European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

COCIR RECOMMENDATIONS
ON REQUIREMENTS FOR SHIPMENT OF USED EEE
WEEE DIRECTIVE RECAST

COCIR represents the Radiological, Electromedical and Healthcare IT Industry in Europe.

The European Parliament is currently discussing the revision of the WEEE Directive in second reading, after the Council adopted its first reading position[1] on March 14, 2011.

While COCIR appreciates the European Council and Parliament having addressed important issues, there are still elements of significant relevance that if not carefully considered could hamper well established practices of reuse, repair and refurbishment of medical equipment with a consequential social impact on equipment availability and affordability.

While Industry recognizes the importance of curtailing and stopping illegal transboundary shipments of WEEE under the guise of being used EEE (laid down in Article 23 and Annex VI), establishing additional requirements for the shipment of used EEE, does not permit medical devices manufacturers a successful claim for legitimate shipments of used EEE.
The proposed wording of Annex VI will curtail if not to say render illegal the majority of the rightful shipments for repair and refurbishment as well as root cause analysis - thus contradicting the spirit of the Directive itself that encourages reuse.

European Parliament's amendment provided a first exclusion for defective equipment shipped under warranty that covered only a small part of all the rightful shipment for repair or refurbishment activities.

Equally, the European Council recognized the need to act e.g. in case of capital investment goods such as medical devices and elaborated exclusions (Annex VI, point 2.). Unfortunately, current wording does not meet the needs of the medical sector as the actual exclusions linked to the requirement of an "**after sales service maintenance contract**" rarely apply, thus the problem remains unsolved.

In other words, **shipment of non-functional devices would be no longer possible, even if for legitimate reasons** such as repair or refurbishment or reprocessing or analysis purposes, as it will be always declared an illegal 'WEEE Shipment' by the authorities.

For the same reason, functional equipment for the purpose of reuse or refurbishment would incur an additional cost for functionality testing. Such costs could exceed the residual value of the equipment, thus causing the equipment to be discarded as waste.

COCIR recommends:

1. **To amend exclusions in Annex VI to facilitate the rightful cross-border shipment of medical devices without lowering the environmental protection.**
2. **To ensure the possibility to ship non-functional equipment for root cause analysis and meeting regulatory requirements, as required by the Medical Devices Directives.**

[1] http://register.consilium.europa.eu/servlet/driver?lang=EN&ssf=DATE_DOCUMENT+DESC&fc=REGAISEN&srm=25&md=400&typ=Simple&cmsid=638&ff_COTE_DOCUMENT=7906%2F11&ff_TITRE=&ff_FT_TEXT=&ff_SOUS_COTE_MATIERE=&dd_DATE_REUNION=&rc=1&nr=4&page=Detail

DETAILED BRIEFING

WEEE Directive Annex VI requirements of full functionality will hinder legitimate activities of repair and refurbishment.

Used complex business to business products, including medical devices, are shipped within and outside of the EU for a variety of reasons: for direct reuse, at end of lease, for re-sale and re-use after repair, refurbishment or remanufacturing. Many of these devices will therefore be non-functioning (since de-installed or defect) or out of any warranty period.

Limiting shipments of used medical devices to those that are fully functional and destined for direct re-use will drastically alter the producers' interest or even jeopardize the legitimacy of activities such as repair, refurbish, re-use of systems, sub-systems, parts or components. Similar applies when performing root cause or failure analysis, as prescribed by the Medical Devices Directives (see e.g. Art. 10, 1. and Annex II, 3.1 of 93/42/EEC). It says that the manufacturer within its quality system and post-production phase responsibility must establish a systematic procedure to review experience gained from devices in the market so it can to apply any necessary corrective action and inform the competent authority.

Current Annex VI requirements e.g. would essentially no longer permit a refurbishment market for professional medical devices. An estimated 1,6 billion Euros are spent on refurbished equipment globally, 50% of this is sold in the EU and the U.S. alone. (*Source: COCIR internal market data*).
While COCIR members already provide conclusive documentation and special packing of rightful shipments, additional testing requirements on functionality and its costs, while acceptable for consumer goods, if applied to medical devices are likely to exceed the residual value of the medical device, thus undermining the Directive's objective of re-use.

Moreover, **the requirement of full functionality would prohibit any shipment of non-functioning equipment for repairing.** In effect any non-functioning equipment, outside the warranty period, would have to be discarded as a waste, if no exemptions are granted.

Exclusions introduced by the European Parliament and Council are not suited for Medical Devices

The European Parliament provided a first exclusion for defective equipment shipped under warranty that covers only a small part of all the rightful shipment for repair or refurbishment activities.

The European Council recognized further the necessity to exclude medical devices and other capital investment goods for professional use from the requirements of Annex VI to allow for the repair and refurbishment practice.

The Council first Reading Position of 10 June 2011 (7906/11) acknowledged also the need for companies to ship non-functional products for root cause or so called failure analysis.

Exclusion 2.b) allows products for professional use to be shipped for repair and refurbishment activities with the intention of reuse. 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 outside the EU. Refurbishment is done by the original manufacturer of the medical device in specialised refurbishment centres of which globally only few exist.

Exclusion 2.c) allows the shipment of defective equipment for professional use or their parts. Such shipments to the manufacturer or to a test house are needed and are sometime required by legislation (e.g. Medical Devices Directives) to investigate after an 'adverse event' in which e.g. a patient or user was harmed.

Unfortunately the two proposed exclusions are limited to the cases where an "**after-sale service maintenance contract**" is in place, a form of contract that is **rarely applied in actual practice.**

In consequence the well intended derogation would not be applicable in virtually all cases. For some, fully functional items, Annex VI point 3. would then require testing which risk to exceed the residual value of devices and the practical impossibility to repair products that would need to be shipped to specialist centres. In most cases however, the rightfully shipped used EEE, would be unilaterally declared illegal as it does not fit any of the exemption cases.

1. COCIR recommends to amend exclusions in Annex VI to facilitate the rightful cross-border shipment of medical devices without lowering the environmental protection.

Current wording of the recast WEEE Directive, Annex VI, with proposed amendments:

> "2*. By way of derogation, point 1 (a) and (b) and point 3 do not apply where EEE is sent to the producer or third parties acting on his behalf 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) the EEE is sent back as defective for repair under warranty with the intention of re-use,*
> *b) the used EEE for professional use is sent for refurbishment or repair under a valid* ~~***after-sales service maintenance***~~ *contract with the intention of re-use, or […]"*

Justification:

COCIR proposes to delete "after sales service maintenance" as the activity of repair, refurbishment or root cause analysis in most cases will not be under the title of an "after sales service maintenance" contract, instead they are performed according to other contractual or regulatory obligations. Thus, deletion of this wording is necessary to allow shipment for repairing and refurbishing equipment for professional use that otherwise would be wasted, contradicting the WEEE spirit and creating an unnecessary environmental burden. Especially for medical equipment professional use with a long lifecycle (e.g. 10 years and often longer), repair and refurbishment are common practice.

The level of environmental protection as well as the deterrence of illegal shipments is not hindered by this amendment as:

- Only genuine companies can provide valid business to business contracts for documentation.
- Medical equipment for professional use is unlikely to be shipped outside Europe for illegal waste treatment due to the positive residual value and long lifetime.
- Genuine companies have long lasting agreements (often intra-company) to provide conclusive proof that the shipment is taking place in the framework of a business-to-business transfer agreement.
- Special, tailored packaging is applied providing additional indication for border authorities.

1. COCIR recommends to ensure the possibility to ship non-functional equipment for root cause analysis and meeting regulatory requirements, as required by the Medical Devices Directives.

Current wording of the recast WEEE Directive, Annex VI, with proposed amendments:

c) the defective used EEE for professional use, such as medical devices or their parts, is sent for root cause analysis under a valid ***~~after-sales service maintenance~~*** *contract* ***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.*

Justification:

COCIR proposes to delete "*after sales service maintenance*" as the wording does not reflect actual business reality. Any rightful shipment will however be covered by valid contract or, in case of root cause analysis obligation under the Medical Devices Directives medical equipment or their parts need to be shipped back to the original manufacturer or specialised centres.

COCIR proposes also to add "*or meeting regulatory requirements under Directive 93/42/EEC (medical devices) or Directive 98/79/EC (IVD medical devices)*" as the current wording does not allow manufacturers to fulfill regulatory requirements.
According to directive 93/42/EEC on medical devices (e.g. Art. 10, 1. and Annex II, 3.1) a manufacturer within its quality system and post-production phase responsibility, must establish a systematic procedure to review experience gained from devices in the market so he can apply any necessary corrective action and inform the competent authority.
Otherwise any mandatory shipment of defective EEE under regulatory requirements would be declared as illegal waste shipment.