

TECHNICAL GUIDANCE ON TRANS-BOUNDARY MOVEMENT OF E-WASTE

REUSE, REPAIR AND ANALYSIS OF MEDICAL DEVICES AT RISK



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

Basel Convention COP 12, 4-15 May 2015

The additional requirements to shipments of used medical devices (MD) included in the text of the draft “Technical Guidance on transboundary movements of e-waste” (TG on TBM), presented at COP 12, will not allow used medical devices to be shipped all over the world for legitimate Repair, Reuse and Root cause analysis activities (RRR).

MEDICAL DEVICES NEED TO BE EXCLUDED

- Used Medical devices cannot fulfill requirements in the TG on TBM
- Medical devices cannot fulfill the criteria in actual point 26.b)
- Manufacturers cannot meet regulatory obligations for root cause analysis or recalls, which are key to ensure safety of patients and doctors.
- Once declared a waste, used MDs and parts cannot be repaired or refurbished as such centers are not authorized/permited to receive waste. (e.g., EU Waste Framework Directive 2008/98/EC, US 40 CFR Parts 260-262.)



MEDICAL DEVICES DO NOT CONTRIBUTE TO THE E-WASTE PROBLEM

- The medical device industry is shipping a relatively small quantity of used MDs and parts for RRR, which have a high market value
- Shipments of medical devices and waste generated from RRR activities are tightly controlled by industry
- Majority of used MDs and parts are repaired in OECD countries

Only 16500 tons/y of used medical devices shipped globally

Only 1500 tons/y shipped to non-OECD countries

Only 84 tons/y waste generated in non-OECD countries

RE-USE OF MEDICAL DEVICES IS IMPORTANT

For patients: RRR of MD's contributes strongly to increased access to healthcare:

- 20%-30% reduced cost for healthcare providers (as good as new), while ensuring safety and high clinical performance.
- Increase in quality of healthcare and safety for patients due to the reduction of the obsolescence of installed equipment.
- Keeping equipment functional

For environment: RRR of medical devices saves energy and CO₂, prevents waste generation and save resources and raw materials

THE MEDICAL DEVICE INDUSTRY NEEDS PARTIES' SUPPORT

Manufacturers of medical devices need the support of the Parties to the Basel Convention at the COP 12 meeting, to introduce a specific exclusion for medical devices in the text of the TG on TBM of e-waste.

Proposed text:

“26(new) Where used medical devices and their components are sent by and to the manufacturer or a third party acting on behalf of the manufacturer, for root cause analysis, failure analysis, diagnostic testing, refurbishment, or repair under a valid agreement”

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DITTA STRONGLY SUPPORTS:

- The objective of the TG on TBM of e-waste to provide additional tools to customs to fight the illegal shipment of waste under the false claim of being destined for reuse
- Narrow exclusions for those industrial sectors with proven track records of legitimate activities for repair, refurbishment and root cause analysis, clearly defined in such a way not to undermine basic principles of the Basel Convention.
- A clear framework in the TG on TBM of e-waste that will allow the continued international movement of used medical devices and parts without opening loop holes for bad actors.

REFURBISHMENT OF MEDICAL SYSTEMS

Refurbishment is defined as the process to restore used equipment or systems into a condition of safety and effectiveness comparable to when new. This includes actions such as; repair, rework, update and replacement of worn parts with original parts. All actions are performed in a manner consistent with product specifications and service procedures as defined by the manufacturer for that equipment or system without significantly changing the equipment's or system's performance, safety specifications and/or changing intended use as in its original registration. The Good Refurbishment Process consists of 5 steps. All the steps are performed by trained experts using the original manufacturer's specifications.

1. Selection of equipment for refurbishment
2. Disassembly, packaging and shipment
3. Refurbishment
4. Reinstallation of refurbished equipment
5. Use of professional services

DITTA

DITTA is the global voice for diagnostic imaging, radiation therapy, healthcare IT, electromedical and radiopharmaceutical manufacturers to better communicate, coordinate and collaborate on matters of common interest between participating associations and member companies. DITTA enables participating associations and their member companies to work more effectively with international policymakers, organizations, professional associations and stakeholders.

