

## 7.0 Exemption Request No. 2: Reuse of Parts from Medical Devices Including X-ray Tube Components in New X-ray Tube Assemblies”

### Abbreviations

Cr Hexavalent Chromium

### 7.1 Description of Requested Exemption

The European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR) has put forward a request an exemption for reuse of parts from medical devices including X-ray tube components in new X-ray tube assemblies.

The applicant therefore puts forward the following main arguments:<sup>39</sup>

- Most used X-ray assemblies are returned to manufacturers who reuse as many parts as possible but some of these, including the housing, contain RoHS-restricted substances and so, without an exemption, would not be reusable in new equipment after 21st July 2014;
- The applicant claims that the reuse of parts from used assemblies will have a smaller negative impact on the environment than if there was no re-use of parts;
- All medical equipment manufacturers will stop using hexavalent chromium before 21st July 2014 for new housings, and so allowing reuse of existing housings after this date will not pose a risk to health or the environment because the only significant risk from this substance is during the production life-cycle phase; and
- Many other medical equipment parts are refurbished and are used to repair medical equipment. These would become waste earlier if they cannot be used to repair medical devices placed on the EU market after 22 July 2014.

Therefore, the applicant proposed three new exemptions for chemicals implicated in the reuse of various items of medical equipment):<sup>40</sup>

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<sup>39</sup> COCIR (2011) Original exemption request document no 2, European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR), September, 2011, [http://rohs.exemptions.oeko.info/fileadmin/user\\_upload/RoHS\\_VI/Request\\_2/COCIR - Exemption request2 - X ray and other parts reuse.pdf](http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_2/COCIR_-_Exemption_request2_-_X_ray_and_other_parts_reuse.pdf)

<sup>40</sup> Ibid.

- a) Lead, cadmium and hexavalent chromium in refurbished parts from professional medical devices that are reused within a closed loop business to business return system used for the repair of medical equipment placed on the EU market after 21 July 2014 until 22 July 2026;
- b) Hexavalent chromium in housings from X-ray tube assemblies that are reused within a closed-loop business to business return system until 22 July 2026; and
- c) Lead in component parts from X-ray tube assemblies that are reused within a closed-loop business to business return system until 22 July 2026.

## 7.2 Applicant's Justification for Exemption

According to the applicant the exemption request consists of two separate parts, reuse of parts from medical devices and X-ray assemblies. The most commonly re-used medical parts are<sup>41</sup>

- X-ray tubes;
- MRI coils;
- printed circuit boards from many different types of equipment; and
- detectors and components of detectors (e.g. radiation detectors).

Some of these will contain small amounts of lead, cadmium and hexavalent chromium.<sup>42</sup>

Article 4 (b) of the RoHS 2 Directive permits the use of spare parts containing Annex II substances, for the repair, the reuse, the updating of functionalities or the upgrading of capacities of medical devices that will be placed on the EU market before 22 July 2014. This article does not apply to equipment placed on the market after this date.

The applicant argues that implementing this Article will lead to more waste (from scrapped devices) on the one hand and to a larger demand for (the production of) new parts needed to replace re-usable parts (that would otherwise be used) on the other hand.<sup>43</sup>

Moreover the applicant claims that re-use of refurbished parts has a smaller environmental impact than disposal of re-usable parts and the use of new parts as re-

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<sup>41</sup> Ibid.

<sup>42</sup> COCIR (2012a) Answers to first clarification questions submitted by the applicant, by the European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR), June 2012;  
[http://rohs.exemptions.oeko.info/fileadmin/user\\_upload/RoHS\\_VI/Request\\_2/Request\\_No2\\_1st\\_Clarification-Answers.pdf](http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_2/Request_No2_1st_Clarification-Answers.pdf)

<sup>43</sup> Op. cit. COCIR (2011)

placements. In general, most used parts are removed from medical devices for repair or refurbishment, and are then reused. Thus only a very small amount enters the waste stream directly<sup>44</sup>.

An X-ray tube, as used as part of a specialist medical device, is a vacuum tube used for the production of X-rays. COCIR<sup>45</sup> explains that X-ray imaging equipment consists of many sub-assemblies including those used for supporting the patient, holding and moving the X-ray tube and the X-ray detector into the required positions, as well as the x-ray tube assembly itself and the detector assembly.

One of the largest parts of the assembly that is reused is the external housing. This is constructed from aluminium alloys, or sometimes brass, some steel parts, lead sheeting (as radiation shielding) and a few other materials. The X-ray housing has some component parts which are protected against corrosion by chromate passivation. Thus, the housing contains a small quantity of hexavalent chromium.<sup>46</sup>

According to the applicant<sup>47</sup> all medical equipment manufacturers will stop using hexavalent chromium before 2014 when medical devices are included in the scope of the RoHS Directive. In the past, at present and in the future, housings that contain hexavalent chromium could be re-used many times unless they are damaged. This is the reason why COCIR has requested the exemption mentioned in Section 7.1, bullet point b). Moreover the applicant states that the reuse of housings in refurbished systems and reusable products in medical equipment has a smaller environmental impact than the production of new medical assemblies.

Additionally, the applicant<sup>48</sup> asserts that re-use of equipment is encouraged by the EU in waste legislation such as the WEEE Directive as this has a smaller environmental impact than allowing it to become waste sooner. This is recognised by the RoHS Directive recast (2011/65/EC) in Article 4.5 which allows the reuse of spare parts, but only if these are recovered from EEE placed on the market before 1 July 2006 when the original RoHS Directive 2002/95/EC came into force. The Article 4.5 exclusion ends on 1 July 2016, i.e. 10 years later. These dates do not take into account that medical devices will be included in scope from 21st June 2014 so that this exclusion cannot be utilised for x-ray tube housings and other medical equipment parts removed from equipment that will have been placed on the EU market between 1 July 2006 and 21 June 2014, during which time they were still excluded from scope. Without an exemption, all of the parts from medical devices placed on the EU market in this period will become waste, and will have to be replaced by new parts. In principle, only parts that contain RoHS substances could not be used but it will be very difficult to determine whether an old part does or does not contain RoHS substances,

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<sup>44</sup> Ibid.

<sup>45</sup> Ibid

<sup>46</sup> Ibid.

<sup>47</sup> Ibid.

<sup>48</sup> Ibid.

and so, to ensure RoHS compliance is maintained, relatively few old parts could be used.

One criterion required for the exclusion in Article 4.5 is that the parts should be part of a closed loop business-to-business return system. According to the applicant<sup>49</sup>, X-ray tubes are supplied only through business-to-business services and their return to suppliers is guaranteed through binding contracts agreed upon in correlation with supplying new imaging equipment. Furthermore many types of defective, used parts removed from medical devices are also returned to manufacturers who provide refunds upon return. The result is that approximately 95% of assemblies are returned to the original manufacturer.

The applicant<sup>50</sup> assumes a time schedule until 2026 regarding the re-use of parts (see also Section 7.2.3). It is explained that as these assemblies have average lives of 5 years, three re-uses each of 5 years totalling 15 years from 2011 will require this exemption until 2026.

It is foreseen that by 2026, most of these repairable parts will be at the end of product life; the rest will be scrapped, therefore COCIR assume the exemption shall be needed until 2026<sup>51</sup>.

### 7.2.1 Possible Substitute Alternatives and Possible Design Alternatives

From the applicant's<sup>52</sup> argumentation, it is suggested that substitution would only be possible through the production of new parts. The applicant states that the goal of this exemption is to save resources. A complete substitution of products using Cr should already be possible in July 2014, when medical devices come in to the scope of the RoHS Directive. This would apply to new products. However, if the exemption is not granted, as the affected parts in current medical devices are already on the market, these would have to be scrapped, because it is impossible, or economically unattractive, to remove the RoHS substances from the parts (e.g. soldering on PCBs) (2012a). That is to say, parts from RoHS non-compliant devices, brought onto the market before 2014, could no longer be reused, even though the practice of using refurbished parts instead of manufacturing new ones is common, and shall probably remain common in the future.

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<sup>49</sup> Ibid.

<sup>50</sup> Ibid.

<sup>51</sup> Ibid.

<sup>52</sup> Ibid.

### 7.2.2 Environmental Arguments

The applicant<sup>53</sup> has submitted information concerning life cycle assessment aspects, to further enhance the argumentation. Information includes reference to energy consumption, carbon dioxide emissions and information concerning the re-use and recycling of waste. In general, the information submitted concerning these aspects also supports the re-use of parts to be the most suitable alternative, noting that:

- Production Phase: The parts are already available: reuse would have a smaller impact as new parts would be needed only to replace those that are damaged;
- Use Phase: There is no evidence that handling of products with passivation coatings poses a risk to users and workers. Risk is relevant only for the production phase, whereas the coating process with hexavalent chromium salt solutions is already being phased out and replaced by safer processes;
- End of Life: Parts may be reused at least five times. Recycling systems [it can be followed that take-back systems are meant – consultants comment] are guaranteed by contracts, the process is straightforward and illegal export for recycling is currently not widespread. Re-used parts entail the use of less energy in comparison to replacement with new parts.

COCIR<sup>54</sup> states that:

*“the environmental benefit of reusing parts in terms of avoiding waste, not consuming raw materials and lower energy consumption... will be the same irrespective of whether a part is used in equipment or in a new product. This will not affect the product’s lifetime. Some used parts are types that are regularly replaced during the lifetime of equipment, such as X-ray tubes, and other parts are designed to last at least the product lifetime and so do not cause medical devices to reach end of life early”.*

Moreover the applicant delivers a credible environmental impact comparison between re-used and new X-ray assemblies. COCIR<sup>55</sup> has estimated that parts from about 16,000 X-ray tube assemblies are reused in the EU annually to construct new assemblies used in both new equipment and as replacements for existing equipment. If these parts could not be re-used, then new parts would first need to be manufactured for up to 160,000 assemblies over 10 years, which will consume nearly four times more energy and create more waste than if the parts may be re-used. The same situation, described above for X-ray tube housings, is also relevant for parts from other medical equipment. That is, the possibility of re-using parts containing lead,

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<sup>53</sup> Ibid.

<sup>54</sup> COCIR (2012b) Answers to further clarification questions submitted per e-mail by the applicant, The European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR) on 09 November 2012

<sup>55</sup> Op. cit. COCIR (2011)

cadmium and hexavalent chromium would have a smaller overall impact on the environment than having to replace these with new parts.

The applicant estimates that only 2kg of hexavalent chromium is placed on the EU market annually by X-ray tube housings and this amount will decrease in the next years. The amounts in other medical equipment are estimated to be less than 200kg of lead, less than 0.1 kg cadmium and less than 5 kg of hexavalent chromium to be present in re-used parts per year. <sup>56</sup>

### 7.2.3 Road Map for Substitution

The applicant<sup>57,58</sup> mentions that research into substitutes for new products has been completed and all medical equipment manufacturers have developed alternative production processes. This is to say that substitution of new products has for the most part been resolved.

It is understood that the only “real” substitute for the use of refurbished parts would be to produce new ones, an alternative that is explained to be more wasteful in the applicant’s argumentation (cf. Section 7.2.2).

Against this background the applicant requests this exemption solely for the reuse of the parts. Taking into consideration an average component life of 5 years along with a re-use of three times, starting 2011, the applicant assumes that the exemption shall be needed *until 2026*.

## 7.3 Stakeholder Contributions

No further contributions were received from other stakeholders.

## 7.4 Critical Review

### 7.4.1 REACH Compliance – Relation to the REACH Regulation

In the consultants’ understanding, as the requested exemption would not apply to the use of new RoHS Annex II resources, nor to the use of potential substitutes for these, it is not subject to any restrictions by REACH.

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<sup>56</sup> Ibid.

<sup>57</sup> Ibid.

<sup>58</sup> COCIR (2012a) Answers to first clarification questions submitted by the applicant, by the European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR), June 2012; [http://rohs.exemptions.oeko.info/fileadmin/user\\_upload/RoHS\\_VI/Request\\_2/Request\\_No2\\_1st\\_Clarification-Answers.pdf](http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_2/Request_No2_1st_Clarification-Answers.pdf)

### 7.4.2 Scientific and Technical Practicability

Though substitution and elimination are for the majority of cases possible, they would apply to the production and placing on the market of new devices, whereas this exemption has been requested for the reuse of spare parts refurbished from products already on the market. Though reused spare-parts can be replaced with new spare parts, this issue has additional impacts that shall be discussed below.

The applicant provides sufficient evidence that the re-use of spare parts from medical devices including X-ray tube components (e.g. housings) would be environmentally beneficial as explained in the Section 7.4.3. The re-use of medical parts may reduce energy and material consumption as well as reducing emissions and waste.

The information provided for comparing the environmental impacts of using refurbished parts to that of substituting refurbished parts with new ones, demonstrates that the total negative environmental, health and consumer safety impacts of substitution would outweigh the total benefits thereof. Hence, an exemption would be justified according to Article 5 (1)(a) of the RoHS 2 Directive.

In this context, it can be understood that some parts can be used as replacements both in old equipment as well as in new equipment without affecting the product's lifetime. Against this background, as in both cases, the re-use of parts can be regarded as environmentally beneficial, the consultants would not recommend limiting this exemption to the re-use of parts in old equipment.

Moreover, COCIR<sup>59</sup> explains that all repairable assemblies in medical equipment have a good quality closed loop business to business system. According to the applicant the number of used assemblies going to landfill is believed to be negligible. This implies that the system is organized in a way that could support the collection, refurbishment and reuse of spare parts from medical devices, further avoiding waste produced once such parts are not reused.

### 7.4.3 Environmental Arguments

The applicant provides sufficient evidence that the re-use of spare parts from medical devices including X-ray tube components (e.g. housings) would be environmentally beneficial. The re-use of medical parts may reduce energy and material consumption as well as reducing emissions and waste.

The evidence submitted by the applicant regarding environmental impacts and statements comparing the life cycles of two options with and without granted exemption is adequate. In the consultants view it is reasonably supported that not granting the requested exemption would result in negative impacts to the environment in terms of consumption of resources and in terms of greater quantities of waste that would outweigh the positive impacts of restricting the reuse of refurbished medical parts containing RoHS substances.

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<sup>59</sup> Cf. footnote 1 (original)

The information provided for comparing the environmental impacts of using refurbished parts to that of substituting refurbished parts with new ones, demonstrates that the total negative environmental, health and consumer safety impacts of substitution would outweigh the total benefits thereof. Hence, an exemption would be justified according to Article 5 (1)(a) of the RoHS 2 Directive.

#### 7.4.4 Conclusions

According to the consultants, the applicant's arguments can be followed and the exemption is scientifically and technically justified. Furthermore, the consultants view X-Ray assemblies to be included in the scope of medical equipment parts. In other words, an exemption permitting the use of Lead, cadmium and hexavalent chromium in refurbished parts from professional medical devices, would be applicable for parts from X-ray assemblies. Therefore we suggest reducing the wording of the three exemptions by the applicant to one singular wording applicable for all medical equipment.

Further support can be found in how this exemption request relates to the general approach apparent in the RoHS Directive, despite its limited applicability to medical products, in the explanation below:

RoHS Directive 2<sup>60</sup> addresses the use of spare parts under two circumstances:

- Article 4 (4) excludes the use of cables and spare parts for the repair, the reuse, the updating of functionalities or the upgrading of capacities of various product groups from the RoHS restrictions. Items (b) through (e) in this article make the exclusion available for:
  - medical devices placed on the market before 22 July 2014; and
  - in vitro diagnostic medical devices placed on the market before 22 July 2016.
- Article 4 (5) excludes the reuse of 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.

Article (3) (27) defines spare parts as separate parts of EEE:

*“that can replace a part of an EEE...The functionality of the EEE is restored or is upgraded when the part is replaced by a spare part.”*

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<sup>60</sup> RoHS Directive (2011) Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast), <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011L0065:EN:NOT>



These two Articles provide that parts are excluded from RoHS provisions throughout the specified timeframes and when used in certain EEE. As the definition of spare parts addresses newly produced spare parts unless otherwise specified (as in Article 4 (5)), the reuse of spare parts will only be available for category 8 products when using parts recovered from products placed on the market before 2006, if they are to be installed in products placed on the market before 1.7.2016. Other reused parts containing Annex II substances will be scrapped, as will older parts after July 2016.

The consultants therefore agree with the applicant that the use of refurbished spare parts in EEE is, for the most part, prohibited where spare parts originating in medical products are concerned, as Article (4) (5) is only applicable under specific circumstances. Hence, to the extent that the exemption request is justified (on technical and environmental grounds) it also seems necessary.

## 7.5 Recommendation

Based on the submitted information, it is recommended that the exemption be granted and adopted to Annex IV of the RoHS Directive. The applicant's arguments are plausible, and an exemption could be justified in line with the requirements of Art. 5(1)(a). Additionally, it is suggested that the intentions of RoHS, apparent in Article 4, give further support to the view that this exemption would be in line with the intentions behind the RoHS 2 Directive. It is also recommended, therefore, that the wording be reformulated similarly to the wording of this Article.

Regarding the scope of this request for exemption, as parts b and c of the requested exemption are effectively covered in the wording of part a, it is assumed that these parts were requested to account for the scenario in which the more general exemption as requested in part a would not have been regarded as justifiable (cf. Section 7.1). It would therefore be sufficient to grant an exemption correlating only to the requested part a:

*“Lead, cadmium and hexavalent chromium in refurbished parts from professional medical devices that are reused within a closed-loop business to business return system used for the repair of medical equipment placed on the EU market after 21 July 2014 until 22 July 2026”*

Regarding the timeline, the arguments brought forth by the applicant regarding the need for this exemption until 2026 are viewed by the consultants as adequate. However, according to Article 4 (2) of the RoHS 2 recast, the maximum period for which an exemption may be granted is 7 years.

Therefore, it is recommended that the exemption be granted with the following wording and validity:

*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 July 22 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.*

The exemption expires on 21 July 2021.

In principal, this exemption may also be relevant for category 9 and 11 as these categories have similar timeframes where inclusion in the RoHS scope is concerned. However as contributions were not received from representatives of other categories to this end, it could not be determined if, or to what extent, such an exemption would be needed. As the scope of any exemption should generally be well defined, and supported by a sound case in support of the exemption, opening the scope for other categories not specifically discussed is not considered appropriate.

## 7.6 References Exemption Request 2

COCIR (2011) Original exemption request document no 2, European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR), September, 2011, [http://rohs.exemptions.oeko.info/fileadmin/user\\_upload/RoHS\\_VI/Request\\_2/COCIR\\_-\\_Exemption\\_request2\\_-\\_X\\_ray\\_and\\_other\\_parts\\_reuse.pdf](http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_2/COCIR_-_Exemption_request2_-_X_ray_and_other_parts_reuse.pdf)

COCIR (2012a) Answers to first clarification questions submitted by the applicant, by the European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR) June 2012; [http://rohs.exemptions.oeko.info/fileadmin/user\\_upload/RoHS\\_VI/Request\\_2/Request\\_No2\\_1st\\_Clarification-Answers.pdf](http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_2/Request_No2_1st_Clarification-Answers.pdf)

COCIR (2012b) Answers to further clarification questions submitted by the applicant, by the European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR) personal communication e-mail November 2012.

RoHS Directive (2011) Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast), <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011L0065:EN:NOT>