DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

PROCESSING OF USED MEDICAL SYSTEMS

FOREWORD

1. DITTA is the only global association that represents medical imaging, radiation therapy, healthcare IT, electromedical and radiopharmaceutical manufacturers. DITTA was originally organized in 2001 as an organization for national and regional trade associations representing the medical imaging industry to address global issues.

2. DITTA provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with a DITTA Publication.

3. All users should ensure that they have the latest edition of this publication.

4. No liability shall attach to DITTA or its directors, employees, servants or agents including individual experts and members of its technical committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this DITTA Publication or any other DITTA Publications.

5. Attention is drawn to the normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.

6. Attention is drawn to the possibility that some of the elements of this DITTA Publication may be the subject of patent rights. DITTA shall not be held responsible for identifying any or all such patent rights.

INTRODUCTION

Keeping up with the latest innovations in medical technology often involves replacing equipment in medical practice before it reaches the end of its expected service life. This is because innovation cycles for medical technology are much shorter than the functional lifecycle of capital equipment. As a result, a sustainable resource management model is required: Early replacement of installed MEDICAL SYSTEMS by newer generation technology is more economically feasible if the residual value of the existing equipment is utilized.

Conserving assets is a fundamental principle of ecological thinking in a recycling economy. The replacement of MEDICAL SYSTEMS with high residual value generates a cascade of trade – which means that after REPROCESSING the ME SYSTEM provides value to a new user. Several MEDICAL SYSTEMS companies have already set up systems to process used MEDICAL SYSTEMS and have delivered this processed used equipment across the healthcare sector for many years. This PROCESSING addresses the high demand for affordable and reliable products. Customers of these used systems are not only small hospitals with limited budgets but also leading medical institutes and biggest consumers of used medical electrical equipment are the EU and US. Processing of used medical systems is a well-established element of the healthcare economy.

If used MEDICAL SYSTEMS are not accurately maintained according to requirements defined by the manufacturer it may result in an additional risk for patients and operators. Consequently some countries have imposed bans on the import of used MEDICAL SYSTEMS to protect public health. These bans fail to distinguish between high-quality processed equipment and second-hand equipment of undefined quality, with the effect that patients may be denied access to the safe and economical medical electrical equipment they need. Another organization, the International Atomic Energy Agency (IAEA), developed a draft document covering the same issue but with a different objective - this shows that the issue ‘used MEDICAL SYSTEMS’ is a matter of discussion not only in standardization but also in a high- ranking international scientific and technical organization.

Safety and effectiveness are the most important aspects to be considered with MEDICAL SYSTEMS and this is no different when reutilizing used medical electrical systems. To ensure safety and effectiveness, used equipment has to be processed in a highly specialized way.

This guidance aims to:

- Ensuring patient access to safe and effective diagnostic procedures and therapies
- Providing stakeholders with information about good PROCESSING practices for used medical systems
- Assisting industry in improving the safety and effectiveness of used MEDICAL SYSTEMS with a clearly defined quality process

Enabling healthcare service providers to distinguish used MEDICAL SYSTEMS processed according to this guidance from second-hand equipment that has not been adequately processed when making a purchasing decision

CONTENTS

1. SCOPE

This Guidance describes the PROCESSING of used MEDICAL ELECTRICAL EQUIPMENT (ME EQUIPMENT) and MEDICAL ELECTRICAL SYSTEMS (ME SYSTEMS). It provides requirements that will ensure the safety and effectiveness of used ME EQUIPMENT and ME SYSTEMS by establishing a clearly defined quality PROCESS.
For the purpose of this guidance, ME SYSTEMS is intended to include ME EQUIPMENT.
This guidance applies to the restoring of used ME SYSTEMS into a condition of safety and effectiveness comparable to when new, including actions such as repair, rework, update of software/hardware, and replacement of worn parts with original parts. All actions shall be performed in a manner consistent with product specifications and service procedures required for that ME SYSTEM without significantly changing the finished ME SYSTEM'S performance, safety specifications and/or changing INTENDED USE as in its original or newer valid registration.

Any ME SYSTEM that is processed following this guidance has to be within its EXPECTED SERVICE LIFE.

Reprocessing of Single Use Devices and routine service ME SYSTEMS are not within the scope of this guidance.

2. NORMATIVE REFERENCES

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies..

ISO 13485:2003, Medical devices – Quality management systems – Requirements for regulatory purposes
IEC 60601 series
ISO 14971:2007

3. TERMS AND DEFINITIONS

3.1. PROCESSING OF USED MEDICAL SYSTEMS

To restore used ME SYSTEMS into a condition of safety and effectiveness comparable to when new including actions such as repair, rework, update of software / hardware and replacement of worn parts with original parts. All actions shall be performed in a manner consistent with product specifications and service PROCEDURES required for that ME SYSTEM without significantly changing the finished ME SYSTEM's performance, safety specifications and/or changing INTENDED USE.

3.2. GOOD PROCESSING PRACTICE (GPP) OF USED ME SYSTEMS

Processing of used ME SYSTEMS in compliance with the requirements of this guidance

3.3. USED ME SYSTEM

ME SYSTEM that has been put into service.

3.4. INTENDED USE / INTENDED PURPOSE

Use of a product, PROCESS or service in accordance with the specifications, instructions and information provided by the MANUFACTURER

NOTE: INTENDED USE should not be confused with NORMAL USE. While both include the concept of use as intended by the MANUFACTURER, INTENDED USE focuses on the medical purpose while NORMAL USE incorporates not only the medical purpose, but maintenance, service, transport, etc. as well.

[IEC 60601-1:2005, definition 3.44]

3.5. MANUFACTURER

Natural or legal person who sells a ME System under their own name, or under a trade-mark, design, trade name or other name or mark with responsibility for the design, manufacture, packaging, or labeling of ME EQUIPMENT, assembling a ME SYSTEM, or adapting ME EQUIPMENT or a ME SYSTEM, , or for assigning to it a purpose regardless of whether these operations are performed by that person or on that person's behalf by a third party

NOTE 1: ISO 13485 defines "labelling" as written, printed or graphic matter affixed to a medical device or any of its containers or wrappers, or accompanying a medical device, related to identification, technical description, and use of the medical device, but excluding shipping documents. In this guidance, that material is described as markings and accompanying documents.
NOTE 2: "Adapting" includes making substantial modifications to ME EQUIPMENT or a ME SYSTEM already in use.
NOTE 3: In some jurisdictions, the responsible organization can be considered a MANUFACTURER when involved in the activities described.
NOTE 4: Adapted from ISO 14971:2000, definition 2.6.

[IEC 60601-1:2005, 3.55]

3.6. MEDICAL ELECTRICAL EQUIPMENT

Electrical equipment having an APPLIED PART or transferring energy to or from the PATIENT or detecting such energy transfer to or from the PATIENT and which is:

a. provided with not more than one connection to a particular SUPPLY MAINS, and
b. intended by its MANUFACTURER to be used:
    1. in the diagnosis, treatment, or monitoring of a PATIENT; or
    2. for compensation or alleviation of disease, injury or disability

NOTE 1: ME EQUIPMENT includes those ACCESSORIES as defined by the MANUFACTURER that are necessary to enable the NORMAL USE of the ME EQUIPMENT.
NOTE 2: Not all electrical equipment used in medical practice falls within this definition (e.g. some in vitro diagnostic equipment).
NOTE 3: The implantable parts of active implantable medical devices can fall within this definition, but they are excluded from the scope of this guidance by appropriate wording in clause 1.
NOTE 4: This guidance uses the term 'electrical equipment' to mean ME EQUIPMENT or other electrical equipment.

[IEC 60601-1:2005, definition 3.63]

3.7. MEDICAL ELECTRICAL SYSTEM / ME SYSTEM

Combination, as specified by its MANUFACTURER, of items of equipment, at least one of which is ME EQUIPMENT to be inter-connected by a functional connection or by use of a multiple socket-outlet

NOTE: Equipment, when mentioned in this guidance, should be taken to include ME EQUIPMENT.

[IEC 60601-1:2005, definition 3.64]

3.8. OPERATOR

Person handling the ME SYSTEM

[IEC 60601-1:2005, definition 3.73]

3.9. PATIENT
Living being (person or animal) undergoing a medical, surgical or dental PROCEDURE

[IEC 60601-1:2005, definition 3.76]

3.10. PROCESS
Set of inter-related resources and activities which transform inputs into outputs

[IEC 60601-1:2005, definition 3.89]

3.11. RISK
Combination of the probability of occurrence of harm and the severity of that harm

[ISO 14971:2007, definition 2.13]

3.12. EXPECTED SERVICE LIFE
Period of useful life as defined by the MANUFACTURER

[IEC 60601-1:2005, 3.28]

3.13. NORMAL USE
Operation, including routine inspection and adjustments by any OPERATOR, and stand-by, according to the instructions for use

NOTE: NORMAL USE should not be confused with INTENDED USE. While both include the concept of use as intended by the MANUFACTURER, INTENDED USE focuses on the medical purpose while NORMAL USE incorporates not only the medical purpose, but maintenance, service, transport, etc. as well.

[IEC 60601-1:2005, 3.71]

4. GENERAL REQUIREMENTS FOR GOOD PROCESSING OF USED ME SYSTEMS

4.1. INTRODUCTION
Processed used ME SYSTEMS shall meet the requirements for safe and effective use as defined in the original or newer valid registration including the requirements according the original MANUFACTURER's released safety updates. PROCESSING shall not modify technical specifications or intended use.

Table 1: Requirements for the organizational framework related to clauses of ISO 13485

Quality management system	ISO 13485:2003
Document control	ISO 13485:2003, clause 4.2.3
Resource management	ISO 13485:2003, clause 6.1
Customer complaints	ISO 13485:2003, clause 7.2.3 c
Control of Design and development changes	ISO 13485:2003, clause 7.3.7
Purchasing	ISO 13485:2003, clause 7.4
Production and service provision	ISO 13485:2003, clause 7.5
Control of nonconforming product	ISO 13485:2003, clause 8.3
Corrective and preventive action	ISO 13485:2003, clause 8.5
Post market surveillance (feedback and improvement)	ISO 13485:2003, clause 8.2.1 and 8.5.1

4.2. QUALITY MANAGEMENT SYSTEM REQUIREMENTS

4.2.1. *GENERAL*

Processing of used MEDICAL SYSTEMS shall be conducted under a Quality Management System (QMS) in compliance with ISO 13485:2003.

4.2.2. *RESOURCE MANAGEMENT*

Consistent with Clause 6.1 of ISO 13485:2003 the organization shall determine and provide adequate resources including trained and qualified people, maintained and calibrated production equipment as well as instructions, procedures, files, records or documents, and an environment for PROCESSING that is in complete compliance with the applicable environmental, work safety and pest control requirements.
Where an organization intends to place a ME SYSTEM into a market not covered by the original MANUFACTURER for the same ME SYSTEM, adequate resources shall be provided to meet the regulatory requirements in that markets.

4.2.3. *CORRECTIVE AND PREVENTIVE ACTION*

Consistent with clause 8.5 of ISO 13485:2003 all information related to the processed ME SYSTEM shall be collected and evaluated systematically by the organization through a comprehensive Corrective Action and Preventive Action (CAPA) PROCESS, addressing the specific aspects of the processing of used MEDICAL SYSTEMS.
In addition, in the event that the organization identifies through its CAPA-system safety related issues, which are in the responsibility of the original MANUFACTURER, it shall inform the original MANUFACTURER accordingly. The organization shall make the original MANUFACTURER aware of any defects discovered during the PROCESSING that are not related to the PROCESSING.

4.2.4. *CUSTOMER COMPLAINTS*

Consistently with clause 7.2.3 of ISO 13485:2003 the organization shall have in place a system for managing complaints from customers.
In addition the organization shall communicate to the original MANUFACTURER all customer complaints that are not related to the PROCESSING of used MEDICAL SYSTEMS.

4.2.5. *PRODUCTION AND SERVICE PROVISION*

Consistently with clause 7.5 of ISO 13485:2003 the Organization shall have documented procedures for production and service including but not limited to process validation, sterilization processes, identification and traceability, packaging.
In addition the organization shall make provisions to have the knowledge and the ability for installing and servicing ME SYSTEMS in those markets where the organization places ME SYSTEMS.
The Organization shall also apply a label to prominently identify that the used ME SYSTEM has been processed and which identifies the organization and the date of PROCESSING.

4.2.6. *CONTROL OF NON-CONFORMING PRODUCT*

Consistent with Clause 8.3 of ISO 13485:2003 a used ME SYSTEM, following PROCESSING, shall be considered nonconforming when it does not meet the product requirements per the original or newer valid registration, including the original MANUFACTURER's released safety updates.

4.2.7. *POST MARKET SURVEILLANCE PROCESS*

Consistently to clause 8.2.1 and 8.5.1 of ISO 13485:2003 the organization shall monitor feedbacks from costumers and established documented procedures to notify regulatory authorities of adverse events.
In addition the Organization shall also establish his own post market surveillance PROCESS, to monitor whether the additional RISKS resulting from PROCESSING have been mitigated adequately. This PROCESS shall also determine if the adverse event is related to the PROCESSING of the used MEDICAL SYSTEMS or if the adverse event needs to be reported to the original manufacturer.

4.2.8. *DOCUMENT CONTROL*

Consistent with clause 4.2.3 of ISO 13485:2003 the organization shall control all work instructions and procedures used to process used MEDICAL SYSTEMS.

4.2.9. *PURCHASING*

Consistent with clause 7.4 of ISO 13485:2003 the organization shall establish dedicated supplier management capabilities when components or services are purchased

4.2.10. *CONTROL OF DESIGN AND DEVELOPMENT CHANGES*

Consistently with clause 7.3.7 of ISO 13485:2003 and ISO 14971 the organization shall review, verify and validate design changes including the introduction of parts not designed by the original manufacturer to ensure the safety and effectiveness of the ME SYSTEM is not significantly changed. The organization shall also establish a risk management process that includes any risk introduced from the PROCESSING of used MEDICAL SYSTEMS.

5. SPECIFIC REQUIREMENTS FOR GOOD PROCESSING PRACTICE

5.1. GENERAL

The organization shall establish a specific process for PROCESSING of used ME SYSTEMS that, in addition to the general requirements as described in clause 4 of this guidance, includes the following specific requirements.

5.2. SELECTION OF ME SYSTEMS FOR PROCESSING

The organization shall determine, based on an assessment of the RISK associated with PROCESSING, for any type of ME SYSTEMS he wishes to process, the criteria the relevant ME SYSTEM must fulfill to qualify for PROCESSING.

This determination shall consider, at least, the following items:

- INTENDED USE and NORMAL USE of the ME SYSTEM
- EXPECTED SERVICE LIFE
- Applicable standards
- Service/maintenance history for the ME SYSTEM
- Existing service/repair/maintenance procedures for the ME SYSTEM

Criteria should allow the organization to evaluate if the processed ME SYSTEM will meet the safety and performance requirements of the original ME SYSTEM.

Used ME SYSTEMS that are at the end of their EXPECTED SERVICE LIFE, or which cannot be restored to at least their original safety and performance levels including all mandatory safety updates shall not be processed.
Only ME SYSTEMS that were safe and met at least all applicable standards valid at the time when it was put into service for the first time shall be processed.

5.3. EVALUATING MARKET ACCESS REQUIREMENTS

To ensure regulatory compliance, the organization shall have a process in place to evaluate market access requirements such as valid registrations and licenses, language requirements for manuals/instructions for use, safety information and warnings, labels, etc.
Used ME Systems for which the registrations/licenses of the original systems have were discontinued shall not be processed as authorization to put into the market has expired.

5.4. PREPARATION FOR PROCESSING, DISASSEMBLY, PACKING AND SHIPMENT

The organization shall have procedures in place to ensure that the ME SYSTEMS has been suitably cleaned and disinfected to avoid harming any person involved in the disassembly, packing and shipment as well as

adequately disassembled, if necessary, packed and shipped to prevent damage during disassembly and transit. Appropriate procedures shall be in place to avoid violation of privacy rules concerning PATIENT data stored on the relevant ME SYSTEMS.

5.5. ACTUAL PROCESSING

A processing plan shall be developed and followed. The processing plan should include the following items:

- Disinfection and cleaning: Any used ME SYSTEMS shall be systematically cleaned and disinfected before actual PROCESSING.
- Inspection of parts or components, and identification of worn parts or components.
- Adjustment or replacement of parts or components which need periodic attention and lubrication.
- Repair or replacement of worn parts or components with original parts or qualified spare parts or original components.
- Additional parts or components necessary to meet customer's requirements shall be original parts or qualified spare parts or original components or qualified accessories.
- Processing shall comprise checking and adjusting of ME SYSTEMS' functions to bring these functions in conformance with specified tolerances
- Verification of availability of original MANUFACTURER user documentation in the required language or a verified translation.

5.6. INSTALLATION OF SAFETY UPDATES (HARDWARE / SOFTWARE)

This activity shall comprise any applicable safety update which is released for the ME SYSTEM, according to original MANUFACTURER instructions.

5.7. INSTALLATION OF PERFORMANCE UPDATES

Only performance updates released for the ME SYSTEM by the MANUFACTURER shall be installed during the PROCESSING, according original MANUFACTURER instructions

5.8. PERFORMANCE AND SAFETY TESTS

Tests specified by the MANUFACTURER for the original ME SYSTEM shall be conducted to verify that original performance and safety specifications are met for the ME SYSTEM (including all mandatory safety updates).

5.9. PACKING, SHIPMENT AND INSTALLATION OF PROCESSED ME SYSTEM

Packing and shipment shall be adequate to prevent damage during and transit and load/unload operations. Installations shall be performed according to installation instructions as released by the original manufacturer.

5.10. RECORD OF PROCESSING

The record should reflect for the relevant ME SYSTEM that all operations, processes, etc., described in the processing plan, have been accomplished. In addition, the record of processing is specifically required to contain, or refer to the location of, the following information:

1. date of PROCESSING,
2. any ME SYSTEM identification(s) and control number(s) used,
3. the primary identification label and labeling used for each processed unit, and,
4. the acceptance records which demonstrate the ME SYSTEM has been processed in accordance with the processing plan.
5. list of replaced parts and their identification information.
6.

5.11. POST-MARKET SERVICES

Following the installation of processed ME SYSTEM, the organization shall offer services and support similar as for the relevant type of new ME SYSTEM.

5.12. AUTHENTICATION OF A PROCESSED ME SYSTEM

The organization shall authenticate any processed ME SYSTEM that was processed according to the requirements of this guidance through means that allow inspection by authorities and verification by customers as requested.

BIBLIOGRAPHY

[1] International Atomic Energy Agency (IAEA), The Acquisition and Use of Second-Hand Equipment in Diagnostic and Therapeutic Radiology Departments of Developing Countries, January 2008,
[2] IEC 60601-1:2005, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
[3] ISO 14971:2007, Medical devices – Application of risk management to medical devices

INDEX OF DEFINED TERMS

ACCESSORY	IEC 60601-1:2005, 3.3
ACCOMPANYING DOCUMENTS	IEC 60601-1:2005, 3.4
APPLIED PART	IEC 60601-1:2005, 3.8
EXPECTED SERVICE LIFE	IEC 60601-1:2005, 3.12
GOOD PROCESSING PRACTICE (GPP)	3.2
INTENDED USE/INTENDED PURPOSE	IEC 60601-1:2005, 3.4
MANUFACTURER	IEC 60601-1:2005, 3.5
MEDICAL ELECTRICAL EQUIPMENT/ME EQUIPMENT	IEC 60601-1:2005, 3.6
MEDICAL ELECTRICAL SYSTEM/ME SYSTEM	IEC 60601-1:2005, 3.7
NORMAL USE	IEC 60601-1:2005, 3.13
OPERATOR	IEC 60601-1:2005, 3.8
PATIENT	IEC 60601-1:2005, 3.9
PROCEDURE	IEC 60601-1:2005
PROCESS	IEC 60601-1:2005, 3.10
PROCESSING OF USED ME SYSTEMS	3.1
RISK	IEC 60601-1:2005, 3.11
USED ME SYSTEM	3.3
SUPPLY MAINS	IEC 60601-1:2005