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COLEGIO NACIONAL DE QUÍMICOS FARMACÉUTICOS BIÓLOGOS MÉXICO, A.C.

international week 2 on regulatory science

Contribution to better health

IEC PAS 63077: Good Refurbishment Practices for Medical Imaging Equipment

Speaker: Patricia Gehrlein
Moderator:
Review by:

Date: 29 – November – 2018
Institution: Siemens Healthineers / DITTA
Presentation number:

PRESENTATION OBJECTIVES

- Introducing DITTA & the Good Refurbishment Practice (GRP) working group
- Presenting the development of the international standard IEC PAS 63077 "Good refurbishment practices for medical imaging equipment"
- Emphasizing on the importance to harmonize the refurbishment practices

EXPECTED RESULTS

- You know that there is an international standard on refurbishment for medical imaging equipment (IEC PAS 63077).
- You know who has been involved in developing this standard.
- You know more about the difference between remanufacturing and refurbishment in the medical equipment industry, the main objectives and the benefits about refurbishment of medical imaging equipment.

TABLE OF CONTENT

Preface (1/5): DITTA

- DITTA is the Global Diagnostic Imaging, Healthcare IT & Radiation Therapy Trade Association
- DITTA is a non-profit trade association, created in 2000 and incorporated in 2012 represents more than 600 companies around the globe.

- DITTA covers the following industry sectors:
  - Diagnostic imaging
  - Radiation therapy
  - Healthcare IT
  - Electromedical
  - and Radiopharmaceuticals

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

- These industry sectors lead in state-of-art advanced technology and provides integrated solutions covering the complete care cycle.

Preface (2/5): DITTA Global Presence

IMDRF AHWP IAEA International Atomic Energy Agency IEC ISO WORLD BANK GROUP World Health Organization

Preface (4/5): DITTA Governance

Board of Directors

MITA MEDICAL IMAGING & TECHNOLOGY ALLIANCE A DIVISION OF NEMA | JIRA | COCIR

DITTA Chair:
- Patrick Hope, MITA Executive Director

DITTA Vice-Chairs:
- Nicole Denjoy, COCIR Secretary General
- Kiyoshi Inaba, JIRA Business Execution Director

Members:
- Founding Organizations
- Executive Management of each organization
- Chairs of their International Groups

Steering Committee

Chair: DITTA Chair

Members:
- Heads of each organization
- Leadership of their International Groups
- Leadership of DITTA WGs

TCONs: one per month

Working Groups (WG)

Chair: One Chair, Two Vice-Chair per WG

Members: Mixture of trade associations and company experts

Coordination: MITA , COCIR or JIRA

TCONs: as needed

Preface (4/5): 10 DITTA Working Groups

1. Regulated Product Submission (RPS) Working Group — MITA
2. Standardization (STA) Working Group — COCIR
3. Unique Device Identification (UDI) Working Group — MITA
4. Clinical Evaluation Working Group — COCIR

→ IMDRF, AHWP, IEC, ISO

5. Medical Device Single Audit Program (MDSAP) Working Group — MITA

→ MDSAP RAC (Regulatory Authority Council)

6. Medical Software (MSW) Working Group — COCIR
7. Global Health (GH) Working Group — COCIR

→ IAEA International Atomic Energy Agency, WORLD BANK GROUP, World Health Organization

8. Environmental Policy (ENVI) Working Group — COCIR

→ BASEL CONVENTION, UNEP

9. Good Refurbishment Practice (GRP) Working Group — JIRA

→ MITA Medical Imaging & Technology Alliance, IEC, ISO

10. Cybersecurity Working Group — MITA

Preface (5/5): DITTA Good Refurbishment Practices (GRP) Working Group

Chair:

- Michael Schmit, GE Healthcare

Vice-Chairs:

- Jeroen van Nistelrooij, Philips Healthcare
- Patricia Gehrlein, Siemens Healthineers

Secretary:

- Susumu Uchiyama, JIRA

Members from the following organizations are active in the GRP working group:

Alcon A Novartis Division
Technology Industries of Finland
MEDEC
EOS imaging
Canon CANON MEDICAL SYSTEMS
PHILIPS
SIEMENS Healthineers

Remanufacturing & Refurbishment in the medical equipment industry (1/3)

- Outside the medical equipment industry the terms remanufacturing and refurbishment are often used as synonyms.

- Within the medical equipment industry we have to consider the term remanufacturer as defined by the U.S. Food and Drug Administration:
  - In the USA, the Food and Drug Administration defines 'remanufacturer' as "*(…) any person who processes, conditions, renovates, repackages, restores, or does any other act to a finished device that* ***significantly changes*** *the finished device's performance or safety specifications, or intended use.*" (CFR 21 Part 820)

Remanufacturing & Refurbishment in the medical equipment industry (2/3)

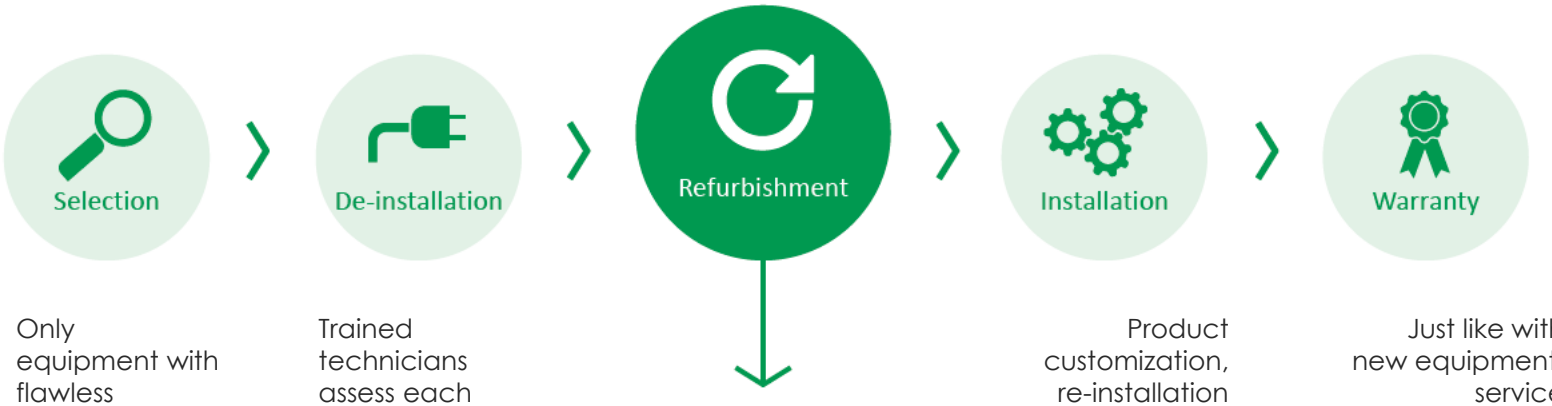
- This means that in the medical equipment industries there are differences between refurbishment and remanufacturing. The most important aspect is: for refurbished medical (imaging) equipment **there is no significant change of the performance or safety specifications, or in the intended use of the equipment compared to the specifications the manufacturer defined for the relevant new equipment.**
- In the EU, there is no official definition of remanufacturing.
- The term is used by other industry sectors with different meanings.

Remanufacturing & Refurbishment in the medical equipment industry (3/3)

- According to IEC PAS 63077 and NEMA/MITA 1-2015 refurbishment of a medical imaging equipment is defined as:

> *"process or combination of processes applied during the expected service life to restore used medical imaging equipment* ***to a condition of safety and effectiveness comparable to when new****.*
>
> *Note 1 to entry: Refurbishment can include activities such as repair, rework, replacement of worn parts, and update of software/hardware but shall not include activities that result in regulatory submissions."*

The refurbishment process



Only equipment with flawless maintenance, performance, and safety records is even eligible for refurbishment.

Trained technicians assess each piece of equipment for eligibility. Disassembly, packaging and shipment to the refurbishing facility are performed with the utmost care.

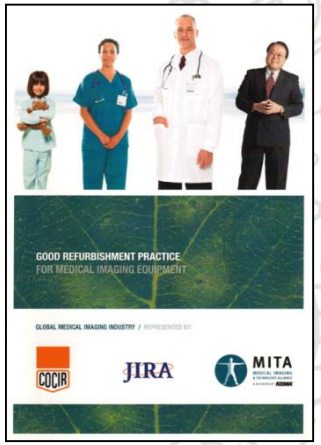
All actions are performed in a manner consistent with product specifications and service procedures defined by the manufacturer. All steps in the process are performed by experts, trained using original manufacturer's specifications. Refurbishment is thorough and well documented. Safety and quality are tested repeatedly.

Product customization, re-installation and training are done according customer needs.

Just like with new equipment, service will be made available in the market where equipment is sold.

Source: DITTA (2016): Good Refurbishment Practices for Medical Imaging Equipment. What customers should know.

Past Developments (1/3): From GRP to IEC PAS 63077



- In 2007, COCIR published the principle of "Good Refurbishment Practices" (GRP) as a **Green Paper**, followed by a "Good Refurbishment Practices Industry Standard" document in 2009.

- In 2009, the industry associations COCIR (EU), JIRA (Japan) and MITA (USA) released a joint "Good Refurbishment Practices" Green paper filling a need in the global healthcare market for safe and effective refurbished medical equipment.

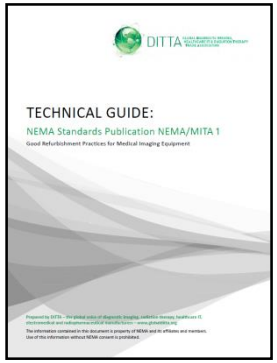
- In 2010, this activity has further resulted in the transfer of the **working group** on "Good Refurbishment Practices" (GRP) at COCIR to the global medical imaging devices association DITTA.

Past Developments (2/3): From GRP to IEC PAS 63077

- The feedback to the COCIR industry standard triggered the idea within the DITTA GRP working group to further develop an **international standard** on GRP.

- From 2014 to 2015 the DITTA GRP working group completely reworked the COCIR industry standard. With the support of DITTA, the US medical imaging and technology alliance MITA managed to develop and publish the out-come of this rework as **NEMA/MITA 1-2015** standard in February 2016.

- At the same time, in 2016, DITTA released an **updated Technical Guide** on the GRP.
  The Technical Guide describes how the standard might be applied.



Past Developments (3/3): From GRP to IEC PAS 63077

- In addition, DITTA (via MITA) collaborated with ANSI (American National Standards Institute) to file a **request to the International Electrotechnical Commission (IEC)** to publish the content of NEMA/MITA 1-2015 standard as an IEC PAS.

- A **Publicly Available Specification (PAS)** is a standardization document in a preliminary stage to an IEC standard. The objective of a PAS is to speed up standardization. PASs are often produced in response to an urgent market need.

- Later in 2016, IEC published **IEC PAS 63077** – content wise identical to NEMA/MITA 1-2015.

Status Quo: IEC PAS 63077 Main Objective

Why do we need an international standard on good refurbishment practices for medical imaging equipment?

- **Ensuring safety and effectiveness of the refurbished medical equipment and the refurbishment process:**
  Safety and effectiveness are the most important aspects to consider with medical imaging equipment, including refurbished equipment.
  By collecting the best practices from across industry and regulatory agencies and documenting the state-of-the-art processes this standard can ensure that all entities complying with it meet these appropriate levels of controls to ensure safety and effectiveness.

Status Quo: IEC PAS 63077
Benefits of refurbishment

Good for the Environment: Refurbishment reduces waste generation and saves energy, resources and raw materials.

Good for the Economy: Refurbishment extends the economic life of medical equipment and contributes to new jobs, growth and investment.

Good for Patients, Hospitals & Society: Refurbished medical equipment can be sold for a lower price than new medical equipment. Therefore, refurbishment strongly contributes to increased access to affordable and high-quality healthcare.

Status Quo: IEC PAS 63077 Content Overview

Foreword

1. Scope

2. Normative References

3. Terms and definitions

3.1 expected service life
3.2 intended use/intended purpose
3.3 manufacturer
3.4 medical imaging equipment
3.5 normal use
3.6 operator
3.7 refurbisher
3.8 patient
3.9 process
3.10 refurbishment
3.11 repair
3.12 rework
3.13 risk
3.14 used medical imaging equipment

4. General requirements for refurbishment of used medical devices

4.1 Quality management system
4.2 Resource management
4.3 Corrective and preventive action
4.4 Customer complaints
4.5 Production and service provision
4.6 Control of non-conforming product
4.7 Post-market surveillance process
4.8 Document control
4.9 Purchasing
4.10 Control of design and design changes

5. Specific requirements for good refurbishment practice

5.1 General
5.2 Selection of medical imaging equipment for refurbishment
5.3 Evaluating market access requirements
5.4 Preparation for refurbishment, disassembly, packing, and shipment
5.5 Planning
5.6 Installation of safety updates (hardware/software)
5.7 Performance and safety test
5.8 Packing, shipment, and installation of refurbished medical imaging equipment
5.9 Record of refurbishment
5.10 Refurbishment label

Status Quo: IEC PAS 63077 Post-market surveillance

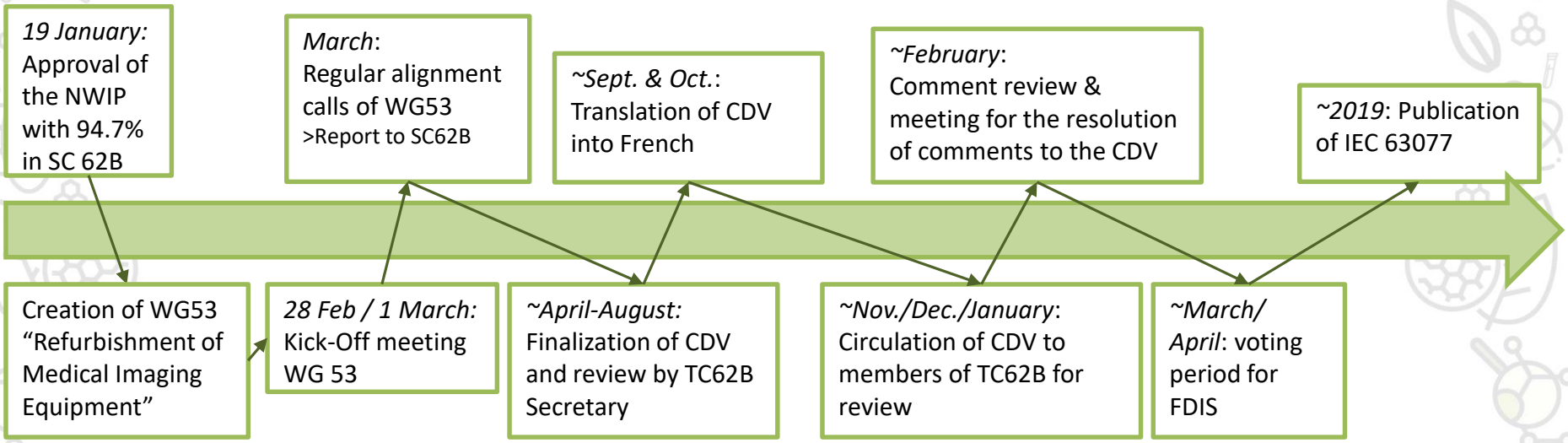
4.7 Post-market surveillance process

The refurbisher shall collect feedback from customers and establish documented procedures to notify regulatory authorities of adverse events. The process shall also determine if the adverse event is related to the refurbishment or needs to be reported to the original manufacturer.

The refurbisher shall also establish his or her own post-market surveillance process to monitor whether the additional risks resulting from refurbishment have been adequately mitigated.

The refurbisher shall enable monitoring of its installed base of refurbished medical imaging equipment to allow for update management for safety and effectiveness.

Way Forward: From IEC PAS 63077 to IEC 63077



Proposal Stage	Preparatory & Committee Stage	Enquiry Stage	Approval Stage	Publication Stage
NWIP approved if : • a simple majority of the committee's P-members approve the new work item and • if the minimum number of experts are nominated by P-members' approving the new work item proposal. For committees with 16 or less P-members, a minimum of 4 experts and for committees with 17 or more P-members, a minimum of 5 experts.		CDV approved if: • a majority of two thirds of the votes cast by P-members is in favor, and if • the number of negative votes cast by all National Committees does not exceed one quarter of all votes cast.	FDIS approved if: • 2/3 majority of P-members voting approve and if • Less than 25% of all votes submitted are negative.	Publication within 1.5 months of approval of the FDIS

Good Refurbishment Practices of Medical Imaging Equipment: Main Take Away's (1/2)

- Refurbishment of medical imaging equipment is **conducted since about two decades** by several medical equipment companies.
- When refurbishing medical imaging equipment, there is **no significant change** of the **performance or safety specifications**, or in the **intended use** of the equipment compared to the specifications the manufacturer defined for the relevant new equipment.
- Aiming at finalizing the development of an international standard, IEC 63077 "Good refurbishment practices for medical imaging equipment", **ensures the safety and effectiveness** of the refurbished medical imaging equipment.

Good Refurbishment Practices of Medical Imaging Equipment: Main Take Away's (2/2)

- Refurbishment of medical imaging equipment has **benefits** for the **environment**, the **economy** as well as **patients**, **hospitals** and **society**.

- The global medical imaging association **DITTA** has triggered the idea to have this international standard and is further dedicated to **promote the use** and **market access** of refurbished medical imaging equipment as well as to emphasize on the importance to harmonize the refurbishment practices globally.

- Currently, **IEC SC62B WG53** is **finalizing the standard** by developing from a Publicly Available Specification (PAS) to an international standard.

GLOSSARY

- **CDV**: Committee Draft for Vote
- **COCIR**: European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (www.cocir.org)
- **DITTA**: Global Diagnostic Imaging, Healthcare IT and Radiation Therapy Trade Association (www.globalditta.org)
- **GRP**: Good Refurbishment Practices
- **IEC**: International Electrotechnical Comission (www.iec.ch)
- **ISO**: International Organization for Standardization (www.iso.org)
- **JIRA**: Japan Medical Imaging and Radiological Systems Industries Association (www.jira-net.or.jp)
- **NEMA**: U.S. National Electrical Manufacturers Association (www.nema.org)
- **MITA**: Medical Imaging & Technology Alliance - A division of NEMA (www.medicalimaging.org)
- **PAS**: Publicly Available Specification

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https://www.globalditta.org/activities/good-refurbishment-practice.html

- DITTA (2015): Refurbishment of medical devices. Contribution to the Circular Economy
https://www.globalditta.org/fileadmin/user_upload/Level_home/Activities/Good_Refurbishment_Practice/14021.DIT.Refurbishment_brochure_web_7-01-2015.pdf

- DITTA (2016): Good Refurbishment Practices for Medical Imaging Equipment. What customers should know
https://www.nema.org/Standards/ComplimentaryDocuments/DITTA%20GRP%20Customer%20Brochure%20WM.pdf

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- DITTA: Technical Guide: NEMA Standards Publication NEMA/MITA 1. Good Refurbishment Practices for Medical Imaging Equipment https://www.nema.org/Standards/ComplimentaryDocuments/DITTA%20GRP%20Implementation%20Guide%20Watermarked.pdf

- IEC PAS 63077:2016. Good refurbishment practices for medical imaging equipment https://webstore.iec.ch/publication/26210

- NEMA/MITA 2015-1: Good refurbishment practice for medical imaging equipment https://www.nema.org/Standards/Pages/Good-Refurbishment-Practices-for-Medical-Imaging-Equipment.aspx

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¡THANK YOU!