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Study for the analysis of impacts from RoHS2 on non-road mobile machinery without an on-board power source, on windows and doors with electric functions, and on the refurbishment of medical devices

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Final Report

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Disclaimer

Eunomia Research & Consulting and Oeko-Institut have taken due care in the preparation of this report to ensure that all facts and analysis presented are as accurate as possible within the scope of the project. However no guarantee is provided in respect of the information presented, and Eunomia Research & Consulting and Oeko-Institut are not responsible for decisions or actions taken on the basis of the content of this report.

4.0 Refurbishment of Medical Devices in the Context of RoHS

4.1 Abbreviations

Cd	Cadmium
COCIR	the European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry
Cr VI	Hexavalent chromium
CT / CAT	Computerised tomography / computerized axial tomography
DHR	Device History Record
EDMA	European Diagnostic Manufacturers Association
Eucomed	Trade association representing the medical technology industry in Europe. Members include national and European trade and product associations as well as medical technology manufacturers
GRP	Good Refurbishment Practice
Hg	Mercury
IVD	In vitro diagnostic [medical devices]
MD	Medical devices
MRI	Magnetic resonance imaging
OEM	Original Equipment Manufacturer
Pb	Lead
PBB	Polybrominated biphenyl
PBDE	Polybrominated diphenyl ethers
PCB	Printed circuit board

4.2 Procedural Issues

In 2011, the European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR) submitted a request for an exemption for:

> "*Reuse of parts from medical devices including X-ray tube components in new X-ray tube assemblies*"

This request was evaluated in 2012[125] and led to Commission Delegated Directive 2014/15/EU of 18.10.2013, amending Annex IV of RoHS 2, through the addition of Ex. 31, which is currently in force, allowing the use of:

> "*Lead, cadmium and hexavalent chromium in reused spare parts, recovered from medical devices placed on the market before 22 July 2014 and used in category 8 equipment placed on the market before 22 July 2021, provided that reuse takes place in auditable closed-loop business-to-business return systems, and that the reuse of parts is notified to the consumer. Expires on 21 July 2021.*"

In 2013, FEI, a manufacturer of electron microscopes, requested a similar exemption, (proposing as an alternative that Ex. 31 be reformulated) to allow the presence of Pb and Cr VI products made available in the EU originating from refurbishment facilities for electron microscopes and their accessories. COCIR participated in the stakeholder consultation of this request, among others resulting in a request, supported by both FEI and COCIR, that the exemption be extended to all RoHS regulated substances. A further change requested was that the exemption be reformulated to support the use of refurbished parts recovered from the global market and placed on the EU market. The evaluation[126] resulted in a positive recommendation to grant an exemption. The EU Commission is still to decide if to grant the exemption as recommended.

The path to use the exemption procedure, as a means for possibly resolving the problems of the refurbishment practices with the RoHS Directive, has been questioned in light of the wide and general scope of an exemption suited to tackle such aspects. The European Commission thus requested the current study be prepared to substantiate the scope of such problems on a more comprehensive level and to establish the scope of impacts (environmental/ economical /social) that different policy options aimed at solving such problems may result in.

In the course of this study, stakeholders were notified of the objectives of the study and of the possibility to contribute information to be evaluated as part of this review. A number of stakeholders expressed their interest in this project, including COCIR, European Diagnostic Manufacturers Association (EDMA) & Eucomed and FEI. Such stakeholders received a first questionnaire (see Appendix A.2.0, outlining the various aspects of interest for the review). A targeted stakeholder meeting was held with these stakeholders as well as with representatives of some of their members on 27 November 2014 in Brussels to allow an open discussion of various aspects. Following the meeting, some of the participants submitted additional information for use in the evaluation. Information obtained through these stages as well as

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[125] For further detail see Section 7 of the evaluation report under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/20130412_RoHS2_Evaluation_Proj2_Pack1_Ex_Requests_1-11_Final.pdf

[126] For further detail see Section 6 of the evaluation report under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/ROHS_Pack5/201410_RoHS_Ex_Pack5_Final_Report_final.pdf

information available from the first two evaluation processes, has been the basis for preparing this report.

4.3 Problem Definition and Background

As an outcome of the RoHS Recast (Directive 2011/65/EU – RoHS 2), medical devices (category 8 of Annex I) have been included in the scope of articles that need to comply[127] with the Directive requirements. This includes complying with the RoHS substance restrictions as required by Article 4(1) of the Directive:

> "*Member States shall ensure that EEE placed on the market, including cables and spare parts for its repair, its reuse, updating of its functionalities or upgrading of its capacity, does not contain the substances listed in Annex II*"

Products of the medical device manufacturing sector can be categorised into a few sub-groups, according to how they are impacted by the RoHS substance restrictions; this includes:

- New devices;
- Device parts; and
- Previously owned devices.

As placing on the market is defined in Article 3(12) as "*making available an EEE on the Union market for the first time*" it is thus understood that both new devices as well as spare-parts need to comply with the substance restrictions at the time they are first placed on the market.

In comparison, second hand devices and second hand parts, are in general not required to re-comply; their compliance is based on the substance restrictions in force when they were originally placed on the market (i.e., as new products). Nonetheless, as shall be explained in the following, in the case of previously owned medical devices which are refurbished, in some cases a refurbished device will be required to comply with the RoHS substance restrictions at the time it is made available on the market, regardless of the compliance of the original device at the time first sold.

For example, this is the case of a product first sold in 2010 on a non-EU market (as a new product), refurbished and then sold as a refurbished product on the EU market in 2015. Since the sale in the EU is the first time the device is placed on the Union market, the product is required to comply with the substance restrictions relevant in 2017 for this product category, regardless of compliance of the new product in 2010.

In the case of medical devices, the various product categories need to comply with the substance restrictions starting 22 July 2014 (general) and 22 July 2016 (in-vitro diagnostics). In this sense, regardless of what market the product was first sold on, before these dates all medical devices were compliant with RoHS because the use of

[127] A product is considered compliant if it either a) does not contain any RoHS restricted substances above the %/weight specified in Annex II of the Directive or b) if the remaining use of RoHS restricted substances in the relevant components is allowed through an existing exemption listed in Annex III of the Directive, at the time the end-product is placed on the EU market.

RoHS substances was not yet restricted in these products. The same article placed on an EU market can be refurbished and resold on the EU market, as the substance restrictions only apply at the first time that EEE is placed on the EU market (when such a device is resold, compliance is related to this first time compliance). Regardless of the presence of RoHS substances in a refurbished device first placed on the EU market, it can be resold on this market without being required to retroactively comply with the RoHS substance restrictions.

Stakeholders have communicated that in the medical sector, refurbishment is often carried out on a global basis (one facility refurbishes all medical devices of a certain model, regardless of where they were first sold and regardless of where they are destined to be resold). Thus concerns have been raised that enforcement of the current RoHS legal text could result in costs higher than the benefits thereof.

Though the benefits of eliminating the use of RoHS substances in refurbished medical devices remain to be quantified, it is possible that compliance with the RoHS substance restrictions may result in significant costs. In this regard, the consultants have identified a scenario, in which the costs of compliance could be significant enough to justify an adjustment of the RoHS legal text and/or annexes for this product category:

- If the compliance of refurbished medical devices with the Directive results in environmental burdens, in terms of medical devices (or parts) reaching end-of-life early (and manufacture of new articles as replacements), which are significantly higher than the benefits expected from the compliance of these devices with the RoHS restrictions.

The use of both refurbished medical devices and refurbished parts recovered from medical devices could be affected in the case that the RoHS Directive would remain unchanged. Thus, in the following parts of this review, the various aspects related to these product groups is to be discussed. Besides product groups to be affected, it is also important to point out that based on information provided by the medical sector[128], at present refurbishment practices are practiced for:

- Imaging equipment such as Magnetic Resonance Imaging (MRI) devices, Computer Tomograghy (CT) devices, etc. (refurbishment practices well established);
- In-vitro diagnostic devices (refurbishment practices well established);
- Patient monitoring devices (refurbishment practices are starting to develop).

It is possible that refurbishment practices are established or in development for other medical devices, however this has not yet been confirmed by stakeholders. Nonetheless, the consultants conclude that both Cat. 8 (general medical devices) and Sub-Cat. 8 In-vitro (in-vitro diagnostic devices) should be taken into consideration in

[128] Medical Sector (2014), Protocol of Targeted Stakeholder Meeting concerning Medical Refurbishment in the Context of RoHS, held in Brussels, Belgium, on 27 November 2014.

any decisions made to resolve the current problems, related to refurbishment in the context of RoHS.

It should further be noted that a manufacturer of electron microscopes (FEI[129]) has mentioned in the past that it has similar refurbishment practices in place and would be similarly impacted by the current terms of the directive. The TOR for this project required a review for medical refurbishment on the context of RoHS, and thus other product groups shall not be discussed. However it should be noted that the aspects raised in this review are also relevant for electron microscopes falling under sub-category 9 "industrial monitoring and control instruments" and possibly also for other products designed for long life and being low volume – high value products.

4.4 Background

Though refurbishment and resale of second hand products is common in various EEE sectors, products of the medical sector have certain characteristics which are of importance where compliance with the RoHS Directive is concerned:

- Medical devices for which refurbishment practices are common, often have a **long planned service life** and are thus more robust in design, to enable a longer product life-time. Refurbishment operations have therefore developed in the medical sector as a means to ensure that such devices operate throughout their planned service life, or beyond. EDMA & Eucomed[130] detail that "*the typical life of a new IVD instrument within a given laboratory is 5 to 7 years, at which time the laboratory will often upgrade its system for a newer or different model. Given that the instrumentation is usually designed to operate much longer, when it is removed from the laboratory, it is typically refurbished and placed into another lab. Clinical laboratory blood analysers, medical optics lab analysers, blood bank analysers and point of care handheld bedside analysers are examples of IVDs which may be allotted typical lifetimes (ranging upwards from 7 years) however, may last far longer when refurbished. Refurbished devices can be out in the field for 15-20 years (and there are some concrete examples of well-maintained instrumentation in the field already 30 years).*" In the targeted stakeholder meeting, participants agreed that for medical devices and electron microscopes, equipment and parts could remain in circulation for 10-20 years if refurbishment practices are not limited.[131]
- Furthermore, products can often be described as "**low volume – high value**", meaning that devices are manufactured in low numbers and have a high market value (cost).[132]

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[129] See Information posted on RoHS Evaluation Web-site, available under: http://rohs.exemptions.oeko.info/index.php?id=206

[130] EDMA & Eucomed (2014a), EDMA & Eucomed Response to Questionnaire Concerning Impacts on Refurbishment, submitted 5.12.2014 per email;

[131] Op. cit. Medical Sector (2014)

[132] Op. cit. Medical Sector (2014)

- The former is an important aspect, as a consequence to these characteristics, manufacturers of the medical sector have developed refurbishment practices on a **global basis**, to ensure the economic feasibility of these operations. Logistically, global operations also allow bridging the differences between supply and demand for refurbished products in certain areas. In the EU, the supply is lower than the demand for such products, whereas the global operation allows sourcing additional devices from outside the EU. A manufacturer shall usually have a single global facility processing the refurbishment of all devices of a certain model. For example EDMA & Eucomed's[133] members, who refurbish, have one or several refurbishment facilities which serve a global market.

From the targeted stakeholder meeting, it is understood that in the course of refurbishment in the medical sector, second hand devices are first inspected to establish that they are still operative, followed by performing various refurbishment activities as required to allow resale of the device. In some cases parts are replaced with new parts, whereas in other cases parts which are still functional shall be subjected to refurbishment actions to allow them to remain in use – i.e. disinfection and system cleaning / aesthetic refurbishment / reconfiguration and software updates etc.[134]

As such parts may remain in circulation 10-20 years, some of them may contain RoHS substances (since at the time placed on the market they were not required to comply with the substance restrictions). In some cases, as shall be explained below, this may create obstacles for the reuse of products in terms of compliance with the RoHS Directive.

4.4.1 Legal Background

Medical devices need to comply with the substance restrictions stipulated in Article 4(1), consequence to Article 4(3): "*Paragraph 1* [i.e., Article 4(1)] *shall apply to* ***medical devices****... which are* ***placed*** *on the market from* ***22 July 2014****; and to* ***in vitro diagnostic medical devices*** *which are* ***placed*** *on the market from* ***22 July 2016***". [135]

Article 4(4), provides an exclusion from the substance restrictions for "*cables and spare parts for the repair, the reuse, the updating of functionalities or upgrading of capacity of… (b) medical devices placed on the market before 22 July 2014; (c) in vitro diagnostic medical devices placed on the market before 22 July 2016;… (f) EEE which benefited from an exemption and which was placed on the market before that exemption expired as far as that specific exemption is concerned."* [136]

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[133] Op. cit. EDMA & Eucomed (2014a)

[134] Op. cit. Medical Sector (2014)

[135] See Directive 2011/65/EU under http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32011L0065

[136] See Directive 2011/65/EU under http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32011L0065

Refurbishment is not mentioned in the context of Article 4(4). However recital 20 of the Directive states that "As product reuse, refurbishment and extension of lifetime are beneficial, spare parts need to be available". Refurbishment is not defined in the Directive. COCIR's Green Paper on Good Refurbishment Practice (GRP) provides a possible definition as well as requirements established by the medical imaging sector, both of which are detailed in Section 4.7 below.

Furthermore, exemptions are available in Annexes III and IV permitting the temporary use of RoHS substances in certain applications, some of which are relevant for medical devices.

The above mentioned articles provide the legal framework for understanding what medical products and parts need to comply with the RoHS Directive.

A further aspect of relevance to compliance concerns the ownership of a device. The RoHS Directive makes a distinction between articles placed on the Union market for the first time and articles made available on the Union market through secondary market operations, i.e., marketing of previously owned products or of products made available through renting and leasing operations. (See Articles 3(11) and 3(12) of RoHS 2).

In light of the formulation of Article 4(1), only articles placed on the market for the first time need to comply with the substance restrictions. However, as a consequence of the reference to the Union market in Articles 3(11) and 3(12), it is to be noted that secondary market operations of products placed on the EU market differ from those of products placed on other-than-the-EU market where the substance restrictions are concerned. The compliance requirement applies when the product is first placed on the EU market, so that though a device previously sold in the EU will be seen as compliant for life, a product first sold outside the EU will need to prove compliance with the Directive requirements relevant at the time it is placed on the market. Compliance with EU regulation at first sale, expressed through CE marking[137], is irrelevant, meaning that if the requirements have changed, the product will need to be demonstrated as compliant or will be denied market access. In other words, whereas a product placed on the EU for the first time, may be refurbished and resold on the EU market, other products placed on external markets will be denied market access from 22 July 2014 unless compliance with the substance restrictions can be proven.

Furthermore, spare parts and cables also need to comply with the RoHS substance restrictions the first time they are placed on the EU market; however, here an exclusion applies depending on the product in which the spare-part is to be used. Article 4(4) allows the use of non-compliant spare parts[138] in products where the

[137] As defined under Regulation (EC) No 765/2008a, Article 2(20): "marking by which the manufacturer indicates that the product is in conformity with the applicable requirements set out in Community harmonisation legislation providing for its affixing".

[138] Cables are not referred to in this review separately, as they are not manufactured by the medical sector, however it should be noted that Article 4(4) also permits the manufacture and use of non-compliant spare parts for repair in the cases specified in items a-f.

restrictions did not apply to such products at the time placed on the market (either as the category was not in scope – items b and c – or as an exemption was valid to permit the use of a RoHS substance – item f). Here too, such parts can be used for repair of articles placed on the EU market in the past and legally not conform to the current substance restrictions. However the same product cannot be repaired with such parts, if it was first placed on an extra-EU market and is only to enter the EU market after repair with non-compliant parts. As medical devices are refurbished globally, this would mean that such operations must either be separated (i.e. performed for EU devices and non-EU devices at different locations), or that logistic systems must be applied to allow tracking and singling out of products first placed on the EU that can be repaired with non-compliant spare parts and resold in the EU. These are the only products in which non-compliant spare parts can be used for repair, both if they are newly manufactured spare parts or if they are refurbished (2nd hand) spare parts[139]. This also means that refurbished spare parts, despite compliance at the first time they were placed on the EU market, are retroactively restricted for use if the substance restrictions have changed at the time they are to be used in the assembly of a new product at a later time. In this regard, some spare-parts are not "placed on the market", in the sense that they are used by the OEM without an actual transaction taking place. However, spare-parts placed on the EU market, will be CE marked and in compliance with RoHS and would thus normally benefit from not having retroactive compliance requirements. This implies that the legal text is inconsistent in this regard.

Article 3(27) provides a legal definition for spare parts from which it can be interpreted what parts would benefit from the Article 4(4) exclusion: "*'spare part' means a separate part of an EEE that can replace a part of an EEE. The EEE cannot function as intended without that part of the EEE. The functionality of EEE is restored or is upgraded when the part is replaced by a spare part*". This definition means that only parts that are relevant for the proper function of an EEE could benefit from the Article 4(4) exclusions. It also means that a decorative refurbished part, which will not affect the functionality of the EEE, cannot be reused for repair of devices to be made available on the EU, despite this being a contradiction to the unlimited secondary market operations granted a product compliant at the time first placed on the market.

Furthermore, in contrast to *"spare parts"*, neither *"components"* nor *"parts"* are defined in the RoHS legal text and are thus treated differently. The RoHS 2 FAQ[140]

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[139] The exemption request evaluation that led to Ex. 31 discussed if both new and used parts could benefit from Article 4(4). Though the report interpreted at the time that this Article was only available for use of RoHS substances in new spare parts, this was only an interpretation which is not legally binding. As Article 4(4) does not specify what kind of spare parts (used, new), it is understood that this is left open to interpretation, with only the devices in which such parts can be used being specified.

[140] See Q7.3 "Do components have to comply with RoHS 2? RoHS 2 provides that EEE has to meet the requirements of the Directive. Since equipment consists of different components, the EEE itself can only meet the substance requirements if all its components and parts meet the substance restriction requirements of RoHS 2, including non-electronic or non-electric components like fasteners or the plastic case of a desktop computer. Therefore components being used in finished EEE or for repair or upgrade of used EEE, which is in the scope of RoHS 2 must meet the substance restrictions according

document clarifies that components are not to be understood as spare parts and that they need to comply. As the consultants understand spare-parts to be a sub-group of parts, it is assumed that some parts would need to comply (for example parts not providing or affecting the functionality of the EEE) and some would not in light of their influence on functionality.

To summarise, it is understood that devices always need to comply with the substance restrictions relevant at the time they are first placed on the EU market. This includes the case of a refurbished product first placed on a non-EU market in which all non-compliant spare-parts used in its refurbishment were first legally placed on the EU market. Though the device is compliant aside from the refurbished parts already placed in the past on EU markets, it loses its compliance through the use of these parts. The device would need to replace these parts with new compliant parts to establish compliance for its first placement on the EU market. In comparison, for spare parts, compliance would depend on the status of the product in which they are intended to be used, and on the RoHS restrictions that applied at the time it was first placed on the EU market. All spare-parts, compliant or not, can be used for repair of a product compliant when first placed on the EU market. However, only spare parts compliant with the RoHS substance restrictions at the time of use can be assembled into products that need to comply with substance restrictions at the time made available on the EU market, and thus have a limited access to the market in secondary operations. See decision trees provided in Figure 4-1 and Figure 4-2 below to further clarify in what cases compliance is required retroactively.

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to Art. 4 but do not need CE marking. Components sold as a stand-alone components or if produced to be used in a product benefiting from an exclusion do not have to be CE marked and do not have to comply with the substance requirements." Cited from EU COM (2012), European Commission, RoHS FAQ Document, last updated 12.12.2012, last accessed 10.12.2014, available under http://ec.europa.eu/environment//waste/rohs_eee/pdf/faq.pdf

Figure 4-1: Can a Refurbished Device be Placed on the EU Market?

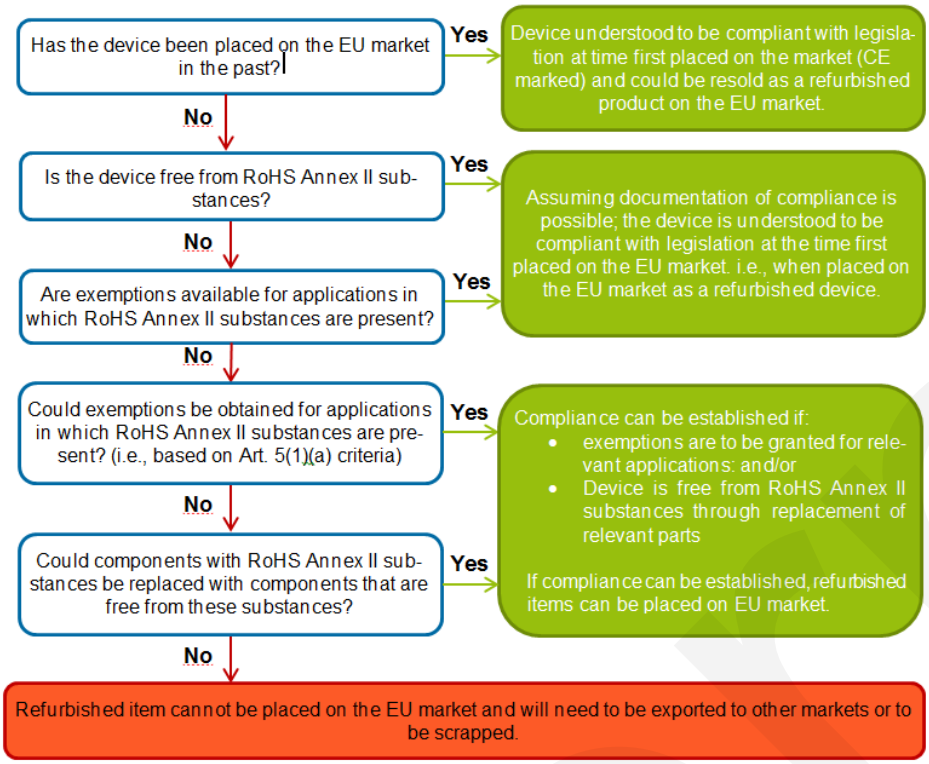
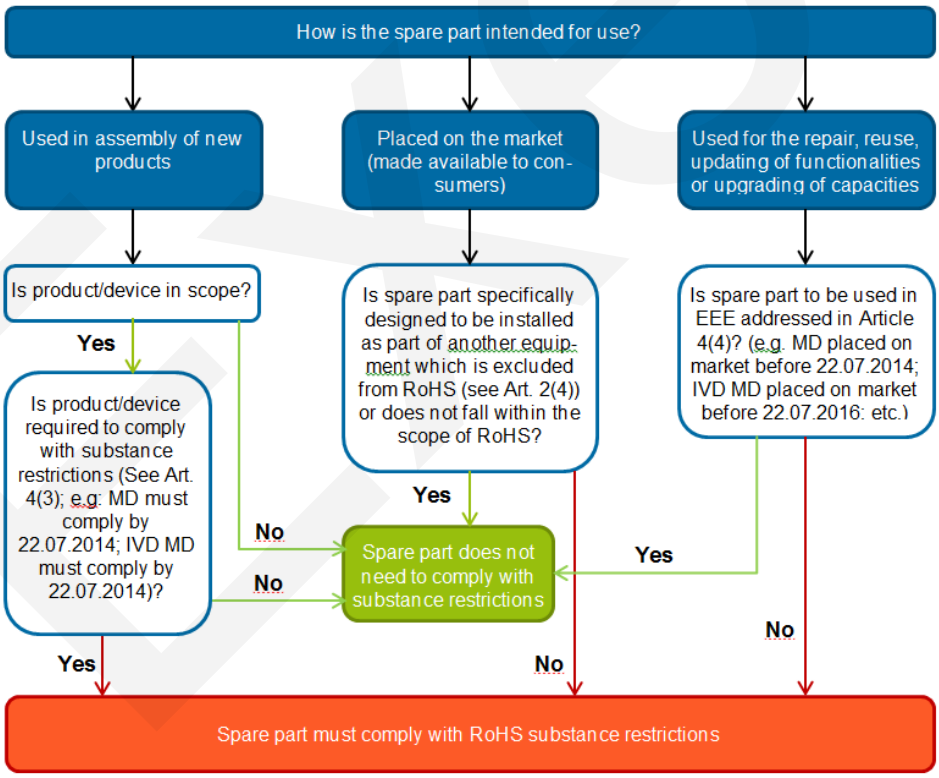
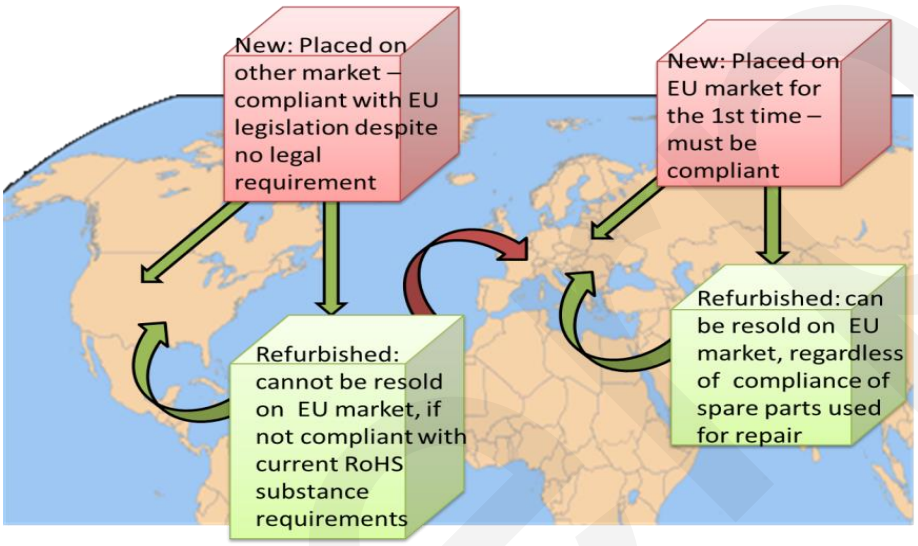


Figure 4-2: Compliance of Spare Parts



As medical devices are often refurbished and resold as second hand products, this aspect is particularly of concern when such products are refurbished outside the EU and then imported and placed on the EU market (as illustrated in Figure 4-3). Certain limitations shall also apply in the case of resale of parts, as explained above. Thus concern has thus been raised by medical manufacturers, that these aspects may impact refurbishment operations in a way that could in some cases lead to adverse impacts. Such impacts and possible solutions to these problems are the focus of the current review.

Figure 4-3: Illustration: RoHS Substance Restrictions and the Possibilities of Placing a Product on the Market



Notes:
- Red box / Green Box –> new devices / 2nd hand (refurbished) device)
- Red arrow / green arrow –> compliance with RoHS substance restrictions required when made available on the market / compliance established when first placed on the market sufficient for secondary market operations in the EU market.

Source: Own illustration

4.5 Objectives

The objective of both the RoHS recast proposal (COM (2008) 809 final) as well as RoHS 2 (2011/65/EU) is *"to contribute to the protection of human health and the environment, including the environmentally sound recovery and disposal of waste EEE".*[141]

The purpose of this study is to look at the impacts of the RoHS substance restrictions on refurbished medical devices and parts where the RoHS 2 legal text is applied as is, compared to an alternative in which adjustments are to be made to allow all CE marked medical devices to enjoy access to the EU market without needing to re-comply with the substance restrictions when resold on the EU market. Policy options

[141] Directive 2011/65/EU, Article 1

are thus evaluated according to the ability to reach the abovementioned overall objective of the RoHS Directive, as well as whether they lead to the following scenario:

- If the compliance of refurbished medical devices with the Directive results in environmental burdens, in terms of medical devices (or parts) reaching end-of-life early (and manufacture of new articles as replacements), which are significantly higher than the benefits expected from the compliance of these devices with the RoHS restrictions.

4.6 Policy Options

The policy options analysed are the following:

Option 1 (Business as usual scenario): As per the original RoHS 2 legal text, refurbishment shall not be explicitly supported through adjustments of the RoHS legal text. *This scenario is investigated in order to understand the range of impacts if refurbished articles were in scope – this is understood to be a baseline scenario which shall provide a reference for the two other scenarios.*

Option 2 (Exemption 31 scenario): Refurbishment allowed through exemptions that need to be renewed from time to time. *This scenario represents the current state of the Directive as amended by Commission Delegated Directive 2014/15/EU of 18 October 2013 with the addition of Ex. 31 to Annex IV.*

Option 3 (Exclusion 4(7) scenario): Refurbishment provided through an adaptation of Article 4. *This scenario is investigated in order to review how a permanent solution would affect impacts.*

A further Sub-Option in which the Exemption 31 scenario is implemented temporarily with the Exclusion 4(7) scenario implemented subsequently shall be discussed shortly on the basis of results for the first three options. The importance of this Option has been raised by stakeholder in light of Option 3 requiring a transition period in light of the time needed to implement changes to the Directive legal text.

Furthermore, policy options shall be analysed referring to aspects related to global refurbishment practices.

4.7 The Baseline

Within COCIR's Green Paper on Good Refurbishment Practice (GRP)[142], refurbishment is defined as*: "a systematic process that ensures safety and effectiveness of the medical equipment without significantly changing the equipment's or system's performance, safety specifications and/or changing intended use as in its original registration"*. Any upgrades processed during GRP refurbishment are thus required to perform in a manner consistent with the original product specifications and service procedures defined by the manufacturer for that equipment or system.

[142] COCIR et. al. (2009), COCIR, JIRA, MITA, Green Paper on Good Refurbishment Practice (GRP) for Medical Imaging Equipment.

Refurbishment can be divided in to two types:

- Refurbishment performed by the OEM;
- Refurbishment performed by 3rd parties.

One advantage of OEM refurbishers concerns their access to the original specifications of a certain device as well as to documentation provided by suppliers at time of manufacture, regarding the use of certain substances. OEMs may further be supported by the original suppliers of some components in the refurbishment of certain parts. In this sense they often offer refurbished products, which are said to be *"as good as when new"*[143]. Little information is available concerning 3rd party refurbishers and it remains to be determined how relevant aspects discussed in this review are for such refurbishers.

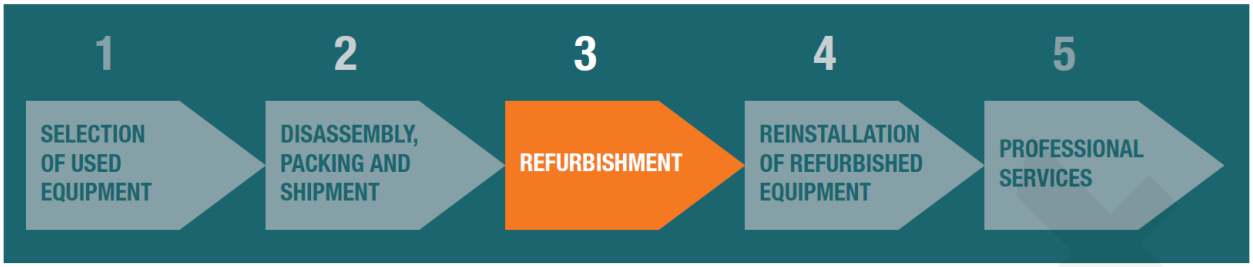
Good Refurbishment Practices are explained[144] to have certain elementary requirements which equipment must adhere to in order to be qualified and eligible for refurbishment. "*The first key factor for refurbishment qualification is the* ***intended use*** *as determined by the manufacturer including its product specifications. Devices intended for single use or designed as not eligible for refurbishment should not be refurbished. The second key factor for refurbishment qualification is that it is good practice to refurbish only* ***equipment that still meets the original standards at time of first placement****. That means used medical equipment that does not meet, or cannot be refurbished to meet, these original standards should neither be refurbished nor utilized any more. The* ***lifetime of medical equipment and serviceability aspects*** *are also key requirements to determine qualification for refurbishment. Medical equipment is designed and manufactured to be used for a planned lifetime. When the healthcare service provider puts the product into service, maintenance procedures defined by the original manufacturer ensure that the intended levels of safety and performance are preserved. The end of planned lifetime is generally reached when original manufacturer service, spare parts and components are no longer available for the product."*

The GRP Green Paper specifies that the most important aspects to be considered in reutilizing used medical equipment are quality, performance, safety and intended use. The document thus describes refurbishment process steps designed to make sure that any system that will be refurbished according to GRP will have the same quality, performance, safety, and intended use - including full warranty and service - as when it was new. These steps regard not only the refurbishment activities but also activities that take place before a device enters the refurbishment pool and after its refurbishment, to enable its being made available on the market. The steps are presented in Table 4-1 below and shortly described thereafter.

[143] Op. cit. COCIR et. al. (2009)

[144] Op. cit. COCIR et. al. (2009)

Table 4-1: GRP Refurbishment Practice Process Steps



Source: COCIR et al. 2009

1. **Selection of used equipment for refurbishment** - Generally, the selection of used equipment is based on the principle that the used system can be refurbished to a system that has the same quality, performance, safety and intended use as when it was new. The equipment is required to fulfil certain criteria such type of equipment; configuration; condition; age, upgradeability and the phase in the life cycle in terms of spare part availability.
2. **Disassembly packaging and shipment** - To avoid any additional risk, the organization that performs refurbishment has to make sure that any system that is to be refurbished will not be damaged during disassembly or shipment. This may include disinfection activities at the place of the disassembly, depending on the kind / type of environment the device was operated in (e.g. emergency room, operating room).
3. **Refurbishment** – this will include a few phases:
    a. *Cleaning and disinfection*; this is to make sure that any system that will be refurbished will bear no risks regarding infection of any person during or after the refurbishment process;
    b. *Refurbishment planning* – The required actions to be undertaken through the refurbishment are planned to ensure that they do not create modification that might impair the original identity and approved configuration of the device, meaning that regulatory implications might arise. The system configuration is defined by the refurbisher or according to a customer order – it must be within the scope of the original product registration from the manufacturer, when the system was originally produced and put on the market for the first time. In any case, the system must keep its original identity (e.g. labelling). Throughout the refurbishing process, the Device History Record (DHR) must be continuously updated. Refurbished equipment that does not comply with the original intended use, specifications, and registration has to be treated like unapproved, unregistered medical equipment. In some countries such significant changes through refurbishment are defined as “fully refurbishing” or “remanufacturing”;
    c. *Cosmetic refurbishment* – Surface treatment and painting are performed as needed, depending on the state if the device;
    d. *Mechanical and electrical refurbishment and system configuration* – this can include replacement of worn parts; actions to avoid violation of

privacy rules concerning patient data stored on medical equipment; performance of planned updates (such as software); customization through options and accessories within the scope of product registration; Updating of DHR to show evidence that the equipment was refurbished according to the specification of the equipment;

e. *System check* - Thorough checking of components and subsystems;

f. *GRP Declaration and release* – When all necessary actions for refurbishment have been successfully completed, the refurbisher releases the equipment, self declares compliance to GRP (GRP-Declaration) and labels the product accordingly (name & place of the organization and date of refurbishment). The GRP-Declaration is handed over to the final customer as a proof for GRP compliance.

g. *Packing and shipment* – process steps for packing and shipment must be identical or equivalent to the process steps for new systems;

4. **Reinstallation of refurbished equipment** – Equipment processed according to GRP is intended to meet original quality, performance and safety standards, hence it is essential to follow original manufacturer installation procedures including site planning and preparation works. A professional installation is to be carried out and to include start-up and repeated check-up of the system's performance, application training, hand-over of required user documentation and GRP Declaration;

5. **Professional services** - A buyer or user of GRP-processed equipment can expect after-sale services and support, identical to what is provided for new systems. Therefore, the refurbisher will ensure that professional services and support are provided in the same way as for a new system. i.e., full necessary support provided over the planned lifetime of the equipment. To this end, the warranty shall be equivalent to a new system, original spare parts will be made available, as well as ensuring that maintenance contracts, application training etc. can be provided.

As mentioned in Section 4.3, it is understood that refurbishment is not practiced at present for all medical devices. However, for certain category sub-groups, refurbishment of second hand equipment prior to resale is quite common.[145] A COCIR member reports that up to 10% of its sales volume for medical imaging equipment is comprised of refurbished equipment. Information collected from EDMA & Eucomed's

[145] It should be noted, that electron microscopes have been shown to have similar operations in place as well as similar problems with compliance with the RoHS Directive. The TOR for his project required a review for medical refurbishment on the context of RoHS. However, as also stated above, it should be noted that the aspects raised in this review are also relevant for electron microscopes falling under sub-category 9 "industrial monitoring and control instruments" and possibly also for other products designed for long life and being low volume – high value products.

Members points out that companies who manufacture and refurbish in-vitro diagnostics (IVD) devices sell between 8-25% refurbished devices[146].

In terms of market shares, at a targeted stakeholder meeting held to collect information for this review, COCIR have mentioned that the general turnover of the medical sector is around 100 Billion € per annum, with around 4 Billion € relevant for imaging devices. Participants emphasized that refurbishment operations of OEMs are often operated as separate business units and that estimating the market share and turnover of the medical sector to those relevant for refurbishment would be misleading in this context. EDMA/EUCOMED mentioned in the earlier discussions that the IVD turnover is around 10.6 Billion. COCIR estimate the turnover of refurbished imaging devices in the EU to be around 100-200 Million € and expected to grow in light of the economic situation.[147] This would represent between 2.5% and 5% of the general medical imaging devices turnover and is relevant only for turnover from refurbished medical imaging devices sold in the EU.

The following points were mentioned by COCIR[148] in an earlier document:

- *"The refurbishment of medical equipment accounted for a global revenue of approximately 480 million euros in 2012. Around 74% of revenues are generated in the U.S. and the EU.*
- *In 2013 refurbished medical equipment worth around 130 million euros was sold in the EU.*
- *39% of all refurbished medical equipment is sold in the EU with Germany accounting for 22% of the EU total. In Germany one of every six installed imaging equipment is a refurbished unit.*
- *The refurbishment market is expected to grow in the coming years due to increased confidence by users in the quality of refurbished equipment and to the budget constraints in healthcare purchasing in the EU. RoHS 2 is therefore going to have a greater impact on the refurbishment market in the coming years.*
- *In 2010, €200 million worth of refurbished medical equipment was sold in the EU and 30 – 50% of these were initially sold to users outside the EU. If those units originally sold outside the EU could not be resold to EU users, there would be a shortage of refurbished equipment to EU hospitals worth up to €100 million".*

EDMA/EUCOMED[149] provide further support for the last point, estimating that the demand for refurbished devices in the EU will likely increase by 5-10% in the next

[146] Op. cit. EDMA & Eucomed (2014a)

[147] Op. cit. Medical Sector (2014)

[148] COCIR (2014b), Impact Assessment of RoHS II on Refurbishment of Medical Equipment Affecting Industry, Environment and EU Patients – Summary, dated 29 April 2014

[149] Op. cit EDMA/EUCOMED (2014a)

year. As the affected products progress through their life cycle and the population ages, the mix of refurbished instruments will increase.

The consultants conclude that on the basis of 39% of refurbished devices being sold in the EU and 30-50% of these initially being sold to users outside the EU, that potentially ~11.7-19.5% of refurbished medical devices sold in the EU may have problems with compliance. In this regard, it should be noted that this is understood to be a worst case estimation, as presumably not all of these products shall exhibit problems with compliance in terms of presence of RoHS substances.

The market for refurbished medical devices is motivated among others by the price of these devices and their ability to allow facilities to provide services at a lower cost. In some cases this allows health facilities to provide a larger capacity of services, at lower costs in comparison to the costs if all devices were bought as new devices. In other cases refurbished devices allow facilities to provide services, which they could otherwise not afford from a budgetary perspective. In this regard EDMA/EUCOMED[150] elaborate that some markets demand the placement of predominantly, if not exclusively, refurbished units, due to price sensitivity. This due to some markets not being able to afford new analysers or larger medical equipment. EDMA/EUCOMED further stated at the stakeholder meeting that purchasers of refurbished medical equipment and instrumentation include health service providers, clinical laboratories and others such as the academic field. Many clinical laboratories, for example, will purchase a new analyser as well as maintain an older model or purchase a refurbished model in order to manage their costs. Laboratories or smaller clinical centres, which need to run a low volume of tests or procedures, would only invest in such second hand equipment. They further mentioned that one manufacturer reports that some markets in Europe rely almost exclusively on refurbished goods to have immediate access to the high quality diagnostics and therapeutic solutions which they otherwise would not have had. [151]

COCIR[152] provide some information as to the cost differences, explaining that refurbished medical systems on average are sold at a 30% lower price as compared to a comparable new system. COCIR further estimate the total difference in cost between refurbished MRI and new MRI sold in the EU annually would be from €4 to 8.5 million.

In an assessment done in 2012 of impacts of Article 2(2) on various product groups, BIOIS wrote that *"The resale value of the older equipment that will be replaced is typically ~10% of the cost of new EEE and hospitals rely on this money for their new equipment budgets."*[153]

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[150] Op. cit EDMA/EUCOMED (2014a)

[151] Op. cit. Medical Sector (2014)

[152] Op. cit. COCIR (2014b)

[153] BIOIS & ERA Technology (2012), Measures to be implemented and additional impact assessment with regard to scope changes, pursuant to the new RoHS Directive – Final Report. Retrieved from: http://rohs.bios.com/documents/RoHS_II_IA_Final Report.pdf

4.7.1 RoHS Compliance

It is understood from stakeholders that the main concern of compliance of refurbished devices and parts with RoHS regards compliance with the substance restrictions. It is subsequently understood that there are two main aspects that need to be clarified to establish the compliance of refurbished devices and/or parts with RoHS. The first aspect concerns the possible **presence of RoHS substances** within refurbished devices and/or parts. The second aspect concerns the respective **documentation of compliance** with the RoHS restrictions.

Potential for Presence of RoHS Substances

Here it is important to make a distinction between two groups:

- RoHS substances that are present in applications for which an exemption is listed in Annex III or IV and valid at the time the device or part is placed on the EU market. For such applications, compliance is achieved in light of the existence of an exemption and the product can be CE-marked. Since the product is compliant when first placed on the market, it can be refurbished and resold without needing to re-comply when re-sold on the market. As explained in Section 4.4.1, refurbished spare-parts have certain limitations in this regard when used in the assembly of new devices or when used to service devices first placed on external markets that are to be made available on the EU market for the first time.
- RoHS substances that are present in applications for which no exemption is available and for which substitutes are already used in new devices and parts. This is understood to be a main focus for this review, as the presence of RoHS substances in these cases is not supported by the Directive and its annexes, making the product non-compliant (i.e. the product is not permitted to be CE-marked).

Identifying applications in which RoHS substances have been phased out over the last 10 years can provide a good basis for understanding where such substances are to be expected, in light of the long time that devices and parts remain in circulation through refurbishment. In 2006, an ERA[154] study prepared for the EU Commission detailed applications in which RoHS substances are used in medical devices, also estimating the respective quantities to be placed on the market per annum. A summary of such applications is provided in Table 4-2 below:

[154] Goodman (2006) Goodman, P., Review of Directive 2002/95/EC (RoHS) categories 8 and 9 – Final Report. ERA Report 2006-0383, July 2006, amended September 2006, http://ec.europa.eu/environment/waste/pdf/era_study_final_report.pdf

Table 4-2: Weight of RoHS Restricted Substances Used in Category 8 Equipment, Including Data for Sub-categories Where Known

	Subcategory					
Substance/ uses	Radio-therapy	Nuclear (PET)	Lab in-vitro	AIMDs	Others types of equipment	Category 8 totals
Lead shielding	43,000	110,000			605,700	758,700
Lead counterweight	9,600	28,000			286,000	323,600
Lead in MCP & CP					1	
Lead X-ray tube bearings					1	
Lead in X-ray test objects					100	
Lead in superconducting connections (MRI)					6,000	
Lead in superconducting connections SQUID detectors					< 0.1	
Lead in refrigerator cold head					100	
Lead in ceramics (ultrasonic transducers)					80	
Lead in single crystal ultrasonic transducers					100 - 200	
Lead in lead stearate X-ray diffraction crystals for X-ray spectroscopy					< 0.001	
Lead in solder to transducers					6	
Lead anode in oxygen sensors					50	
Lead in solder			6,000	800		66,000
Lead PVC stabilisers					500	
Lead in alloys			3,000			
Lead in electrode glass			70			
Cadmium plating					0.5	
Cadmium in switches and contacts						
Cadmium in phosphors					13 - 103	
Cadmium tungstate					630	
Cadmium semiconductor radiation detectors					300 (of Cd)	
Cadmium in superconducting alloys					600	
Copper - cadmium wire					50	
Cadmium pigments					5	
Cadmium stabilisers in cables						Should be zero
Hex Cr in alkali dispensers					1	
Hex Cr passivation						7
Mercury in position switches					1	
Mercury in backlights & other lamps						0.7
Mercury in electrodes			2 - 10			

Source: Goodman (2006)

Regarding this data, the ERA[155] study further explains that the quantities are constantly changing. For example, new restrictions in the USA have resulted in significant reductions in the quantity of mercury used in electric products in the EU as early as 2004, so data for earlier years is already out of date. Many manufacturers

[155] Op. cit. Goodman (2006)

are already using lead-free solders in new models, although not changing designs. This will result in a decrease in the quantity of lead used in Cat. 8 and Cat. 9 products in future years. At the time of the study, EDMA estimated 6 tonnes of lead to be in use in solders in in-vitro diagnostics equipment, with this number expected to decrease to 600 kg regardless of the inclusion of Cat. 8 in RoHS.

It is understood that the medical sector was already working on compliance with RoHS in 2009, requiring possible substitute candidates to be tested and recertified for use in medical devices. As six years have gone by, it can be assumed that at least in some areas further substitutes have been developed and are currently implemented in the manufacture of new products. Nonetheless, RoHS substances are still expected to be present in such applications where devices and parts are refurbished. This is tied to the relatively long planned lifetime of such products. Thus, it is expected that refurbished devices and parts, where RoHS substances are used in applications for which no exemption is in place, could still be circulated for many years if this were to be permitted by the RoHS Directive.

Stakeholders have provided some estimations as to where Annex II substances are currently (December 2014) expected to be found in refurbished medical devices, and for how long they may continue to be found:

- EDMA/Eucomed[156] assume that for the parts that are not compliant [i.e., no exemptions in place for RoHS substance use], the ROHS restricted substances, most likely to be present, are Pb and CrVI. A safe assumption would be that all material could be in circulation until retirement for all affected platforms. Further information was thus provided stating that *"the average lifetime for a new IVD or larger medical equipment is 7 – 15 years. When a device is refurbished, not all parts are replaced. Those that are replaced can be replaced with new parts or recovered used parts. The new parts will be RoHS compliant (at the latest by July 2014/2016 respectively for MD and IVD). But the used parts could be non-compliant. The used parts could remain in the refurbished device another 7-15 years. Regardless of how long a part or instrument could last if repeatedly repaired or refurbished, the use of all platform related material ceases with the platform retirement date."*
- Participants of the targeted stakeholder meeting[157] mentioned that typical RoHS substances are expected in parts of refurbished devices: lead in PCBs, lead in solders; substances in plastics. An OEM refurbisher of imaging devices estimated that for 2014 the average manufacture year of devices entering the refurbished pool is 2005 – devices may be circulated as refurbished devices for 10 years on average and parts probably for longer. Participants agreed that a transition period of 10-15 years may be needed for medical devices and electron microscopes, where parts are robust and have a long planned service life and thus could re-main in circulation for 10-20 years if refurbishment practices are not limited. This period is the average time needed from when a

[156] Op. cit EDMA/EUCOMED (2014a)

[157] Op. cit. Medical Sector (2014)

substance is phased-out of a specific part and until when it is no longer expected to be present in refurbished parts/devices.

- In COCIR's original request application[158] (which resulted in Ex. 31 of Annex IV), a few interesting examples were given:
  - "*Many other parts from medical devices are refurbished and then used as spare parts. These include MRI coils, PCBs from many types of equipment, ultrasound transducers, monitors, grids, collimators, etc. Some of these will contain small amounts of lead, cadmium and hexavalent chromium although mercury, PBB and PBDE are unlikely to be present.*"
  - "*X-ray tube assemblies have to be periodically replaced and so the X-ray tubes with their housing assemblies are returned to the manufacturer who re-uses as many of the constituent parts as possible including the housings, to make new X-ray tube assemblies. New assemblies built from re-used parts are used as replacements for existing X-ray systems and also to construct new systems. Typically, the parts from an X-ray assembly housing can be re-used on average at least five times and as each has an average lifetime of 5 years, they are used for on average at least 25 years before recycling of materials. This period would be very much reduced if RoHS substance restrictions prevented re-use.*"

  It is thus important to note that in some cases, refurbished parts can also be used in the assembly of new devices. Regarding X-ray tube assemblies, it is further mentioned that they may contain Pb, in aluminium/brass/steel alloys which may be used for housing and other parts, as well as in Pb sheet used for radiation shielding. Cr VI may be present in passivation coatings used for small inserts of the housing. COCIR also mention that all medical equipment manufacturers intended to stop using this Cr VI passivation coating processes before 2014.

Difficulties Concerning Documentation of Compliance

Regardless of the actual presence of RoHS substances, stakeholders have explained that one of the problems with actual compliance is tied to the requirement to provide sufficient documentation in declarations of conformity. In their contribution to the stakeholder consultation of Ex. Re. 2013-6, COCIR[159] explain that it is usually

[158] COCIR (2011), Application for new exemption, submitted 29.9.2011, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_2/COCIR_-_Exemption_request2_-_X_ray_and_other_parts_reuse.pdf

[159] COCIR (2014a), Contribution to RoHs Stakeholder Consultation of Ex. 2013-6, submitted 5.2.2014, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/ROHS_Pack5/Request_2013-6/20140205_COCIR_Contribution_to_RoHS_stakeholder_consultation_5Feb2014.pdf

impossible to determine whether used parts contain RoHS restricted substances as the example for reuse of used MRI magnets demonstrates:

- 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.

Participants of the targeted stakeholder meeting[160] also mentioned that some RoHS substances are not expected to be present; however there is a difficulty in obtaining documentation to prove this, especially for older products. For mercury this was said to be less of a problem as California, USA regulations from 2006 have restricted the use of Hg in medical devices, resulting in good documentation of use since 2006 and possibly also in a lower likelihood for this substance to be present in refurbished devices and parts. Documentation is thus also understood to be less of a problem for new products and parts than for old – an aspect that should be considered in relation to the ease of documentation, should new substances be restricted.

Regardless of the actual presence of RoHS substances, it can be followed that where proper documentation is not available, devices (or parts) could be rendered non-compliant in light of failure to establish a suitable declaration of conformity.

4.8 Results from the Public Consultation

A public consultation was not held for this review in light of the short period provided for the review. Information was collected through direct correspondence and through the targeted stakeholder meeting. Among others, information was provided by COCIR, EDMA/EUCOMED, Siemens Healthcare, PHILIPS Healthcare and FEI. Furthermore, documents and data collected in the past through the evaluations of the two earlier requests were also used a source of information.

4.9 Analysis of Impacts

The baseline of this assessment is the RoHS Directive which entered into force on 21.7.2011, before the addition of Ex. 31 to Annex IV, according to which, only some

[160] Op. cit. Medical Sector (2014)

refurbished articles could be made available on the EU market without needing to re-comply with the Article 4(1) substance restrictions. Analysis of impacts shall only regard the differences between this Baseline scenario (Option 1) and between the Exemption 31 scenario (Option 2) and the Exclusion 4(7) scenario (Option 3). Furthermore, estimations shall refer to refurbished medical devices and parts, that will need to re-comply with the RoHS substance restrictions at the time resold on the EU market, as such articles are understood to be the source for possible impacts in the various scenarios.

4.9.1 Impact Indicators

To clarify if an exclusion from the scope of RoHS or if exemptions would be justified on the basis of expected impacts, the analysis of the three options, must demonstrate that the benefits expected from the implementation of each scenario would be similar or larger than possible costs therefor. The overarching objective of the Directive is to contribute *"to the protection of human health and the environment…"*. This would require that costs and benefits relevant for the environment, for the economy and for society would be reviewed. On this basis, the impact indicators shown in Table 4-3 have been chosen as relevant in this context.

Table 4-3: Impact Indicators for the Refurbished Medical Devices and Parts

Environmental indicators	Economic indicators	Social indicators
Impacts tied to use of RoHS substances	Impacts on manufacturers of new devices	Impacts on employment of manufacturers of new devices
Impacts tied to emissions of RoHS substances (focus on end-of-life)	Impacts on operators of refurbishment facilities	Impacts on employment of refurbishers of new devices
Impacts tied to use of Renewable and non-renewable resources	Possible distortions of internal market – focus on differences in impacts on OEM refurbishment and 3rd party refurbishment	Impacts on employment at medical facilities
Impacts on energy consumption	Possible changes to market structure (including wider impact on trade with non-EU countries) – mainly shift from global to regional refurbishment logistics	Impacts on health of patients (consumers of medical services)
	Administration costs for public authorities (market surveillance, health service budgets, RoHS exemptions)	Impacts on health of patients
	Impacts on consumers (medical service facilities) shift away from refurbished devices – impacts on product portfolio (age, diversity and range of services) and budget.	

4.9.2 Environmental Impacts

It is understood that new medical devices are by now compliant with the RoHS substance restrictions, either through the use of substitutes for RoHS substances used in the past **or** through exemptions existing in Annexes III and IV, allowing further use of RoHS substances where substitution is not yet possible. With time it is expected that substitutes shall become available for additional applications and that some of the exemptions used today for establishing compliance shall become invalid. That said, it should be noted that it is unclear how fast this process is to phase out further RoHS substances in light of the small amount of RoHS substances that have been removed from new devices. COCIR[161] have pointed out results of an analysis which show that RoHS by now only achieved removal of < 5% by weight of the content of the six substances, and that the remaining 95% is still present in light of existing exemptions (mainly lead for radiation protection).

As explained above, it is understood that only certain refurbished items are expected to have a problem with compliance. This regards:

- Refurbished devices first placed on an external market, which are to be made available on the EU market;
- Refurbished parts first placed on an external market, which are to be made available on the EU market (economic transaction, i.e., sale of spare parts to repair operations and/or to 3rd party refurbishers);
- Refurbished parts first placed on an EU market, which are to be used for assembling new devices or for repair of refurbished devices first placed on external markets which would otherwise comply with the RoHS substance restrictions at time of re-sale.

In such items, phase-out is expected to occur in applications for which substitution has been implemented in new devices and parts, however as these items may remain in circulation for an average of 10 to 15 years (with some circulating even longer), this phase-out shall be delayed in relation to the phase out in new items. Furthermore, as progress of phase-out in new items is said at present to be developing slowly in the medical sector, related environmental benefits would be expected to occur slowly and over a long period of time. As mentioned in Section 4.7.1, the average time needed from when a substance is phased-out of a specific part and until when it is no longer expected to be present in refurbished medical parts/devices could be 10-15 years in light of the robustness and long-life of products. In the past, the ERA study[162] had estimated that 21,000-46,000 tonnes of medical devices are placed on the EU market per year, estimating the following quantities of RoHS substances are thus placed on the market: 1060 tonnes of Pb; 1.8 tonnes Cd; 12 kg Hg; less than 0.3-0.8 tonnes of Cr VI (estimated for both Cat.

[161] Op. cit. Medical Sector (2014)

[162] See Presentation of study under http://ec.europa.eu/environment/waste/weee/pdf/era_presentation.pdf

and Cat. 9) and less than 10 tonnes of PBB and PBDE (estimated for both Cat. and Cat. 9).

If indeed replacements have been implemented for < 5 % (weight) of RoHS substances used in the past, the average time that a medical device may remain in service when refurbished and resold would be a basis for understanding the expected phase-out of these substances from medical devices. Based on the estimations of stakeholders that devices remain in service between 10-15 years, when refurbishment allows fulfilling the planned lifetime, the following amounts of RoHS substances could phase out of refurbished items over a period of 10-15 years if such items are not limited in terms of secondary market operations: 53 tonnes of Pb; 0.09 tonnes Cd; 0.6 kg Hg; less than 0.015-0.04 tonnes of Cr VI and less than 0.5 tonnes of PBB and PBDE.

If secondary market operations of refurbished items with compliance problems are to be limited, as in Option 1, the respective amounts of RoHS substances would be removed from the EU market immediately. In some cases devices and parts could be recirculated as this is allowed where the device was first placed on the EU market. Thus the amounts to be phased-out are expected to be smaller than the above numbers. However in parallel, for some devices this would either result in a shift of RoHS substances from the EU market to external markets (export of non-compliant refurbished items) or in products being scrapped earlier. If new devices would need to be manufactured to partially replace refurbished ones in medical facilities, this would further mean that additional resources and energy would need to be consumed.

In the following areas, impacts as a result of the three policy options are shortly discussed:

- Impacts tied to use of RoHS substances: The use of substances in refurbished devices and parts is related to the use at the time the product was manufactured. This use cannot be avoided regardless of which refurbished parts can circulate on the EU market and which cannot. In parallel, where refurbished items cannot be circulated and need to be removed (exported or sent to waste), this will result in the manufacture of new devices and parts to replace refurbished ones. As long as exemptions are still available in the annexes, the use of RoHS substances in such manufacture will also be unavoidable, even if the amounts shall slowly decrease over time where effective substitutes become available.
- Impacts tied to emissions of RoHS substances (focus on end-of-life): As the use of RoHS substances in manufacture shall not change in refurbished items, emissions associated with manufacture shall remain the same in all scenarios. Emissions associated with the other life-cycle phases could be distributed differently in time (if articles reach end-of-life early this could reduce emissions during use as the use phase is shortened, while emissions at end-of-life shall occur earlier) or they could be distributed differently geographically (if articles are exported, possible emissions shall occur elsewhere, with the range of end-of-life emissions depending on the nature of treatment [whether recycling or disposal] as well as on the quality of facilities; emissions in some cases may be expected to increase). Substances to be used in manufacture of replacement devices and parts shall exhibit emissions similarly, as new

substitutes become available, creating problems with items when they reach the refurbishment phase in cases where exemptions have expired. Nonetheless, impacts shall be small, in light of the slow phase-out pace of RoHS substances from Cat. 8.

- **Impacts on renewable and non-renewable resources**: Restriction of secondary market operations of refurbished items could result in early end-of-life of such items or in their export. The BIOIS[163] assessment explains "*One stakeholder has pointed out the large quantity of uncommon strategic materials that are in medical equipment. If refurbished equipment could not be re-used in the EU after July 2019, it will either be exported to users outside the EU or be recycled. There is an incentive that the equipment reaches its end-of-life in the EU so that it is recycled in the EU. The large weight of medical equipment such as MRI, CT and X-ray systems is a disincentive to export it outside the EU for recycling. A study by one manufacturer has shown that 94% of the weight of medical equipment can be either recycled (64%) or refurbished for second users (30%) so only 6% is land-filled. Another study found that large quantities of scarce materials are used and for one EU-based manufacturer in one year, this includes: 9 tonnes of niobium titanium superconductor, 61 tonnes copper, 57 tonnes stainless steel, 254 tonnes of aluminium alloys and 41 tonnes of neodymium iron boron magnets*." Though the successful recycling of materials can be seen as a benefit, this benefit is one that would occur anyway at end-of-life, and possibly with a larger range, as recycling processes develop. Nonetheless such differences in impacts would probably be very small and possibly negligible. Thus the different distribution of environmental benefits over time is not necessarily a net benefit as potential for benefits in the future is the same or larger. If items are exported, this would result in a geographical shift of impacts, including impacts related to end-of-life, such as those connected to recyclable materials (though also those connected to emissions mentioned above). In parallel, manufacture of new devices to replace refurbished ones shall use a large amount of resources which would otherwise be used at a later time. As this process would mean that the same resources needed for manufacture remain in use for a shorter period, it is to be understood as a negative impact in terms of resource use and probably a significant one in light of the weight of refurbished medical devices such as imaging devices.
- **Impacts on energy consumption** – COCIR[164] claim that "*the refurbishment of medical equipment saves energy and resources by extending the lifetime of products that would otherwise be substituted with new ones. COCIR estimated that around 30 MWh can be saved for each ton of refurbished medical equipment, further specifying that between 2010 and 2012 more than 3600 tons of CT and MRI were refurbished (waste reduction) accounting for a saving of 97 GWh of energy*". The report does not explain how these sums were

[163] Op. cit. BIOIS 2012)

[164] Op. cit. COCIR (2014b)

calculated. However, it can be followed that extension of the lifetime of a product will mean that energy consumption tied to manufacture and recycling is related to a longer product life, assumed as a significant benefit. In contrast new devices may be more efficient in terms of use of energy during the use-phase of the equipment, in comparison with older ones, casting a shadow upon benefits related to the other life-cycle phases. Thus benefits related to longer circulation of refurbished products are expected but their significance could differ due to the difference in energy consumption of devices of different ages.

To conclude, in terms of environmental impacts, both policy options 2 and 3, in which refurbished terms enjoy unlimited circulation on the EU market, show benefits in relation with Option 1.

4.9.3 Economic Impacts

As explained in the previous sections, restrictions to the circulation of refurbished products shall only apply to certain types of equipment. However, depending on the range of devices and parts that are denied EU market access this may have significant impacts related to the decrease in refurbishment operations, probably leading to loss of business and in some cases to close of certain facilities.

The various economic impact indicators have been analysed against this background:

- **Impacts on manufacturers of new devices:** Where new devices need to be manufactured to replace refurbished ones, manufacturers could increase volume of production, leading to benefits. The range of such benefits would depend on the range of refurbished devices affected, with the worst case being that refurbishment operations need to close if compliant activity does not justify such facilities from an economic perspective. Changes to the circulation of refurbished products shall not affect the use of RoHS substances directly, as it shall not impact the progress of finding and using substitutes in exempted applications (i.e. R&D also not expected to be affected). However if a significant amount of devices cannot be refurbished, such devices may reach end-of-life early (or be exported) requiring increased manufacture of replacement devices and parts. In this respect, impacts of limited refurbishment on the manufacture of new devices are expected to be positive differing in range according to how many devices are replaced and after what part of their planned lifetime.
- **Impacts on operators of refurbishment facilities:** On the background of the explanations provided above, it can be estimated that refurbishers (both 3rd party and OEMs[165]) could have significant costs related to loss of business and in some cases closing of facilities. Once phase-out of RoHS substitutes stabilizes (available exemptions remain unchanged), the range of such costs shall decrease until either phase-out is completed in refurbished devices or

[165] It should be noted here that OEM refurbishment is usually run as a separate business.

new substance restrictions are added to Annex II, meaning that the phase-out process begins anew for certain products.

- **Possible distortions of internal market (focus on differences in impacts on OEM refurbishment and 3rd party refurbishment**): Though OEM refurbishers and 3rd party refurbishers are assumed to have the same restrictions to circulation of refurbished items, these could affect 3rd party refurbishers more heavily, as OEM refurbishers shall have easier access to information regarding the documentation of RoHS compliance. As time goes by, OEM refurbishers shall improve in terms of available information concerning presence of RoHS substances, as use of RoHS substances in newer devices is already documented more carefully. In contrast, 3rd party refurbishers are expected to have similar problems in access to information, which is often considered at least in part proprietary.
- **Possible changes to market structure (including wider impact on trade with non-EU countries):** If circulation of refurbished devices is to be limited, this shall mainly affect the possibility:
    - of using refurbished parts for repairing devices to be re-sold on the EU market first placed on external markets;
    - of using refurbished parts for assembly of new devices (placed on the market after category needs to comply with substance restrictions; and
    - of reselling refurbished devices on the EU, which were first placed on external markets.

  Such refurbished items shall be denied access to the EU market but could still be exported for use in external markets. This is expected to lead to a surplus of refurbished items in external markets (possibly lowering their prices on such markets at the risk of economic feasibility of refurbishers), parallel to a lack of sufficient supply in the EU, which is currently a key market for such items (subsequently resulting in additional impacts on consumers / health service facilities / public health etc., as detailed below). This may also require logistic changes to the structure of refurbishment operations, either in tracking and distributing refurbished items or in creating separate facilities to avoid "contamination" between RoHS compliant and non-compliant devices and parts. One could argue that this may stimulate an EU specific refurbishment business, however it is difficult to say if this would result in a net benefit or not. Though additional operations could have a positive impact on employment, the establishment of such facilities shall also require investments and decreasing the scale of facilities may also have a negative impact on economic feasibility. Furthermore, stakeholders (COCIR 2014b) estimate that between 30-50% of refurbished devices sold in the EU were initially sold outside the EU. It is thus understood that a separation is likely to result in insufficient supply of refurbished articles in the EU market as well as a surplus in non-EU markets where the sale of refurbished devices is not yet as developed.
- **Administration costs**: Administration costs for public authorities are expected to be significant where market surveillance needs to enforce restrictions on refurbished items (limited market access) as well as to check compliance of

refurbished items with exemptions that could change from time to time. Costs are also expected where exemptions need to be reviewed for renewal from time to time, in light of the involvement of Member States in the process of granting exemptions. Where exemptions create administration costs, such costs would be expected to be lower, assuming that an exemption is aligned for all product groups regarding duration, since exemptions then only need to be reviewed every seven years, whereas market surveillance of restricted items is constant. Administration costs for industry are expected in terms of costs for maintaining documentation of compliance with substance restrictions (where substances with lacking documentation are not exempted/excluded for use) as well as costs for dealing with exemption requests where this is relevant.

- **Impacts on consumers:** Here impacts are mainly expected in terms of possible changes to product portfolio, i.e. changes in availability of devices and services in use. Such impacts shall be a consequence of a limited budget for purchasing medical devices, which shall be burdened more heavily if only new devices are available (or a limited variety of refurbished ones).

To conclude, in terms of economic impacts, both policy options 2 and 3, in which refurbished terms enjoy unlimited circulation on the EU market, show benefits in relation with Option 1. Though manufacturers may have a small positive impact in Option 1 where the limitations to the circulation of refurbished products creates an increase in manufacture of new devices, for all other indicators, benefits are expected to be higher in both Options 2 and 3.

4.9.4 Social Impacts

Concerning social impacts, it is assumed that both impacts on employment and impacts on consumers would be sensitive to limitations on secondary market operations of refurbished items on the EU market.

The social indicators are thus analysed as follows:

- **Impacts on employment:** With regards to employment it is worth noting that COCIR[166] explain that *"most category 8 and 9 manufacturers have only one refurbishment centre for each type of product…"*. It is also understood that manufacture (including assembly of supplied parts) of a certain device or of certain models shall also be performed at a single location. It should further be kept in mind that refurbishment operations of OEMs are often managed as a separate business, with 3rd party refurbishers also depending on the ability to refurbish devices. If refurbishment activities are to decrease, this may have a negative impact on employment, with its range depending on how many refurbished items are denied access to the EU market. One could argue that limited access to the EU for refurbished items would mean that more items are

[166] Op. cit. COCIR (2014a)

available for refurbishment and sale in non-EU countries, causing an increase in employment opportunities outside the EU. However to begin with, the location of operations is not limited by RoHS, which only limits the sales, and facilities would not necessarily be expected to move to other countries. Though the origin and the destiny of devices may influence the location of a facility, it is understood that both transaction types shall in any case be distributed over the world and would not necessarily change enough to impact location, if Option 1 were to limit the resale of refurbished items. In contrast it has been communicated by a key manufacturer of imaging devices that the location of suppliers and manufacturers of components can be of relevance to locating a refurbishment facility[167]. As these are not expected to change in the various options, the main impact on employment is expected to be related to the volume of refurbishment. Since at present, the EU is the most significant market for refurbished equipment (39%), limiting sale of such equipment to this market could flood external markets with refurbished items, possibly resulting in a decrease in market prices. If prices are to go down significantly, this would have an impact on feasibility of refurbishment operations from an economic point of view possibly leading to the closing of some of facilities. Impacts on employment in facilities manufacturing new devices shall either be non-existent (no change to the range of refurbishment) or small (manufacture of new devices to replace refurbished ones). As for impacts on employment at medical facilities, restrictions on the circulation of refurbished devices shall raise costs for facilities in light of the limited supply of refurbished (and cheaper) devices on the EU market. In some facilities, this will result in the use of older devices and in some in the provision of fewer devices, i.e., fewer services. It is difficult to say how this would impact employment in the medical sector. Fewer devices could mean less employment for servicing devices (e.g. medical imaging technicians). However, if this is to have medical impacts on patients in light of larger waiting times or impacts on the exactness of diagnostics, this could also create additional employment for administration and/or nursing. As newer devices may be more automated, the longer use of older devices may also require more servicing employees in some cases.

- **Impacts on health of patients (consumers of medical services)** – BIOIS[168] explain that "*The result of including category 8 in scope of RoHS is that there would be less refurbished equipment available after 21 July 2014 because of hospital's budgetary constraint that prevents them from buying more expensive new equipment. Many hospitals that would have bought a refurbished system will either have to wait longer to acquire one until one originally placed on the EU market becomes available or they will have to buy new instead. This could either prevent purchase of other equipment or delay*

[167] It was explained that during refurbishment, some operations would be carried out by the original supplier, for example aesthetic „touch-ups" of casings. As equipment can be heavy, location of suppliers and manufacturers of components can be an important factor in locating a refurbishment facility.

[168] Op. cit. BIOIS (2012)

purchase of equipment until sufficient funds are available for a new unit. Overall, this will result in the average age of medical equipment becoming older as equipment replacement is delayed. It is known that the performance of old equipment for diagnosis accuracy and treatment success is inferior to newer machines although it is not possible to quantify this as there are many variables that influence medical treatment. Old equipment also tends to be less reliable and so there will be delays to treatment when breakdowns occur and this can have serious implications." This can be followed, and it is thus concluded that patients shall likely have negative impacts where access to health services decrease, though it is difficult to estimate the range of such effects. A negligible to small impact is assumed to be a conservative estimation.

To conclude, in terms of social impacts, both policy Options 2 and 3, in which refurbished items enjoy unlimited circulation on the EU market, are expected to have benefits in relation with Option 1.

4.10 Summarised Comparison of Options

The results of the assessment of the various identified indicators relevant to environmental, economic and social impacts are summarised in Table 4-4.

Table 4-4: Comparison of Options – Range of Impacts in Relation to Option 1 (Business as Usual)

Impact indicators	Option 1: Business as usual – certain refurbished items denied market access	Option 2: Exemption 31 – refurbished items can be circulated	Option 3: Exclusion 4(7) - refurbished items can be circulated
Environmental Indicators			
Impacts tied to use of RoHS substances	=	+	+
Impacts tied to emissions of RoHS substances (focus on end-of-life)	=	+	+
Impacts tied to use of Renewable and non-renewable resources	=	++	++
Impacts on energy consumption	=	=/+	=/+
Total Environmental Impacts	**=**	**Between + and ++**	**Between + and ++**
Economic Indicators			
Impacts on manufacturers of new devices	=	-	-
Impacts on operators of refurbishment facilities	=	++ / +++	++ / +++
Possible distortions of internal market	=	+ / ++	+ / ++

Impact indicators		Option 1: Business as usual – certain refurbished items denied market access	Option 2: Exemption 31 – refurbished items can be circulated	Option 3: Exclusion 4(7) - refurbished items can be circulated
(focus on differences in impacts on OEM refurbishment and 3rd party refurbishment)			Impacts on 3rd party refurbishers to increase with time in comparison with Option 1	Impacts on 3rd party refurbishers to increase with time in comparison with Option 1
Possible changes to market structure (including wider impact on trade with non-EU countries) – mainly shift from global to regional refurbishment logistics		=	++ (impacts related to logistic changes of refurbishment operations	++ (impacts related to logistic changes of refurbishment operations
Administration costs	Administration costs for public authorities (market surveillance, health service budgets, RoHS exemptions)	=	+	++
	Administration costs for industry	=	+	++
Impacts on consumers (medical service facilities) shift away from refurbished devices – impacts on product portfolio (age, diversity and range of services) and budget.		=	+	+
Total Economic Impacts		**=**	**+**	**++**
Social Indicators				
Impacts on employment of manufacturers of new devices		=	-	-
Impacts on employment of refurbishers of new devices		=	+/++/+++	+/++/+++
Impacts on employment at medical facilities		=	-/+	-/+
Impacts on health of patients (consumers of medical services)		=	=/+	=/+
Total Social Impacts		**=**	**Between - and +++**	**Between - and +++**

Annotation Used

+++	Substantial positive effect
++	Positive effect
+	Slight positive effect
=	No effect

Impact indicators	Option 1: Business as usual – certain refurbished items denied market access	Option 2: Exemption 31 – refurbished items can be circulated	Option 3: Exclusion 4(7) - refurbished items can be circulated
- Slight negative effect -- Negative effect --- Substantial negative effect ? Unknown effect			

In relation to the overall policy objective of RoHS 2, namely *"to contribute to the protection of human health and the environment, including the environmentally sound recovery and disposal of waste EEE"*[169], the discussion above shows that including restriction of refurbished devices and parts by RoHS 2 are not expected to contribute to this objective. In general, the Business as Usual is only expected to have benefits in terms of impacts on manufacturers of new devices and parts as well as impacts related to employment at such facilities. The two other options show similar costs and benefits, with the Exclusion 4(7) Option, showing slightly higher benefits where administrative costs of regulation authorities and industry are concerned.

4.11 Recommendation

Based on this assessment, it is recommended to resolve issues of the medical sector through exclusion of refurbished devices and parts from the scope of the directive via a new Article 4(7) to incorporate the general intention of the current Ex. 31.

Although these issues could be resolved through exemptions, this would create uncertainty as well administrative costs for both public and private (commercial) administration without an expected difference in environmental impacts (i.e., additional environmental benefits) that could set-off such costs. In comparison, resolving these issues through an Article 4(7) exclusion would reduce such efforts and costs.

It should also be noted that Ex. 31 in its current formulation does not resolve the problems of the medical sector, as it refers to the market, which in the context of RoHS is the Union market. Thus the exemption does not allow for the resale of refurbished equipment in the EU market, which was not placed on the market before July 2014 for medical devices and before July 2016 for IVD medical devices. Furthermore, this exemption formulation only allows the presence of Pb, Cd and Cr VI in reused spare parts. This means that where documentation is lacking to prove that other RoHS substances are not present, resale on the EU market shall be forbidden as well. Though the formulation of this exemption is being discussed as a result of the evaluation of Ex. Re. 2013-6, it is not yet known if an amended formulation is to be granted, providing a temporary solution to bridge the time needed for approving an exclusion.

[169] 2011/65/EU, Article 1

Without a temporary solution (i.e. a time limited exemption) significant negative impacts could be expected to the various players, in light of the restrictions to apply to refurbished devices and parts until an amendment of Article 4 comes into force. For IVD devices, which shall only need to comply with the substance restrictions in July 2016, such impacts may be smaller in comparison with other medical devices in scope such as imaging devices. However, as long as there is uncertainty, as to if an exclusion is to be granted, this could affect the scale of existing refurbishment operations as well as the potential development of such operations for additional medical devices. As refurbishment operations are understood to provide environmental benefits in light of the extended use of devices, this would not be beneficial. The provision of a temporary exemption shall also allow learning as to the suitability of a specific wording formulation for exempting the existing operations for which it is meant. As the current experience with Ex. 31 already shows that arriving at the optimal wording formulation could be complicated and require time, this is also understood to have a benefit, both for industry and for regulators who need to enforce the exemption. The following wording which is being discussed as an amendment for Ex. 31 is recommended as a starting point, whereas it would also be recommended to discuss this formulation and its suitability again as part of the process of approving an exclusion:

Exemption	Duration
Lead, cadmium, hexavalent chromium, and polybrominated diphenyl ethers (PBDE) in spare parts recovered from and used for the repair or refurbishment of medical devices, including in vitro diagnostic medical devices, or electron microscopes and their accessories, provided that the reuse takes place in auditable closed-loop business-to-business return systems and that each reuse of parts is notified to the customer. Expires on:	Expires on i. 21 July 2021 for the use in medical devices other than in-vitro diagnostic medical devices; ii. 21 July 2023 for the use in in-vitro diagnostic medical devices; iii. 21 July 2024 for the use in electron microscopes and their accessories.

It should further be noted that the recommended solution may also be relevant for electron-microscopes, for which it has been confirmed that there are many similarities in the devices and the aspects of their refurbishment.

Though additional product groups may also be of relevance, information as to the existence of such operations has not been made available by stakeholders. Without an in depth review of such operations and the environmental, economic and social aspects related to their continuation, concluding as to the relevance of an exemption/exclusion from RoHS for such products would not be recommended.

4.12 References

BIOIS & ERA (2012)	BIOIS & ERA Technology (2012), Measures to be implemented and additional impact assessment with regard to scope changes, pursuant to the new RoHS Directive – Final Report. Retrieved from: http://rohs.biois.com/documents/RoHS_II_IA_Final Report.pdf
COCIR et. al. (2009)	COCIR, JIRA, MITA (2009), Green Paper on Good Refurbishment Practice (GRP) for Medical Imaging Equipment.
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COCIR (2014b)	COCIR (2014b), Impact Assessment of RoHS II on Refurbishment of Medical Equipment Affecting Industry, Environment and EU Patients – Summary, dated 29 April 2014
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EU COM (2012)	European Commission (2012) , RoHS FAQ Document, last updated 12.12.2012, last accessed 10.12.2014, available under http://ec.europa.eu/environment//waste/rohs_eee/pdf/faq.pdf
Goodman (2006)	Goodman, P. (2006), Review of Directive 2002/95/EC (RoHS) categories 8 and 9 – Final Report. ERA Report 2006-0383, July 2006, amended September 2006, http://ec.europa.eu/environment/waste/pdf/era_study_final_report.pdf
Medical Sector (2014)	Medical Sector (2014)Protocol of Targeted Stakeholder Meeting concerning Medical refurbishment in the context of RoHS, held in Brussels, Belgium, on 27 November 2014

A.2.0 Appendix 2: Questionnaire Concerning Impacts on Refurbishment - Technical and Socio-economic Considerations Concerning Refurbishment Practices in the Context of RoHS

Questionnaire Concerning Impacts on Refurbishment

Technical and socio-economic considerations concerning refurbishment practices in the context of RoHS

Background

Directive 2011/65/EU (RoHS 2) restricts the use of certain hazardous substances in electrical and electronic equipment .The scope RoHS 2 is stipulated in Article 2 of the legal text, in short stating that the "*Directive shall… apply to EEE falling within the categories set out in Annex I*.

Recently stakeholders have notified the European Commission (EU COM) that a number of problems were identified in this regard, which should be analysed in depth. The EU COM has thus launched a study with the purpose of assessing economic, social and environmental impacts of various scope related provisions as well as the need for clarifications or for a legal amendment in accordance with the Commission's right of legislative initiative.

Refurbishment operations in the medical sector have been identified in this regard. An important part of the EEE business is refurbishment. Expensive hi-tech equipment such as larger medical devices will rather be refurbished than recycled. According to new stakeholder input, the material flows in this sector have changed over the past few years. More and more refurbished (i.e. new) products are sold (placed on the market) in Europe, and more and more old ("non-compliant") products from outside Europe that had not been placed on the EU market before enter the refurbishment facilities in the EU.

Article 4(5) of the Directive exempts certain spare parts from the need to comply with the substance restriction: "*Paragraph 1 shall not apply to* ***reused spare parts****, recovered from EEE placed on the market before 1 July 2006 and used in equipment placed on the market before 1 July 2016, provided that reuse takes place in auditable closed-loop business-to-business return systems, and that the reuse of parts is notified to the consumer*." Refurbishment practices are understood to be partially addressed in this article, though the dates of applicability would not allow for

the medical sector to benefit from this paragraph. None the less, this section was one of the Directive entries, supporting past interpretations that refurbishment practices were understood to be beneficial from an environmental perspective by the European Parliament at the time of the recasting of RoHS. This is further supported by Item 20 at the beginning of the legal text, stipulating "As product reuse, refurbishment and extension of lifetime are beneficial, spare parts need to be available".

Though it can be understood from these articles that refurbishment is common practice in some sub-sectors of the EEE industry, recent inquiries made by representatives of categories 8 (medical devices) and 9 (monitoring and control instruments) suggest that such practices are at present implemented only for some product groups:

Refurbishment practices of the medical sector have been raised in the past in the context of requests for exemptions and have resulted in the addition of Exemption 31 in Annex IV of RoHs 2[176].

A further request was made by a manufacturer of electron microscopes (Sub-Cat. 9 industrial) in 2013, for which an evaluation completed in October 2010[177].

The Oeko-Institut has been appointed within a framework contract[178] to provide the European Commission with further input aimed at substantiating:

- the share of products affected;
- The categories (or sub-categories where these practices exist and where they are expected to develop;
- their manufacturers' (or refurbishment operator's) technical or procedural problems with RoHS compliance;
- where in the product and in the supply chain the problems can be located and tackled;
- what remedies might help solve such problems;

The objective of this questionnaire and the review process is to collect and to evaluate information and evidence relevant for establishing the various environmental, the economical and the social impacts that different policy options

[176] See Amendment under: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014L0015&from=EN

[177] See final report under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/ROHS_Pack5/201410_RoHS_Ex_Pack5_Final_Report_final.pdf

[178] Contract is implemented through Framework Contract No. ENV.C.2/FRA/2011/0020 led by Eunomia

may result in. Additionally, information clarifying the application of RoHS regulated substances (see Annex II of Directive 2011/65/EU[179]) and the technical aspects of their substitution in this product category are also of interest.

The following questions have been formulated to gather more information on "*refurbishment practices*" which are understood to fall in the scope of the RoHS Directive, as well as information concerning the *refurbishment operators and their* supply chain and "consumers", regarding possible impacts that they may have in relation with the RoHS Directive. Input provided in this regard shall be used to review if the impacts of possible scenarios for addressing such practices in the RoHS Directive.

We are thus approaching your organisation in request of information of relevance in this regard and shall appreciate if you could answer the following questions. Please be aware that some of the questions may refer to specific aspects or sub-product groups. Please clarify if certain aspects are of less relevance for your type of organisation/products.

Questions:

1. Scope of refurbishment practices

Please specify product groups of relevance for your organisation for which refurbishment practices exist. Please also refer to:

i. The RoHS Annex I category of relevance;
ii. Logistic aspects of refurbishing (i.e. do facilities refurbish and remarket products only within the EU or on a global scale);
iii. The relevance of cases in which similar products are impacted differently by the Directive where refurbishment is concerned (i.e., with some products in scope and others of similar design excluded from scope or falling in different categories such as in the case of medical and veterinary devices);
iv. Please estimate how long parts recovered from such products could continue to circulate through refurbishment practices in terms of expected functional service life;

[179] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011L0065:EN:NOT.

2. Market share of refurbished products

To allow quantification of impacts of various scenarios, it shall be important to understand the range of market share of refurbished products from the total sales relevant to a specific product group. In this respect:

i. Please provide information as to the general sales volume of example product groups of relevance;
ii. Please provide information as to the market shares of new products and refurbished products from the sales volumes mentioned above;
iii. If possible please provide forecasted trends for the next 10 years:
iv. Please indicate in your answers what information (or market share) is relevant for the EU and what is relevant for the global market;

3. Compliance of refurbished items with RoHS

The RoHS Directive restricts the use of certain hazardous substances in EEE that is to be marketed on the European market (2011/65/EU, Annex II). Annex II specifies maximum concentration values of the different hazardous materials that are tolerated by weight in homogeneous materials Currently the following substances listed in Annex II are restricted above a maximum concentration values (%/weight): lead (0,1 %); mercury (0,1 %); cadmium (0,01 %); hexavalent chromium (0,1 %); polybrominated biphenyls (PBB) (0,1 %); polybrominated diphenyl ethers (PBDE) (0,1 %).

i. Please specify what substances may be present above the maximum concentration levels specified an Annex II to the Directive in product groups for which refurbishment is practices;
ii. As refurbishment allows older products (or parts therefor) to remain in circulation, please estimate how long substances are expected to remain in circulation through refurbishment practices (i.e., once substitution is implemented in new products how long shall substances still be circulated);

4. Possible scenarios to address refurbishment under RoHS

As described above, at present refurbishment practices are addressed in part through Article 4(5) and in part through Annex IV Exemption 31. The following scenarios are under investigation as a means for addressing refurbishment practices under RoHS in the future:

- The **2011 scenario**: Refurbishment shall only be allowed in line with the current formulation of Article 4(5) – i.e. exemptions for refurbishment practices in products not covered under this article shall not be available;[180]
- The **exemption scenario**: Refurbishment to be covered through temporary exemptions that shall need to be renewed from time to time according to necessity for various product categories or product groups;
- The **long-term scenario**: Refurbishment to be covered through an amendment of the RoHS legal text (for example through addition of a new item to Article 4), allowing refurbishment practices for certain product categories and/or product groups;

i. Please indicate what scenario could cover the needs of products relevant for your organisation in terms of refurbishment;
ii. Please propose a formulation for the preferred scenario which covers aspects of importance for the refurbishment practice of your organisation (its members). Please clarify how various terms within this formulation are understood/defined (please also see questions regarding "Terms and Definitions of Importance in this regard);
iii. Please specify aspects of relevance in the respective refurbishment practices that could be incorporated into a possible scenario and explain their importance, for example:
    1. Relevance of product category or product group;
    2. Relevance of global operations and EU operations;
    3. Relevance of presence of RoHS substances / RoHS compliance (i.e., CE marking of products placed on the market in the past);
    4. Additional aspects;
iv. Please detail what consequences the various scenarios may have for your organisation (it's members) in terms of:
    1. Economic impacts: costs and benefits among others for:
        a. Manufacturers (including SMEs where relevant);
        b. the supply chain(including SMEs where relevant);
        c. impacts on competition (also concerning non-European manufactures);
        d. impacts on consumers (commercial and/or private);
    2. Environmental impacts: among others costs and benefits related to:
        a. Phase-out of RoHS substances;

[180] Please note that it is not anticipated that such a scenario be approved in light of the COM's decisions in this regard in the past, however the scenario is investigated as a base line for comparing costs and benefits related to other alternatives.

b. Impacts on end-of-life

3. Social impacts:
   a. Impacts on health;
   b. Impacts on employment;
   c. Impacts on consumers;

5. Terms and definitions of importance

How certain terms are understood by various players shall have an important role in how the formulation of an exemption or of an adaptation of the RoHS legal text is to be interpreted and applied by various stakeholders. In reviews related to refurbishment that have been performed in the context of the RoHS Directive so far, a number of terms have been identified, for which definitions are lacking or do not provide sufficient clarity for stakeholders as to what is covered by the term and what is not.

i. Please detail how, or on the basis of what legal documents or standards, your organisation understands the following terms and what their relevance is to the possible scenarios for addressing refurbishment under RoHS:
   1. Spare parts;
   2. Components;
   3. Parts;
   4. Refurbishment;
   5. Placing/making available on the market (i.e., does market refer to EU market/global market, etc.)

ii. Please propose additional terms of importance if this is relevant for addressing refurbishment activities for which the exemption (or exclusion) is being reviewed;

In case parts of your contribution are confidential, please clearly mark relevant text excerpts or provide your contribution in two versions (public /confidential).

Please be aware that input is preferred in writing in order to allow for referencing various views and for documentation reasons, however conducting a first telephone interview to clarify the areas of interest and the focus of information that your organisation may provide is possible.

If such an interview is relevant, please contact:

Ms. Yifaat Baron – Project Manager - RoHS exemptions evaluation

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