COCIR INDUSTRY STANDARD

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MEDICAL ELECTRICAL EQUIPMENT:
GOOD REFURBISHMENT PRACTICE (GRP)

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INTRODUCTION

Keeping up with the latest inventions in medical technology often involves replacing equipment in medical practice before it reaches the end of its EXPECTED SERVICE LIFE. The reason is that innovation cycles for medical technology are much shorter than the functional lifecycle of the investment goods. As a result, a sustainable resource management model is required: Early replacement of installed medical equipment by newer generation technology is more economically feasible if the residual value of the existing equipment is utilized. This is a key driver for REFURBISHMENT.

Conserving assets is a fundamental principle of ecological thinking as in a recycling economy. The replacement of medical equipment with high residual value generates a cascade of trade – which means that after REFURBISHMENT the replaced equipment provides additional value to a new user. Several medical equipment companies have already set up REFURBISHMENT PROCESSES and have delivered refurbished equipment across the healthcare sector for many years. REFURBISHMENT addresses the high demand for affordable and reliable products. Customers of refurbished systems are not only small hospitals with limited budgets but also leading medical institutes. REFURBISHMENT is a well-established element of the healthcare economy.

If used medical equipment is not accurately maintained according to requirements defined by the MANUFACTURER it may result in an additional RISK for PATIENTS and OPERATORS. Consequently some countries imposed bans on the import of used medical equipment to protect public health. These bans fail to distinguish between high-quality refurbished equipment and SECOND-HAND EQUIPMENT of undefined quality, with the effect that patients may be denied access to the safe and economical ME 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 equipment’ 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 equipment and this is no different when reutilizing used ME EQUIPMENT. To ensure the safety and effectiveness, used equipment has to be PROCESSED in a dedicated way. In practice, there is a wide variation in the interpretation of REFURBISHMENT. Therefore, there is a need to define GOOD REFURBISHMENT PRACTICE (GRP) in an international standard.

This standard aims to support:

- Healthcare service providers to enable them to distinguish refurbished medical equipment processed according to this standard from SECOND-HAND EQUIPMENT when making a purchase decision
- PATIENTS to get easier access to safe and effective diagnostic PROCEDURES and therapies
- All stakeholders with information about GOOD REFURBISHMENT PRACTICE for healthcare
- Industry to improve the safety and effectiveness of used medical equipment with a clearly defined quality PROCESS

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1 SCOPE

This International Standard describes GOOD REFURBISHMENT PRACTICE for MEDICAL ELECTRICAL EQUIPMENT (ME EQUIPMENT) and MEDICAL ELECTRICAL SYSTEMS (ME SYSTEMS). It provides requirements that will improve the safety and effectiveness of used ME EQUIPMENT and ME SYSTEMS by establishing a clearly defined quality PROCESS.

For the purpose of this standard, ME SYSTEMS is intended to include ME EQUIPMENT.

REPROCESSING of single use devices, REMANUFACTURING and fully REFURBISHMENT are not within the scope of this standard.

An ME SYSTEM that has reached the end of its EXPECTED SERVICE LIFE is to be dismantled and/or recycled and is not within the scope of this standard.

2 NORMATIVE REFERENCES

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 13485:2003, Medical devices – Quality management systems – Requirements for regulatory purposes

3 TERMS AND DEFINITIONS

For the purposes of this standard, the terms and definitions given in IEC 60601-1:2005 and/or in ISO 14971:2007 and the following apply.

3.1
REFURBISHMENT
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 defined by the MANUFACTURER for that type of ME SYSTEM without significantly changing the finished ME SYSTEM'S performance, safety specifications and/or changing INTENDED USE as in its original registration.

3.2
GOOD REFURBISHMENT PRACTICE (GRP)
PROCESSES for REFURBISHMENT in compliance with the requirements of this standard

3.3
REMANUFACTURING
Actions taken, such as PROCESSING, conditioning, renovating, repackaging, etc. on a used ME SYSTEM that significantly changes the ME SYSTEM'S performance, safety specifications, or INTENDED USE

3.4
SECOND-HAND-EQUIPMENT
Equipment that has been in service, and is put into service again, usually at another location

3.5
REPROCESSING
Cleaning, in particular sterilisation and quality control of multiple use medical ME EQUIPMENT
- NOTE 1 REPROCESSING is also used in relation with re-use of ME EQUIPMENT intended for single use which is not included within the scope of this standard.
- NOTE 2 REPROCESSING may apply to electrical (e.g. endoscopes) and nonelectrical (e.g. trocars) parts of ME EQUIPMENT.

3.6
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]

3.7
MANUFACTURER
Natural or legal person with responsibility for the design, manufacture, packaging, or labeling of ME EQUIPMENT, assembling an ME SYSTEM, or adapting ME EQUIPMENT or an ME SYSTEM, 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 standard, that material is described as markings and ACCOMPANYING DOCUMENTS.
- NOTE 2 "Adapting" includes making substantial modifications to ME EQUIPMENT or an 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]

3.8
REFURBISHER
Legal or natural person that performs REFURBISHMENT

3.9
MEDICAL ELECTRICAL EQUIPMENT
ME 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 standard by appropriate wording in clause 1.
- NOTE 4 This standard uses the term 'electrical equipment' to mean ME EQUIPMENT or other electrical equipment.

[IEC 60601-1:2005, definition 3.63]

3.10
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 standard, should be taken to include ME EQUIPMENT.

[IEC 60601-1:2005, definition 3.64]

3.11
OPERATOR
Person handling the equipment
[Source: IEC 60601-1:2005, definition 3.73]

3.12
PATIENT
Living being (person or animal) undergoing a medical, surgical or dental PROCEDURE
[IEC 60601-1:2005, definition 3.76]

3.13
PROCESS
Set of inter-related resources and activities which transform inputs into outputs
[IEC 60601-1:2005, definition 3.89]

3.14
RISK
Combination of the probability of occurrence of harm and the severity of that harm
[ISO 14971:2007, definition 2.13]

3.15
EXPECTED SERVICE LIFE
Period of useful life as defined by the MANUFACTURER
[IEC 60601-1:2005, 3.28]

3.16
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 REFURBISHMENT PRACTICE

4.1 INTRODUCTION

After REFURBISHMENT, ME SYSTEM shall meet the requirements for safe and effective use as specified by the MANUFACTURER. ME SYSTEM shall remain within the original registration: the REFURBISHMENT process shall not modify its technical specifications or intended use.

TABLE 1 PROCESSES TO BE ESTABLISHED TO MEET THE REQUIREMENTS FOR THE ORGANIZATIONAL FRAMEWORK OF GOOD REFURBISHMENT PRACTICE AND RELATED CLAUSES OF ISO 13485

	Quality management system	ISO 13485:2003
	Resource management	ISO 13485:2003, clause 6.1
	Corrective and preventive action	ISO 13485:2003, clause 8.5
	Customer complaints	ISO 13485:2003, clause 7.2.3 c
	Production and service provision	ISO 13485:2003, clause 7.5
	Control of nonconforming product	ISO 13485:2003, clause 8.3
	REFURBISHMENT labelling	ISO 13485:2003, clause 7.3.3
	Post market surveillance PROCESS	ISO 13485:2003, clause 8.2.1 and 8.5.1
	PROCESS of instructions for validation and document control	ISO 13485:2003, clause 4.2.3
	Supplier management PROCESS	ISO 13485:2003, clause 7.4

4.2 QUALITY MANAGEMENT SYSTEM REQUIREMENTS

4.2.1 GENERAL

REFURBISHMENT shall be conducted under a Quality Management System (QMS) in compliance with ISO 13485:2003.

4.2.2 RESOURCE MANAGEMENT

In addition to clause 6.1 ISO 13485:2003 the REFURBISHER 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 REFURBISHMENT that is in complete compliance with the applicable environmental, work safety and pest control requirements.
Where a REFURBISHER intends to place an ME SYSTEM into a market not covered by the 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

In addition to clause 8.5 ISO 13485:2003 all information related to the refurbished ME SYSTEM shall be collected and evaluated systematically through a comprehensive Corrective Action and Preventive Action (CAPA) PROCESS, addressing the specific aspects of the REFURBISHMENT PROCESS. In the event that the REFURBISHER identifies through his CAPA-system safety related issues, which are in the responsibility of the MANUFACTURER, he shall inform the MANUFACTURER accordingly. The REFURBISHER shall make the MANUFACTURER aware of any defects discovered during the REFURBISHMENT PROCESS that are not related to the REFURBISHMENT.

4.2.4 CUSTOMER COMPLAINTS

In addition to clause 7.2.3 c ISO 13485:2003 the REFURBISHER shall communicate to the MANUFACTURER all customer complaints that are not related to REFURBISHMENT

4.2.5 PRODUCTION AND SERVICE PROVISION

In addition to clause 7.5 ISO 13485:2003 the REFURBISHER shall make provisions to have the knowledge and the ability for installing and servicing ME SYSTEMS in those markets where the REFURBISHER places ME SYSTEMS.

4.2.6 CONTROL OF NONCONFORMING PRODUCT

Clause 8.3 of ISO 13485:2003 applies. An ME SYSTEM, following REFURBISHMENT, shall be considered nonconforming when it does not meet the MANUFACTURER'S specifications per the product registration when the relevant type of ME SYSTEM was placed on the market, including the MANUFACTURER'S released updates for this type of ME SYSTEM

4.2.7 REFURBISHMENT LABELLING

In addition to clause 7.3.3 ISO 13485:2003 the REFURBISHER shall be easily identified by the responsible organization, OPERATOR, inspector, or regulating authority. This shall be documented with a special REFURBISHMENT label.

4.2.8 POST MARKET SURVEILLANCE PROCESS

In addition to clause 8.2.1 and 8.5.1 ISO 13485:2003 the REFURBISHER shall establish his own post market surveillance PROCESS, to monitor whether the additional RISKS resulting from REFURBISHMENT have been mitigated adequately. This process shall also cover the adverse event reporting.

4.2.9 PROCESS OF INSTRUCTIONS FOR VALIDATION AND DOCUMENT CONTROL

In addition to clause 4.2.3 ISO 13485:2003 the REFURBISHER shall validate detailed REFURBISHMENT instructions, which are controlled documents.

4.2.10 SUPPLIER MANAGEMENT PROCESS

In addition to clause 7.4 ISO 13485:2003 the REFURBISHER shall establish dedicated supplier management capabilities when components or services are purchased

5 SPECIFIC REQUIREMENTS FOR GOOD REFURBISHMENT PRACTICE

5.1 GENERAL

The REFURBISHER shall establish a specific process for GOOD REFURBISHMENT PRACTICE that, in addition to the general requirements as described in clause 4 of this standard, includes the following specific requirements.

5.2 SELECTION OF ME SYSTEMS FOR REFURBISHMENT

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

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

Used ME SYSTEMS that are at the end of their EXPECTED SERVICE LIFE shall not be refurbished under GOOD REFURBISHMENT PRACTICE. Refurbished ME SYSTEMS shall be safe and meet all applicable standards valid at the time when it was put into service for the first time. Used ME SYSTEMS that do not meet these standards shall not be refurbished.

5.3 EVALUATING MARKET ACCESS REQUIREMENTS

To ensure regulatory compliance, the REFURBISHER 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.

5.4 PREPARATION FOR REFURBISHMENT, DISASSEMBLY, PACKING AND SHIPMENT

The used ME SYSTEMS shall be checked before disassembly regarding unit identification and the condition of the relevant ME SYSTEMS as defined by the refurbisher or buyer.

Used ME SYSTEMS shall be suitably cleaned and disinfected to avoid harming any person involved in the disassembly, packing and shipment as well as shall be adequately disassembled, if necessary, packed and shipped to prevent damage during disassembly and transit. Appropriate actions shall be taken to avoid violation of privacy rules concerning PATIENT data stored on the relevant ME SYSTEMS.

5.5 ACTUAL REFURBISHMENT

A REFURBISHMENT plan shall be developed and followed. Any used ME SYSTEMS shall be systematically cleaned and disinfected before actual REFURBISHMENT. Any used ME SYSTEMS shall be maintained comprising activities like inspection, identification and replacement of worn parts or components, adjustment or replacement of parts or components which need periodic attention and lubrication. Worn parts or components shall be repaired or replaced with original parts or original spare parts or original components. Additional parts or components necessary to meet customer's requirements shall be original parts or original spare parts or original components or original accessories. REFURBISHMENT shall comprise providing the original MANUFACTURERS user documentation in the required language or a verified translation. REFURBISHMENT shall comprise checking and adjusting of ME SYSTEMS' functions to bring these functions in conformance with specified tolerances

5.6 INSTALLATION OF SAFETY UPDATES (HARDWARE / SOFTWARE)

This activity shall comprise any applicable safety update which is released for this type of ME SYSTEM.

5.7 INSTALLATION OF PERFORMANCE UPDATES

Any performance update installed during the REFURBISHMENT shall be released for this type of ME SYSTEM by the MANUFACTURER.

5.8 PERFORMANCE AND SAFETY TESTS

For any GRP refurbished ME SYSTEM, tests shall verify that it meets performance and safety specifications defined for its type.

5.9 PACKING, SHIPMENT AND INSTALLATION OF REFURBISHED ME SYSTEM

This step shall be equivalent to the PROCESS steps defined for the relevant type of new ME SYSTEM.

5.10 GRP DECLARATION (RELEASE)

When all necessary actions for REFURBISHMENT have been successfully completed, the REFURBISHER shall release the ME SYSTEM, shall declare compliance with the requirements for Good Refurbishment Practice (GRP declaration) and shall label the ME SYSTEM accordingly. The product label shall include name and place of the refurbisher and date of REFURBISHMENT.

5.11 RECORD OF REFURBISHMENT

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

- date of REFURBISHMENT,
- any ME SYSTEM identification(s) and control number(s) used,
- the primary identification label and labeling used for each refurbishing unit, and,
- the acceptance records which demonstrate the ME SYSTEM is refurbished in accordance with the REFURBISHMENT plan.

5.12 POST-MARKET SERVICES

Following the installation of refurbished ME SYSTEM, the REFURBISHER shall provide services and support similar as for the relevant type of new ME SYSTEM.

5.13 AUTHENTICATION OF A GRP REFURBISHED ME SYSTEM

The REFURBISHER shall authenticate any refurbished ME SYSTEM that was processed according to the requirements of this standard through means that allow inspection by authorities and verification by customers.

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

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