Application for granting a new RoHS exemption: Reuse of parts from medical devices including X-ray tube components in new X-ray tube assemblies

1. Name and address of applicant

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2. Summary

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, these cannot be reused in new equipment after 21st July 2014. 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. An exemption is justified because allowing the reuse of parts from used assemblies will have a smaller negative impact on the environment than without re-use as a result of not having this exemption. Many other medical equipment parts are refurbished and are used to repair medical equipment. These would become waste early if they cannot be used to repair medical devices placed on the EU market after 22 July 2014

3. Description of materials and equipment for which the exemption is required

Many types of part are removed from medical device for repair or refurbishment and are then reused. It is permitted by the RoHS directive to use spare parts containing RoHS substances to repair and refurbish medical devices that will be placed on the EU market before 22 July 2014 but not equipment placed on the market after this date. This will mean that increasing quantities of re-usable parts will become waste and need to be replaced by new parts. Re-use of refurbished parts has a smaller environmental impact than disposal of re-usable parts and replacement with new parts. Almost all of the used parts removed from professional medical devices are returned to manufacturers for refurbishment so that only very small amounts enter the waste stream directly.

X-ray tube assemblies are regularly replaced during the life of imaging equipment whereas other parts are replaced only when a fault occurs. One manufacturer takes-back over 2500 types of part from defective equipment which it refurbishes for re-use for repairs although only about 650 of these will be re-used after 21 July 2014 and some will contain RoHS substances. Of these, the most commonly re-used parts are:

- MRI coils
- Printed circuit boards from many different types of equipment and

- Detectors and components of detectors (e.g. radiation detectors)

X-ray imaging equipment consists of many sub-assemblies including those used for patient supporting, holding and moving the X-ray tube and the X-ray detector into the required positions and the, the x-ray tube assembly and detector assembly. X-ray imaging systems typically have very long lives often exceeding 25 years but the X-ray tubes have shorter lives, which can be as short as 6 months and as long as 15 years depending on the frequency and intensity of use. Some types of tube assembly are returned on average every two years whereas other types are returned on average after longer periods. The average period for all tubes is estimated to be ~5 years.

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.

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 sheet as radiation shielding and a few other materials. The aluminium alloys and the brass in some cases are also alloyed with lead which acts as radiation shielding. The lead radiation shielding is needed to protect hospital staff from radiation exposure and is permitted by Exemption 5 of Annex IV of the recast RoHS directive 2011/65/EC.

The X-ray tube assembly housing has a number of small inserts which have in the past been, and some are currently chromate passivation treated to prevent corrosion and so contain a small quantity of hexavalent chromium. Chromate passivation treatment has already been replaced by at least two manufacturers, another is planning to stop using hexavelent chromium before the end of 2011 and all medical equipment manufacturers will stop using this process before 2014 when medical devices are included in the scope of the RoHS Directive.

Housings that contain hexavalent chromium will be re-used many times unless they are damaged or if this is prevented by the RoHS directive due to the presence of a restricted material that has no exemption. This new exemption is required because allowing the reuse of housings and other reusable parts would have a significantly smaller environmental impact than preventing their reuse as will be shown in this request dossier.

All other parts of X-ray tube assembly are reused if possible but most do not contain RoHS restricted substances. Some designs contain printed circuit boards some of which are made with lead solders. Many contain electric motors and cables where older parts may contain lead stabilisers in the PVC insulation although lead solders and lead stabilisers will not be used to make new parts.

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.

4. Justification for exemption

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 early. 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 when it Was 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 principal, only parts that contain RoHS substances could not be used but it will be very difficult to determine whether an old part contains RoHS substances and so to ensure RoHS compliance is maintained, relatively few old parts could be used. Construction of new X-ray tube housings consumes raw materials and energy and risks emissions of hazardous substances and so has a larger negative impact on the environment than re-use. Collection and dismantling assemblies is required whether the parts are re-used or not.

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. X-ray tubes are supplied only to businesses and their return to suppliers is guaranteed by contracts agreed when the new imaging equipment is supplied. Typically, the contract will define a payment to the user of the imaging equipment when they return the used X-ray tube assembly to the original supplier. This payment can be as much as €1000 and so ensures a very high return rate; in fact it would be surprising if used assemblies were not returned. All manufacturers in the EU use these arrangements and pay for the return of their x-ray assemblies because they contain valuable parts. Typically ~95% of assemblies are returned to the original manufacturer. The fate of the rest is unclear but some at least are collected and the parts re-used by different organisations, sometimes by competitors of the original manufacturer. The number of used assemblies going to landfill is believed to be negligible.

A very high proportion of the many types of defective used parts removed from medical devices are also returned to manufacturers because they give refunds when these are returned. This guarantees that a high proportion is returned and refurbished and is not disposed of. Re-use of refurbished parts has a lower cost than making new parts and this reduces the costs to healthcare providers in the EU. As all hospitals in the EU have limited budgets, minimising repair costs allows the hospitals to buy more new equipment which has a direct benefit on diagnosis and treatment of patients. This health benefit is however difficult to quantify.

This approach also ensures that where a part is returned to the manufacturer but cannot be reused, the manufacturer will have complete knowledge of the constituent materials and so can recycle the parts safely and recover all critical and scarce materials.

5. Analysis of possible alternatives

5.1. X-ray tube assemblies

The health and environmental benefit can be demonstrated by comparison of the two alternative options.

1. With exemption allowing reuse or
2. Without exemption so that parts become waste and have to be replaced

Life cycle comparison of alternative options

Life cycle phase	1. With exemption	2. Without exemption
Production of materials and manufacture of parts	Parts already produced so smaller impact as new parts needed only to replace those that are damaged	New materials would have to be produced and parts constructed to replace all parts. Impact quantified below
Use phase	No evidence that passivation coatings pose a risk (discussed below)	Parts identical except for alternative passivation coating used in new parts
End of life	Re-used at least five times. Would eventually be recycled but this is delayed	Older parts would become waste sooner and this would consume energy to recycle metals.

5.2. Risk from hexavalent chromium

Hexavalent chromium is toxic and a carcinogen by inhalation. There is however no scientifically validated research data that would show that hexavalent chromium in passivation coatings is a carcinogen by skin contact, i.e. from handling coated parts. The main risk from hexavalent chromium is to workers who carry out processes using aqueous solutions of chemicals that contain chromate salts such as the passivation treatment of metals and cases of cancer have occurred in the past before the risks were known. There is also a risk to the public if waste solutions is not correctly treated and it is present in drinking water supplies but this has occurred only very rarely.

There is no scientific evidence that handling metal parts that have chromate passivation coatings has any harmful effect despite treated parts being frequently handled by many thousands of workers over many years in the past. At end of life, processes that recycle metals such as melting will complexly destroy hexavalent chromium by converting it into safer trivalent chromium. For example, if chromate passivated aluminium is melted, the coating which has a complex composition which contains metal chromates typically reacts as follows:

$$6Al + Al_2(Cr_2O_7)_3 = 4Al_2O_3 + 3Cr_2O_3$$

Cr_2O_3 is trivalent chromium oxide. So it is clear that the only significant risk is during the production phase where aqueous solutions of chromate salts are

handled. Once parts have been made, there is no evidence of a health or environmental risk to users or to workers who handle coated parts when they are reused to construct new assemblies. The coating process with hexavalent chromium salt solutions is already being phased out and replaced by safer processes.

5.3. Risk from early recycling

Housings contain lead used for shielding. While housings are in use or are re-used, this lead is stable and there are no emissions so that it poses no risk. When the housings are recycled, the lead needs to be separated from the aluminium or brass so that lead, aluminium and brass can be recycled, usually by melting. High yield and safe recycling processes exist in the EU and elsewhere but unsafe recycling is carried out in some developing countries where waste containing lead would pose a risk if it were to be illegally exported to these countries. Illegal export for recycling is currently a widespread problem in the EU, although not of medical equipment, but in the future, it is hoped that enforcement and changes to legislation will stop this trade.

5.4. Environmental impact comparison

It has been estimated that parts from about 16,000 x-ray tube assemblies are reused in the EU annually to construct new assemblies that are used in both new equipment and as replacements for existing equipment.
Re-use of these parts consumes very little energy or raw materials and no waste arises as the procedure used is to dismantle used assemblies and then assemble new assemblies using these parts. If these parts could not be re-used, then new parts would first need to be fabricated for up to 160,000 assemblies over 10 years and this will consume more energy and create more waste than if the parts could be re-used.

Although x-ray tube assemblies that contain RoHS substances can be used as replacement spare parts in medical equipment that is placed on the market before 21st June 2014, it is impractical to segregate the construction of RoHS compliant (for new systems) and non-RoHS compliant X-ray tube assemblies (for older systems) as this would require separate parts storage, two separate production lines and systems to prevent mistakes by using the wrong parts. Without this exemption many parts from older housings are very unlikely to be used as manufacturers will want to avoid producing non-compliant products as a result of using the wrong tube assembly or build an assembly with the wrong parts due to an error. Manufacturers of electrical equipment that has been in scope of 2002/95/EC since 1 July 2006 experienced severe problems trying to maintain separate lead-free and lead-solder production lines, mainly due to mistakes in parts segregation and so very few now operate dual segregated production lines.

The quantities of energy consumed, raw materials consumed and waste arising varies depending on the design and type of x-ray assembly. Each manufacturer has their own designs and so uses different combinations of materials. Each manufacturer produces a range of designs where the size (and weight) of parts also varies. Therefore the environmental benefits for each model are different. Two medical equipment manufacturers have estimated the environmental

benefits from re-use of either the housing only or all parts of the assembly as follows:

Manufacturer A – Reuse of assembly housing only (typical housing weight ~10kg Al)

Process / materials	Benefit	Assumptions
Energy consumption per unit	72kWh	Data from supplier of housings includes energy for mining and refining metals
Energy per year	1.1 GWh	Assumes 16,000 re-used in EU annually
Carbon dioxide emission saving	404 tonnes / year	0.35kgCO2/kWh generated

Manufacturer B – reuse of all reusable parts for a typical design (typical housing weight ~10kg Al)

Process / materials	Saving per x-ray assembly	Saving for 16,000 per year	
Manufacture of all materials	764 kWh	12.2 GWh	Assumes virgin metals extracted and refined
Production of parts (melting, casting, machining, etc.)	902 kWh	14.4 GWh	Average value for all types of parts made
Recycling	-421 kWh	-6.7 GWh	Negative as this reduces the demand for virgin metals
Total	343 kWh	5.5 GWh	Takes into account the use of scrap
Total materials reused	29.2 kg	467 tonnes	Weight assuming 100% re-used

The figures above from Manufacturer A are the energy saving by reuse of the aluminium housing that contains a small amount of hexavalent chromium and the data from manufacturer B is for the reuse of all parts although only a few of the parts contain RoHS restricted substances.

Production of virgin aluminium from bauxite is very energy-intensive and typically consumes 20 times more energy than for recycling scrap aluminium. The ratio of virgin to scrap varies due to availability of scrap and the type of aluminium alloy used.

If materials reuse were not permitted, then the materials would be recycled and some will be lost as recycling is not 100% efficient. These losses must be made up by production of more virgin metal. The recovery rate varies depending on composition and process but one manufacturer estimates that 94% is achievable but this would result in the loss of 28 tonnes (6% of 467 tonnes) of material (most to landfill) per year if no reuse were carried out.

Another way of estimating energy consumption for fabrication and recycling of the aluminium parts of the housing is from published data as follows:

Energy to produce new (virgin) aluminium = ~10 – 20 MWh/tonne (if scrap is not available[1]

- 16,000 housings at 10kg each = 160 tonnes = 1.6 – 3.2 GWh / year

End of life energy consumption:

- Recycling aluminium housing typical weight 10kg, energy to melt = 500kWh electricity/tonne so 50kWh each [2]. This is equivalent to ~125KWh of primary energy.
- 16,000 per year = 160 tonnes / year consuming = 200 MWh / year

The environmental impact of the manufacture of X-ray tube assembly housings is estimated below assuming an average x-ray tube assembly life-time of 5 years, 85% of housings are reusable and average of 10kg aluminium per assembly. Energy consumption saved per housing estimated by manufacturer A is 72kWh. The calculated energy consumption value to manufacture each new aluminium housing from manufacturer B is 307 kWh.

[1] From IPPC BREF Non-ferrous metals ftp://ftp.jrc.es/pub/eippcb/doc/nfm_2d_07-2009_public.pdf

[2] See table 65 of http://www.eco-furnace.org/open_docs/043122753%20Draft%20Task%201-5%20Rep%20final.pdf

The impact assessment below compares the energy saved and materials reused by the two options: i) with an exemption and ii) with no exemption and assumes that each assembly has a life of 5 years and 15% are too damaged to be re-used.

Option	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
i) Reuse of parts permitted										
Number of new	2,400	2,400	2,400	2,400	2,400	2,400	2,400	2,400	2,400	2,400
Number recycled	13,600	13,600	13,600	13,600	13,600	13,600	13,600	13,600	13,600	13,600
ii) Reuse of non-compliant parts not permitted										
Number of new	16,000	16,000	16,000	16,000	16,000	2,400	2,400	2,400	2,400	2,400
Number recycled	0	0	0	0	0	13,600	13,600	13,600	13,600	13,600

Under option ii), assuming an average life of five years, assemblies supplied in 2014 will be returned five years later in 2019 and the constituent parts of these assemblies can be reused. In reality, however, assemblies are returned after periods ranging from 2 to 15 years and so with option ii, some will be returned before 2019. Also, in 2019, some of the 2014 assemblies will continue to be in use and so the actual number of new assemblies needed in 2019 and subsequent years will be larger than 2,400 although will gradually decrease towards this figure.

Option	10 year totals		
	Numbers	Total energy consumption (72 to 307 kWh / new housing)	Total new materials needed (assumes 10kg / new housing)
i) Reuse of parts permitted		1.7 - 7.4 GWh	240 tonnes
Number of new	24,000		
Number recycled	136,000		
ii) Reuse of non-compliant parts not permitted		6.6 - 28 GWh	920 tonnes
Number of new	92,000		
Number recycled	68,000		

The energy and new materials consumption without an exemption with option (ii) is nearly four times larger than option (i) when calculated over a ten year period. The difference is even larger for the five year period between 2014 and 2018 when 80,000 new housings must be made with option (ii) whereas with option (i) only 12,000 are needed, the majority being reused.

These figures are estimates for the housings only which are the largest part by weight but many other parts are also reused. Some manufacturers will have parts in older returned assemblies that contain lead as solders or lead additives in PVC which they could also reuse with associated energy and raw materials savings.

6. Parts from other medical equipment

It is estimated that about 3000 tonnes of parts are refurbished and then re-used in the EU annually. One EU-based medical equipment manufacturer reports that they plan to re-use 650 types of parts returned from customers after 21 July 2014. A proportion of these will contain small amounts of RoHS substances but as these were originally constructed when medical devices were out of scope, no records of which contain RoHS substances exist and so if this exemption is not granted, none could be used as chemical analysis is impractical (and usually destructive). If these could not be re-used, there would be an additional 3000 tonnes per year of waste electrical equipment generated in the EU and 3000 tonnes of new parts would need to be made which will consume large amounts of raw materials, energy and create additional waste.
Re-use of parts does not increase additional waste; it merely delays the time when it becomes waste. Replacement of defective parts with new creates more waste and consumes more energy than re-use of parts because the average component lifetime is shorter. This is the same situation as has been demonstrated above for X-ray tube housings.
Therefore, an ability to re-use parts containing lead, cadmium and hexavalent chromium would have a smaller overall impact on the environment than having to replace these with new parts.

7. Other Information

The estimated quantity of hexavalent chromium in average size X-ray tube housings is 0.15 g. Therefore the quantity present in all housings returned to manufacturers annually for re-use in the EU will be 85% of 16,000 housings:
i.e. 85% x 16,000 x 0.15g = **2kg** hexavalent chromium per year. As some manufacturers have already stopped using hexavaelnt chromium, after 2014, a significant proportion of returned housings will not contain hexavalent chromium and so the amount present annually will be less than 2kg and gradually decrease.

The amounts of RoHS substances present in reused parts is not known for the reasons explained above. Lead will be the most common as it used in solders and it is estimated that less than ~200kg of lead will be present annually in 3000 tonnes of parts. Cadmium will be very uncommon and apart from exempt applications such as electrical contacts, much less than 0.1 kg per year is likely to be present. Less than 5 kg of hexavalent chromium is estimated to be present in re-used parts per year.

8. Re-use and recycling of materials from waste EEE

If this exemption is granted, then as many housings and other parts as possible will be re-used and these will be reused as many times as possible. Parts will be recycled thermally only when they are too badly damaged to be re-used and then they are recycled thermally for metals recovery (with ~6% loss of materials that must be replaced by virgin metal). As mentioned above, hexavalent chromium in passivation coatings is converted into safe trivalent chromium by thermal recycling. Without this exemption, all housings and other parts that contain RoHS substances will be recycled but many could not be reused.

9. Proposed plan to develop substitutes and timetable

Not applicable for this exemption request. Research is complete and all medical equipment manufacturers have developed alternative passivation processes but this exemption is needed to allow manufacturers to continue to re-use parts as this has a smaller negative impact on the environment than having to thermally recycle materials from used parts (as shown above). 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.

10. Proposed wording for exemption

Reuse of the following parts from professional medical equipment:

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**
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**