COCIR CONTRIBUTION TO THE ROHS EXEMPTION STAKEHOLDER CONSULTATION ON EXEMPTION REQUEST 2013-6

"Lead and hexavalent chromium in reused spare parts, recovered from industrial monitoring and control instruments placed on the global market before 22 July 2017 and used in category 9 equipment placed on the market before July 22 2024, provided that use and reuse takes place in auditable closed-loop business-to-business return systems, and that the reuse of parts is notified to the consumer"

Name and address of applicant

COCIR : European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry
Blvd A. Reyers 80
1020 Brussels
Contact: Mr. Riccardo Corridori
Tel: 027068966
corridori@cocir.org

Background

COCIR recently submitted a similar exemption request to allow used parts that contain RoHS substances which had been removed from used medical devices to be reused in equipment that is placed on the EU market after 22 July 2014. The Commission's consultants the Oko Institute agreed that there would be a smaller negative impact on the environmental with this exemption than without this exemption[1] and this was published as exemption 31 of Annex IV. The wording chosen by the consultants and agreed by COCIR is based on RoHS Article 4.5. However, COCIR has since realised that this wording creates insurmountable difficulties for medical equipment refurbishers, reuse and repair operations, as identification of whether parts arise from within the EU or outside of the EU is not possible with 100% certainty. COCIR would like to resolve this issue by varying the wording of new exemption 31. Reuse is ranked in the waste hierarchy and has the potential to drive EU towards resource efficiency and recycling economy which are topics high on the agenda of EU Institutions.

COCIR's opinion on this exemption request

COCIR fully supports the FEI's exemption request because of the way that spare parts are collected, refurbished and then reused is very similar to the closed loop business models used by COCIR member companies and has a less negative impact on the environment than these parts becoming waste and having to be replaced by new parts. It

[1] See section 7.5 of:
http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/20130412_RoHS2_Evaluation_Proj2_Pack1_Ex_Requests_1-11_Final.pdf

is clear that reuse of existing parts consumes far less energy and raw materials and will create less emissions than the manufacture of new replacement parts. It is also clear that reuse results in much less waste electrical equipment than the disposal of parts and replacement by new parts.

It is usually impossible to determine whether used parts contain RoHS restricted substances as the example for reuse of used MRI magnets explains:

- Complete Bills of Materials (BOM) are available for MRI magnet types. However a significant percentage of original piece part suppliers no longer exist to obtain RoHS compliance certification.
- The original piece part components for the MRI magnet types are no longer available for Laboratory Testing/Analysis to determine RoHS compliance. Components have been obsoleted by supplier and are not carried in inventory.
- Magnet tear down for each of the magnet types could be performed to retrieve suspect piece part components for Laboratory Testing/Analysis. But magnet tear downs will violate the ASME/PED/AD2000 Pressure Vessel certification and essentially mean that the magnets will become unusable scrap suitable only for waste disposal . Also, a significant sample of each magnet type will often have to be torn down to accurately verify full compliance.

Based on the unavailability of original component suppliers, piece part inventory and the invalidation of the magnet Pressure Vessel Certification, MRI Magnet RoHS Compliance assessment is not possible.

Difficulty implementing the proposed wording for category 8 parts reuse

COCIR also agrees with FEI that it is normal practice to collect used parts from equipment located world-wide, to refurbish them at a single specialist refurbishment centre and then ship these parts to wherever they can be used world-wide. Parts that are collected globally and refurbished parts should be permitted to be used globally, including in the EU because of the insurmountable difficulties of segregating parts that were used parts from equipment that was placed on the EU market before the compliance deadline and to use these after refurbishment only in the EU. As most category 8 and 9 manufacturers have only one refurbishment centre for each type of product, segregation of parts by where the equipment was first sold will at best create an extremely difficult logistics problem and in reality is impossible to manage and guarantee that mistakes do not occur.

Moreover this would limit the possibility to use parts where and when needed, thus reducing the reuse potential and resulting in more generated waste. Medical devices in the EU, for instance could not be repaired or substituted with refurbished ones because of the shortage of such systems and parts which can be used in the EU, even if manufacturers could have large supplies of the very same parts, but recovered from products that were placed on extra-EU markets, and therefore not usable. This could eventually result in reduced access to healthcare because; new equipment and parts are more expensive than refurbished.

Most professional category 8 equipment and its constituent parts are the same irrespective of where they are sold globally. Most category 8 parts and systems are manufactured at one factory and usually, this factory is the only location parts and systems that it has made are refurbished. Examples of how two of COCIR's members refurbish parts are as follows:

1. One company makes a very diverse range of medical devices at eight factories globally. Each factory manufacturer's different parts and systems. Most of these factories collect their own used parts and systems from the global market and refurbishes the parts which may be used for repairs of customers equipment or for refurbishment of used equipment. Some of the parts used to refurbish systems will be from different systems. Some parts will be beyond repair and so become waste. Refurbishment of each part is a separate process and so parts sourced globally will pass through the refurbishment process and at the end, all will be indistinguishable from each other so their original source will not be known.
2. Another COCIR member refurbishes X-ray tubes at two locations globally, one in the EU and the other in the USA. However, each factory refurbishes different types of X-ray tube assembly, so all of each particular type will be refurbished at only one location, irrespective of its source. This company has noticed that there are more sales of new equipment outside the EU than in the EU, due to growing non-EU markets and this affects where the refurbished X-ray tube assemblies are sourced and used. In 2012, 46% of assemblies refurbished at the EU refurbishment centre were estimated to be from X-ray machines used in the EU whereas only 40% of assemblies from this factory were supplied to EU users.

When the equipment and constituent parts are manufactured and packaged, it is not known where each item will be sold and used and so it is not possible to mark constituent parts with information that will inform a refurbisher whether the EEE in which it is used is placed on the EU market or elsewhere. Finished equipment has a serial number and this can be used to indicate when and where it was first sold. However, used parts (e.g. X-ray tubes or faulty parts) are removed from equipment by service engineers or by end users and then shipped to the refurbishment centre. These parts will not be marked to identify them in any way so it is usually not possible to determine:

- Which item of EEE it had been removed or
- Where the EEE was previously sold

Labelling parts to show where the EEE from which they were removed had been placed on the EU market or markets outside the EU will not be practical or acceptable for the following reasons.

If a refurbishment centres were to suggest to its customers that they label used parts with the EEE's serial number in order to trace the parts origin, it is highly likely that end users will fail to do this (also they may make unintentional mistakes such as adding an incorrect number). Even if they are correctly labelled, during refurbishment, these labels will have to be removed at the refurbishment centre and then keeping track of many parts of identical appearance throughout

the often complex multi-stage refurbishment process is probably impossible or at best extremely difficult. The likelihood of mistakes occurring is therefore relatively high if this were to be attempted. Medical device manufacturers must comply with RoHS and so cannot use procedures that risk non-compliance, even if the risk is fairly small.

RoHS exemption wording that is closely based on Article 4.5, which refers to equipment "placed on the market", i.e. the EU market as defined by Article 3 (12), will not allow:

Non-RoHS compliant parts removed from category 8 equipment that was constructed before 22 July 2014 using RoHS substances and which was sold and used outside of the EU until after 22 July 2014 cannot be reused in medical devices placed on the EU market on or after 22 July 2014.

A similar situation exists with IVD medical devices but the corresponding dates are 2016

As explained above, this will create unnecessary waste, as it is not feasible to determine where a part had previously been used. Therefore, as refurbishers cannot guarantee that any recovered part from EEE was placed on the EU market before 22 July 2014, these will become waste. It will often not be feasible to use parts containing RoHS substances in EEE destined for non-EU countries because when medical devices are refurbished, their ultimate destination is not known and so all of these parts will need to become waste.

However, an option exists where refurbished parts can be reused without a more negative impact on the environment or increasing the amounts of RoHS substances in the EU. Two example scenarios; (1) and (2) are compared below to explain this;

Option 1. The reuse of parts from EEE placed on the global market;

Will have a less negative impact on the environment than on either of the following alternatives;

Option 2a. Having no exemption or;

Option 2b. Having an exemption that is limited to reuse of parts from EEE placed on the EU market before 22 July 2014 only.

The following illustrative example uses the actual amounts of parts collected by one COCIR member

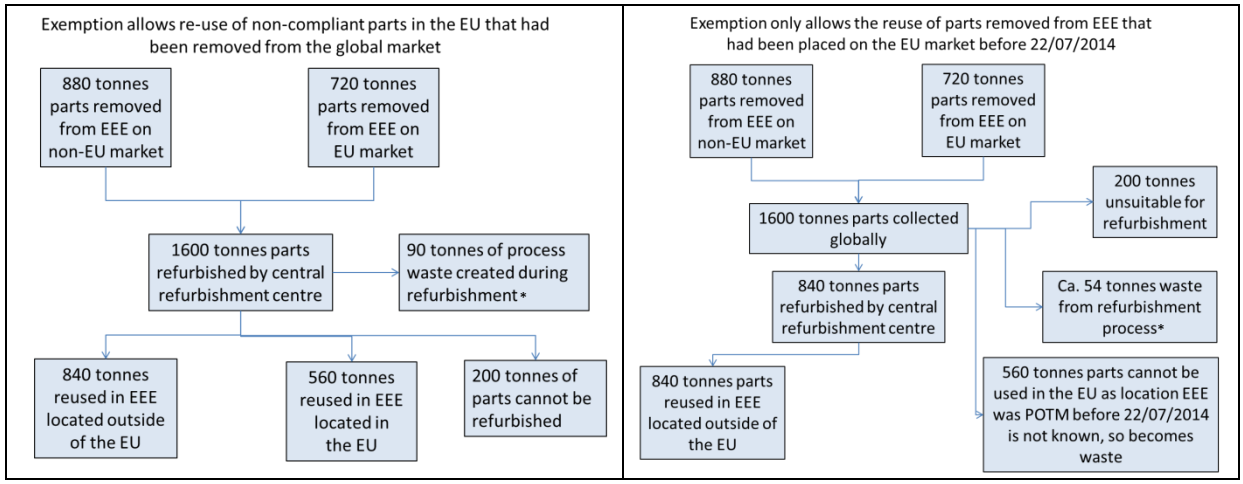

Figure 1. Impact of option 1 (left) and option 2 (right).
Additional waste generated by materials used in the refurbishment process which adds to the mass balance.

In this illustrative example of a refurbishment plant located in the EU (operated by a member of COCIR), 200 tonnes of parts are too damaged to be reused and 90 tonnes of process waste (waste generated during the refurbishment of parts) is generated under option 1 making a total of **290** tonnes of waste. Under option 2 without the exemption being applicable to parts from the global market, 200 tonnes of parts are too damaged to be reused, 560 tonnes of parts could be reused but have to be discarded as it will not be known if they are from EEE that was POTM in the EU before 22 July 2014 and 54 tonnes of process waste would be generated. Under option 2, the total quantity of waste would be 200 + 560 + 54 tonnes = **814** tonnes. Also, there will be waste generated from manufacture of new replacement parts in addition as well as additional energy and raw materials consumption. Therefore if the exemption applies **only** to EEE placed on the EU market before 22 July 2014 (option 2), there will be at least 814 tonnes waste (excluding estimated waste from replacement parts production) from 1600 tonnes of collected parts, whereas if global part reuse was permitted (option 1), only 290 tonnes of waste would be created.

When a defective part is removed from a medical device being used in a hospital, it needs to be replaced, either by a new part or by a refurbished part as soon as possible to allow the medical device to continue to be used by the hospital to treat patients. Therefore the removed part will not be reused in the same equipment that it was removed. Most professional category 8 and 9 equipment manufacturers have only one factory where they carry out refurbishment from each type of part removed. It will usually be impractical to have one refurbishment centre in each country or continent, due to the relatively small number of parts that are available to be refurbished and the skilled engineers needed to carry out refurbishment, which will usually be available only where the parts were originally made. As a result, most refurbished parts will be reused in different countries (and continents) to the ones from where they were originally removed.

Figure 1 also clearly shows that the total amount of RoHS substances in the EU will not increase by allowing the reuse of parts from EEE placed on the global market before 22 July 2014, in fact as some parts are not repairable the amount will be less. There will always be a one for one replacement of parts, and replacement parts must be identical to the original parts in order to function correctly. Figure 1 also shows that the amounts of RoHS substances in non-EU countries will also not increase with this exemption being applicable to all parts from the global market.

COCIR explained in its exemption request for reuse of parts that medical device manufacturers are in the process of phasing out hexavalent chromium passivation coatings. As a result, all EEE that contains an X-ray tube that had been placed on the EU market before 22 July 2014, will include a certain proportion of X-ray tubes that contain CrVI and the rest will be CrVI free. A very similar proportion of the same type of EEE that had previously been placed on non-EU markets will have CrVI coatings. X-ray tube life is similar overall in the EU and outside of the EU and so the proportion of X-ray tubes used as replacements in the EU that contain CrVI will be the same irrespective of whether these replacement parts are only from EEE that was first placed on the EU market before 22 July 2014 or is from EEE placed on the global market before this date. As a result, the amount of CrVI in X-ray tubes in use at any time in the EU will be the same if the replacement tubes are only from EU EEE, from non-EU EEE or from EEE from the global market.

It will clearly be better to reuse all available refurbished parts than have some become waste and have to be replaced by new.

IVD parts: COCIR's original parts reuse exemption request that was considered by the Oko Institut and recommended for granting also omitted to take into account the different compliance dates for IVD medical devices which enter scope two years after medical devices. Parts from professional IVD equipment are collected and can be reused after refurbishment. Refurbishment is usually at one refurbishment centre globally and is usually the factory that originally made the part. This is therefore a controlled closed loop reuse system. The quantities of RoHS substances in reused IVD parts are a small proportion of all medical devices (these quantities were provided in COCIR's original exemption request). However the weight of refurbished parts is many tonnes so not being able to reuse these would have a significant negative environmental impact. One factory in the EU, for example, refurbishes about 130 tonnes of IVD equipment each year and another 22 tonnes of used parts per year and these refurbished units contain a significant proportion of reused parts that were removed from different equipment. Therefore COCIR request that the new wording (below) takes account of the compliance dates for IVD equipment.

PBDE and PBB in used parts: COCIR members have discovered that some parts that are reused include plastic parts such as enclosures and connectors that contain flame retarded materials. The presence of PBDEs in used refurbished parts will often not be known as there was no requirement to determine this when the equipment was first placed on the market. The original parts suppliers will often not have this information. It is possible to non-destructively determine if brominated flame retardants are present in a

plastic material using XRF analysis, but it not possible to determine whether any identified bromine compounds are one of the PBDE or PBB flame retardants. This would require the refurbisher to carry out chemical analysis (GC-MS) but this procedure will require destruction of the parts. Accurate GC-MS analysis requires several grams of each plastic which must be ground to a powder for solvent extraction before GC-MS analysis of the solvent extract[2]. As this procedure would destroy the parts and so prevent reuse, COCIR is asking for PBDE and PBB to be added to the list of substances exempted in reused parts, although COCIR believes that the presence of PBB is extremely unlikely.

Mercury in used parts: COCIR's members are not aware of mercury in parts that it reuses, but the materials present in many older parts is not known as there was no requirement for suppliers to provide this information when the parts were originally sourced. Usually, the suppliers will not have recorded this information, some will have ceased trading and usually additional parts from the same batch will not be available for chemical analysis. Therefore, the medical equipment refurbisher has no way of establishing whether mercury (or the other RoHS substances) is absent.

Suggested new wording

The following alternative wording is proposed. This includes the following changes:

- Replace "reused spare part" by "reused part", although most refurbished used parts are used as replacements in existing equipment, i.e. as spare parts as defined by Article 3 (27) of the RoHS directive, a small proportion are used to construct new equipment and so are not "spare parts".
- *initially: refurbished parts can be reused multiple times (also in products sold after 07-22-2014). This exemption shall also apply for parts recovered from products sold after 07-22-2014, if the recovered part was initially placed in a product sold before 07-22-2014.
- The RoHS directive defines "the market" as the EU market whereas it is often impossible to determine where a part is from once it is being refurbished (as explained above). Therefore this is replaced by "the global market".

COCIR proposed wording:

"Lead and hexavalent chromium in reused parts, initially* recovered from industrial monitoring and control instruments placed on the global market before 22 July 2017 and used in category 9 equipment placed on the market before July 22 2024, lead, cadmium, hexavalent chromium, mercury, PBB and PBDE in reused parts initially* recovered from medical devices placed on the global market before 22 July 2014 and used in category 8 equipment placed on the market before July 22 2021 and lead, cadmium, hexavalent chromium, mercury, PBB and PBDE in reused parts initially* recovered from in-vitro medical devices placed on the global market before 22 July 2016 and used in category 8 equipment placed on the market before July 22 2023 ; provided that use and reuse takes place in auditable closed-loop business-to-business return systems, and that the reuse of

[2] Analysis method in IEC 62321

parts are notified to the consumer. "Placed on the global market" means making available for the first time globally".