Medical Technology Industry Position on the Draft Technical Guidelines on Transboundary Movements of E-Waste

12 March 2015

DITTA is the global voice for diagnostic imaging, radiation therapy, healthcare IT, electromedical and radiopharmaceutical manufacturers. DITTA members include, but not limited to, COCIR, the European Coordination Committee of Radiological, Electromedical and Healthcare IT Industry, JIRA, the Japan Medical Imaging and Radiological Systems Industries Association, MEDEC, the Association of Canada's Medical Technology Companies and MITA, the US Medical Imaging Technology Alliance.

DITTA contributed actively to the definition of the draft Technical-Guidance and in the past 4 years and **clearly demonstrated that reuse and repair of medical devices, when managed by manufacturers, do not contribute to the e-waste problem.**

Global medical technology manufacturers engage in legitimate activities of reuse through medical device refurbishment and spare part repair, which occurs mostly in OECD countries.[i]

DITTA believes many proposals advanced by Parties, while well intentioned, will block medical technology manufacturers from shipping used devices and their parts for refurbishment, repair and root cause (failure) analysis.

DITTA believes that an exclusion specifically for medical technology manufacturers and third parties acting on their behalf is necessary, as medical devices cannot be confused with IT and household equipment, for which the adoption of more stringent criteria may be justified.
Therefore, we ask for your support to include the proposed wording below in the Technical Guidelines on Transboundary Movements of E-Waste.

> ***26(b) Where used medical device 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;***

DITTA considers this proposed exclusion for medical devices to be judicious, free of loopholes and supported by results shown below obtained from a DITTA survey of four leading international medical devices manufacturers making up 80% of the medical device market.[ii]

Repaired parts are critically important in keeping previously installed devices functional. Refurbishment ensures an adequate supply of affordable medical devices that are considered good as new, with warranty, at a fraction of the cost of new[iii]. Also critical to medical technology manufacturers is the ability to perform root cause analysis on devices that have experienced failure. Manufacturers must continue to be able meet regulatory obligations for carrying out root cause analysis and product recalls. Used devices and parts must be shipped transboundary because there are few facilities worldwide that are certified to complete these activities.

DITTA has also considered that the SIWG is discussing adding possible criteria regarding the obligation of re-exporting the waste produced by the above mentioned activities to an Annex VII Countries for environmentally sound management. If the criteria is adopted, DITTA can support its application also to medical devices, despite, as already mentioned, medical devices do not contribute to the e-waste problem.

Used Medical Devices and their parts must not be considered waste when shipped transboundary for repair, refurbishment or root cause analysis (RRR) because:

- **The medical device industry is shipping a relatively small quantity of used medical devices and parts for RRR, which have a high market value**
    - 16,486 metric tons of used electronic medical devices and parts are shipped transboundary annually for RRR,[iv]
    - Approximately 9705 metric tons (59%) of used parts and equipment are shipped globally for repair, 6109 metric tons (37%) are shipped for refurbishment and 672 metric tons (4%) are shipped for root cause analysis (RCA) every year by and to medical device manufacturers, or third parties acting on their behalf, and
    - These shipments are valued at more than $3.4 billion USD and provide thousands of refurbished devices and millions of repaired parts annually.

- **Shipments and wastes generated from RRR activities are tightly controlled[v] by the industry**
    - RRR must be performed under highly controlled conditions and processes. There are only a few facilities worldwide that can perform these activities.
    - 100% of used equipment and parts are packaged separately,
    - 100% are protected against damage during transport,
    - 100% of shipments are insured,
    - 93% include an invoice with a description of the contents,
    - 72% of shipments to non-OECD countries for RRR include financial assurance from the shipper that the shipment can be returned to the company when necessary,
    - 63% include a copy of the contract relating to the sales and/or transfer of ownership, and
    - 100% Percent of OEMs have an audit processes to ensure adequate environmental protection for the management of e-waste.

- **Majority of used medical devices and parts are repaired in OECD countries**
    - 14978 tons (91% of the total) are sent to OECD countries for repair, refurbishment and RCA. USA, Germany, Hungary, Netherlands, Japan and France receive 86% of the used parts for repair or refurbishment,
    - 1508 tons of used products and parts (9 % of the total) are shipped to non-OECD countries for repair, refurbishment, and root cause activities 1263 tons shipped to China, 228 tons to India, 11 tons to Malaysia, 6 tons to Singapore and 0 tons to African Group countries, and
    - 78% of the repair facilities and 69% of refurbishing facilities are located in OECD countries.

- **Manufacturers cannot meet regulatory obligation for RCA or recalls**
    - After an ‘adverse event’ in which a patient or user is harmed the equipment must be returned to the manufacturer or to a test house for investigation. This requirement is mandatory in Europe under the Medical Devices Directive, the USA under FDA legislation and other country legislation.

- **Once declared a waste, used medical devices and parts cannot be repaired or refurbished**
    - Used medical devices and parts cannot be shipped as waste into OECD countries as national legislation requires shipments to be received only by authorized waste treatment facilities. Refurbishment, remanufacturing, and repair centers are not authorized/ permitted to receive waste. (e.g., EU Waste Framework Directive 2008/98/EC, US 40 CFR Parts 260-262.), and
    - Under Basel Controls, the transboundary movement of repairable parts and refurbishable devices will stop due to cost, time, and administration obstacles

- **Used medical devices and parts will become locked in country resulting in:**
    - Reduced availability of refurbished devices,
    - Spare parts inventory for repairs and maintenance activities reduced by 9705 metric tons per year,
    - Obsoleting legacy devices more quickly due to lack of spare parts (medical devices have a long service life, potentially in excess of ten years beyond the warranty period),
    - Delayed repairs and maintenance (longer repair wait times) interrupting medical services due to “all new” spare parts business model where parts are made to order and inventory is minimal,
    - Cost to healthcare industry for service and maintenance increases due to higher cost of new parts, cost to purchase replacement devices earlier than necessary and loss of trade-in values, and
    - Potential breach of confidentiality of patient/customer sensitive information due to improper local “destruction.”

- **Reuse keeps system and service costs down, avoiding adverse environmental, social, and health impacts, while enabling resource efficiency and circular economy.**
    - Repair and refurbishing activities prevent 16,486 tons of waste per year and fewer natural resources are extracted and processed.

Sincerely,

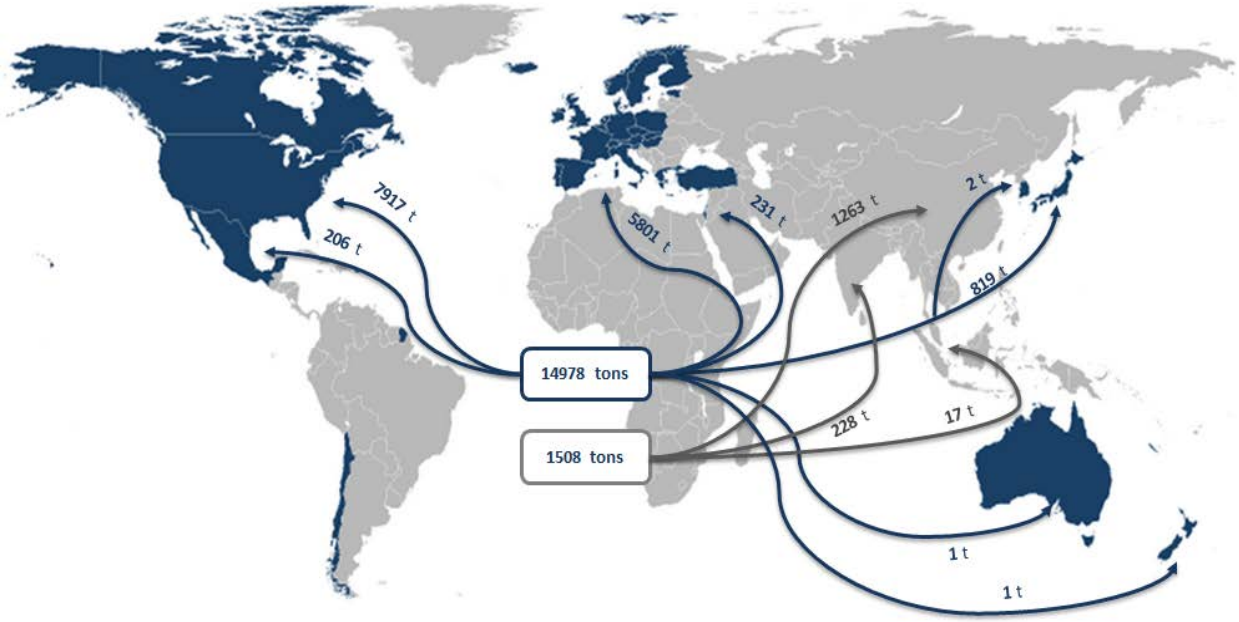
Wendy Phippen, CHMM, MBA

DITTA ENVI WG Chair

Sustainability Director, Product Stewardship

Philips Healthcare

Geographical distribution of the main fluxes of used devices and part for reuse, refurbishment or RCA



[i] USA, Germany, Hungary, Netherlands, Japan and France receive 86% of the used parts for repair or refurbishment. 9% of the total used products and parts were shipped to non-OECD countries (China, India, Malaysia, Singapore and Mexico)

[ii] Cameron , L. (2009) MaRS Market Insights. p.7. Retrieved 13-Feb-2015 from: http://www.marsdd.com/dmsassets/reports/MaRS_Diagnostic_imaging.pdf

[iii] Refurbished device are used, high quality, state-of-the-art systems which on average are sold at 25% less when compared to a comparable new system including X-ray equipment, computed tomography (CT), magnetic resonance imaging (MRI), Ultrasound and Nuclear Medicine (NM).

[iv] Data taken from a DITTA survey of the four leading medical device manufacturer's constituting approximately 80% of the diagnostic imaging market completed August 2013. The survey was intended to characterize the scope of global legitimate movement of used equipment and parts for repair, refurbishment and RCA.

[v] Strict controls are mandated by national governments concerning safety and reliability of medical devices and parts. COCIR published an industry standard for refurbishment found at http://www.cocir.org/index.php?id=136.