COCIR
GOOD MAINTENANCE SERVICES PRACTICE GUIDE

APRIL 2013

OPTIMISING THE EQUIPMENT LIFE CYCLE

COCIR

SUSTAINABLE COMPETENCE IN ADVANCING **HEALTHCARE**

European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

TABLE OF CONTENTS

FOREWORD

AN IMPORTANT GUIDE FOR SMART SERVICING

Technology innovations are creating every day new opportunities to improve access to healthcare and quality of care. This is also generating new requirements to ensure a safe and optimal performance during the lifecycle of the equipment. In times of economic pressure, customers want to get the most of their investment. This can translate into uptime, peak performance or increased lifetime for example. In the meantime, regulation keeps evolving to improve safety for patients and employees. New areas of regulation, such as environment protection or data privacy, may also impact the equipment during its lifetime.

When designing new products, medical equipment manufacturers do their best to anticipate these trends. They have to think not only about the quality of the technology delivered but also to the ability for the user to operate the equipment in the safest and most effective manner. This is where maintenance plays a critical role. It goes beyond the traditional view of repairing an equipment when it breaks. Actually, new technologies combined with evolving regulation, require to expand the traditional frontiers of maintenance. It can impact the product itself; more often a medical equipment will face technology upgrades, needs for integration with information systems during its lifecycle. It can also impact the operating or technical staff with new needs for training.

In this guide, our intent is to cover all the elements that need to be considered at the time of definition and implementation of the maintenance strategy for a medical equipment. It provides common good practice that our industry elaborated in order to ensure a good supporting element of reference is given to users to help them keep its investment safe and performing as per manufacturer specifications during its lifecycle.

Kevin HAYDON
COCIR President

1 INTRODUCTION

The intention of this document is to describe good practice for maintenance service related tasks from medical device manufacturers, to their customers and device users in order to ensure the use of their equipment in the safest way. The user is responsible for implementing a strategy ensuring that the device can be used safely and within manufacturer specifications.

Maintenance service is the combination of all technical, administrative and managerial actions during the life cycle of an item intended to retain it in, or restore it to, a state in which it can perform the required function [Definition from EN 13306:2010 - Maintenance. Maintenance terminology].

This guide also describes the main roles and responsibilities between service providers, customers (or responsible organization), and device users. When reference is made to “service provider”, these terms cover both maintenance and repair services rendered by the manufacturer itself and by independent service providers.

Current medical devices delivered to customers, though of high quality, are also more and more comprehensive. Therefore regular and consequent maintenance service is the basis for a safe, efficient and long lasting use of such medical devices. These maintenance services start at handover of the medical device and last until end of life. Maintenance services in this content do not only consist of pure technical services but also of product innovation, communication and education.
The greatest economic benefit and highest safety for the user and customer can only be reached by optimization of high quality products with highly educated staff and continued product maintenance over the lifespan of the product.
This guide is intended to help the user and customer understanding what they can expect from manufacturers and service providers and determining the most appropriate servicing strategy related to quality and economic value for his equipments.

This guide is not intended to supplant or supersede supranational, national or local laws or regulations that may impose particular requirements

2 PLANNING AND START OF MAINTENANCE SERVICES

2.1 INTRODUCTION

Regular maintenance service for a medical device is required during its lifetime to ensure that the medical device will do its job in a safe way.
Careful planning upfront and well performed handover tasks are prerequisites for a good start to good practice maintenance service.
An appropriate maintenance and repair policy established by the organization operating the medical device will bring the best guarantee to have equipment operating safely and efficiently as per manufacturer specifications.
As new medical devices are often integrated within customer networks, an appropriate risk management is essential. Initial user training should give the staff sufficient knowledge to use the new equipment safely.
Responsibilities regarding maintenance planning and organization differ between the customer/user, the medical equipment manufacturer and the services provider. It is the responsibility of the manufacturer to specify the maintenance activities required to ensure that the medical equipment can operate safely and within specifications as required by the Medical Device Directive MDD 93/42/EEC Annex I Essential Requirements. We recommend customers to follow manufacturers' maintenance recommendations. Should the customer decide to specify maintenance operations different from the manufacturer's recommendations, they should be supported by the appropriate risk assessment.

2.2 GOOD PRACTICE

To ensure good practice maintenance service during the lifetime of the medical device, adequate planning of the service provision must be carried out at the time of the acquisition of the device.

2.2.1. BEFORE MAINTENANCE STARTS

Manufacturers and service providers usually provide diverse service offerings to help to set up a service plan based on relevant legal requirements and customer needs.
Such service plans should fit into the daily work routines of the customer.
Following items should be planned:

- The service provider should be chosen
- Operation hours and maintenance hours defined
- Maintenance Plan (weekly, monthly, yearly...)
- Maintenance tasks
- Safety and quality checks
- Cleaning procedures (daily, weekly, monthly etc.)
- Integration in customer networks
- Integration into quality management systems
- Integration into clinical work flow
- Hand over checklists
- Initial user training

The service provider should:

- Offer service contracts adjusted to the needs of the customers
- Provide the customer with order specific delivery lists & prices,
- Provide the customer with a complete maintenance plan (date, location etc.),
- Inform the customer on potential required additional user trainings and agree on training schedule
- Review the maintenance on a periodic level for effectiveness together with the customer.

2.2.2. QUALITY MANAGEMENT SYSTEM (QMS)

An adequate maintenance service policy shall describe the strategy and provisions taken by the customer to ensure that all equipment under its responsibility is serviced in a timely manner, by trained and competent personnel.
For those customers having a quality system (QS), service provisions should be also part of their QS requirements.

Customers shall take into account as a minimum, the following topics:

- Define the organization(s) in charge of each medical equipment maintenance and repair (can be the manufacturer itself, an independent service provider or the customer's own service organisation, etc…)
- Qualification of the personnel selected for the maintenance & repairs if an in-house service organisation
- Internal process to escalate a medical equipment failure and get it fixed by the service provider
- Requirements and processes to insure that service providers operate in/on a safe and decontaminated environment/ medical equipment
- Internal process to report adverse incident related to equipment failure. (Refer also to section 7).

GOOD PRACTICE

- *Maintenance & repair is based on the manufacturer requirements & instructions (replacement procedures, requirements on spare parts, adjustments, test specifications, etc.).*
- *Any deviation from manufacturer's requirements should be supported and documented by an appropriate risk assessment.*
- *There must be documented evidence of the executed maintenance and repair operations (service report, and eventually an entry in the device logbook). These records must be archived, including the results of tests & measurements as required by manufacturer's instructions.*

2.2.3. SELECTION OF MAINTENANCE SERVICE PROVIDER

The customer can choose to either perform the maintenance service himself, partly or in total, or to outsource the maintenance service of the device to the manufacturer or specialised third party maintenance service provider.
The customer should select a maintenance service provider able to perform proper maintenance and repair of the equipment. Such maintenance service provider must have:

- Appropriately trained personnel
- Training should also include knowing & following Environmental Health & Safety (EHS) rules to protect the environment & people.
- Appropriate use of adequate spare parts
- Appropriate and, when applicable, calibrated tools
- Appropriate software when applicable

GOOD PRACTICE

- *Customers are encouraged to use maintenance service providers who can demonstrate to have appropriate quality controls in place.*
- *Select service providers having access to the required tools & documentation of the OEM for safe and effective repairs.*
- *Select properly trained and experienced service providers.*
- *Set, whenever possible, contractual agreements with service providers to define roles & responsibilities, as well as appropriate Service Level Agreements (SLAs), in the implementation of the maintenance & repair policy.*

2.2.4. LOGBOOK

Medical device availability, reliability and safety are critical requirements for customers/end-users' daily work.

The Logbook is designed to ensure the traceability of all service operations. It documents all the technical interventions performed on the equipment, and therefore brings the documented evidence that equipment can be used in a safe and efficient way.
Some EU countries have implemented local regulations requesting customers/users to formally register all installation, maintenance & repair activities in a service logbook; this logbook being attached to unique equipment and physically located on site.
These requirements shall be followed and documented through organized maintenance policies which include formal traceability of all service events (for example: requirement to keep all completed preventive maintenance checklists stating that equipment has been checked as per manufacturer recommendations and is within equipment specifications including measurements results when specified by manufacturer).

Though customers/users have the primary responsibility to document this logbook, service providers shall offer customers/users their support to fulfil this requirement.

GOOD PRACTICE

- *Record all technical operations performed on the equipment by the service provider (maintenance, repairs, as well as quality controls or safety & functional checks performed after equipment repair) including measurements results when specified by manufacturer.*
- *Primary responsibility to record service operations is under the medical device user organization. Considering that service providers create most of the documents required for the logbook, they shall offer the possibility to document & maintain the logbook itself through adequate service document provision.*

2.2.5. TOOLS AND MEASURING EQUIPMENT

Special tools and measuring equipment may be required for installation, repair and maintenance of medical devices.

If a service provider is chosen to perform the maintenance activities, this service provider should supply all required tools himself. In case certain or all maintenance tasks are performed by in-house service teams, the provision of adequate tools is the responsibility of the customer.

Measuring equipment requires regular calibration and testing and therefore needs to be identified and traceable.
This will allow adequate action to be taken in case a tool would be found out of tolerance during a periodical calibration/verification.
Service providers shall have a process in place ensuring tools traceability and regular calibration.

GOOD PRACTICE

If the customer desires to perform certain services himself, information about tools can be found in the equipment service documentation or can be obtained from the manufacturer.

- *Manufacturers and/or service providers should use accredited or certified test and calibration providers to calibrate their measuring equipments.*
- *Adequate training shall be provided for the safe and qualified use of specific tools by the manufacturer or service provider.*
- *Calibrated tools used for installation, repair and maintenance of medical devices, should be documented to assure traceability.*

USERS AND SERVICE PROVIDERS WILL WORK IN A SAFE ENVIRONMENT

2.2.6. CLEANING & DECONTAMINATION

Medical devices are used in a clinical environment generating potential risks of biological, chemical or radioactive contamination. Personnel (users and service providers) shall work in a safe environment which means a work environment protected against any potential contamination risk by adequate procedures and practices.
It is required to have these appropriate procedures & practices in place to ensure that service providers perform technical interventions (or equipment removal/transport) in a safe manner. It is the primary responsibility of the customer/user to ensure that their equipment is properly decontaminated using suitable methods (in accordance with hospital good practice) and that the equipment is risk-free from biological, chemical or radioactive contamination.
Such a statement may be required by a service provider in a formal way (before technical intervention or equipment removal/transport) through a decontamination declaration to be filled and signed by customer.
The service provider must also establish procedures and practices when applicable to prevent its personnel from becoming contaminated.

GOOD PRACTICE

Through these practices, service providers shall ensure that:

- *Their employees are properly trained on the biological, chemical and radioactive (when and if applicable) contamination hazards.*
- *Have competent personnel carry out decontamination tasks on equipment used in clinical environments (equipment returned to service supplier facilities for maintenance & repair purpose).*
- *There are suitable processes and methods for decontamination (personal protective equipment & designated decontamination areas).*
- *Their employees use agents/chemicals approved by equipment manufacturers.*
- *Repaired customer equipment is returned and re-installed free of any contamination risk.*

2.2.7. DATA PRIVACY

While performing maintenance & repair operations on medical devices, service providers may access personal information for which they shall apply strict rules to protect the confidentiality and security of this information. Maintenance activities need to have the appropriate safeguards in place to comply with law in the European Union.

The most common sensitive information that a service provider may access during a technical intervention - either on site or remotely - relates to patient information that includes both data on identified or identifiable individuals (patient address, phone numbers,…) and diagnostic information (images, medical reports, etc…).
This sensitive information is mostly stored, by electronic means, on the equipment storage media (hard disk).

It is then highly recommended for service providers to implement policies and work instructions through which they shall guarantee the privacy and security of the patient information they may access.

GOOD PRACTICE

Through these policies and work instructions, service providers shall ensure that their employees:

- *Are trained on the general principles of personal data privacy, security and employee responsibilities. Employees should sign a statement, where they recognise that they have been informed that they may be accessing sensitive information and commit to treating it in compliance with national laws, as explained in the training.*
- *Understand that handling patient information imply the same confidentiality obligations as those fulfilled by the medical staff.*
- *Understand the ground rules for protecting patient information from inappropriate or unauthorized use or disclosure*
- *Restrict the use/processing of patient information to the required minimum and to what is strictly needed for a legitimate purpose.*
- *Take appropriate care when handling, storing or transmitting this information outside customer site.*
- *Use appropriate tools when remotely assessing customer equipment (authorised access and traceability).*
- *If personal or patient data needs to be transferred outside the customer's site such action should be approved by the customer (and patients if data not anonymized). Those data have to be removed or destroyed once no longer required for the maintenance activities.*

Service providers shall –as much as possible - imbed privacy by design and privacy enhancing technologies in their products and services.

Anonymization of data remains under responsibility of the customer in case this information needs to be transmitted outside customer site.

ALL BEST PRACTICE SHALL ENSURE THE PROTECTION OF CUSTOMER'S PERSONAL DATA/PATIENT INFORMATION FROM INAPPROPRIATE USE.

3 PREVENTIVE MAINTENANCE

Medical devices need to operate safely and at the performance level specified by the manufacturer. In order to meet this requirement, manufacturers may define maintenance operations that are required to be completed even when the device is operating effectively. These operations are defined as preventive maintenance. They are defined at the time of the design of the device by the manufacturer's engineering teams. Their intimate knowledge of the device and its components is critical to such definition.

Preventive maintenance is the best way to prevent unplanned repairs and ensure that the device can reach its expected lifetime. The nature and frequency of the preventive maintenance must be communicated to the user of the equipment in the "instructions for use" delivered with the device. Due to the nature of the maintenance tasks, it might be required to have well-trained personnel equipped with specified tools to perform these tasks.

3.1. NATURE OF PREVENTIVE MAINTENANCE

Preventive maintenance is usually defined by a checklist of operations to be completed at a specified frequency.
Preventive maintenance schedule may require the replacement of parts identified as subject to wear & tear over time or activity. These parts are identified and documented by the manufacturer in its technical documentation to ensure the safety, performance and reliability of the device.
Like any other service operation, the preventive maintenance will be registered in the logbook.

More and more, service providers are using remote maintenance to identify in advance:

- parts of the device that may be failing soon
- environmental conditions outside of manufacturer's specifications
- software issues created by bugs, file overload
- etc.

In such cases, a preventive operation can be planned (on-site or remotely) with the user's agreement. That action will prevent an unplanned failure of the device and ensure it will keep operating as per its original specifications. We can consider that remote maintenance can also include some preventive maintenance operations.

If the service provider identifies a safety risk with the device during preventive maintenance, he will recommend not putting the device back in operation until the safety risk is remediated. Should the user refuse to replace such part, he would do so under his own responsibility. The service provider may document the user's decision in the service report.

3.2 PLANNING OF PREVENTIVE MAINTENANCE

The frequency of the preventive maintenance is either based on pre-defined time periods (e.g. quarterly, yearly…) or other criteria defined by the manufacturer.
Such criteria can include but are not limited to:

- the number of exams performed with the device
- the number of hours of operation
- etc.

The frequency provided by the manufacturer should help the user to plan adequately the periods when the device will not be available for use.

Failing to perform the preventive maintenance operations at the frequency defined by the manufacturer can have the following impacts:

- Generate unplanned downtime
- Reduce the life of the device
- Increase repair costs

Manufacturers usually offer service plans covering the preventive maintenance. In such cases, the manufacturer will schedule the preventive maintenance together with the user.
The frequency of the planned maintenance should be considered as a minimum requirement. User may decide to increase the frequency of preventive maintenance.

GOOD PRACTICE

- *Including preventive maintenance in a service plan is a good way for the user to plan financially and meet the minimum maintenance requirements set by the manufacturer of the device.*
- *When selecting a service provider, the user should confirm if the maintenance plan will cover the preventive tasks specified in the manufacturer checklist.*
- *Preventive maintenance needs to be planned after the first use of the device even during the period of warranty covering the device. Failing to perform the preventive maintenance activities may impact the warranty coverage.*

3.3 SPECIFIC EXAMPLE OF BATTERIES

More and more medical devices are using batteries. Batteries are either disposable or rechargeable and they all will naturally discharge over time and utilization. In the case of disposable batteries, preventive maintenance plan should allow either for a replacement by the user at the time when the battery fails or a replacement by the service provider before the battery life has been fully used. In the case of rechargeable batteries, preventive maintenance should include charging the batteries according to the manufacturer's instructions. In most cases, this should be done by the user according to the instructions for use. These instructions may not be limited to the frequency of recharge and also include recommendations regarding the charger specifications.

GOOD PRACTICE

- *Following the manufacturer recommendation is usually the way to ensure a longer life for the battery. Over time it generates less replacements and downtime which are sources of costs and disruption for the user.*
- *When selecting a service provider, the user should ask for details on the parts sourcing and traceability. It is critical to ensure that the parts fitted will match the specifications established by the manufacturer.*
- *When disposed, batteries must be handled respectfully of the environment and according to the applicable regulation.*

3.4 ADDITIONAL PERIODICAL OPERATIONS

In some cases, there may be additional periodical operations required by local regulations. These checks (e.g. quality control) are specifically designed to ensure that the device is operating within the specifications defined by the local authorities. Therefore they come as an addition to the preventive maintenance schedule defined by the manufacturer.

4 CORRECTIVE MAINTENANCE

4.1. NATURE OF CORRECTIVE MAINTENANCE

The repair of a medical device has two aspects, the technical repair itself and the service around it. The repair itself of course needs to be technically sound and complete. The service, scheduling and communication together with the repair, is the key to having satisfied customers. The communication of the planned repair times and the fulfilment of the repair duties helps the customers to adequately work around the down times and keep his/her own service provision alive. Clear, up front offers show the customers the potential costs and avoid misunderstandings about costs and repair amount (this is not applicable, if a service contract covers such repairs).

GOOD PRACTICE

To ensure good repair service, the service provider must have access to the adequate spare parts and must have adequately trained personnel and knowledge of the equipment to be repaired. The use of adequate spare parts is required to operate the device safely and within the original manufacturer's specifications. The customer should describe the repair need as precise as possible; as the service provider can find described errors easier than not described errors (it sometimes helps the service provider to find the failure by demonstrating the failure in real life, if it is safe to do so).

The service provider should:

- *Offer initial inspection (diagnosis of the error) of the device/equipment before repair (diagnosis and repair can be done in one or in different sessions).*
- *If the error is not traceable to a product error, but to an incorrect use of the product, the service provider should suggest additional application training for the customer's staff (see chapter 6).*
- *Make a detailed and clear quotation for the equipment- the quotation should include both problem diagnostic and problem correction (if required).*
- *After agreeing on the repair amount provide a service schedule to the customer.*
- *Agree with the customer together on remote access times.*
- *Perform repair of the equipment in time.*

4.2. REPAIR / EXCHANGE OF SPARE PARTS

The repair should be performed by adequate product trained personnel. Spare parts for the repair must meet the required manufacturer specifications. All steps of the repair should be adequately documented in a technical service report (i.e. spare part serial numbers when required, performed tasks). This also applies to remote maintenance.

GOOD PRACTICE

To ensure good repair practice, the service provider should:

- *Use adequate tools and measuring equipment (calibrated, maintained etc.)*
- *Appropriate use of adequate spare parts.*
- *Perform the repair according to the manufacturer's guidelines.*
- *Document all exchanged spare parts in the technical service report.*
- *Document all work steps in the technical service report (name of device serviced, device identification and control numbers, date of service, Individual servicing of the device, service performed & test and inspection data).*
- *Document all updated software versions to the technical service report.*
- *Document all corrected settings to the technical service report.*
- *Document (if possible) the cause that led to the problem in the service report.*
- *Check the product after the repair according the manufacturer's recommendations (to check the completion of the repair and potential other failures).*
- *Communicate additional errors to the customers (see 4.1).*
- *Consider, whether software or hardware upgrades require additional user training.*

ADDITIONAL TRAININGS MIGHT BE REQUIRED TO ADEQUATELY USE THE EQUIPMENT

THE REPAIR SHOULD BE PERFORMED BY ADEQUATE PRODUCT TRAINED PERSONNEL

4.3. AFTER THE CORRECTIVE MAINTENANCE

Returning the repaired equipment does not finish the corrective maintenance. Additional required documents and trainings might be required to adequately use the equipment in future.

GOOD PRACTICE

The service provider should:

- *Have adequate hand over of the repaired equipment to the customer.*
- *Inform the customer about the repair status, preventive measures, etc.*
- *Handover of the technical service report.*
- *Provide additional training after repair if necessary.*

5 UPGRADE IMPROVEMENT / MODERNISATION OF MEDICAL EQUIPMENT

5.1. INTRODUCTION

The medical devices industry is constantly improving patient care. Therefore it is possible that during the lifetime of the equipment improvements will become available.
Such improvements are typically offered and implemented by the original manufacturer or from a third party manufacturer. They are usually referred to as upgrade.

5.2. UPGRADE OF MEDICAL EQUIPMENT

From time to time, manufacturers offer upgrades of existing medical devices. They can create a financially viable alternative solution compared to the purchasing of a complete new product and reduce the total cost of ownership. The upgrade of the product might be performed by the original manufacturer or a third party manufacturer.
Examples of such upgrades are:

- X-ray components
- Application software
- Operating software, etc.

GOOD PRACTICE

- *Any upgrade needs good planning and communication to reduce down times for the customer (see for planning activities chapter 2).*
- *Implementation and documentation of upgrades should be performed as in chapter 2.*
- *If the equipment upgrade leads to changed/new functions, the responsible manufacturer of the product upgrade has to hand out a manual which covers all equipment changes and train the new functions, if training is necessary (see chapter 6).*
- *If a new declaration of conformity is issued for the upgraded equipment, this declaration of conformity should be added into the logbook.*

5.3. COMBINATION OF PRODUCTS

Generally the combination of medical devices is allowed and is frequently done in hospitals. Most combinations of medical devices are described within the manuals (or related brochures) of the relevant devices. After combining two or more products all related manufacturers are still fully responsible for their part of the system. Generally there are three different types of combinations:

a) Both manufacturers claim compatibility to each other product. This is one way to combine two medical devices.
b) Only one manufacturer claims compatibility to another equipment. This is the second way to combine two medical devices. Here, only the combination claiming manufacturer declares compatibility for the combined medical result of the medical equipment and consequently becomes responsible for this combination.
c) The third is the combination of two devices outside the intended use and without a written declaration of compatibility with the combined product. Here such a combination is regarded as new equipment and needs to be approved according to MDD 93/42/EEC, if the intention is to legally place such combination on the market.

GOOD PRACTICE

- *Consult involved manufacturers or distributors.*
- *Ensure adequate compatibility is documented and available.*
- *If new functions are available due to the combination of the product, the responsible manufacturer for the new function possibilities has to issue a new or revised manual which covers the equipment changes and provide the required training on the new functions (see chapter 6).*

The same good practice apply to modifications of the medical equipment decided by the user or the service provider.

6 REGULAR AND CONTINUOUS EDUCATION

6.1. INTRODUCTION

In addition to operator training and documentation there-of, investment in additional training throughout the product lifecycle is strongly recommended:

- to enable medical personnel to maintain the best clinical outcomes,
- to keep up with latest innovations and
- to broaden their clinical scope.

Continuous education and support of operators will help to ensure optimal use of the medical equipment over the product's lifecycle.

6.2. HANDOVER (POST-INSTALLATION) TRAINING

Handover (post-installation) training shall ensure that the designated medical and support personnel receive sufficient instruction to enable them operate the medical device according to the declared intended use, and in accordance with operator and patient safety legislation, and manufacturer's guidelines.
It shall be the responsibility of the vendor to provide a training plan in advance of the training, which shall be performed by a competent trainer.
The training plan should include, but is not limited to:

- who and how many groups have to be trained (operator, clinical user, day shift, etc.)
- basic operation of the equipment according to the operator manual
- safe, efficient and effective use
- clinical use within the customer workflow according to the manufacturers intended use

GOOD PRACTICE

Planning of the initial handover training is essential for the success of the training itself. The training plan should be agreed with and signed off by the customer prior to the start of the training. The training plan should include, but is not limited to:

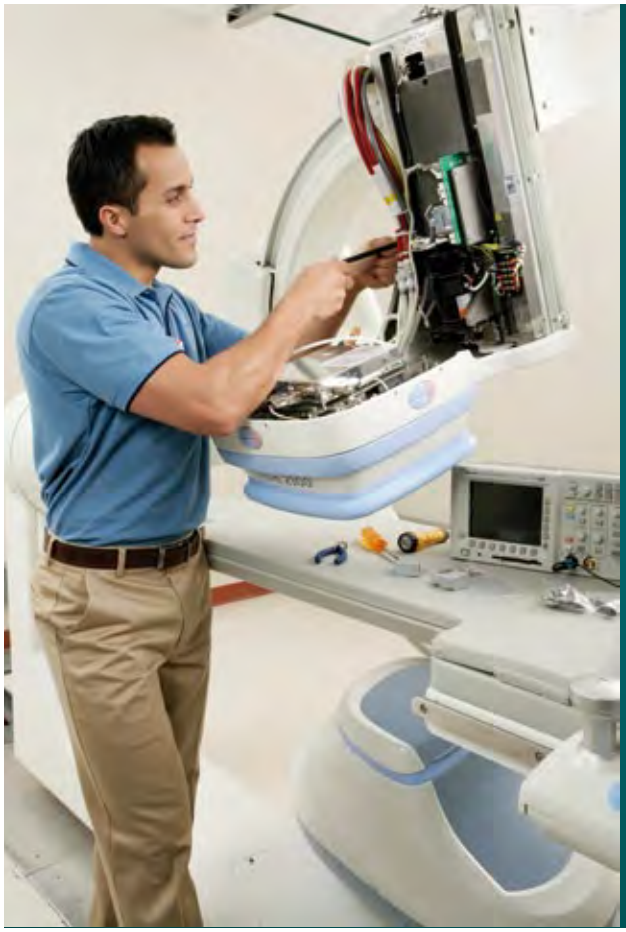
- *Personnel to be trained.*
- *Scope and content of the training (what is part of the training, what is not) and duration.*
- *Availability of required accessories (e.g. injectors, contrast media, catheters, etc.).*
- *Availability of, and scheduling of appropriate patients if relevant.*
- *Type of training delivery (classroom, virtual, web based training, etc.).*
- *At the end of each training, the attendees should be recorded and the content of agreed training plan should be signed off by the customer, and the trainer.*
- *Training records should be archived at the customer site.*

6.3. FOLLOW-UP TRAINING

While handover training prepares the customer to start with the medical use of the system, follow-up training will ensure that the customer can realise the full potential of the system. Follow-up training shall be planned in the same way as the handover training and should be offered shortly after the hand-over training as well as throughout the product lifecycle.
The goals for a follow-up training can be diverse, including, but not limited to:

- Support the customer in the integration of the system in his clinical workflow
- Use of advanced applications
- To support employee turnover in retraining new staff
- Increase efficiency and effectiveness
- To support new applications, functions and innovation

GOOD PRACTICE
Refer to Good Practice in section 6.2.



THE FOLLOW-UP TRAINING WILL ENSURE THAT THE CUSTOMER CAN REALISE THE FULL POTENTIAL OF THE SYSTEM

7 CUSTOMER COMPLAINTS AND SAFETY EVENT REPORTING

7.1. INTRODUCTION

Within this paper we do want to emphasize the importance of the legal requirements related to Incident Reporting. The European Commission guideline MEDDEV 2.12-1 describes how the MDD requirements should be implemented.
We would like to point out that:

- Regulation specifies reporting obligations for manufacturers based on risk and is not related to any liability consideration.
- The main goal is to detect at the earliest stage any potential remaining safety deficiency. Therefore reporting from users should not be limited to actual incidents but also include events that could have potentially led to a safety event.
- Less obvious, user errors are also important to be known as they can be the consequence of wrong labelling or instructions for use, or could be avoided by product design change.
- Our mutual legal/regulatory obligations can only be fulfilled via a good cooperation between the customer, service providers and the manufacturers.
- Reporting also contributes to the delivery of better products as well as increasing the overall customer's satisfaction.

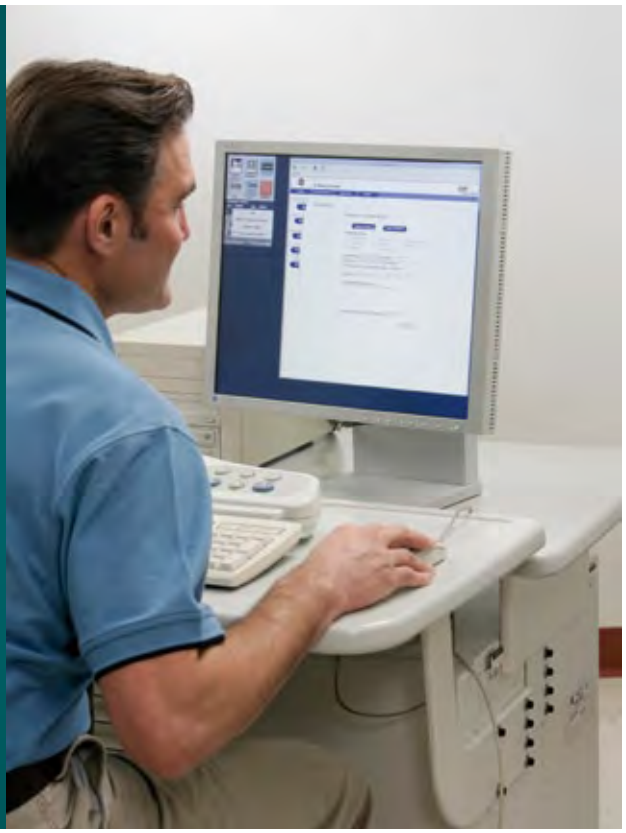
GOOD PRACTICE

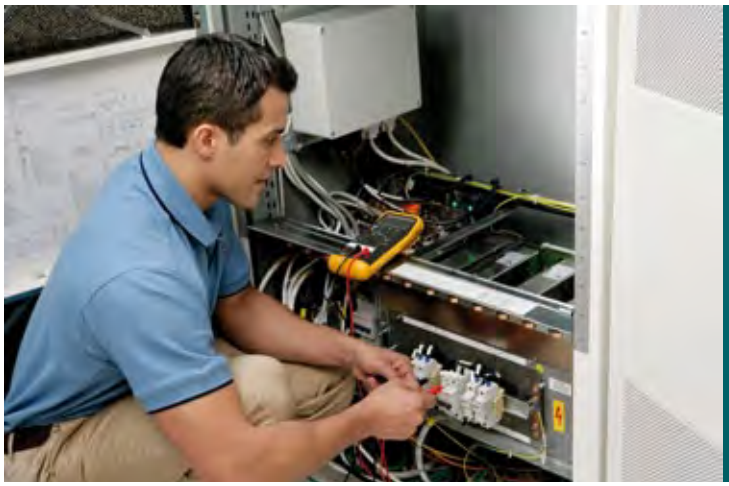
In order to comply with regulatory requirements, manufacturers have established feedback systems for handling of quality problems and patient safety issues. Therefore, manufacturers will:

- *Review and document all customer complaints and product malfunctions to detect potential safety issues*
- *Assess reportability to Competent Authority and inform customers.*
- *Ensure the exchange or repair of malfunctioning product in collaboration with the customer according the existing contractual agreement and applicable regulation.*
- *Give clear instruction to the customer on the possibility to continue using the equipment until repair.*

In case of a systemic safety issue leading to an unacceptable risk, a field safety corrective action (FSCA) shall be taken by the manufacturer, and a field safety notice (FSN) will be sent to the customer describing the planned corrective actions.

A FIELD SAFETY NOTICE WILL BE SENT TO THE CUSTOMER DESCRIBING THE PLANNED CORRECTIVE ACTIONS





IN SOME COUNTRIES, LOCAL REGULATIONS MAY REQUIRE THE USERS TO PLAY AN ACTIVE ROLE AS WELL.

7.2. WHAT IS EXPECTED FROM USERS/CUSTOMERS?

For the successful operation of the vigilance system the user's involvement is vital, although not being legally required. Manufacturers rely on the user that suspected safety event to be made known to the Manufacturers and to support the implementation of Field Safety Corrective Actions.
In some countries, local regulations may require the users to play an active role as well.

MANUFACTURERS ENCOURAGE USERS / CUSTOMERS TO:

With regard to safety events:

- Communicate all safety events (actual or potential) to the manufacturer as soon as possible, even if already reported to Competent Authority.
- Collaborate to provide as much relevant technical and clinical details as possible initially as well as during investigation.
- Take the necessary measures to quarantine the equipment (if necessary), safeguard relevant data (avoid resetting the equipment, clearing memories, etc.)

With regard to complaints and product malfunctions:

- Communicate feedback to the manufacturer related to their satisfaction using the equipment and/or product malfunctions

With regard to Field Safety Notice (FSN) and Field Safety Corrective Actions (FSCA):

- Take the actions advised in the manufacturer's field safety notice. These actions ought to be taken in co-operation with the manufacturer where required a) facilitating manufacturer access to the device if this is required, and b) work with the manufacturer when needing to balance the individual risks and benefits for any dependent patients using affected devices. (Extract MEDDEV 2.12-1 Annex 9).
- In order to ensure adequate traceability and remain able to execute FSCA on all affected devices, we encourage the users to communicate equipment moves to the manufacturer (or to the distributor). Otherwise, some equipment would disappear from the list of the equipments known by the manufacturer and FSCA would not be applied leading to risk for patients.

8 END OF LIFE

8.1. INTRODUCTION

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 state of the device and possible contamination. For electrical and electronic equipment, the EU Directive on Waste Electrical and Electronic Equipment (WEEE) deals with recovery and treatment of waste at the European level.

Manufacturers have designed formal processes for the termination of global service and support of their products. Such procedures will improve service to customers by:

- Providing an orderly planned process for the withdrawal of support for products.
- Controlling service costs through planned parts ordering to provide economic quantities.
- Reducing down time through scheduling parts availability for the life of the product or device.

Manufacturers remain responsible for their marketed and users for their used equipment/medical devices -regardless of the age of the product- to ensure a safe clinical use over time. If a safe clinical use is not given anymore, the use of such equipment must be stopped.

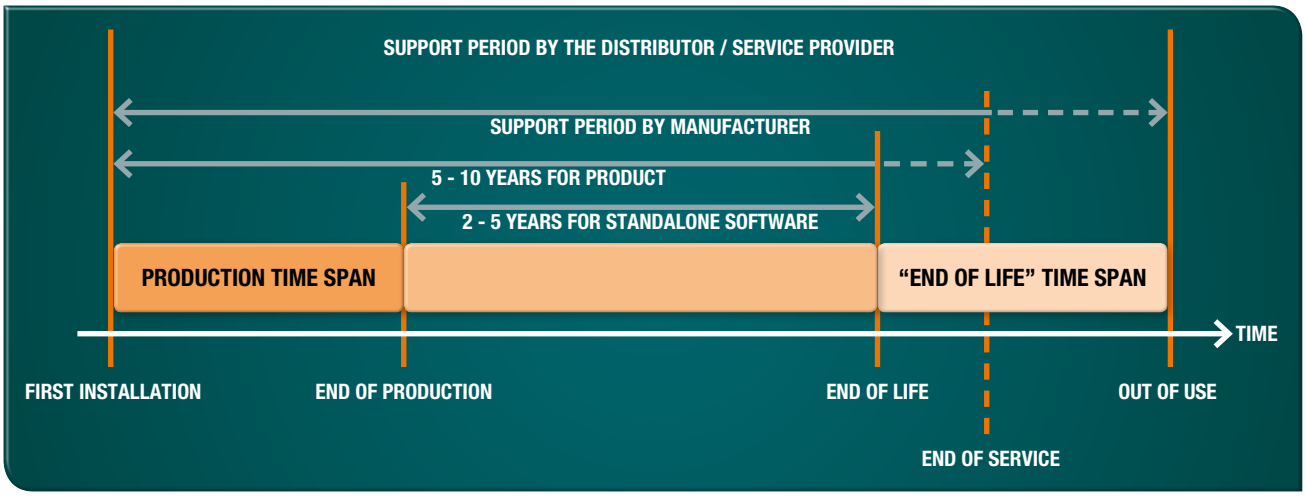
8.2. GOOD PRACTICE

DEFINITIONS

It is important to first define the terms used to understand the different stages of the product life cycle.

- **END OF PRODUCTION:** The date the last product is produced.
- **END OF LIFE:** The date that defines the end of economic maintenance, sustaining engineering or further upgrade development of a product by the manufacturer.
- **END OF SERVICE:** The date that defines the final end of support by the manufacturer.
- **OUT OF USE:** The date that defines the actual end of use of an individual device because either it does not meet the minimum safety essential requirements anymore or it does not meet clinical needs (obsolescence) anymore and it must not be used anymore.

PRODUCT LIFE CYCLE



SUPPORT PERIOD BY MANUFACTURER

Manufacturers are committed to ensure long-term support of their products following installation in respect of product safety and clinical relevance.

For long term support within a changing field of application and in a changing technological environment, manufacturers strive to offer upgrades, which include enhanced performance and functionality while improving manufacturers' ability to support the products.

MANUFACTURERS' SERVICE SUPPORT NO LONGER AVAILABLE

The target for the total support time of a Medical Device is the "production time span" plus an additional time span which can vary up to a maximum of 10 years after last production depending on product type and technologies used. For instance, due to rapid obsolescence of IT technologies or other special circumstances, it could be reduced to a period of time not lower than 5 years. This support period is defined by international market standards, but there is no legal obligations related to End of Service.

Manufacturers shall inform all affected customers sufficiently in advance in order to perform proper analysis and plan appropriate equipment replacement. In order to take into account at least one budget cycle, this communication should be at least 12 to 18 months in advance.

End of Service doesn't necessarily mean that the equipment cannot be used anymore. The service provider can continue servicing the product, which can be used as long as it complies with the essential requirements and passes the preventive maintenance safety and quality tests, unless the manufacturer had issued a recall asking use of such equipment be stopped or that a Competent Authority has withdrawn such equipment from the market for safety reasons.

Where spare parts are no longer available, the service provider may propose to the customer to provide used or compatible parts, as long as the equipment remains within its specifications.

Manufacturers shall make all reasonable attempts to provide service repair and support after End of Service; however, service cannot be guaranteed and Manufacturers won't be liable in case the equipment cannot be repaired if the customer has been informed about End of Service on due time.

Where the product is deemed obsolete and the termination of product service is the end of service life for this product, manufacturers should inform their customers accordingly.

GOOD PRACTICE

- *Several manufacturers offer upgrade packages (hardware and/or software). These packages can be sold to the customer while the product has not passed the End Of Service milestone, preferably these packages are offered before the End Of Life milestone. These packages can be used to extend the life time of the medical equipment. It is recommended to contact relevant service providers and manufacturers of such solutions.*
- *When equipment is sold for re-use, customers are encouraged to communicate this information to the relevant manufacturer or distributor who can only fulfill their regulatory obligations related to customer information (Field Safety Notice) if they are aware of the new location of the equipment. It is the responsibility of the re-saler to ensure that the equipment is safe and operating as per original specifications. For more details, customers can refer to the COCIR Good refurbishment practice guide issued in 2009[1].*
- *When disposing and scrapping a medical device, customers shall use accredited recycling channels, which comply with the WEEE Directive and its local transpositions. The easiest way is to ask for advice to the equipment manufacturer or distributor (e.g. recycling passport).*
- *WEEE Directive scope does not include de-installation, which will have to be organized under the responsibility of the equipment owner.*

1. http://www.cocir.org/uploads/documents/-731-cocir_grp_guidelines_version_2_-_2_oct_2009.pdf

9 DEFINITIONS

1. SERVICE DESCRIPTION

[Definition from EN 13306:2010 - Maintenance. Maintenance terminology].

MAINTENANCE SERVICES

Maintenance service is the combination of all technical, administrative and managerial actions during the life cycle of an item intended to retain it in, or restore it to, a state in which it can perform the required function.

2. PRODUCT DESCRIPTION

[Definitions from the Directive concerning medical devices 2007/47/EC]

MEDICAL DEVICE

Medical device means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

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

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

ACCESSORY

Accessory means an article which whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device.

3. PRODUCT END OF LIFE DESCRIPTION

END OF PRODUCTION

The date the last product is produced.

END OF LIFE

The date that defines the end of economic maintenance, sustaining engineering or further upgrade development of a product by the manufacturer.

OUT OF USE

The date that defines the actual end of use of an individual device because either it does not meet the minimum safety essential requirements anymore or it does not meet clinical needs (obsolescence) anymore and it must not be used anymore.

4. MANUFACTURER AND CUSTOMER DESCRIPTION

[Definitions from the Directive concerning medical devices 2007/47/EC]

MANUFACTURER

Manufacturer means 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.

The obligations of this Directive to be met by manufacturers also apply to the natural or legal person who assembles, packages, processes, fully refurbishes and/or labels one or more ready-made products and/or assigns to them their intended purpose as a device with a view to their being placed on the market under his own name. This subparagraph does not apply to the person who, while not a manufacturer within the meaning of the first subparagraph, assembles or adapts devices already on the market to their intended purpose for an individual patient.

AUTHORISED REPRESENTATIVE

Authorised representative means any natural or legal person established in the Community who, explicitly designated by the manufacturer, acts and may be addressed by authorities and bodies in the Community instead of the manufacturer.

CUSTOMER

Customer is a party that receives or consumes products (goods or services) and has the ability to choose between different products and suppliers.

USER

A medical device user is a person who operates a medical device for the treatment and/or care of him/herself or someone else.

5. SAFETY CORRECTIVE ACTION AND SAFETY NOTICE DESCRIPTION

[Definitions from the Guidelines on a medical devices vigilance system, MEDDEV 2.12-1 rev 8, January 2013]

FIELD SAFETY CORRECTIVE ACTION (FSCA)

A Field safety corrective action is an action taken by a manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. Such actions, whether associated with direct or indirect harm, should be reported and should be notified via a Field safety notice.

FIELD SAFETY NOTICE (FSN)

A Field safety notice is a communication to customers and/or users sent out by a manufacturer or its representative in relation to a Field Safety Corrective Action.

10 CONCLUSION

The information provided in this document should help customers to keep their medical equipment safe and operating according to the relevant regulations. This guide lists good practices which allow the customer to establish a maintenance strategy, to select an appropriate service provider and to execute preventive and corrective maintenance. This document further helps the industry and service providers to support their customers with appropriate maintenance service offerings that protect the value of the medical equipment over its entire lifetime.

GENERAL INFORMATION ABOUT COCIR

Founded as a non-profit trade association in 1959, COCIR represents the radiological, electromedical and healthcare IT industry in Europe. As such, our members play a driving role in developing the future of healthcare both in Europe and worldwide.

COCIR is committed to supporting its members and communicating with its partners in Europe and beyond on issues which affect the medical technology sector and the health of EU citizens.

COCIR also works with various organisations promoting harmonised international standards and fair regulatory control that respects the quality and effectiveness of medical devices and healthcare IT systems without compromising the safety of patients and users.

We encourage the use of advanced technology to support healthcare delivery worldwide.
COCIR's key objectives include promoting free worldwide trade of medical devices and maintaining the competitiveness of the European health sector.

COCIR COMPANY MEMBERS:

AGFA HealthCare · Alcon · BOSCH · Canon · care innovations an Intel • GE company · Carestream · CSC · ELEKTA · EOS imaging · FUJIFILM · GE · HITACHI Inspire the Next · HOLOGIC The Women's Health Company · iba · IBM · IMS Since 1965 · KONICA MINOLTA · Microsoft · ORACLE · orange · PHILIPS · QUALCOMM · saludnova · SAMSUNG · SHIMADZU Solutions for Science · SIEMENS · T · TOSHIBA Leading Innovation

NATIONAL TRADE ASSOCIATIONS MEMBERS:

AGORIA no future without technology — BELGIUM

FiHTA — FINLAND

snitem creating the tools for medical progress — FRANCE

SPECTARIS German Industry Association for Optical, Medical and Mechatronical Technologies — GERMANY

ZVEI: — GERMANY

ASSOBIOMEDICA — ITALY

FHI MEDICAL TECHNOLOGY — THE NETHERLANDS

Holland HealthTech — THE NETHERLANDS

Federación española de empresas de TECNOLOGÍA SANITARIA — SPAIN

Medtech — SWEDEN

TIP GÖR DER — TURKEY

AXrEM — UNITED KINGDOM

COCIR HOW TO JOIN US
COCIR aisbl :: Diamant Building :: Boulevard A. Reyerslaan 80 :: 1030 Brussels :: Belgium
Tel +32 (0)2 706 8960 :: Fax +32 (0)2 706 8969 :: Email info@cocir.org :: www.cocir.org