**JOINT HEALTHCARE INDUSTRY CONTRIBUTION**
**TO THE PUBLIC CONSULTATION[1] ON**
**DRAFT TECHNICAL GUIDELINES**
**ON TRANSBOUNDARY MOVEMENTS OF E-WASTE**

COCIR, the European Coordination Committee of Radiological, Electromedical and Healthcare IT Industry, MITA, the Medical Imaging and Technology Alliances, JIRA, the Japan Medical Imaging and Radiological Systems Industries Association, AMCHAM EU, the American Chamber of Commerce in Europe, MEDEC, the Canadian Medical Technology Companies, EDMA, the European Diagnostic Manufacturers Association and ADVAMED, the Advanced Medical Technology Association support the principles behind the "**Draft technical guidelines on transboundary movements of electronic and electrical waste"** now under public consultation until 15 June 2012.

According to the accompanying note we understand that there are still many options open regarding the shipment of used EEE for reuse, refurbishment and repair that need to be correctly addressed not to destroy legitimate activities that are extremely beneficial to the environment and to EU healthcare.

We would like to underline again the consequences of not allowing the smooth continuing of such activities for medical devices including in vitro diagnostic medical devices and, at large, for capital investment goods.

1. The Guidance mixes together consumer electronics and capital investment goods. While household equipment has hardly any intrinsic value at the end of its life, capital investment goods such as medical devices are extremely valuable.
2. Used consumer electronics have very limited market demand due to obsolescence, while the market demand today for refurbished product is higher than the offer. The economic crisis has increased such demand and the trend is not going to get lower.
3. The actual wording of the Guidance does not allow in any way the shipment of used capital investment goods for professional use as in most cases, testing can only be performed at destination in a few specialized centers. Therefore, no test report can be shown at authority request prior to the shipment.
4. Used equipment cannot, under any circumstance, be shipped as waste. Once waste, no repair or refurbishment facility is or will ever be allowed to receive and treat it. Used equipment, once waste, cannot cease to be waste and the only possible alternative is for them to be scrapped.
5. The voluntary procedure under Section IV B of the guidelines for the shipment of used EEE needing repair or refurbishment represents a non-viable solution for

[1] *http://www.basel.int/techmatters/index.html*

capital goods. It represents a heavy burden that will not allow the smooth continuing of such important legitimate operations of repair and refurbishing. The procedure allows individual interpretation of the requirements causing confusion and conflicting implementation.

6. Shipments for root cause analysis or regulatory compliance requires a specific exclusion as they are mandatory according to EU legislation therefore cannot be hindered by unnecessary additional requirements and cannot be handled at all if considered as waste.

The Healthcare Industry recommends amending the TG, to ensure that legitimate and environmental friendly activities will not be hindered or even prohibited, according to the following recommendations:

1. **To establish a clear distinction between consumer goods and capital investment goods for professional use.**

2. **To develop sets of criteria for capital investment goods for professional use.**

3. **To add exclusions in line with the ones in Annex VI of the WEEE Directive.**

## DETAILED BRIEFING

### Need to distinguish between consumer goods and capital investment goods

We would like to underline a critical aspect of the Guidelines document**. It does not distinguish between consumer goods and capital investment goods for professional use.** The latter, in particular medical devices, can have very long service life (higher than 10 years) and are subject to refurbishment or repair practice under very strict and controlled conditions. Due to their high technologic content they can often be repaired only at the site of the original manufacturer or their specialized centers of which only a few exist worldwide.

While the criteria proposed in the Guidance are applicable to consumer goods they are not suited for capital investment goods and, if applied, they will hinder, if not prohibit the shipment for legitimate activities.

Chapter I.B of the Technical Guidelines about E-waste is clearly referred to e-waste from consumer goods and not from capital investment goods for professional use however the distinction is not stated in the text. The Guidelines document has to be amended accordingly.

### Criteria to distinguish between used EEE and e-waste could hinder legitimate activities

The Technical Guidelines document proposes a set of criteria based on functionality testing and proper packaging and suggests declaring any used equipment that could not meet the aforementioned criteria as waste. Such criteria will impact legitimate shipment of:

**Functioning medical devices**

Functioning medical devices, shipped for reuse or refurbishment should undergo very complex testing to meet the proposed criteria (testing the functionality of a magnetic resonance is far different than testing a refrigerator). The cost of such testing could easily be higher than the residual value of the equipment rendering the whole operation un-economic thus leading to the creation of unnecessary waste. Moreover testing can be performed only in specialized destination centers of which only a few exist worldwide. No additional documentation on testing can be provided prior to the shipment.

**Non-functioning medical devices**

The shipment of non-functioning medical devices for repair, refurbishment and other activities is normal practice, and should not be confused with the illegal shipment of consumer goods e-scrap under false claims.

Non-functional medical devices are shipped worldwide for a variety of reasons, including devices that will no longer be covered by a warranty (chapter III.B.b). They will be declared waste by authorities. Reasons for such shipments can be:

- Return to the manufacturer or to a test house for investigation after an 'adverse event' in which a patient or user was harmed (root cause analysis meeting regulatory compliance or quality assurance monitoring of devices as required by applicable national regulations e.g. the EU Medical Device Directives, (Art. 10, 1. and Annex II, 3.1 of 93/42/EEC).
- Return to the manufacturer for repair. Medical devices can have a very long service life, to well in excess of ten years and therefore far exceeding the warranty period. Highly specialized or intricate repairs may require that the device be returned to the manufacturer or a regional authorized repairer in another Member State, or based outside the EU.
- Return for refurbishment, remanufacturing or reprocessing of systems, subsystems or parts under highly controlled conditions and processes. These are necessary to ensure that the systems, subsystems or parts maintain their performance and safety when reused. Refurbishment is done by the original manufacturer of the medical device in specialised refurbishment centres of which globally only few exist.

The application of the provision of the Guidelines to the above mentioned legitimate shipments of used professional equipment **would prohibit any activity of repair and refurbishment** thus leading to the unnecessary generation of waste, not to mention the social impact on healthcare following the increased scarcity of refurbished equipment..

Moreover **mandatory requirements** provided by the Medical Devices Directives could not be satisfied as the shipment of such non-functioning equipment would be considered an illegal shipment of waste by custom authorities.

**Voluntary Notification Procedure could not provide a suitable solution**

The Healthcare Industry would question the introduced "voluntary notification procedure". The procedure does not distinguish between consumer goods and capital investment goods such as medical devices. Moreover the impact on shipments for legitimate activities has to be further and carefully assessed to avoid adverse effects on environmental friendly activities as already discussed in the present paper.

Different application of the requirements of this voluntary procedure in different Countries (the Guide has no legal value) would add a huge burden on Companies thus de facto hindering the mentioned legitimate activities.

**Recast of the European Directive on waste electric and electronic equipment**

The European Directive on Waste Electric and Electronic Equipment (2002/96/CE), now approved and waiting to be published, integrates in Annex VI the content of the Guidelines, in particular regarding the requirements for distinguishing between used EEE and waste.

The European Parliament and the European Council recognized the request of producers of capital investment goods and introduced specific exemptions for such equipment.

Exclusion 2.b) exempts equipment for professional use from all the requirements when shipped to OECD Countries for repair and refurbishment activities.

Exclusion 2.c) exempts defective equipment for professional use from all the requirements when shipped for root cause analysis.

These two exclusions are still not perfect and would need to be refined at least in how they will be applied. Nonetheless, European Institutions recognized the need to distinguish between professional equipment and consumer goods, and to grant exclusions not to prohibit well-established practices delivering environmental benefits through reuse and refurbishing. The TG, with a much broader global impact, should not consider incorporating a requirement for shipping products to OECD countries as this would inhibit establishing refurbishing, remanufacturing and repair centers outside this select group of countries, creating a trade barrier.

**HEALTHCARE INDUSTRY RECOMMENDATIONS**

The Healthcare Industry suggests amending the Draft Technical Guidelines according to the following recommendations:

1. **To establish a clear distinction between consumer goods and capital investment goods for professional use**

The Guidelines should clearly state a distinction between consumer goods and professional capital investment goods such as medical devices.

2. **To develop sets of criteria for capital investment goods for professional use.**

Different sets of criteria should be developed for consumer goods and capital investment goods. For the latter criteria have to be carefully defined not to hamper legitimate activities, as explained in the present paper. We suggest focusing the criteria on the proper packaging. Such packaging to prevent damages is already provided by responsible producers and actors but would be a deterrent for actors illegally shipping e-waste.

**3. To add exclusions in line with the ones in Annex VI of the WEEE Directive.**
Specific exclusions from any requirement related to functionality testing, as included in the recast of the EU Directive on waste electric and electronic equipment (WEEE) have to be added.

The Healthcare Industry proposes the following exclusions for:

**EEE sent to the producer or third parties acting on his behalf , or 3rd party repair or refurbishment centres, when it is documented by conclusive proof that the shipment is taking place in the framework of a business-to-business transfer agreement and where:**

**a) Electrical and electronic equipment sent back as defective for repair under warranty with the intention of re-use,**

**b) Used electrical and electronic equipment for professional use sent for refurbishment, remanufacturing, reprocessing or repair under a valid contract with the intention of re-use, or**

**c) Defective used electrical and electronic equipment for professional use or their parts, is sent for root cause analysis, or meeting national regulatory requirements, such as on medical devices, in case such an analysis can only be conducted by the producer or third parties acting on his behalf.**

**ADVAMED**
*The Advanced Medical Technology Association (AdvaMed) is a US-based association that represents manufacturers of medical devices, diagnostic products and health information systems sold in the US. AdvaMed advocates for a legal, regulatory and economic environment that advances global health care by assuring worldwide patient access to the benefits of medical technology. Members range from the largest to the smallest medical technology innovators and companies.*

**AMCHAM EU**
*AmCham EU speaks for American business committed to Europe on trade investment and competitiveness issues. It aims to ensure a growth orientated business and investment climate in Europe. AmCham EU facilitates the resolution of transatlantic issues that impact business and play a role in creating better understanding of EU & US positions on business matters. Total US investment in Europe amounts to $702 billion, and currently supports over 4.1 million jobs.*

**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**
*Committed to raising awareness of the important role of diagnostics in the entire healthcare equation, the European Diagnostic Manufacturers Association (EDMA) provides services and activities to members engaged in the research, development, manufacturing or distribution of in vitro diagnostic (IVD) products in Europe. Founded in 1979, EDMA advocates for an appropriate regulatory system and a realistic economic environment for healthcare in Europe.*

**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 the national association created by and for the Canadian medical technology industry 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. MEDEC's goals are to advance health outcomes for Canadian patients and to support the growth and vibrancy of the medical devices industry in Canada. We focus on ensuring access to proven, safe technology and new, innovative medical technology developed by our 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.*