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

Good Refurbishment Practices of Medical Imaging Equipment

Past Developments, Status Quo and Way Forward to an International Standard

The 4th IEC International Medical Equipment Standards Forum
12 April 2018, Shanghai

Patricia Gehrlein,
Co-Chair of the DITTA Working Group „Good Refurbishment Practices“

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Structure of Presentation

- Preface: DITTA & the Working Group on Good Refurbishment Practices
- Past Developments: From GRP to IEC PAS 63077
- Status Quo: IEC PAS 63077
- Status Quo: From IEC PAS 63077 to IEC 63077
- Status Quo: IEC WG53 Medical Imaging Equipment
- Way Forward: From IEC PAS 63077 to IEC 63077

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:

1. Diagnostic imaging
2. Radiation therapy
3. Healthcare IT
4. Electromedical
5. and Radiopharmaceuticals

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

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Preface (2/5): DITTA Global Presence

Preface (3/5): DITTA Governance

Board of Directors

DITTA Chair:
- Patrick Hope, MITA Executive Director

DITTA Vice-Chairs:
- Nicole Denjoy, COCIR Secretary General
- Satoshi Kimura, JIRA Executive 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

Chair: One Chair, Two Vice-Chair per Working Group

Members:
- Mixture of trade associations and company experts
- Coordination: MITA , COCIR or JIRA

TCONs: as needed

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Preface (4/5): 9 DITTA Working Groups

1. Regulated Product Submission (RPS) Working Group
2. Standardisation (STA) Working Group
3. Unique Device Identification (UDI) Working Group
4. Medical Device Single Audit Program (MDSAP) Working Group
5. Medical Software (MSW) Working Group*1
6. Global Health (GH) Working Group
7. Environmental Policy (ENVI) Working Group
8. Good Refurbishment Practice (GRP) Working Group
9. Cybersecurity Working Group

IMDRF AHWP IEC ISO

MDSAP RAC
(Regulatory Authority Council)

IAEA International Atomic Energy Agency WORLD BANK GROUP World Health Organization

BASEL CONVENTION UNEP

MITA MEDICAL IMAGING & TECHNOLOGY ALLIANCE A DIVISION OF NEMA IEC ISO

new

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

- Chair:
  - Michael Schmit, GE Healthcare
- Co-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:

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Remanufacturing & Refurbishment in the medical equipment industries

- Remanufacturing
  - Outside the medical equipment industries the terms remanufacturing and refurbishment are often used as synonyms.
  - Within the medical equipment industries 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)
  - 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.

- Refurbishment
  - According to IEC 63077 PAS 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."

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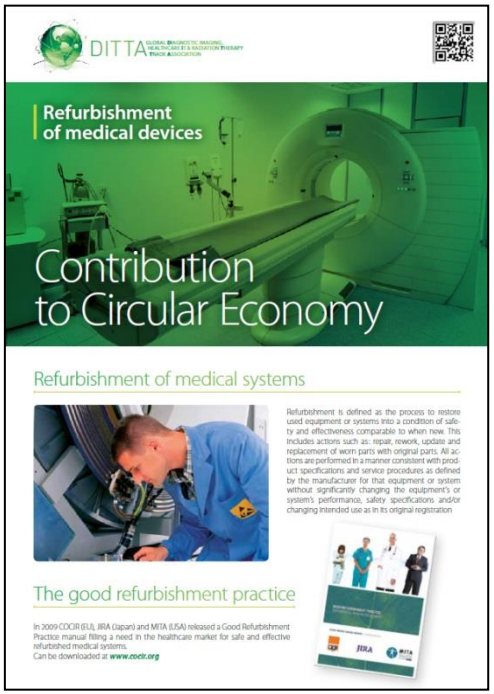
Past Developments (1/2): From GRP to IEC PAS 63077

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



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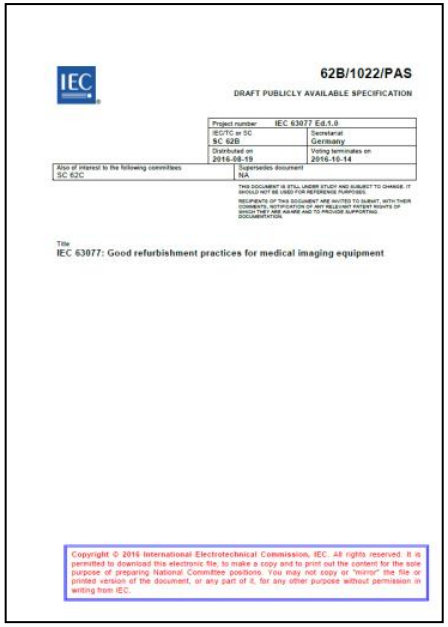
Past Developments (2/2): From GRP to IEC PAS 63077

- From 2014 to 2015 the DITTA GRP working group completely reworked the COCIR industry standard. With the support of DITTA, the US-based industry association 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 **Green Paper** on the GRP. The Green paper describes how the standard might be applied.
- 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.



62B/1022/PAS

DRAFT PUBLICLY AVAILABLE SPECIFICATION

Project number: IEC 63077 Ed.1.0

IEC/TC or SC: SC 62B | Secretariat: Germany

Distributed on: 2016-08-19 | Voting terminates on: 2016-10-14

Also of interest to the following committees: SC 62C | Supersedes document: NA

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Title:
IEC 63077: Good refurbishment practices for medical imaging equipment

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Status Quo: IEC PAS 63077 Main Objective & Benefits

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

- **Ensuring safety and effectiveness of the refurbished medical devices:** Safety and effectiveness are the most important aspects to consider with medical imaging devices, including refurbished devices. 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.

What are the benefits of refurbishment of medical imaging devices?

- There are benefits for the environment and the economy as well as for patients, hospitals and society that result from refurbishing medical devices.

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Status Quo: IEC PAS 63077 Benefits

- **Good for the Environment:** Refurbishment reduces waste generation and saves energy, resources and raw materials.
  - By minimizing the production of new parts for the devices, refurbishment contributes to save energy. DITTA estimates that around 30 MWh can be saved for each ton of refurbished medical devices.
  - DITTA estimates that in 2012 around 16.400 tons of used medical devices have been prevented from becoming waste, instead being shipped world-wide for refurbishment and repair. Europe and Unites States account for most of the refurbishment activities worldwide.
- **Good for the Economy:** Refurbishment extends the economic life of medical devices and contributes to new jobs, growth and investment.
  - According to DITTA, the refurbishment of medical devices accounted for a global revenue of approximately 480 million euros in 2012. Approximately 74% of all refurbished medical devices are sold in both the U.S. (48%) and the EU (26%).
- **Good for Patients, Hospitals & Society:** Refurbished medical devices can be sold for a lower price than new medical devices. Therefore, refurbishment strongly contributes to increased access to affordable and high-quality healthcare.
  - In current times of constrained budgets, refurbished medical devices help hospitals and medical centers with budget restrictions to purchase high-quality devices and substitute their used devices.
  - By substituting used, outdated devices with refurbished medical devices, the overall quality of healthcare for patients can be improved, e.g. by providing better diagnosis, which allows for better therapy and increasing chance of survival; by reducing radiation exposure thanks to latest features; by ensuring faster diagnosis and improving patient comfort.

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Status Quo: IEC PAS 63077 Content Overview

1. Foreword

2. Scope

3. 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

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Status Quo: IEC PAS 63077 Definition of Refurbishment

- According to IEC 63077 PAS, article 3.10 refurbishment:

  "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."

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Status Quo: From IEC PAS 63077 to IEC 63077

- In 2017, DITTA (via MITA and ANSI) filed a request via a **new work item proposal (NWIP)** to IEC SC62B to set up an IEC working Group on GRP to transfer the IEC 63077 PAS into IEC 63077 standard.
- In January 2018, **the NWIP was approved with 94.7% of positive votes** in IEC SC62B.
- As a result, **WG53 "Refurbishment of Medical Imaging Equipment"** was created.

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Status Quo: IEC WG53 of Medical Imaging Equipment

- Reports to the Subcommittee (SC) 62B “Diagnostic Imaging Equipment”, which reports to the Technical Committee (TC) 62 “Electrical Equipment in Medical Practice” (Secretary for both: Norbert Bischof)
- Has launched its activities on 28 February 2018 in a meeting in Vienna
- Acting Convener: Dr. Markus Braun, Siemens Healthineers
- Members:

Last name	First name	NC	Last name	First name	NC
Bernard	Michael	GB	Kasahara	Takayuki	JP
Braun	Markus	DE	Maringer	Franz	AT
Chu	Fei	CN	Molnar	Alexandra	US
Citron	Israel	IL	Polignano	Massimo	IT
Deng	Liping	CN	Schmit	Michael	US
Gao	Chunyu	CN	Shin	Ki-Young	KR
Godin	Johan	FR	Sun	Zhiyong	CN
Habara	Atsushi	JP	Toyofuku	Shoji	JP
			Uchiyama	Susumu	JP

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Way Forward (1/2): From IEC PAS 63077 to IEC 63077

- WG 53 will propose to circulate a **"Committee Draft for vote" (CDV)** as next draft, subject to approval by SC 62B.
  - WG 53 believes that IEC PAS 63077 can be a CDV after revising reflecting effective comments received with the vote on the 62B/1071/NP.
  - The draft distributed with the 62B/1071/NP is based on IEC PAS 63077 (2016) and it is referring to the NEMA standard NEMA/MITA 01-2015.
  - WG 53 reviewed and discussed the observations to the comments and decided to revise the requirements referring to the observations we agreed during the meeting and believes that the next step should be CDV, i.e. skipping the "Committee Draft" (CD).

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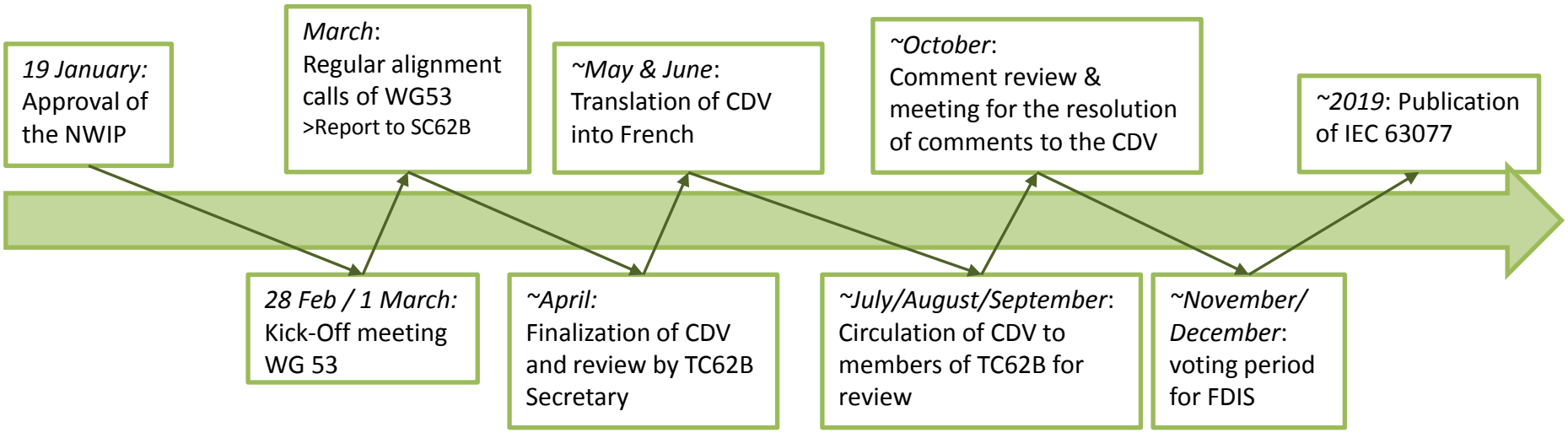
Way Forward (2/2): From IEC PAS 63077 to IEC 63077



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

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Good Refurbishment Practices of Medical Imaging Equipment: Main Take Away's

- Refurbishment of medical imaging equipment is **conducted since about two decades** by several medical equipment companies.
- 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.
- 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.
- Currently, **IEC WG53** is **finalizing the standard** by developing from a Publicly Available Specification (PAS) to an international standard.

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Contact Details

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