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**JOINT HEALTHCARE INDUSTRY CONTRIBUTION  
TO THE PUBLIC CONSULTATION<sup>1</sup> ON  
DRAFT TECHNICAL GUIDELINES  
ON TRANSBOUNDARY MOVEMENTS E-WASTE**

COCIR, the European Coordination Committee of Radiological, Electromedical and Healthcare IT Industry, MITA, the Medical Imaging and Technology Alliances, JIRA, the Japan Industries Association of Radiological Systems and AmCham EU, the American Chamber of Commerce in Belgium, support the principles behind the “**Draft technical guidelines on transboundary movements of used electronic and electrical equipment and e-waste**” now under public consultation.

While understanding the need to provide additional tools to control and custom authorities to stop the illegal shipment of e-waste to developing countries under false claims of repair and refurbishment activities, the Healthcare Industry is worried for the consequences of the proposed criteria on legitimate shipments of used Medical Devices.

The Technical Guidelines document proposes a set of criteria based on functionality testing and proper packaging to help authorities to distinguish between used EEE and e-waste 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 for refurbishment and reuse, as the cost of testing could exceed the residual value of the equipment.

They will also impact on the shipment of non-functional medical devices for repair, root cause analysis or meeting regulatory requirements as such non-functional equipment would be considered waste by custom authorities.

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/exclusions for capital investment goods for professional use.**

<sup>1</sup> <http://www.basel.int/techmatters/index.html>



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## 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. The cost of such testing however 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.

#### **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



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- compliance or quality assurance monitoring of devices as required by the Medical Device Directives, e.g. 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.

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.

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

The European Directive on Waste Electric and Electronic Equipment (2002/96/CE), now under recast process, partially integrate 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 for repair and refurbishment activities if accompanied by proofing documentation.

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

The two exclusions are still far from perfect and need to be refined in the second reading process to render them fully applicable. Nonetheless, European Institutions recognized the need to distinguish between professional equipment and consumer goods, not to prohibit well-established practices delivering environmental benefits through reuse and refurbishing.



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## HEALTHCARE INDUSTRY RECOMMENDATIONS

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

### **3. 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.

### **4. To develop sets of criteria/exclusions 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.

This should be combined with specific exclusions for used capital investment goods from any requirement related to functionality testing, as proposed by European Institutions for the recast of the Directive on waste electric and electronic equipment.

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 regulatory requirements under Directive 93/42/EEC (medical devices) or Directive 98/79/EC (IVD medical devices) in case such an analysis can only be conducted by the producer or third parties acting on his behalf.*



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**COCIR**

*COCIR is the voice of the European Radiological, Electromedical and Healthcare IT Industry. COCIR is a non-profit trade association, founded in 1959, representing the medical technology industry in Europe. COCIR's members play a driving role in developing the future of healthcare in Europe and worldwide.*

**NEMA**

*With headquarters in Rosslyn, Virginia, NEMA represents a global network of over 400 large, medium, and small businesses that manufacture products used in the generation, transmission and distribution, control, and end-use of electricity. Annual shipments of these products exceed \$100 billion. The Medical Imaging and Technology Alliance (MITA) constitutes a division within NEMA and serves as the collective voice of medical imaging equipment manufacturers in the US."*

**JIRA**

*The Japan Industries Association of Radiological Systems (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.*

**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.*