MEDICAL TECHNOLOGY INDUSTRY
JOINT CONTRIBUTION TO THE PUBLIC CONSULTATION OF THE DRAFT TECHNICAL GUIDELINES ON TRANSBOUNDARY MOVEMENTS OF E-WASTE
(Version: 22 December 2012)

COCIR, the European Coordination Committee of Radiological, Electromedical and Healthcare IT Industry, **EDMA**, the European Diagnostic Manufacturers Association, **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, are pleased to submit the following comments to the Basel Secretariat and the Parties on the new draft of the Technical Guidance on e-waste shipments dated 22 December and in public consultation until 28 February.

Global medical technology manufacturers are pleased to see that their recommendations for amending the Technical Guidelines (TGs) to support legitimate activities of "reuse" while addressing illegitimate activities have been understood and supported by many Parties. It appears there is agreement to seek a formulation to exclude such activities from certain requirements without opening loopholes that reduce the level of environmental protection the TGs seek to provide.

Nonetheless, the Medical Technology Industry believes many proposals, while well intentioned, do not meet all the needs of manufacturers of medical devices. Their adoption would effectively ban activities that bring environmental and social benefits and are consistent with the most advanced proposal of the EU agenda on resource efficiency.

The medical technology industry appreciates the opportunity to continue being a part of the discussion to develop the technical guidelines.

POINT 26
ANALYSIS OF CURRENT PROPOSALS

EXCLUSION I

This first exclusion is required to allow the shipment of products under warranty which are shipped by the individual customer, the manufacturer, the component supplier or any other party who has a role in the warranty chain.

The Medical Technology Industry does not have any particular preference over the GRULAC, BAN and US, and EU proposals. Nonetheless the final wording of the exclusion should clearly refer to both consumer and professional goods and should cover all involved actors and business models.

Proposal EU
The equipment is sent back as defective for repair to the producer or a third party acting on his behalf (under warranty) with the intention of re-use; or

Proposal GRULAC
Shipments by individual customers of their own defective equipment under warranty or subject to a law allowing for a right of return of the equipment, for repair and refurbishment for re-use.

Batches of defective equipment under warranty that have been collected from individual customers or consolidated by manufacturers, original component suppliers, or their contractual agents, sent back to the manufacturer, original component suppliers, or their contractual agents, for re-use.

Proposal BAN and US
Shipments by individual customers of their own defective equipment under warranty or subject to a law allowing for a right of return of the equipment, for repair and refurbishment [and where the same type or similar product is intended to be returned to the customer]. This does not include equipment from take back programs.

Batches of defective equipment under warranty that have been collected from individual customers or consolidated by manufacturers, original component suppliers, or their contractual agents, sent back to the manufacturer, original component suppliers, or their contractual agents, and for which the same type or similar product has been or will be returned to the customer. This does not include equipment from take back programs.

EXCLUSION II

This exclusion is required for the legitimate shipment of used EEE, in particular professional EEE (*i.e.,* capital investment goods) for repair, remanufacturing, refurbishment and reuse. Used medical devices are sourced worldwide, shipped to specialized repair/refurbishment facilities, and then sold on global markets, mostly EU and USA.

Proposal ITI and COCIR
ii) The used equipment is sent for refurbishment or repair under a valid contract with the intention of re-use to:
a. the producer or a qualified third party facility acting on his behalf; or
b. a third party facility as long as such export does not involve exports from Annex VII to non-Annex VII countries;

Intra-company shipments organized by medical device manufacturers in the context of an established operation (business-to-business transfer agreement) for repair or refurbishment never result in illegal waste dumping. Used medical devices eligible for refurbishment are typically high technology products designed to have long life spans and are therefore valuable assets for the manufacturer as well as any healthcare system. The above holds equally true when the EEE is managed by the producer or when the refurbishment facility is managed by a third company acting on behalf of the manufacturer for the logistic and refurbishment/repair operations. In the first case, ownership of the device has not been transferred and in the second case, the contractual relationship ensures traceability and responsibility.

Waste dumping is an illegal practice run by criminal organizations offering low cost waste treatment solutions to holders of waste. Instead of proceeding with environmentally sound treatment and disposal, waste is shipped to developing countries for disposal (*e.g*. landfill). The original manufacturer of the equipment is never involved nor is there a contractual relationship between the producer and a third party acting on their behalf. Indeed, the lack of a direct relationship between the producer and a third party creates the potential for abuse of WEEE and illegal dumping in some cases.

The Medical Technology Industry believes that the Technical Guidelines should be risk appropriate and the Annex VII Countries limitation should be linked only to the third party facility where there is no direct, demonstrable relationship to the producer.

The Medical Technology Industry can accept the restriction of the COCIR proposal to "**professional**" equipment only.

Other proposals

Below please find comments on the other proposals in the December draft of the Technical Guidelines. The Medical Technology Industry underlines the importance of amending the Technical Guidance to take on board the wording of the ITI and COCIR proposal, which provides the best guarantee for allowing the passage of legitimate business while closing loopholes to illegitimate ones.

Proposal EU

ii. the used equipment for professional use is sent to the producer or a third party acting on his behalf or a third party facility as long as such export does not involve exports from Annex VII to non-Annex VII countries for refurbishment or repair under a valid contract with the intention of re-use;

This proposal introduces geographical limits on all shipments. While understanding the reasons behind the proposal, the Medical Technology Industry considers it unacceptable. The destination of a shipment should not be used by Control Authorities as a criterion for distinguishing between legal and illegal activities. Objective criteria, based on the nature of the shipped goods, are more appropriate. On the other hand, the destination could provide Control Authorities very important hints on risk profiling and where to focus their surveillance activities. This criterion therefore is more suited to other guidance documents, such as IMPEL Guidelines.

In particular, intra-company shipments (or shipments to authorized third parties acting on behalf of the manufacturer) do not constitute illegal waste movements as ownership does not change or a contractual relationship exists. Geographical limitations are thus not required; add red tape, and burden manufacturers and Control Authorities unnecessarily. The COCIR/ITI proposal ensures no loopholes are available to illegal traders and at the same time allows the continuation of legitimate activities.

Proposal GRULAC

The used equipment for professional use is sent to the producer or third party acting on his behalf for repair under a valid contract with the intention of re-use;

This proposal restricts shipments for repair only, therefore excluding the shipment of devices for refurbishing. The Medical Technology Industry considers this proposal would only be acceptable with the addition of 'refurbishment' to that of 'repair'. For many sectors, shipping to a manufacturer or its representative is not an option because specialized repair facilities are required.

Proposal Japan

ii. the used equipment is sent to the producer or a third party acting on his behalf for refurbishment or repair under a valid service contract for re-use;

The Medical Technology Industry appreciates the proposal from Japan, which recognizes the need to allow legitimate activities to continue operating without disruption. The requirements of a "service contract," however, threaten to limit legitimate activities to certain kinds of contractual agreements that are not clearly defined. Therefore our industry proposes to keep "contract" rather than "service contract".

Proposal BAN
ii. the used equipment for professional use is sent to the producer or a third party acting on his behalf for refurbishment or repair under a valid contract for re-use, as long as it is not exported from Annex VII to non-Annex VII countries;

This proposal is not acceptable as it introduces geographical limitations to any shipments of used medical devices and misses the "third parties" that are included in other proposals. In many cases, the original manufacturers are no longer present in the market and repair and refurbishment can be performed only by specialized service companies. This is an established practice in sectors such as industrial equipment. Regarding the geographical limits, see comments regarding the EU Proposal.

Proposal African Group
ii. the used equipment for professional use is sent to the producer or a third party acting on his behalf for refurbishment or repair under a valid contract, accompanied by a movement document and declaration (similar to PACE Appendix 7), as long as it is not exported from Annex VII to non-Annex VII countries

This proposal reflects a misunderstanding regarding testing. The PACE annex 7 clearly requires 'full functionality". However products shipped to be repaired are non-functional ***by definition*** (they need to be repaired) - therefore testing requirements are not applicable.
For complex products such as medical devices, testing on-site at hospitals, clinics, etc. is not possible. The used equipment must be sent to a specialized centre where testing could happen only after the shipment, not before. Industry considers this proposal unacceptable as it would prevent used medical devices from being shipped for legitimate re-use activities.

EXCLUSION III

Other proposal
iii. the defective used equipment for professional use, such as medical devices or their parts, [enterprise Information and Communications Technology (ICT) equipment (e.g. networking and infrastructure equipment)] is sent to the producer or a third party acting on his behalf for root cause analysis under a valid contract, in cases where such an analysis [as required under national law can only] [is needed for corrective and preventative actions as required by industry standards to] be conducted by the producer or third parties acting on his behalf; or

This exclusion is extremely important for medical devices. The Medical Technology Industry supports the following wording: [*is needed for corrective and preventative actions as required by industry standards to*] and considers the wording [*as required under national law can only*] to be unacceptable.

While EU legislation (*i.e.,* the Medical Device Directives) considers root cause analysis a mandatory requirement, it is not true for other countries. At the same time, a globally distributed manufacturing model, which is common in the industry, necessitates that root cause analysis be possible at a site or sites which may be located along the manufacturing chain worldwide. As root cause analysis is a mandatory requirement in Industry standards such as quality management systems, the formulation indicated above should be preferred.

EXCLUSION IV

Other proposal
iv) the used equipment is administered by or on behalf of a person engaged in the business of leasing equipment and such equipment is removed from service and shipped by the lessor or third parties acting on their behalf with the intention of reuse.

The Medical Technology Industry supports this proposal as leasing of medical devices is an increasingly prevalent practice. Legitimate leasing activities should not be hampered, given the environmental benefits deriving from re-use.

COCIR
COCIR, the European leading industry voice in medical imaging and health ICTs, is a non-profit organisation founded in 1959. In 2007, COCIR opened an office in Beijing, the COCIR China Desk, to support its members present on the Chinese market. COCIR members, companies and national trade associations, play a driving role in defining a sustainable future for healthcare in Europe and worldwide.

EDMA
EDMA, European Diagnostic Manufacturers Association, advocates for the interests of the in vitro diagnostics (IVD) industry and its enormous contribution to transforming healthcare systems by improving healthcare efficiency and reducing costs. EDMA's strength lies in its close co-operation with European institutions, patients groups, trade associations, health professionals, and academia, working together to shape EU policy that will most impact the lives of Europeans and reinforce the European IVD industry's voice globally.

JIRA
The Japan Medical Imaging and Radiological Systems Industries Association (JIRA) is the voice of industries in Japan comprising companies that develop, manufacture and sell diagnostic imaging equipment and systems such as medical x-ray equipment, CT, MRI, ultrasound scanners, radiotherapy systems, and related products.

MEDEC
MEDEC is the national association created by and for the Canadian medical technology industry. MEDEC is the primary source for advocacy, information and education on the medical technology industry for members, the greater healthcare community, industry partners and the general public. Our goals are to advance health outcomes for patients in Canada and the growth and vibrancy of the industry in Canada. We focus on ensuring access to proven, safe technology and new, innovative medical technology developed by member companies.

MITA
The Medical Imaging & Technology Alliance (MITA), a division of the National Electrical Manufacturers Association (NEMA), is the principal trade group representing US medical imaging equipment manufacturers, innovators, and product developers. Sales of MITA members comprise more than 90 percent of the global market for medical imaging technology. MITA also functions as a leading standards-development organization for medical imaging and radiation therapy equipment.