store.

The financial implications of asset sharing should be clarified. Each directorate may have to contribute to the costs of depreciation, servicing, maintenance and replacement. Responsibilities for organising and monitoring servicing and maintenance schedules and for planning replacement must be defined.

10. Maintenance

10.1 Planned preventative maintenance programme

Anaesthetic equipment which is not serviced regularly is liable to break down with potentially life-threatening consequences. A planned preventative maintenance programme is essential. A maintenance log for each device must be kept, linked to the technical department inventory. A record of all breakdowns should also be kept. Regular review of each class of item should reveal the incidence of breakdowns, which could indicate the need for modification of equipment, frequency of maintenance or its urgent replacement, or even a need for further user training.

10.2 Choice of provider

All suppliers must support their equipment, and this includes maintenance. At the time of purchase, the 'life time' cost should be determined, including the frequency and cost of regular servicing proposed by the supplier. It is recommended that the cost of maintenance contracts should be inclusive of emergency call outs and travel time for engineers, as well as fixed interval servicing and parts. Cheaper alternatives usually exclude the cost of emergency call outs and travel time and may be appropriate for hospitals with sufficient back-up equipment.

Trusts may prefer 'in-house' maintenance, as this could have logistic and cost advantages. The support to be provided by manufacturers must be defined when equipment is purchased and should include the provision of service manuals, on-going technical training and spare parts. If upgrading or modification of equipment is required at a later date, there are likely to be additional costs even if the work is to be done in-house. An annual maintenance budget of at least 10% of the equipment's purchase cost is necessary.

Software upgrades must only be undertaken by the supplier.

Third party servicing is another option which may be of particular value for the maintenance of equipment which requires specialist knowledge and testing, e.g. vaporisers. Care should be taken to make sure only original equipment manufacturers (OEM) spare parts are used.

Whichever of these options are chosen, it is essential that they are fully integrated into the planned maintenance programme.

10.3 Equipment breakdown

The equipment officer should ensure that a complete set of back-up equipment is available. If it is not, removal of faulty equipment from service may result in the cancellation of operating lists with consequent distress to patients and possible implications for the fulfilment of contracts. The equipment officer should agree a departmental policy covering the unusual event that two identical items break down at the same time, and should support colleagues who invoke this policy. The policy should be written so that the patient's best interests are protected whatever the prevailing circumstances.

In the interests of patient safety, it is essential for all theatres to keep available manual resuscitation equipment for emergency use (see *Checking Anaesthetic Equipment 3, 2004*) [1]. All theatre staff should be trained in the procedures to be followed for instances of equipment failure.

10.4 Training in maintenance

Suppliers and their agents are externally audited in all their procedures, and these include the provision of maintenance. These standards for quality management systems aid effective control through the definition and documentation of activities, the keeping of records to prove that these activities are being effectively executed and the audit of records by both internal and external personnel.

For 'in-house' departments, quality manuals which document operating policies and procedures need to be verified. These will cover not only existing activities such as purchasing, repair and pre-planned maintenance but also other activities such as document control, corrective action and quality records.

If 'in-house' maintenance is chosen, enough time and money must be allocated for training of technicians to a level equivalent to that of the supplier so that they are able to provide a high-quality, safe service. Regular on-going training provided by the supplier should be the norm.

10.5 Spares

Suppliers have a responsibility to provide spares for seven years after delivery of the last example of a particular model.

The responsibility for obsolete devices more than seven years old is that of the Trust, and the need for insurance should be assessed and acted upon.

10.6 Modifications

If a modification is undertaken on a CE marked device, other than by the manufacturer, then responsibility for the safety and liability for the modification changes to the organisation that has completed the modification. One particular example is if a device labelled as single-use is reprocessed for further use.

11. Replacement

11.1 Planned equipment replacement programme

Equipment must be condemned and replaced before it becomes unreliable and endangers the patient, and it is recommended a planned equipment replacement programme, which is phased over a number of years, is prepared and continuously updated. This should be planned in conjunction with Trust management and the finance department. The choice of new equipment can then be made after appropriate trials, and should take into account department needs, such as plans for standardisation and rationalisation (see section 6).

11.2 Timing of equipment replacement

Nationally recognised guidelines on the timing of equipment replacement do not exist. Therefore it is recommended that equipment be replaced when it has reached the end of an agreed time-period, and in consultation with finance officers. This time period will depend on the type of equipment that needs replacing.

Replacement of electronic equipment should be considered at five years and mechanical equipment at eight years. Financial forecasting should take into account the agreed equipment life cycle and budgets should be adjusted accordingly to ensure replacement funding is available, thus avoiding delays and potential associated patient risks. When delays are inevitable, clinicians should seek, in writing, an 'extension of use' beyond the agreed time-periods with the relevant medical and financial officers.

In the past, many items of anaesthetic equipment were mechanical. Today, most devices contain a high electronic content, including software. This is placing an increasing burden on equipment replacement budgets, owing to the increased pace of obsolescence of electronic equipment.

12. Disposal

12.1 General

Unreliable, damaged or worn out equipment should be removed from service and destroyed. Obsolete but functional equipment has potential resale value but carries with it liabilities under the CPA and LDPA. There are companies who can manage such transactions. The DoH has issued guidelines on the resale of medical equipment in MHRA DB2006(05) [3]. Alternatively, equipment can be donated to a charity. The donor has a moral responsibility to ensure that the recipients are given all relevant information about the equipment.

Full service history, usage, fault log, replacement parts and decontamination status should be available when equipment is offered for sale or donation.

Disposed equipment must be removed from the capital asset register.

12.2 European WEEE Directive

The European WEEE Directive enforces the recovery and recycling of certain types of electrical and electronic equipment (EEE) when it is disposed of. The Directive places a requirement on producers and/or final users to recover and recycle the equipment in line with specific rules. Producers of electrical and electronic items are required to register with the Environment Agency, through organisations referred to as 'compliance schemes', and are required to provide information relating to material content and recycling [12].

12.3 Re-use of equipment

Equipment that may be used on more than one patient should be decontaminated or sterilised according to manufacturer's instructions and the AAGBI guidelines (see *Infection Control in Anaesthesia 2, 2008*) [13]. Some equipment has a limited

number of re-uses (e.g. re-usable LMAs) and a record card or similar device must be used to maintain an accurate record of the number of re-uses. Any equipment bearing the mark of a figure 2 with a line crossed through it is for single use only and must not be re-used.

13. User training

13.1 General

Anaesthetists must be trained in the use of all the equipment that they may use. Training requirements clearly vary widely between different devices, some requiring little or no additional training apart from common sense, others being unusable without complex and specific training. There is little or no national framework for the standardisation of training in use of devices in anaesthesia or indeed in any other clinical field, with the result that currently it is the responsibility of the individual clinician to ensure that he or she has received the appropriate training and that it is kept up-to-date. A record of training received by department members should be kept, and it should form part of the annual appraisal process.

In more than half of the adverse incidents reported to the Medicines and Healthcare products Regulatory Agency (MHRA) there is no readily identifiable equipment fault. Although often difficult to define precisely, it seems more than reasonable to assume that many of these have resulted from user related issues. In some cases it is clear that the user has been the sole cause of the adverse incident which would not have occurred if the device had been correctly used.

13.2 Manufacturers' obligations

Manufacturers of medical devices have a legal obligation to supply Instructions For Use (IFU) which cover not only how to use the device but also a description of the intended use of the device. Using the device outside of the IFU removes much of the manufacturer's responsibility and transfers it to the user. Manufacturers should be encouraged to produce IFUs which are easy to read and understand; there may be a significant advantage in producing a summary of the important points or key instructions. Where practical, these should be available on the equipment, or held in close proximity.

Where new equipment is purchased the amount of training offered and taken up is very variable. For example, with complex devices, such as the new generation of anaesthetic machine workstations, it is usual for manufacturers to supply a significant amount of user training.

13.3 CCT and CPD

Training in anaesthesia, as described in the CCT documents published by the Royal College of Anaesthetists, includes numerous references to anaesthetic related equipment, and both Primary and Final FRCA examinations cover the basic principles and more advanced use of a range of medical devices.

Information about new devices and updates on existing ones is frequently included in Continuing Professional Development (CPD) programmes, and clinicians should use this as a way of keeping up-to-date.

13.4 E-learning, simulation and revalidation

E-learning material is now becoming available, in particular (from the MHRA) on the general principles in using medical devices safely, e.g. electrosurgery and the anaesthetic machine. These programmes underline the importance of maintaining a good understanding of the basic principles behind device function. For complex devices such as anaesthesia workstations complementary device-specific educational material is required. To maintain the necessary independence of bodies with national regulatory roles means that this type of material will, most probably, be developed by partnerships between manufacturers, the Association of Anaesthetists and the Royal College of Anaesthetists.

There is a coexistent need to develop effective training in the use of equipment in unanticipated and emergency situations, particularly in the recognition and management of equipment failure. These situations fortunately occur infrequently, and

anaesthetic simulators already play an important role in appropriate training.

Users of complex equipment outside of the healthcare setting (for example in the aviation industry) are subject to much more clearly defined appropriate training in safety. All responsible clinicians will use the opportunities provided by CPD to keep their equipment based skills up-to-date but there are concerns that the less motivated can still function on a daily basis without adequate checks on acquisition or retention of skills.

Revalidation of all clinical staff will help to ensure that all practitioners have up-to-date equipment based skills and have received appropriate training. Effective training material, with meaningful assessments, need to be developed. Such material is already available in some clinical disciplines through e-learning.

14. Incident reporting and investigation

As a profession which emphasises life-long learning, we must promote an open culture in which all staff will discuss and report incidents where errors or service failures have occurred. This encourages the profession to learn from mistakes and identify any continuing risks.

Each NHS Trust should have risk management systems in place involving the reporting, analysis, control and prevention of incidents [14]. It is the responsibility of each anaesthetist to be aware of the incident reporting procedures of their organisation. This procedure may include risk managers, medical device liaison officers and anaesthetic equipment officers.

In addition to the Trust's local incident reporting system, there are several organisations, listed below, that may need to be made aware of adverse incidents associated with anaesthesia.

14.1 Medicines and Healthcare products Regulatory Agency (MHRA)

The MHRA investigate reports of adverse incidents involving medical devices or their instructions for use that have led to, or could lead to, death, life-threatening illness or injury. The manufacturers of medical devices must report such incidents to the Competent Authority (the Vigilance System) and investigate them as part of their post market surveillance responsibilities, as required by the MDD. Therefore, manufacturers must be informed of such incidents. However, medical devices (with any packaging and labelling) which have been involved in an incident have also to be kept and isolated until MHRA has been given the opportunity to carry out an investigation.

Where the MHRA investigation concludes there are safety

implications for patients or users the Agency will issue a Medical Device Alert (MDA). MHRA also publish Device Bulletins and One-Liners to give safety information and guidance on general safety issues.

There are separate user reporting systems for medical device incidents which occur within the devolved administrations of Northern Ireland, Scotland and Wales (see useful numbers and websites section on page 37).

14.2 National Patient Safety Agency (NPSA)

The NPSA has implemented an anonymised National Reporting and Learning System across England and Wales. This system allows reporting of all failures, mistakes, errors and near misses, with the aim of ensuring that lessons are both learned and shared throughout the health service. They undertake various safety initiatives, publish updates on the reports received, and provide guidance in the form of bulletins and newsletters. The anonymous reporting allowed under the NPSA system prevents a full investigation, therefore the NPSA actively encourages reporting of all medical device incidents directly to the MHRA. There is an NPSA initiative underway with the Royal College of Anaesthetists and the AAGBI to institute a specific anaesthetic reporting system.

14.3 Health and Safety Executive

Incidents involving work-related deaths, major injuries or injuries resulting in over three days off work, work-related diseases, and dangerous occurrences (near-miss accidents) whether involving medical devices or not, should also be reported under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR '95) to the relevant enforcing authority for the premises at which the incident occurred. For healthcare premises, this will usually be the local office of the Health and Safety Executive (HSE) but for some it may be the local authority. Further information is

available from www.hse.gov.uk

14.4 DoH Estates and Facilities

Incidents involving non-medical equipment, including engineering plant, parts of the fabric of the building and gas pipelines should be reported to the Head of Engineering at the DoH Estates and Facilities in the Department of Health. Further information is available from www.nhsestates.gov.uk

14.5 Police

The police will investigate where there is the suspicion of criminal activity, such as malicious tampering with medical equipment. There is a concordat between the police, HSE and DoH for the investigation of such incidents; therefore should the police decide no further action is required the investigation will pass to the HSE and DoH. Due to the rare and unusual nature of these investigations there are no established national guidelines; however advice should be available from your hospital's legal department, medical defence organisations, MHRA and the Association of Anaesthetists.

14.6 Dissemination of safety information to users

Safety information from the MHRA and NPSA is distributed via the DoH Central Alerting System (CAS) [15]. All internal and external communications concerning equipment and patient safety must be cascaded to all the users of equipment through Trust communication channels.

14.7 Manufacturers

The manufacturer has a legal obligation under the provision of the European MDD to monitor performance of their devices in a post production phase, i.e. after placed into clinical use. Typically this is achieved by a proactive post market surveillance programme, of which incident reporting may be a part.

15. Audit

15.1 Internal

This is part of the Trust's clinical governance arrangements and should consist of regular/annual review of policies and systems for managing medical equipment.

Healthcare professionals must ensure their own training and skills remain up-to-date, and this should form part of the annual staff appraisal.

15.2 External

The Care Quality Commission undertakes audits and inspections of healthcare organisations regularly to ensure that the MHRA guidance on safe use of medical devices has been followed.

Strategic Health Authorities audit the performance of Trusts, including performance against deadlines for action required by the issue of DoH Safety Alert Broadcast System notices.

Glossary of acronyms

| | |
|---------|---|
| BSI | British Standards Institution |
| CA | Competent Authority (e.g. in the UK, the MHRA) |
| CCT | Certificate of Completion of Training |
| CE | Conformité Européene |
| CEN | Comité Européen de Normalisation (For Mechanical Devices) |
| CENELEC | Comité Européen de Normalisation (For Electrical Devices) |
| CEP | Centre for Evidence-based Purchasing (part of PaSA) |
| CPA | Consumer Protection Act 1988 |
| CPD | Continuing Professional Development |
| CVC | Central Venous Catheter |

| | |
|--------|---|
| DB | Device Bulletin |
| DoH | Department of Health |
| EBME | ElectroBioMedicalEngineering (Hospital Equipment Technicians) |
| EC | European Community |
| EU | European Union |
| FRCA | Fellowship of the Royal College of Anaesthetists |
| HN | Hazard Notice |
| HSE | Health and Safety Executive |
| IEC | International Electrotechnical Commission |
| IFU | Instructions For Use |
| ISO | International Organization for Standardization |
| LDPA | Liability for Defective Products Act |
| LMA | Laryngeal Mask Airway |
| MDA | Medical Device Alert |
| MDD | Medical Device Directive |
| MHRA | Medicines and Healthcare products Regulatory Agency |
| NICE | National Institute for Health and Clinical Excellence |
| OEM | Original Equipment Manufacturer |
| OJEU | Official Journal of the European Union |
| PaSA | (NHS) Purchasing and Supply Agency |
| PAT | Portable Appliance Testing |
| PPQ | Pre-Purchasing Questionnaire |
| RIDDOR | Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 |
| SFI | Standing Orders and Standing Financial Instructions |
| SID | Suppliers Information Database |
| WEEE | Waste Electrical and Electronic Equipment |

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Useful numbers and websites

For reporting adverse incidents and further information

MHRA

Tel: 020 7084 3080

Website: www.mhra.gov.uk

Email: aic@mhra.gsi.gov.uk

NPSA

Tel: 020 7927 9500

Website: www.npsa.nhs.uk

Email: enquiries@npsa.nhs.uk

RIDDOR

Tel: 0845 300 9923

Website: www.riddor.gov.uk

Email: riddor@natbrit.com

DoH Estates

Tel: 0113 254 5172

Website: www.nhsestates.gov.uk

Email: nhs.estates@dh.gsi.gov.uk

Northern Ireland

Tel: 028 9052 3704

Website: www.dhsspsni.gov.uk/niaic

Email: niaic@dhsspsni.gov.uk

Scotland

Tel: 0131 275 7575

Website: www.hfs.scot.nhs.uk

Email: enquiries@hfs.scot.nhs.uk

Wales

Tel: 029 2082 3505

Email: health.enquiries@wales.gsi.gov.uk

Eire

Tel: 00353 1 676 4971

Website: www.imb.ie

Email: imb@imb.ie

Buying Solutions

Tel: 0345 410 2222

Website: www.buyingsolutions.gov.uk

Email: info@buyingsolutions.gsi.gov.uk



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