USE OF MEDICAL DEVICES

improving safety and performance

a COCIR and EUROM VI document

EUROM VI "Medical Technology"

USE OF MEDICAL DEVICES

improving safety and performance

1. Introduction

These User Guidelines relate to medical devices, more specifically to electro-medical equipment. The Guidelines are intended to help increase the safe use and the maintenance of the intended performance of the devices and, thus, decrease the adverse incident rate.

It is in the interest of the patient, and thus of healthcare providers, MANUFACTURERS and regulators, that medical devices achieve their full potential to give patients the high standard of care expected by the patients.

Medical devices, placed on the market under the requirements of the Medical Device Directive (93/42/EEC), are designed and manufactured not to compromise the clinical conditions or the safety of patients or other persons, when used under the conditions and for the purposes intended. The safe use and the performance, however, could be negatively affected by unqualified modifications, improper maintenance or inadequate use whether or not caused by insufficient training. This may not only increase RISK, but also have an impact on the liability of the MANUFACTURER and of the owner of the device. These Guidelines advise how to deal with foreseeable situations.

The advice given fits closely with an approach related to the application of quality assurance (QA) principles to the use of the medical devices. This is well in line with current international activities that aim for the publication of a guidance document for applying ISO 9004:2000 ideas in the healthcare industry.

Furthermore, various initiatives on user guidance, or even user regulation, have recently been launched, sometimes at international level but mostly at local or national level. Medical devices such as capital-intensive medical equipment, in particular, usually differ little, if at all, in the various European member states. A common approach to such user guidelines in Europe would probably be very cost effective for all parties involved (e.g. tools, training, etc.) and stimulate the healthcare providers to adopt similar levels of quality management across boundaries within Europe.

The objective of this guideline is to describe the management of the user related life cycle elements of a medical device from procurement until end of life to minimise use-related RISK and to assure safe and effective use of medical devices by intended users.

The document will give answers to those questions that are most frequently asked.

Note that the terms HARM, HAZARD and RISK are being used in this document as defined in [1].

Note that terms printed in small caps are defined terms; see annex A1.

2. Procurement & purchasing

2.1 CE-marked medical devices

The MDD came into force on June 14, 1998. Medical devices now normally bear the CE-marking, which indicates that these products have been subject to an assessment of their conformity with the provisions of the MDD. Active medical devices intended for implantation are covered by the AIMD; they will not be considered separately in this document, as most of the situations described do not apply to them.

Intended use/purpose means: ”the use for which the device is intended according to the data supplied by the MANUFACTURER on the labelling, in the instructions and/or in promotional materials” [2]

The safety and performance of the device is to a greater or lesser extent dependent upon the in-use situation (the user and his qualification, the medical procedure, the medical condition of the patient, circumstances, the man-machine interface, the intended use, calibration, maintenance etc). Therefore, it is very important that the appropriate device is selected and put into service for a specific procedure, occasion and patient. The procurement and purchasing are therefore important steps. The user’s requirements and wishes must be conveyed via the distributor to the MANUFACTURER so he can offer the most appropriate solution.

HARM may occur if at least one of the following elements is not appropriately covered:

- The wrong device might be bought due to misunderstanding regarding the actual use in the practitioner-engineer-clinic-procurer-distributor-MANUFACTURER chain.
- The wrong device is bought due to inexperienced clinical, technical and administrative staff – what was needed was never really understood or carried forward.
- The intended use of a device has shifted since the first specifications were written.
- An inappropriate device is selected due to: tradition, similar devices already in use, existing consumables, lack of funding, user policy etc.
- A mismatch may result in the incorrect operation or inferior performance of a device/system, unsafe combinations with other devices or costly maintenance.
- An expensive combination of devices might be bought because of the selection of a cheap main unit and costly consumables.

Recommendations

The user should create clear communication channels within and outside his organisation, to the distributor and to the MANUFACTURER. The MANUFACTURER should, likewise, do the same. Over-specification should be avoided. Specifications and selection criteria should be stated, preferably from a multi-disciplinary team. Life cycle cost analysis could be one tool to examine the costs for various devices for the expected in-service period. Standards can also be a tool to help ensure that a certain safety feature or function is specified.

The user could choose to state what procedures and performances are required from the device or to state the intended purpose of the device. For devices intended for use by laypersons, it is important to take into account the abilities of the patients/users and the use environment.

The user should also study conditions and costs for upgrading, maintenance and spare parts as well as for initial and repeated training of staff.

The user or his organisation should ensure that the intended performance of the purchased product fulfil the intended use. Any new medical devices must be CE marked in accordance with the MDD and its national implementation law.

If a new CE marked medical device is to be connected with some equipment already in place, the connectivity and compatibility of the CE marked device and the other equipment (either CE marked or not) will have to be checked and documented.

Note - There is a restricted possibility to buy used medical equipment without CE Marking. If that equipment was put on the market before June 1998, and not fully refurbished after that date, CE marking is not mandatory. See 2.1. In addition, national regulations should be checked.

Interested parties such as clinical engineering staff and the Radiation Protection Advisor should be involved at the contract stage.

The medical device will be delivered with

- all information needed to verify whether the device is properly installed and 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 [3],
- where appropriate, information to avoid certain RISKS in connection with implantation of the device,
- information regarding the RISKS of reciprocal interference posed by the presence of the device during specific investigation or treatment,
- in the case of devices capable of emitting radiation for medical purposes, details of the nature, type, intensity and distribution of this radiation [4], [5],
- the instructions for use, including details allowing the medical staff to brief the patient on any contra-indications and any precautions to be taken [6].

The required language of all documentation is to be clearly defined in the contract, taking into account the prevailing national regulations.

2.2 Non CE-marked medical devices

The MDD came into force on June 14, 1998. Medical devices now normally bear the CE-marking, which indicates that these products have been subject to an assessment of their conformity with the provisions of the MDD. The MDD also mentions medical devices intended for clinical investigation and custom-made devices, which in most cases do not bear the CE-marking.

All medical devices, which were put on the market before June 14, 1993 do not bear a CE-marking under the MDD; but they may have CE-marking under directives, e.g. the European Directive on Electromagnetic Compatibility (EMC). Likewise, medical devices put on the market between June 14, 1993 and June 14, 1998 may or may not bear the CE-marking under the MDD.

Impacts/HAZARDS:

HAZARDS may occur if at least one of the following elements is not appropriately covered:

- information on the products
- information on interfaces
- information on (declarations of) mutual compatibility with other devices or accessories
- availability of approved spare parts
- availability of qualified service and maintenance
- availability of measuring instruments for testing and maintenance

Recommendations

- identify the products as medical devices or as accessories
- check whether products are medical devices within the scope of the MDD, or perhaps products for clinical investigation or custom-made devices
- check –where possible- the latest safety standards harmonised [7] to the relevant directive and determine if the product satisfies the latest requirements. If not, additional precautionary measures may have to be established or the product may need to be upgraded or replaced.

3. Handing over

If hand over documentation is not available or incomplete, it is often impossible for the user to claim for guarantee or, where required, approval for operation of the equipment (e.g. for radiological equipment).

Recommendations
The customer should draw up relevant documentation covering the handing over and the initial training of staff. This could be combined with a logbook (see chapter 5.1). It should describe the delivery, documentation (such as the results of the acceptance test and safety test) and special agreements with the MANUFACTURER.

If it is necessary to carry out performance testing for quality assurance -for example, mandatory for X-ray equipment in some countries- the necessary measurements should be carried out together with the MANUFACTURER or with authorised persons. It is advisable to have unambiguous documentation and easy to comprehend measuring records.

Upon delivery, the customer should check for completeness of the order and intactness of the medical device.
It is necessary to document the delivery for potential warranty claims and to control parameters during the life cycle of the equipment. In addition, the customer should ensure that prior to the first use of the equipment the following steps are performed and documented:

- functional tests and safety tests as specified by the MANUFACTURER and by national regulations, where applicable,
- training of staff according to the instructions for use,
- provision and explanation of safety-related information regarding proper handling, use and operation of the medical device,
- validation of the connection with other medical devices or non-medical devices and accessories.

4. Instruction and training

4.1 Instructions for use

The operating instructions or instructions for use give important information for the proper use of the medical device, for example:

- definition of the intended use of the equipment
- explanation of the user interface
- safety instructions and warnings for the user
- instructions how to deal with inherent residual RISKS
- avoidance of misuse
- cleaning and/or sterilisation instructions
- list of accessories and consumables validated by the MANUFACTURER
- requirements for safety inspections of the equipment
- requirements for (planned) maintenance

Ignoring or not fully recognising or understanding the instructions for use may result in:

- decreased efficiency of operation
- false treatment/intervention or diagnosis
- detrimental effects on the health of the patient, the user or other persons
- deterioration of the equipment

Recommendations

The user should check that the appropriate instructions for use as well as the technical documentation are supplied together with the medical device in the required language. The instructions for use should be directly accessible for the operators of the medical device at any time.

If these documents are lost, not accessible or incomplete, they need to be ordered from the MANUFACTURER for this specific device.

If low- to medium-risk medical devices (class I and class IIa) can be used safely without instructions for use, no formal obligation exists to provide such instructions [8], [9].

4.2 Training

Lack of training or inadequate training of staff may result in:

- decreased efficiency of operation
- false treatment/intervention or diagnosis
- detrimental effects on the health of the patient, the user or other persons
- deterioration of the equipment

For complex and/or high-risk class medical devices, a training program for users is indispensable. Correct user- and application-training and continued support are conditions for optimal and safe use of the device.

Where applicable, health care providers must ensure that there are adequate arrangements for such training at different levels, for instance:

- Novice/acquaintance training
- Advanced user training
- Application training
- Refresher courses

The health care provider is responsible for having each user of the device trained to the right level. The users must have the correct adaptation and background for receiving the training. The training program must be well documented, with a training log, and regularly reviewed for new equipment and/or new staff members [9].

Recommendations:

Set up a training plan and training log based upon equipment and user dynamics.
Include application training, if applicable.
Training should preferably be obtained from the MANUFACTURER or other appropriate parties identified/qualified by the MANUFACTURER. This might be a healthcare facility or a qualified clinical engineering function.

5. Use of the medical device

5.1 Device and maintenance Logbook

In many cases, it is very helpful, or even required by national regulations, to keep record of the use aspects of the device, including maintenance.

Impacts/HAZARDS
HARM may occur because one or more of the following elements are not appropriately covered

- information on products
- information on interfaces
- information on (declarations of) mutual compatibility with other devices or accessories
- information on software
- availability of approved spare parts

Recommendations
The user should create a logbook, called Medical Devices File (MDF) for example.

When the device and its accessories are handed over to the user, a new logbook should be initiated. The content of such a logbook should be data such as:

- initial configuration (products, interfaces, accessories, software, documentation)
- dates of initial delivery, handover & first use
- inventory number
- changes to the initial configuration and date of such changes
- responsible department/person
- place where used
- category of medical device
- model of that category
- class of product according to MDD
- product identification
- MANUFACTURER/supplier
- service contact
- operational maintenance protocols
- preventive maintenance scheme
- nomenclature item, e.g., according to GMDN, ECRI, UDMNS

Furthermore, acceptance tests and safety tests such as constancy tests may be carried out. The results of such tests are to be logged as well.

In many cases, proper training for the intended users should be ensured. Such trainings can be recorded in the logbook. Periods of refresher courses should be fixed and recorded also.

Malfunctions or deterioration in the characteristics of a device should be reported and documented in the logbook. If relevant, the MANUFACTURER should be notified, as well as competent authorities (see 5.3).

5.2 Instructions for use inaccessible

The operating instructions/instructions for use give important information for the proper use of the medical device; see 4.1. These essential instructions have to be directly accessible for the users of the medical equipment at any time [9]. For certain medical devices instructions for use do not need to be provided, see also 4.1.

Impacts/HAZARDS

- decreased efficiency of operation,
- false treatment or diagnosis,
- detrimental effects on the health of the patient, the user or other persons
- deterioration of the equipment

Recommendations

If the documents are lost, inaccessible, incomplete or out-of-date, an up-to-date and comprehensive version of the instructions for use needs to be ordered from the MANUFACTURER, instantly.

Upon any modification of the equipment, the status of the instructions for use needs to be checked for compliance with the new hardware/software configuration by whoever is responsible for the modification.

5.3 Incident reporting

Adverse events (AE) and near-AE relating to medical devices are considered incidents that must be reported to competent authorities for monitoring and possible enforcement of corrective action. An AE implies death, serious injury to patient(s) or user(s) and serious public health concerns.

AE and near-AE can be grouped in two major categories based on their causes:

- Use error: Act or omission of an act that has a different result to that intended by the MANUFACTURER or expected by the operator,
- Abnormal use: Act or omission of an act by the operator of a medical device as a result of conduct that is beyond any reasonable means of RISK control by the MANUFACTURER.

MANUFACTURERS have knowledge and responsibilities for use error incidents for which they can perform AE and near- AE reporting; MANUFACTURERS have limited knowledge of abnormal use incidents and no means to control these RISKS. Therefore, guidance is required to split the incident reporting between MANUFACTURERS and users, i.e. health care providers.

Recommendations

- Use errors resulting in death, serious injuries and serious public health concerns should be reported by the user to the MANUFACTURER who, in turn, will report to the national Competent Authority, preferably in the country where his Notified Body resides
- Use errors not resulting in death, serious injuries or serious public health concerns need not be reported to the Competent Authority. However, they should be reported to the MANUFACTURER, who can use this information within his quality and RISK management system.
- AE due to abnormal use should be handled by the health care facility and national authorities under schemes not covered here.

Note – Within GHTF, a proposal has been launched that use errors become reportable to a national Competent Authority when the MANUFACTURER notes a change in trend. This will usually be an increase in frequency or a change in pattern of an issue that can potentially lead to death, serious injuries or public health concerns. The MANUFACTURER then has to initiate corrective action to prevent death, serious injuries or serious public health concerns. This proposal has been launched to reduce the administrative burden in case of a very large number of devices in use. See also [10].

6. Maintenance and repair

6.1 Instructions for Maintenance and Repair

Under the MDD, all medical devices are accompanied by instructions for maintenance and repair, which is required in order to maintain the safety level of the medical device. Ignoring or not fully recognising or understanding the instructions for maintenance and repair may result in:

- Decrease of performance
- Deterioration of the equipment
- Detrimental effects on the health of the patient, the user or other persons
- Contravention of any laws and regulations that may exist

The maintenance and repair instructions give important information for the proper maintenance of the device, e.g.:

- Nature and frequency of maintenance
- Safety checks
- Internal and external quality control
- Calibration requirements

Recommendations

The user should check that appropriate and complete instructions for maintenance and repair are supplied with the medical device in a language as specified in the purchase contract.

Note: according to the essential requirements of the MDD, the MANUFACTURER must provide documentation. This must contain "all the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the devices operates properly and safely at all times" [11].

The instructions for maintenance and repair should be directly accessible to the persons in charge of the maintenance (external or internal). If the maintenance and repair instructions are lost, inaccessible or incomplete, they need to be ordered from the MANUFACTURER for this specific device.

It is recommended to keep a record of the date and nature of the maintenance or repair performed on the equipment. See also 5.1, where the logbook is mentioned.

6.2 Spare parts & repair

HARM may occur when the spare parts used are not equivalent to the original parts:

- Loss of reliability of the equipment
- Deterioration of performances
- Increase of the safety RISKS
- Impact on the CE Marking of the medical device

Moreover, in case of an incident related to the use of inappropriate spare parts, difficulties may occur in the identification of the root causes and responsibilities.

Recommendations:

There are several sources of spare parts:

- The device MANUFACTURER
- Other MANUFACTURERS
- Second-hand stockists
- The health care facility itself
- A service provider
- The use of parts from other medical devices of the same type ("Cannibalisation", see chapter 9)

The user or his organisation should ensure that:

- Spare parts and consumables match those specified by the MANUFACTURER.
- The use of an alternative specification is demonstrated to be equivalent with the specifications by the MANUFACTURER. An alternative specification needs to take into account all RISKS to patients and users and document the assessment of these risks completely.
- Second-hand parts are accepted only if a RISK assessment of their use is performed and documented.
- All critical replacement spare parts and components used in a repair or maintenance are traceable.

Note: 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 or his 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, user or other person.

6.3 Support from Original MANUFACTURER no longer available

If support from the original MANUFACTURER of the medical device or from the vendor who placed the device on the market is no longer available, this will complicate the further use of the medical devices. It may even require stopping to use the medical device in question.

There may be several different reasons for this situation, such as:

- the product is no longer supported by the manufacturer
- the company is no longer on the market
- the product segment has been divested and is now being marketed under a different name

Impacts/ HAZARDS:

When the support of the original MANUFACTURER or from the vendor is no longer available, this may lead to:

- Safety RISKS due to missing market surveillance and corrective actions
- Qualified training and application support not being available
- Qualified service, maintenance and approved spare parts not being available
- Mutual compatibility statements for new accessories or other medical devices not being available.

Recommendations:

Especially for capital equipment, the user normally will be contacted by the original MANUFACTURER ahead of time, if the product support will be terminated. The user should discuss with the MANUFACTURER the implications of this, such as a phase-out or replacement of the medical device in question. There may also be alternative means of continued support.

In those cases where the product responsibility has been transferred officially from the original manufacturer to another organisation, the user should establish contact with the successor organisation as quickly as possible. This will help to ensure the traceability of the medical device, the availability of user training, the continuation of service and maintenance contracts and the future supply of spare parts.

The user should evaluate to what extent compatibility statements will be provided by the successor company. Where no successor company has been nominated, there are some criteria that a new contractor for the above services should fulfil and these are given in 7.1.

6.4 Outsourcing of the maintenance

The user can choose to outsource the maintenance of the device to the MANUFACTURER or to THIRD PARTY MAINTENANCE.

Impact/HAZARDS:
When the maintenance is not well performed, this may lead to:

- Loss of reliability of the equipment
- Deterioration of performances
- Safety HAZARDS

With THIRD PARTY MAINTENANCE, there are additional issues. For example, in case of an adverse event (AE) with the equipment, it may be difficult to identify respective responsibility of the equipment MANUFACTURER and the third party service provider. This may affect the right to warranty as well as the liability of the health care facility itself.

Recommendations:
The user should select a maintenance service provider able to perform proper maintenance and repairs of the equipment. Such maintenance service provider must have:

- Appropriately trained technicians
- The appropriate spare part(s) (refer to 6.2 Maintenance and repair)
- Appropriate and, where applicable, calibrated tools
- Access to the applicable technical documentation of the medical device, which often goes beyond the instructions for use
- In special cases further technical support from the original MANUFACTURER

Most maintenance service providers comply with such requirements.

Note: according to the essential requirements of the MDD, the MANUFACTURER must provide documentation. This must contain "all the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the devices operates properly and safely at all times" [11].

The user organisation should only use a maintenance service provider who can demonstrate compliance with relevant quality system standards [12].

6.5 Refurbishment

Refurbishment is the act of restoring the device to its original specifications and is normally carried out by the MANUFACTURER. Refurbishment may involve taking apart the medical equipment and replacing parts that show signs of wear or other loss of performance compared with new parts. Refurbishment, therefore, goes beyond repair but does not constitute a modification of the medical device or a change of intended use, as discussed in chapter 7.

Note: the term "full refurbishment" or "fully refurbished" also exists; see [13]. This term usually refers to used medical equipment that has been largely or fully brought to the specification level of new products that are being placed on the market at the time of such full refurbishment.

7. Technical modifications

7.1 Combination of old and new medical devices

In many cases, the user wants to combine different products for special reasons. Normally, the user does not want to become a MANUFACTURER in the sense of the MDD.

Impacts/HAZARDS

RISKS may be increased if the following elements are not appropriately covered

- information on the products
- information on interfaces
- information on (declarations of) mutual compatibility with other devices or accessories availability of approved spare parts
- availability of qualified technical service and maintenance
- availability of measuring instruments

Recommendations

- Differentiate between old and new equipment according to the date of placing on the market/putting into service
- Check whether or not the different products are medical devices for the MDD [14]
- Identify the medical devices and the non-medical devices in the intended combination of products
- Identify the intended purpose of the new combination
- Check whether the envisaged combination is a combination of medical devices (with CE marking) within the limits of use specified by their MANUFACTURERS
- Check whether the envisaged combination is medical electrical equipment or a medical electrical system [15], [16]
- Verify that a declaration on mutual compatibility between the different products is available
- If the combination is not compatible in view of the original intended use of the devices, the combination must be treated as a device in its own right [17]. It is then subject to a conformity assessment procedure according to the Medical Device Directive, if the user wants to place it on the market! If he wants to use it for his own purposes, he should carry out a RISK analysis of the intended combination of products and its use.

  Note - Modification of medical devices may be permitted, however all medical devices have to fulfil the requirements of the MDD when put into service [18]. Some countries may have additional rules in force.
- Check whether the combination can be treated as admissible or not admissible or admissible only under some strict limits
- Decide whether the own staff or an external organisation should carry out the technical work to combine the products and document the process
- Document all necessary steps and the responsibility of all involved persons
- Document the technical status, for example following [19].

7.2 Modifications of medical devices

Modification may have impact on the former conformity assessment of the medical device, primarily concerning safety, reliability and intended use. If so, the CE-marking is no longer valid and the product liability is seriously affected: both are based on the state of the Medical Device when it was put into service for the first time.

If the user substantially modifies a device, he becomes the MANUFACTURER of a new device, according to the MDD, and he must take legal and regulatory requirements into account.

Such a modified device can no longer be used under the original CE-marking. The modified device will still have to comply with the prevailing regulations, but a new CE marking is not needed, if the modification is for on site use (i.e. within the same legal entity) only. The original MANUFACTURER's responsibility and liability can be limited and the user or modifier may be exposed to legal action, if the device is involved in an adverse event.

If a device is used outside the original intended purpose, as indicated by the MANUFACTURER, the user must be aware that the device has not been validated for this off-label use by the original MANUFACTURER. Again, the responsibility and liability of the original MANUFACTURER are limited and the user will be exposed to legal action, if an adverse event occurs.

Recommendation
For any modification of the medical device the status of the documentation and instructions for use needs to be verified for compliance with the new hardware/software configuration, by the person responsible for the modification. That person should also fulfil the requirements imposed on a MANUFACTURER of medical devices, such as to perform a RISK analysis and, if needed, do RISK mitigation through RISK management.

Note - Modification of medical devices may be permitted, however all medical devices have to fulfil the requirements of the MDD when put into service [18]. Some countries may have additional rules in force.

8. Clinical evaluation and clinical research

Three different situations can be distinguished:

- Clinical evaluation of the medical device in order to assess conformity for CE-marking: see [20]; this is usually done in close co-operation with the MANUFACTURER,
- Clinical research with CE-marked equipment **within** the intended use (as defined by the MANUFACTURER): see [21],
- Clinical research with CE-marked equipment **outside** the intended use (as defined by the MANUFACTURER). Note that this situation differs from the change of use described in 7.2.

Clinical research is intended to include the study of medical applications, which are beyond clinical routine, whether or not within the intended use of the equipment. If the research is outside the initial intended use of the equipment, the user or his organisation must realise that the equipment has not been validated for that use.

Recommendations

The user or his organisation is advised to discuss the plan for the clinical research with the MANUFACTURER. As a result, there are two possible scenarios:

1. If the MANUFACTURER becomes involved (perhaps the application objectives are of general interest or may be evaluated commercially) then there should be a mutual approach to conduct a clinical research according to [20];
2. If the MANUFACTURER is not involved (because he is not interested or not consulted), the user should proceed as is usual for medical investigations. The MDD is not applicable in such cases. The instructions for use should be studied carefully to be aware of available warning instructions, application recommendations and restrictions to minimise the RISKS for the new field of applications.

Note: National regulations on clinical research may impose measures beyond the MDD. The user should take care of this, particularly if he wishes to proceed without the support of the MANUFACTURER.

9. End of life considerations

At the end of its life, a product is taken out of service. European legislation and, sometimes, national laws rule the basic principles on how to treat the product. Different rules apply, depending on possible contamination. For electrical and electronic equipment, the EU Directive on WEEE deals with recovery and treatment of waste at the European level.

In some occasions, cannibalising equipment can be part of the end of life considerations. Cannibalising is the process of extracting parts from one device to repair another device. This procedure is usually used for older equipment for which new spare parts are no longer available.

Recommendations:
The user should be familiar with the WEEE. The user should try to get information about the composition of his devices. This information should be collected, for example in the logbook.

The user should contact the MANUFACTURER in case he is uncertain about how to dispose of equipment that is to be taken out of service.

Cannibalising practice by users is not recommended: The quality and suitability of these parts for use as spare parts needs to be determined and documented before use as spare parts. This task can normally not be performed by the user. The traceability of the parts also becomes impossible, which is for example relevant in case of a MANUFACTURER's recall. Moreover, the user assumes responsibility and liability, e.g., in case of adverse events.

A1. Abbreviations and definitions

Abbreviations:

AIMD	Active Implantable Medical Device directive, 90/385/EEC
BSSD	Basic Social Systems Directive, 96/29/Euratom
CE	Conformité Européen (related to CE-marking)
ECRI	Emergency Care Research Institute
EN	European Norm
GHTF	Global Harmonisation Task Force
GMDN	Global Medical Device Nomenclature
IEC	International Electrotechnical Commission
ISO	International Standards Organisation
MDD	Medical Device Directive, 93/42/EEC
MED	Medical Exposure Directive, 97/43/Euratom
SG	Study Group (of GHTF)
UMDNS	Universal Medical Device Nomenclature
WED	Work Equipment Directive, 89/655/EEC
WEEE	Waste Electric and Electronic Equipment Directive, 2000/96/EC

Definitions:

Term	Definition	Reference
HARM	*physical injury or damage to the health of people, or damage to property or the environment*	ISO 14971:2000 Original reference: ISO/IEC Guide 51:1999, definition 3.1
HAZARD	*potential source of HARM*	ISO 14971:2000 Original reference: ISO/IEC Guide 51:1999, definition 3.5
MANUFACTURER	*natural or legal person with responsibility for the design, manufacture, packaging or labelling of a medical device, assembling a system, or adapting a medical device before it is placed on the market and/or put into service, regardless of whether these operations are carried out by that person himself or on his behalf by a third party*	ISO 14971:2000 See note below for the definition according to the MDD
RISK	*combination of the probability of occurrence of HARM and the severity of that HARM*	ISO 14971:2000 Original reference: ISO/IEC Guide 51:1999, definition 3.2
THIRD PARTY MAINTENANCE	*any individual or organisation, other than the user organisation or the equipment MANUFACTURER, undertaking repair and/or maintenance activities*	This document

Note that the definition of manufacturer in the MDD is slightly more restrictive:

the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.

A2. References

[1] ISO 14971:2000 Medical devices – Application of RISK management to medical devices
[2] MDD, article 1.2(g)
[3] MDD, 93/42/EEC, article 2, annex I: 1, 4, 13.1, 13.6 (d), 13.6 (h)
[4] BSSD, 96/29/Euratom, article 22
[5] MED, 97/43/Euratom, article 4.3, 6.1, 7, 8, 11
[6] WED, 89/655/EEC (amendment 95/63/EC), article 3, 4.2, 6, 7
[7] http://europa.eu.int/comm/enterprise/newapproach/standardization/harmstds/reflist.html or http://www.newapproach.org/Directives/Default.asp
[8] MDD, annex I, chapter 2, paragraph 13.1
[9] MDD, annex I, chapter 2, paragraph 1 and chapter 13, paragraph 11.4
[10] GHTF SG2 documents SG2N21 and SG2N31 (check GHTF website http://www.ghtf.org)
[11] MDD, annex I, chapter 2, paragraph 13.6.d
[12] ISO 9001:2000, for example
[13] NB-MED 2.1/rec5 „Placing on the market of fully refurbished medical devices“ (March 2000)
[14] Notified Bodies NB-MED/2.5.5/Rec2 „Combination of CE-marked and non-CE-marked medical devices and non-medical devices "; (draft December 2000)
[15] EN IEC 60601-1, Medical electrical equipment Part 1: General requirements for safety
[16] EN IEC 60601-1-1, Medical electrical equipment Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems
[17] MDD, article 12, paragraph 2
[18] MDD, article 2
[19] MDD, annex I, chapter 13
[20] MDD, article 15, paragraph 1 or 2
[21] MDD, article 15, paragraph 8

See also: U. Heil, Medizinprodukte Journal, 10, vol. 4, 2003, pp. 112-119 (paper in German)