COCIR
Advancing Healthcare

GOOD MAINTENANCE SERVICES

A PRACTICAL GUIDELINE BY COCIR

2024

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

INTRODUCTION

Operators of medical devices are often faced with a challenge: "How to sustain reliable operation of a medical device, secure maximum uptime and in doing so, break-even in the short-term to secure the investment made?". The choice of the right maintenance provider is a key element but not an easy one. Experience shows that lack of careful selection and attention to the clauses in the service contract can cause unintended negative consequences for medical devices operators.

COCIR, the European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry provides medical devices operators with this guideline about good maintenance service practices that have been established throughout the medical devices industry, and which builds upon the state-of-the-art for medical devices regulations, guidance, and standards. Necessary maintenance activities may depend on the type of medical device, the instructions for service defined by its manufacturer, and its commercial value.
Starting from installation until de-commissioning and potential re-furbishing, this guideline provides valuable insights to medical device operators about the different aspects of a medical device's lifecycle, the roles involved in servicing and maintenance activities, as well as the nature and frequency of the various requirements for the involved parties. This document intends to provide operators of medical devices with oversight concepts, and insights into the servicing and maintenance of medical devices. It also addresses the interactions between service providers and points to consider for the selection of a maintenance service provider.

> *NOTE: This guideline is not intended to supplant or supersede supranational, national, or local laws or regulations that may impose particular requirements.*

CONTENTS

1. THE LIFECYCLE OF A MEDICAL DEVICE

The life of a medical device starts before its first use at the point of care. Medical devices are subject to extensive verification and validation activities performed by their manufacturers. Systems and components undergo various tests to verify basic safety and essential performances.

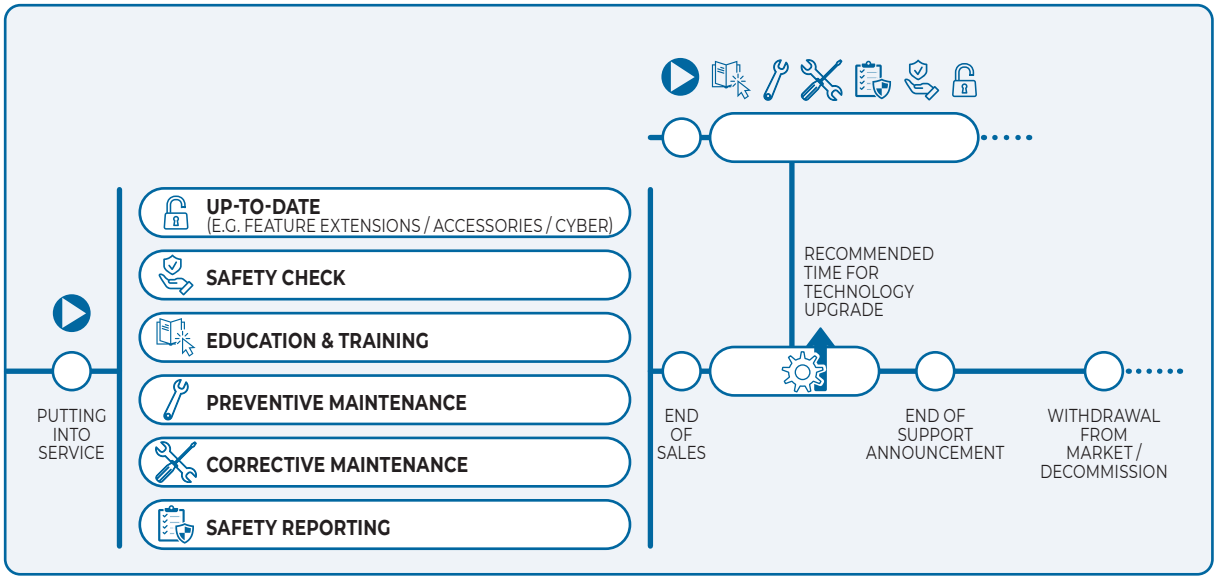


Figure 1 *The lifecycle of a medical device*

Today's medical devices, in particular capital equipment devices, are becoming more and more comprehensive. Therefore, a regular and consequent maintenance service is the basis for safe, efficient and long-lasting use. The maintenance service starts at the time when a device is put into service and lasts until the end of life.

IMPORTANT TO KNOW
PUTTING INTO SERVICE

Prior to placing on the market, based on the regulations under which medical device manufacturers operate, all service activities must go through user requirements, design, verification and validation testing, just as for any feature of the device; the services work must be kept as record in the Design History File.

Thus, the creation of service manuals and associated documentation to put a device into service is completed as part of the overall product release to a specific geographical area.

Service activities that may be needed for the medical device include: installation, preventative maintenance, corrective maintenance, upgrade and product removal at discontinuance.

'PUTTING INTO SERVICE' means the stage at which a device [...] has been made available to the final user as being ready for use [...] for the first time for its intended purpose[1]

Maintenance services in this context do not only consist of purely technical services, but also of product innovation, communication, and education. The greatest economic benefit and highest safety for the user and operator can only be reached through the optimization of high-quality products with highly educated staff and continued product maintenance throughout the lifespan of the product.
This guideline is intended to help users and operators in understanding what can be expected from manufacturers and service providers. It helps to determine the most appropriate servicing strategy related to quality and economic value for the equipment.

1 Regulation (EU) 2017/745, Article 2 (29)

1.1 PREVENTIVE MAINTENANCE

Medical devices must be able to operate safely and efficiently at the point of care. In order to meet this requirement, manufacturers may define maintenance operations that are required to be completed even when the device is still operating effectively. These maintenance 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 a definition. Preventive maintenance is the best way to prevent unplanned repairs and to ensure that the medical device reaches its expected lifetime. The nature and frequency of the preventive maintenance must be communicated by the manufacturer to the user of the equipment in the "instructions for use", which are delivered with the device.

> *'INSTRUCTIONS FOR USE' means the information provided by the manufacturer to inform the user of a device's intended purpose and proper use and of any precautions to be taken*[2]

Due to the nature of the maintenance tasks, it might be recommended or even required by the medical device manufacturer that maintenance service providers have well-trained/well-experienced personnel, equipped with highly specific tools and a specific base level of knowledge.

1.2 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, are the key to having the shortest possible interruptions of availabilities of the medical device at the point of care.
Careful planning and communication of repair times and the fulfilment of the repair duties by maintenance service providers help operators adequately address down times and sustain the provision of healthcare.
As a purchasing practice for medical devices, the service agreements should provide clear, up-front potential costs. It is key that all details of how services are to be provided and billed are documented to avoid misunderstandings about costs and repair amounts.

1.3 IMPROVEMENTS

The medical devices industry is constantly improving patient care. Therefore, it is possible that during the lifetime of a medical device, improvements will become available. Such improvements are typically offered and implemented by the original manufacturer or a third-party service provider. They are usually referred to as "upgrades/updates".
Continuous improvements of a medical device can sustain its operation, secure the investment, and reflect the technical and clinical state of the art, which can have an influence on reimbursement of procedures performed with the medical device.

IMPORTANT TO KNOW
SAFETY REPORTING

Whenever a medical device is purchased, the owner, user, or technical repair team for that device has a duty to report to the medical device manufacturer and sometimes local authorities when a safety issue occurs.

Typically, an organization will have an internal process for the various roles, such as nursing, clinical users, repair technicians or others to escalate safety issues. This process should have a portion that addresses the local regulatory requirements and notifications to the original medical device manufacturer.

2 Regulation (EU) 2017/745, Article 2 (14)

1.4 SUPPORT PERIOD OF THE MANUFACTURER *(UNTIL END-OF-SUPPORT)*

Medical device manufacturers, in a changing field of application and technological environment, are committed to ensure long-term support of their products after installation in respect to product safety and clinical relevance in the form of improvements as mentioned above.

1.5 SERVICE PERIOD OF THE MANUFACTURER *(UNTIL END-OF-SERVICE)*

After ending the product support period, manufacturers also stop providing service support when their device reaches the end of its "lifetime", which is the period for which the device is expected (designed and evidenced) to remain safe and to continue to perform as designed. Manufacturers do not recommend the use of their product outside of this period. Any change to such a period may only happen if supported by additional data and assessment.

Medical device manufacturers shall inform all affected medical device operators sufficiently in advance in order to perform proper analyses and plan appropriate equipment replacement.

Medical device operators may also actively consult manufacturers or service providers on improvement packages (hardware and/or software) before having passed the "end-of-service" milestone. These packages can be sold to operators while the product has not passed the end-of-service milestone. These packages can be used to extend the lifetime of the medical equipment.

The end of the manufacturer service does not necessarily mean that the equipment will not be used anymore; in this case, however, the user and service provider must ensure that the product remains within its specifications.
Where used or non-original spare parts are installed by the maintenance provider, the operator and the maintenance provider shall ensure that the equipment remains within its specifications.
However, in consideration of a lack of updates/upgrades or improvements by the medical device manufacturer, a replacement strategy over time should be started.
If basic safety and essential performance can no longer be supported by the original medical device manufacturer (on the basis of available evidence), then the use of such equipment should be stopped.

1.6 DECOMMISSIONING

When the operator decides to decommission the device, the device is taken out of service, with further possibilities for reuse by the medical device industry. Re-using valuable raw materials and parts contributes to sustainability.
European legislation and sometimes national laws stipulate basic principles on how to dispose of products after their use. Different rules apply, depending on state of the device and possible contamination.
For electrical and electronic equipment, the EU Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE) deals with recovery and treatment of waste at the European level.
Manufacturers have designed global service procedures for decommissioning products. Such procedures:

- Provide an orderly planned process for the withdrawal of products.
- Ensure coordination between the decommissioning of the old device and the installation of the new one (if required) to reduce unavailability of healthcare services as much as possible.

Medical device operators should take into consideration the following points:

- ☐ **Ensuring proper de-installation operations are included in the contract with the service provider.**

  NOTE: The scope of the WEEE Directive does not include de-installation, which will have to be organized under the responsibility of the equipment owner.

- ☐ **Disposal of medical devices only through accredited recycling channels.**

  NOTE: When disposing of a medical device as waste in the EU, operators must use accredited recycling channels that comply with the WEEE Directive and its local transpositions or contact the OEM depending on the contractual clauses.

  NOTE: operators of medical devices in the EU can contact the manufacturer for proper disposal through the official WEEE Directive schemes, unless different agreements have been stipulated in the contract at the time of purchasing (de-installation, collection and disposal)

2. ROLES AND INTERACTIONS

Regular maintenance service for a medical device may be required during its entire lifetime, to ensure that the medical device continues to perform as designed. Careful planning to take products out of service and clear communication around transition in and out of clinical use are prerequisites of high-quality interactions for maintenance services.
An appropriate maintenance and repair policy established by the organization operating the medical device will provide the best guarantee of safe and efficient equipment operation as per manufacturer specifications. The policy should include IT, clinical users and staffing availability considerations. As a new medical device is often integrated into new or existing IT-networks, appropriate IT risk management (for example ISO/IEC 27001) is essential.

The manufacturer, the service provider and the operator have different responsibilities regarding maintenance planning and organization. Figure 2 depicts the involved parties and their areas of responsibility and interaction:

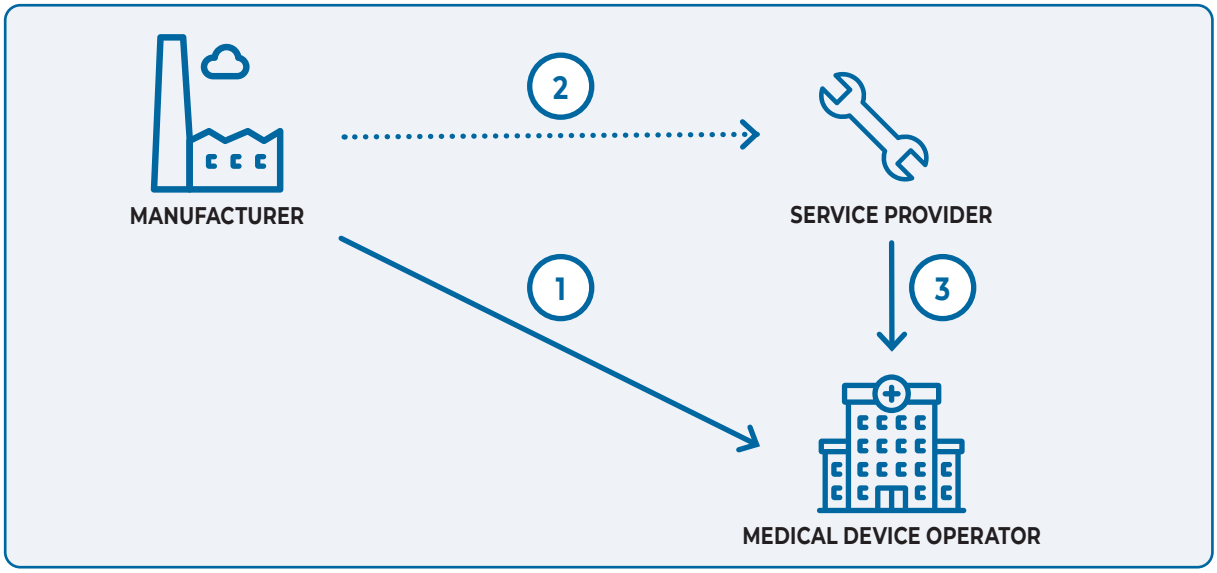


Figure 2 *Interactions between manufacturer, service provider and operator*

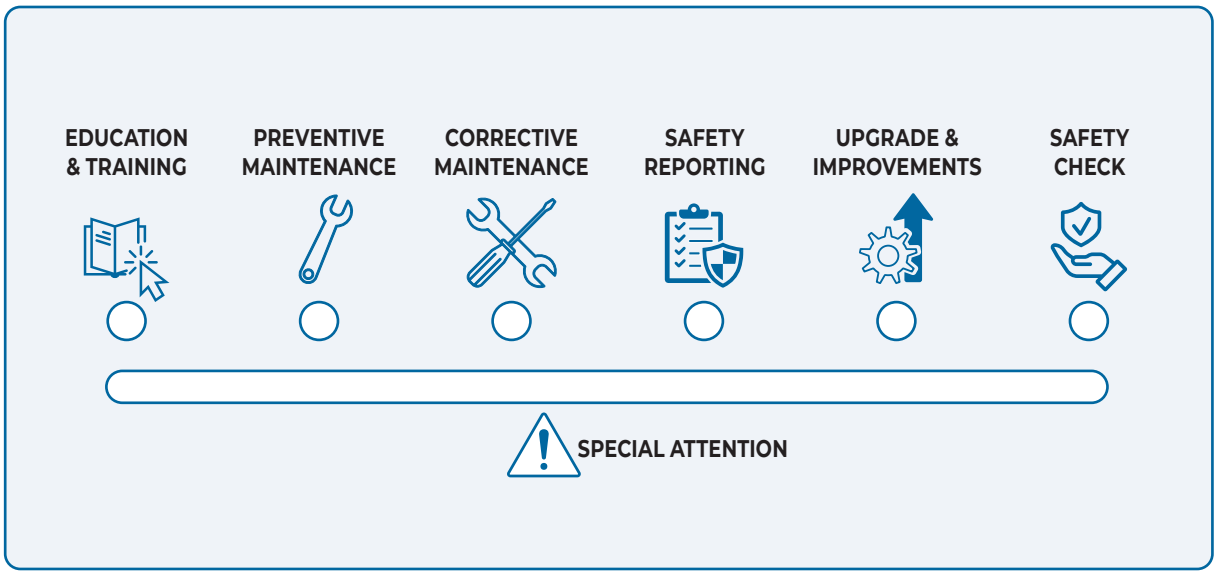
1	It is the responsibility of the **MANUFACTURER** to design and manufacture the devices in such a way that maintenance can be performed safely and effectively. Manufacturers must also provide information in the instructions for use on the nature and frequency of preventive and regular maintenance as required by the Medical Device Regulation MDR 2017/745 Annex I General Safety and Performance Requirements (GSPR).
2	The manufacturer may provide the **SERVICE PROVIDER** with selected information, training and spare parts required to facilitate the servicing.
3	A maintenance service provider provides its services directly to and contracted by a **MEDICAL DEVICE OPERATOR**.

COCIR recommends organizations and their users to follow manufacturers' service and maintenance instructions.
Should the operator decide to specify maintenance operations that differ from the manufacturer's recommendations, this decision should be supported by an appropriate risk assessment following the organization's policies on risk management.

3. HOW GOOD MAINTENANCE WORKS

Maintenance is a broad term that includes all the operations performed on a medical device that ensure proper functioning, performance, safety, improvements, safety updates, etc. Proper maintenance ensures that the medical device is best positioned to perform its functions until the end of its lifetime.
Maintenance service providers must have access to the adequate spare parts and must have appropriately experienced personnel and knowledge of the equipment to be serviced.
The following chapters in the guideline encompass different timepoints and aspects in the life of a medical device; their related actions, interactions and important points to consider.
A proper maintenance service contract should cover all of the following elements:

- Planning and start of maintenance services (see section 3.1)
- Preventive maintenance (see section 3.2)
- Corrective maintenance (see section 3.3)
- Safety reporting (see section 3.4)
- Improvements (see section 3.5)
- Special considerations (see section 3.7)



3.1 PLANNING AND START OF MAINTENANCE SERVICES

To ensure that best practices are used for maintenance services during the lifetime of a medical device, adequate policies should be created by the operator to enable the planning and the provision of maintenance services. The policy should be created at the time of the acquisition and the installation of the device.

MEDICAL DEVICE LOGBOOK

A medical device logbook is designed to ensure the traceability of all service operations. It documents all of the technical interventions performed on the equipment, and therefore provides the documented evidence that the equipment can be used in a safe and efficient way.
Some EU countries have implemented local regulations requesting medical device operators to formally register all installation, maintenance, and repair activities in a medical device logbook; with this medical device logbook being attached to unique devices and physically located on site.

These requirements should be followed and documented through organized maintenance policies, which include the formal traceability of all service events. For example: the requirement to keep all completed preventive maintenance checklists stating that the equipment has been checked as per manufacturer recommendations or instructions and is within equipment specifications, including measurement results when specified by the manufacturer.
Even though medical device operators, by local regulations, inherit the responsibility to keep a medical device logbook, maintenance service providers should offer their support to fulfil this requirement.

Maintenance service providers should:

- ☐ Help operators and users to maintain their medical device logbook

Operators should:

- ☐ Record all technical operations

  NOTE: 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 measurement results when specified by manufacturer.

3.2 PREVENTIVE MAINTENANCE

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

IMPORTANT TO KNOW

If a maintenance service provider identifies any issues in the functioning of the device that do not imply a safety risk, they must inform the operator.

If a maintenance service provider identifies a safety risk related to a part in the device during preventive maintenance, they must recommend not putting the device back into operation until the safety risk is remediated. Should the medical device operator choose not to replace the part, they would do so under their own responsibility.

The maintenance service provider may be required to document the information provided to the user and the user's decision in the service report.

Maintenance service providers are increasingly using remote maintenance methods to identify in advance, for example:

- parts of the device that may be failing soon
- environmental conditions outside of the 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 agreement of the medical device operator.

That action will prevent an unplanned failure of the medical device and ensure that it will keep operating as per its original specifications.

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.

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 medical device manufacturer. Such criteria can include, but are not limited to: the number of exams or operations performed with the device, or the number of hours of operation.
The frequency provided by the manufacturer should help the medical device operator to adequately plan the periods when the device will not be available for use. If medical device operators chose not to perform preventive maintenance operations at the frequency defined by the manufacturer, this can generate the following impacts:

- Unplanned downtime of the medical device and resulting lack of availability for its clinical use
- Reduction of the lifetime of the medical device
- Increased repair costs due to more intensive corrective maintenance activities required

Medical device manufacturers and service providers usually offer service plans covering preventive maintenance. In such cases, the preventive maintenance is scheduled together with the medical device operator. The frequency of the planned maintenance should be considered as a recommended minimum interval.

Medical device operators are recommended to consider the following points:

- ☐ Including preventive maintenance in a service plan

  NOTE: Including preventive maintenance in a service plan is a good way for the operator to plan financially and meet the minimum maintenance requirements set by the manufacturer of the device.

- ☐ Confirming the maintenance plan and preventive tasks with the maintenance service provider

  NOTE: When selecting a service provider, the user should confirm whether the maintenance plan will cover the preventive tasks specified in the manufacturer checklist.

- ☐ Planning preventive maintenance after first use and during the warranty period

  NOTE: 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 CORRECTIVE MAINTENANCE

Corrective maintenance is usually defined as the task of identifying, isolating and repairing a fault in order to restore a medical device to an operational condition so that it can perform its intended function.
The use of adequate spare parts is required to operate the device safely and within the original manufacturer's specifications.
When choosing a service provider, a medical device operator should describe the repair needs as precise as possible.

A maintenance service provider should:

- [ ] Offer an initial inspection (diagnosis of the error) of the device/equipment before repair (diagnosis and repair can be done in one or in different sessions)

  NOTE: 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 operator's staff

- [ ] Provide a detailed and clear quote for the equipment repairs.

  NOTE: The quote should include both problem diagnostics and problem correction.

- [ ] Provide a reliable service schedule and agreement on remote access times
- [ ] Ensure the timely completion of the repair of the medical device

AFTER THE CORRECTIVE MAINTENANCE

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

A maintenance service provider should:

- [ ] Ensure adequate hand-over of the repaired equipment to the medical device operator
- [ ] Inform the medical device operator about the repair status, preventive measures, needs to perform quality control, etc.
- [ ] Hand over the technical service report and offer help in compiling the logbook
- [ ] Provide additional training after repair if necessary

IMPORTANT TO KNOW
NEW ELEMENTS INTRODUCED BY THE MDR

If the service provider conducts one of the following activities:

1. Changes the intended purpose of a device already placed on the market or put into service, or
2. Modifies a device already placed on the market or put into service in such a way that compliance with applicable requirements may be affected

The maintenance service provider or medical device operator assumes the obligations incumbent on the manufacturer specified in Article 10 of the Medical Device Regulation MDR 2017/745 including all requirements for their quality management systems. The operator should require to:

- Be informed for authorization about the intention of performing such operations
- Be informed about the risk assessment results

3.4 SAFETY REPORTING

This section intends to emphasize the importance of the legal requirements related to incident reporting. The European Commission guideline, MEDDEV (Guidelines on a Medical Devices Vigilance System) 2.12-1 rev. 8 and MDCG 2023-3 provides guidance on how the requirements of the Medical Device Regulation MDR 2017/745 should be implemented.
It should be noted that:

- The regulation specifies reporting obligations for manufacturers based on risk and is not related to any liability consideration.
- The main goal is to detect any potential remaining safety deficiency at the earliest possible stage. 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 obviously, user errors are also important to be reported as they can be the consequence of wrong labelling or instructions for use, or they might be avoided by product design change.
- The mutual legal/regulatory obligations can only be fulfilled via a good cooperation between the operator, service providers and the manufacturers.
- Reporting also contributes to the delivery of better products as well as increasing the overall user satisfaction.

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

- Review and document all customer complaints and product malfunctions to detect potential safety issues
- Assess reportability to Competent Authority and inform operators and users
- Ensure the exchange or repair of malfunctioning products in collaboration with the medical device operator according to the existing contractual agreement and applicable regulation
- Give clear instructions to the operator on the possibility to continue using the equipment until repair

In the case of a systemic safety issue leading to an unacceptable risk, a **field safety corrective action (FSCA)** must be taken by the manufacturer, and a **field safety notice (FSN)** must be sent to operators and users describing the planned corrective actions. Manufacturers rely on the operator to inform them about suspected safety events 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.

With regard to safety events, medical device operators are encouraged to:

- ☐ 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, medical device operators are encouraged to:

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

With regard to the Field Safety Notice (FSN) and Field Safety Corrective Actions (FSCA), medical device operators are encouraged to:

- ☐ 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) working with the manufacturer when needing to balance the individual risks and benefits for any dependent patients using affected devices. (MDCG 2023-33).

- ☐ In order to ensure adequate traceability and remain able to execute the FSCA on all affected devices, we encourage the users to communicate:
  - The equipment sales to the next user to the manufacturer.
  - The FSN to the next user they have sold the equipment to.

  Otherwise, certain devices could disappear from the list of equipment known by the manufacturer and the FSCA would not be applied, leading to risks for patients.

3.5 IMPROVEMENTS

The medical devices industry is constantly improving patient care. Therefore, it is possible that improvements or new technology levels will become available during the lifetime of the equipment. Such improvements are typically offered and implemented by the original manufacturer or by a third-party service provider. They are usually referred to as "upgrades or updates". Improvements can create a financially viable alternative solution compared to the purchase of a completely new product and reduce the total cost of ownership for the user. The improvement of the product might be performed by the original manufacturer or a third-party service provider.

IMPORTANT TO KNOW

According to Regulation (EU) 2017/745 (MDR) Article 23(2), when the improvement **significantly modifies** the performance or safety characteristics or the intended purpose of the device, this improvement or the improved device shall be considered to be a "device" in the sense of EU MDR (i.e. a "new/other" device on its own) and shall meet the requirements of the MDR (see details in section 4.2).

Examples of such improvements can include:

- Hardware components
- Application software
- Activation / change of a software license
- Operating software

3. MDCG 2023-3 Questions and Answers on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 on medical devices, https://www.medical-device-regulation.eu/mdcg-endorsed-documents/

Maintenance service providers should consider the following items:

- [ ] Any improvement requires good planning and communication to reduce down-times for the medical device operator
- [ ] If the equipment improvement leads to changed/new functions, the responsible manufacturer of the product improvement must hand out a manual which covers all equipment changes and train the new functions, if training is necessary
- [ ] The implementation and documentation of the improvement should be ensured
- [ ] If a new declaration of conformity is issued (in case of significant modification) for the upgraded equipment, this declaration of conformity should be added into the medical device logbook.

3.6 SPECIAL CONSIDERATIONS

To ensure that all the equipment of a medical device operator is serviced in a timely manner by trained and competent personnel, a maintenance service policy describing the strategy and provisions should be established by the operator.

Medical Device Operators should consider, as a minimum, the following points:

- [ ] Definition of the organization's responsible person for each medical device maintenance and repair
- [ ] Qualification of the personnel selected for the maintenance and repairs if an operator has an in-house service organisation
- [ ] Establishing of an internal process to escalate a medical equipment failure and have it fixed by the service provider
- [ ] Requirements and processes to ensure that maintenance service providers operate in a safe and decontaminated environment, with safe and decontaminated medical devices.
- [ ] Internal process to report adverse incident related to equipment failure.

TOOLS AND MEASURING EQUIPMENT

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

When a maintenance service provider is chosen by the medical device operator to perform maintenance activities, this service provider should supply all the required tools themselves. If certain or all maintenance tasks are performed by in-house service teams, the provision of adequate tools is the responsibility of the medical device operator.

Measuring equipment requires regular calibration and testing and therefore needs to be identified and traceable. This will allow adequate action to be taken if a tool is found outside of the tolerance limits during a periodical calibration and verification.

Service providers must:

- [ ] Have a process in place ensuring the traceability and regular calibration of tools and measurement equipment.
- [ ] Use accredited or certified test and calibration providers to calibrate their measuring equipment.

  NOTE: to be done

Operators should consider the following items:

- [ ] Medical device operators should require the service provider to provide a statement that they have adequate tools and measurement equipment and that such tools are properly calibrated and tested by accredited or certified providers.
- [ ] If medical device operators desire to perform certain maintenance services themselves, information about tools can be found in the equipment service documentation or be obtained from the manufacturer.
- [ ] If medical device operators desire to perform certain maintenance services themselves, they should attend adequate training provided for the safe and qualified use of specific tools by the manufacturer or a maintenance service provider.
- [ ] Calibrated tools used for the installation, repair, and maintenance of medical devices should be documented to assure traceability.

REPAIR AND SPARE PARTS

Any maintenance of a medical device should be performed by personnel who are appropriately experienced for the specific product. Spare parts must meet the specifications stipulated by the medical device manufacturer. All the steps of a maintenance activity should be adequately documented in a technical service report (i.e., spare part serial numbers when required, performed tasks). This service report should be filed in the medical device logbook. This also applies to remote maintenance.

Maintenance service providers should pay special attention to EU MDR new obligations (Articles 23) related to parts and components:

- [ ] Maintenance service providers should ensure that their intervention does not adversely affect the basic safety and essential performance of the device.
- [ ] Maintenance service providers should avoid using parts that are intended to specifically replace a part or component of a device and that significantly change the performance or safety characteristics, or the intended purpose of a device.

  NOTE: An item that is intended specifically to replace a part or component of a device and that significantly changes the performance or safety characteristics, or the intended purpose of the device shall be considered to be a device and shall meet the requirements of the EU MDR (EU MDR, Article 23 (2)).

To ensure good repair practices, maintenance service providers should:

- ☐ Use only spare parts which are fit for their intended purpose.
- ☐ Perform the repair according to the manufacturer's instructions.
- ☐ Document all exchanged spare parts in the technical service report (and thus in the Medical Device Logbook)
- ☐ Document all work steps in the technical service report.

  NOTE: 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 in the technical service report.
- ☐ Document all corrected settings in the technical service report.
- ☐ Document (if possible) the cause that led to the problem in the service report.
- ☐ Check the product or affected parts after the repair, according to the manufacturer's recommendations.

  NOTE: This is to check the completion of the repair and potential other failures.
- ☐ Communicate additional failures to the medical device operator.
- ☐ Inform the operator if software or hardware upgrades require additional user training

CLEANING AND DECONTAMINATION

Medical devices are used in a clinical environment, which exposes them to potential risks of biological, chemical, or radioactive contamination. However, personnel (medical device operators and maintenance service providers) must 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 and practices in place to ensure that maintenance service providers perform technical interventions (or equipment removal or transport) in a safe manner. It is the primary responsibility of the medical device operator to ensure that the equipment is properly decontaminated using suitable methods (in accordance with hospital good practices and manufacturer's instructions) and that the equipment is free of risk 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 the medical device operator.

The service provider should also establish procedures and practices to prevent their personnel from being contaminated, when applicable.
The definition of a medical device in the EU MDR has been extended to cover the products specifically intended for the cleaning, disinfection, or sterilization of medical devices.
Maintenance service providers must only use products for cleaning, disinfection and sterilization that comply with applicable

EU regulations and the manufacturer's instructions. Through these practices, maintenance service providers should consider the following points:

- ☐ Their employees should be properly trained on the biological, chemical, and radioactive (when and if applicable) contamination hazards. Medical device operators can ask maintenance service providers for confirmation of training regarding contamination hazards.
- ☐ They should have competent personnel carry out decontamination tasks on equipment used in clinical environments (equipment returned to service supplier facilities for maintenance & repair purposes).
- ☐ There should be suitable processes and methods for decontamination (personal protective equipment & designated decontamination areas).
- ☐ Their employees should use agents/chemicals approved by equipment manufacturers.
- ☐ Repaired equipment should be returned and re-installed free of any contamination risk.

SPECIFIC EXAMPLE OF BATTERIES

More and more medical devices require batteries. Batteries are either disposable or rechargeable and they all will naturally discharge over time and utilization. In the case of disposable batteries, the preventive maintenance plan should allow either for a replacement by the user at the time when a battery status indicator sets an alarm or the battery fails, or for 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 include recommendations regarding the charger specifications.

Medical Device Operators are recommended to require service providers to consider the following items:

- ☐ Following the manufacturers' recommendations is usually the best way to ensure a longer life for the battery.

  NOTE: Over time this generates less replacements and downtime, which are sources of costs and disruption for the user.
- ☐ Provision of details and traceability of battery sourcing

  NOTE: It is critical to ensure that the parts fitted will match the specifications established by the manufacturer.
- ☐ Disposal of end of life batteries with respect for the environment and according to applicable regulations.

GENERAL INFORMATION ABOUT COCIR

COCIR is the European Trade Association representing the medical imaging, radiotherapy, health ICT and electromedical industries.

Founded in 1959, COCIR is a non-profit association headquartered in Brussels (Belgium) with a China Desk based in Beijing since 2007. COCIR is unique as it brings together the healthcare, IT and telecommunications industries.

Our focus is to open markets for COCIR members in Europe and beyond. We provide a range of services in the areas of regulatory, technical, market intelligence, environmental, standardisation, international and legal affairs.

COCIR is also a founding member of DITTA, the Global Diagnostic Imaging, Healthcare IT and Radiation Therapy Trade Association (*www.globalditta.org*).

COCIR COMPANY MEMBERS:

ACCURAY · AGFA HealthCare · AGFA · aidence (human sense in artificial intelligence) · Alcon · Apple · BARCO · BAYER · Canon Medical · Carestream · CMR Surgical · Dedalus HealthCare Systems Group · Elekta · EOS imaging · Epic · esaote · FUJIFILM · GE HealthCare · HOLOGIC (The Science of Sure) · HUAWEI · tba · KONICA MINOLTA · LUXIUM SOLUTIONS · PHILIPS · SAMSUNG · SIEMENS Healthineers

NATIONAL TRADE ASSOCIATIONS MEMBERS:

Healthtech Finland — FINLAND

LE DISPOSITIF MÉDICAL SNITEM Pour faire avancer la santé — FRANCE

bvitg — GERMANY

zvei electrifying ideas — GERMANY

ETOSZ Association of Health Technology Suppliers and Medical Device Manufacturers — HUNGARY

CONFINDUSTRIA Dispositivi Medici — ITALY

Associação Portuguesa das Empresas de Dispositivos Médicos apormed tecnologias para a saúde — PORTUGAL

FMed Federatie van Medische Technologiebedrijven — THE NETHERLANDS

FME Powered by Dutch Technology — THE NETHERLANDS

Fenin Tecnología Sanitaria — SPAIN

Swedish Medtech — SWEDEN

TIP GÖR DER — TURKEY

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