

**Discussion Points: Medical Technology Industry Position on the
Draft Technical Guidelines on Transboundary Movements of E-Waste
(Version: 22 December 2012)**

16-October-2013

New Barriers to Trade in Used Electronics

- Governments are moving to restrict most exports of used electronics destined for repair, refurbishment and reuse in response to longstanding concerns over the mismanagement of used/end-of-life products.
- Basel Convention sets the framework for controlling the “transboundary” movements of hazardous wastes and developed the criteria for “environmentally sound management.”
- Basel Technical Guidelines (TG) are not legally binding, but are created to provide a formal recommended interpretation of Basel Convention, setting a standard for future legislation in over 170 countries (Basel Parties) that have ratified it.
- Draft TG on transboundary movements of e-waste and used electrical and electronic equipment (EEE), in particular regarding the distinction between waste and non-waste under the Basel Convention was published on 22nd December 2012.
- These measures would subject untested, used medical equipment and parts destined for repair and refurbishment for the purpose of reuse to stringent prior informed notice and consent controls typically applied to hazardous waste.
- As a result, international shipping of used equipment and parts will encounter more administrative processes, red tape and additional costs creating a barrier to legitimate international trade in used equipment and parts destined for reuse after repair or refurbishment.

What is at Risk?

- The proposed Basel e-waste TG will severely limit (and in most cases stop) transboundary movement of used medical equipment and parts for repair, refurbishment and root cause analysis.
- New regulatory controls and trade bans impact shipments of:
 - Warranty returns
 - Non-warranty repairs
 - Off-lease equipment
 - Service arrangements
 - Refurbishment operations
 - Product recalls
 - Intra-company transfers
- As a result, more than 16486 metric tons of used medical equipment and parts shipped globally for repair or refurbishment annually will become e-waste and manage within the

country they originate adding to the growing waste issues. Furthermore, e-waste may be locked within countries that lack environmentally-sound management facilities.

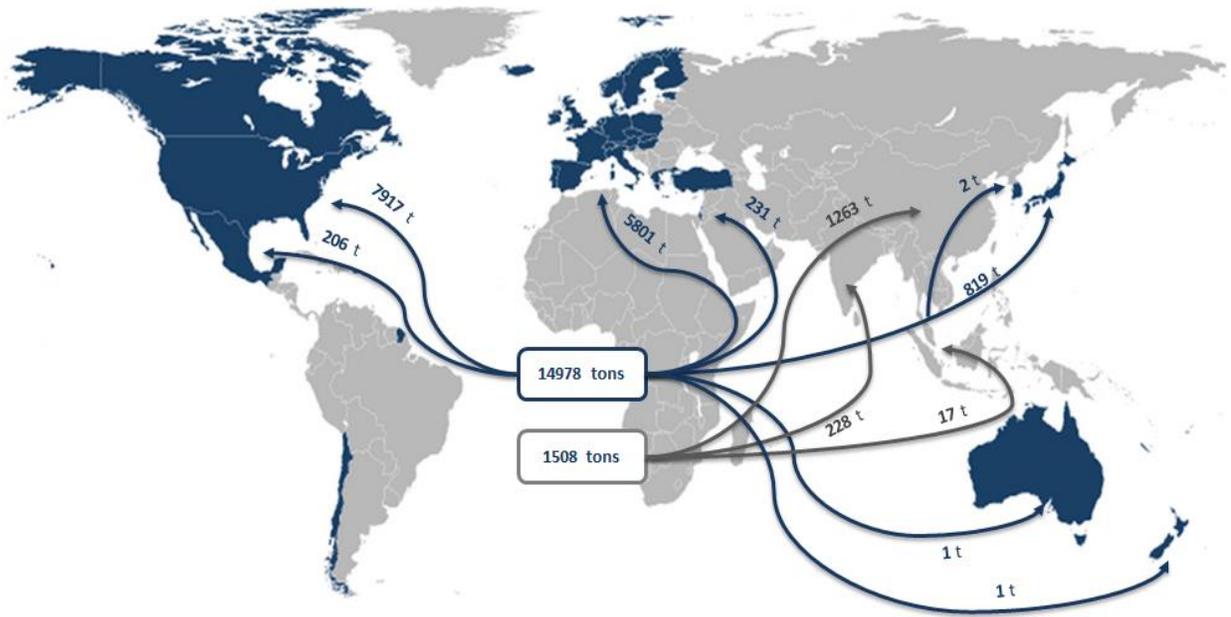
- Repaired parts from service and reuse operations are critically important for maintaining previously installed equipment (extending product lifetime).
- Refurbished systems enable more patients to have access to up-to-date technology while helping governments mitigate the rising costs of healthcare. Since the global economic crisis, the demand for refurbished systems has surged worldwide.
- Reuse keeps system and service costs down, avoiding adverse environmental, social, and health impacts, while enabling resource efficiency and circular economy.

DITTA Survey on global shipments of used medical equipment

A survey of the four leading medical device manufacturer's constituting approximately 80% of the diagnostic imaging market* was undertaken by DITTA and completed in August 2013. The survey was intended to characterize the scope of global legitimate movement of used equipment and parts for repair, refurbishment and root cause analysis. The survey provided the following results:

- 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 every year by and to the participating medical device manufacturers, or third parties acting on their behalf.
- These shipments are valued at more than \$3.4 billion USD and provide an inventory of refurbished medical equipment and repaired parts for servicing and maintaining installed equipment in a timely manner.
- 78% of the repair facilities and 69% of refurbishing facilities are located in OECD countries.
- 14978 tons (91% of the total) are sent to OECD countries for repair, refurbishment and root cause analysis. These activities generate 2691 metric tons of waste (18% of the total shipped). 100% is managed in accordance with local environmental management standards. USA, Germany, Hungary, Netherlands, Japan and France receive 86% of the used parts for repair or refurbishment.
- Only 1508 tons of used products and parts (9 % of the total) are shipped to non-OECD countries for repair, refurbishment, and root cause activities - mainly China, India, and Malaysia.
- The tons shipped to non-OECD Countries are distributed as follows: 1263 to China, 228 to India, 11 to Malaysia, 6 to Singapore and 0 to African Group countries.
- Only 206 tons are shipped to Grulac (only Mexico) to be repaired or refurbished.
- Repair, refurbishment and root cause analysis activities in non-OECD countries generate 84 metric tons of waste (5.5% of the total shipped), virtually all of the waste is managed in-country and all of the facilities have environmental certifications to standards or local regulations. Lower percent of waste generated in non-OECD activities is due to different activities in OECD versus non-OECD and different "quality" of used medical devices repaired or refurbished.

* Cameron , L. (2009) MaRS Market Insights. p.7. Retrieved 13-Sept-2013 from:
http://www.marsdd.com/dmsassets/reports/MaRS_Diagnostic_imaging.pdf



Geographical distribution of the main fluxes of used MDs for reuse, refurbishment or analysis

Moreover:

- 72% of shipments to non-OECD countries for repair or refurbishment include financial assurance from the shipper that the shipment can be returned to the company when necessary.
- 100% of used equipment and parts are packaged separately, 100% are protected against damage during transport, 93% include an invoice with a description of the contents, 100% of shipments are insured, and 63% include a copy of contract relating to the sales and/or transfer of ownership.
- 100% Percent of OEMs have an audit processes to ensure adequate environmental protection for the management of e-waste.
- 5% of shipments can be tested for functionality per industry protocol prior to shipment

In summary, used medical equipment and parts are not a significant contributor to the total quantity of used electronics shipped globally. The vast majority of used medical equipment and parts are repaired, refurbished or undergo root cause analysis in OECD countries. These shipments have a high monetary value and provide manufacturers with the necessary inventory of high quality, affordable refurbished equipment and parts needed to maintain and extend the lifetime of existing installed equipment in a timely manner. Currently all repair, refurbishment, and root cause analysis activities in non-OECD countries occur in APEC countries (99%). Manufacturers take care in packaging and shipping used equipment and parts, providing financial assurance for used parts and products shipped to non-OECD countries for repair or refurbishment and traceability in accompanying shipping papers. Testing for functionality per industry protocol prior to shipment is scarcely possible (5%).

Proposed Exemption for Basel E-waste Technical Guidelines for Used Medical Equipment and Parts

DITTA proposes a new approach that offers an effective compromise between protecting legitimate activities and stopping illegal waste dumping. Because equipment, practices and business models vary widely between industry sectors, DITTA recognizes that crafting acceptable exclusions that work for all sectors is extremely difficult, as shown by the discussions of the past 2 years. DITTA members believe that specific exclusions should be developed for each sector with legitimate repair and refurbishment activities that could be hindered by the additional requirements on shipments. Each exclusion and associated criteria/definitions should be proportionate to the risks potentially generated by the specific re-use activities.

Presented below, therefore, is proposed text for a new exclusion specific to used medical equipment and parts in subsection 26(b) of the TG, which are sent by and to the manufacturer or third parties acting on its behalf, for repair, refurbishment or root cause analysis. DITTA considers this proposed exclusion for medical equipment to be judicious, free of loopholes, and, as discussed below, supported by results obtained from a recent survey of four leading international medical equipment manufacturers. As shipments by and to third parties are not in the core of DITTA Members' activities, DITTA is not proposing any specific exclusion. It should be up to the relative sector to advance its own one for discussion with the Basel Parties.

Hereafter is a proposed alternative wording for clause III B (26)(b):

26 (b) Unless stipulated otherwise by the provisions of national law of one of the Countries Concerned (import, export or transit), the following used equipment should not be considered waste where the criteria in paragraph 24 (c) and (d) are met and it is documented that:

i. Used medical equipment¹ and their components sent by and to the manufacturer or third party acting on behalf of the manufacturer, for any of the following purposes:

- *root cause analysis,*
- *refurbishment, or*
- *repair*

under a valid agreement² (such as a purchase order, contract or warranty); and

ii. Hazardous³ wastes resulting from the operations in 26(b)(i) are shipped for environmentally sound management to Annex VII Countries or to non-Annex VII countries as long as systems are in place to achieve the equivalent level of environmental protection.

1. *Definition of Medical Device in GHTF in SG1(PD)/N71R04. Click here to go to the document. Medical device means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent, software, material or other similar or related article:*

- a. *intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of: diagnosis, prevention, monitoring, treatment or alleviation of disease, diagnosis, monitoring, treatment, alleviation of or compensation for an injury, investigation, replacement, modification, or support of the anatomy or of a physiological process, supporting or sustaining life, control of*

conception, disinfection of medical devices, providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and

- b. which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.*

Note 1: Products which may be considered to be medical devices in some jurisdictions but for which there is not yet a harmonized approach, include: disinfection substances, aids for persons with disabilities, accessories to a medical device (see Note 2), components of a medical device, devices incorporating animal and/or human tissues.

Note 2: Some jurisdictions include accessories to a medical device within the definition of a medical device. Other jurisdictions do not adopt this approach but still subject an accessory to the regulatory controls (e.g. classification, conformity assessment, quality management system requirements etc.) that apply to medical devices.

- 2. *'valid agreement': a long term contract between the manufacturer and the third party shipping or performing the refurbishment, repair or root cause analysis identifying responsibilities and procedures for the correct handling of used EEE.*
- 3. *As per definition under Basel Convention*

