Questionnaire 1 (Clarification) Exemption 5 of RoHS Annex IV

Wording of the Requested Exemption:

Lead in shielding and in collimators used for ionising radiation

Requested validity: *7 years*

1. Acronyms and Definitions

EoL	end of life
Pb	lead
W	tungsten

2. Background

Bio Innovation Service, UNITAR and Fraunhofer IZM have been appointed[1] by the European Commission through for the evaluation of applications for the review of requests for new exemptions and the renewal of exemptions currently listed in Annexes III and IV of the RoHS Directive 2011/65/EU.

COCIR, JBCE and TMC submitted a request for the renewal of the above-mentioned exemption, which has been subject to a first review. As a result we have identified that there is some information missing. Against this background the questions below are intended to clarify some aspects concerning the request at hand.

We ask you to kindly answer the below questions until 29 August 2020 latest.

3. Questions

1. You added collimators to the exemption. Why would they require an exemption now and not already in 2014?

Collimators are an application of shielding. While not included in the wording in the original exemption that was part of RoHS 2 at the time of publication, they were covered by the exemption anyway. This time we thought it was would be better to name them explicitly in the exemption wording.

2. The table on page 12 of your exemption request shows the required thicknesses of steel and concrete at different energy radiations.

    a. The units of radiation energy should probably be keV, not kV? That is correct and was a mistake in the document

    b. Could steel and concrete not be appropriate as shieldings for the high radations used in radiotherapy?

[1] It is implemented through the specific contract 070201/2020/832829/ENV.B.3 under the Framework contract ENV.B.3/FRA/2019/0017

Radiotherapy devices are not included in the RoHS scope as Large Scale Fixed Installations. While it was not clear in 2011, the EC FAQ clarified it later in 2014. No exemptions for Radiotherapy have been submitted for renewal.

c. Could you add W to this table, or do you have data showing a comparison of required thicknesses for Pb and W?

Calculating the required thickness is not straightforward as it depends on the wavelength of the radiation (as shown in the table on page 12), density and atomic number as well as other variable, such as the "K-edge absorption energy" of the absorbing element. The calculated thickness values that were used by COCIR for comparison of lead with tungsten for the LCA is as follows:

Lead	10 mm thickness (1.13g/cm^2)
Tungsten	8 mm thickness (1.54g/cm^2)
Iron (for comparison)	55 mm thickness (5g/cm^2)

While the thickness of tungsten is lower, the total mass per cm^2 is larger.

3. You argue that the larger thickness of most other than materials than lead consumes too much of precious space, which is plausible. You mention that W would require less space and thus may allow building smaller X-ray and similar devices, enable smaller rooms for examinations, etc. (assuming that manufacturers would design their devices in future to use the space saving potential).

The use of lead in examining rooms as shielding does not fall under the scope of RoHS, as the shielding is part of the building. The choice is the right material is decided when the room is designed, taking into consideration all constraints.

As explained in the exemption renewal request, the use of tungsten is not technically possible for most uses of lead as well as the overall environmental and health impacts.

a. Why is the additional space requirement a problem, but the less space-consuming aspect not an advantage in newly designed devices? We are aware that W might not allow forming all shapes, but we assume that there are a lot of simple shieldings in most devices also.

As detailed in the dossier, there are certain applications where tungsten or tungsten composites are used. The choice is left to the engineering department to find the best overall solution for the application. There are many constraints we mentioned when using a hard and brittle material (in thin sheets) as tungsten. But the main argument of the dossier is not about the technical unfeasibility of the use of tungsten, but about the huge overall environmental and health impact that tungsten entails, making it a poor alternative to lead.

b. Heavier weights of less effective shieldings are a plausible argument as well. The higher shielding efficiency of W may, however, at least partially compensate the higher weights?

See previous answer

4. You state that "Medical device manufacturers aim to minimise the amount of lead used to reduce weight and so the total quantity may have decreased since 2006." How was this possible, since certain energies of radiation require certain thicknesses of materials to provide the necessary protection, and the number of devices may even have increased in the past years?

   Lead is moderately expensive, therefore minimizing its use is always welcome, but also reducing weight is beneficial when transporting equipment. EN IEC 60601-1-9 also requires medical device manufacturers to design in an environmentally friendly manner including less resource use and minimizing the amount of hazardous substances. Some of the ways that have been used to reduce the amount of lead used are:

   - Better design of shielding to ensure that only the minimum thickness and no more is used
   - Positioning of electronic circuits in places where shielding is not required or is already provided by shielding for other components or for the patient

5. You argue that "It is very common for X-ray imaging equipment, PET and SPECT to be returned to manufacturers by users. These are refurbished for reuse if possible otherwise parts are removed for reuse. Damaged and unusable parts are recycled. Therefore most equipment is collected within a closed loop system." We assume that most hospitals in richer countries prefer buying new equipment with cutting edge technologies rather than older ones. Used equipment thus may be sold – or donated - to lower income countries, including developing countries. In many of these countries infrastructure and organization for sound recycling is lower quality than in the EU or missing.

   This is a common misunderstanding. Refurbished medical devices are mostly purchased by US and EU. 76% of the market actually. For some complex reasons developing countries do not purchase refurbished equipment. Germany is the country that purchases most refurbished equipment in EU, therefore reconfirming the richest and most advanced regions are the ones purchasing most refurbished equipment. JBCE report that in Asia, the main markets for refurbished medical equipment are Japan and South Korea.

   a. Do you have figures for sales or donations of used equipment outside the EU, in particular to lower income countries?

      Donations are handled by hospitals or EU programs run by the EU commission. We do not have the numbers. But many developing countries are not accepting donations anymore as they do not have the skills to maintain such equipment. COCIR also does not collect data on sales of used equipment that contains radiation shielding to non-EU countries. However as most refurbished equipment is sold to EU countries, the USA, Japan and South Korea, very few, if any, are sold to lower income countries.

   b. Do the manufacturers maintain their producer responsibility and take care of the sound treatment at EoL when devices are sold outside the EU to such countries?

      The device is a property of the hospital. Manufactures do what they can to convince owners to return the old equipment, but medical imaging devices have a very high recycling value due to their composition of valuable metals, therefore they are sometimes sold to scrappers or brokers. Manufacturers cannot prevent this.

For refurbished equipment, these are sold with a warranty similar to the one for new products. In addition, spare part availability and after sale service are also secured.

c. Do you have experiences how the end of life of such devices would look like in those countries, in particular the treatment at end of life?

In almost every country of the world there are facilities operating according to the best environmental standards that can easily recycle medical devices and recover all the metal content. Such facilities are used by manufacturers to recycle medical equipment that cannot be reused. If such facilities are used or not by the owner, or which waste management company is involved we do not know.

d. You say that lead parts from medical devices are not treated in the extremely dirty circumstances like lead acid batteries. Besides the acids, why should lead sheets not be molten in the same plants like those which treat lead-acid batteries and probably other lead scrap as well?

Lead shielding is a clean metal that can be simply melted for reuse. Recyclers therefore select this material for remelting (e.g. to make new shielding) when it is available. It is probably also used in battery circuits where it is a suitable feedstock. Battery recycling plants in the EU are well controlled and are not operating in the dirty circumstances that we refer to in footnote 12. If an EOL medical device is shipped from a developing country, the shielding will be removed and can be remelted for sale as lead ingot, without the generation of lead-containing dust that has been reported from uncontrolled PCB and battery recycling in some developing countries. JBCE confirms this by stating that lead shielding contains approximately 96.2 % of lead. To avoid unintentionally adding elements from other scrap metals, it seems to be better to recycle shielding separately.

6. Could you please let us know the source of the data in table 2 of your exemption request?

Global warming potential from mining, refining and production of heavier metals as outlined in Table 2 is sourced from reference 4. This is downloadable from
http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0101298

7. You mention that W is used as shielding material in some applications.

a. Which ones besides the pin hole collimators?

b. What are the reasons why W is used in these cases?

Tungsten is used inside X-ray tubes for X-ray shielding when used directly in vacuum when the shielding component needs high mechanical stiffness. Another application is the use of tungsten in a pinhole camera to assess focal spot size in accordance with IEC60336. Tungsten is used in this application due to it is manufacturability to allow the creation of high precision holes through spark erosion and longevity of the pin-hole as it does not corrode.

8. You state that W might have toxic effects, while such effects are well known for Pb, also including the mining phase, and including people living near such mines.[2] You present LCA data showing that the human toxicity of W is by far higher than for Pb. Were non-energy-related effects like emissions of Pb and W from mining and recycling, etc. taken into account in the LCA as well? Which ones?

   Yes, non-energy impacts were taken into account. All materials used, waste generated and emissions from primary lead mining, refining and production of lead metal are included in the LCA as well as emissions and wastes from lead-acid battery recycling.

9. Lead from informal, highly contaminating recycling of lead acid batteries may enter the market also in the EU, the more as metal markets are global, not mainly local. How would this impact the result?

   We do not understand this question. Any lead used in the EU needs to meet quality and purity standards. As shown in slide 13, secondary lead produced from recycling of used lead acid batteries is included in the LCA.

10. Why are 11.7 kg of lead compared to 15.4 kg of W? Based on your statements about the physics of shielding less W should be required than Pb. Possibly, the core is that less thickness/volume of W would be needed, but the higher density still results in a higher mass? If so, please illustrate this with a calculation.

    As explained in our answer to Q2.c. although 8mm thickness tungsten shielding is equivalent to 10mm thickness lead shielding, due to the much higher density of tungsten (19.35g/cm^3), compared to lead (11.35g/cm^3), the mass of tungsten shielding (15.5kg on page 23 of COCIR's exemption renewal request) has equivalent shielding performance at 70keV to 11.3kg of lead. See calculation below for 1m^2 of shielding:

    Lead: density 11.35 x area 10,000cm x thickness 10mm = 11.35kg

    Tungsten: density 19.35 x area 10,000cm x thickness 8mm = 15.5kg

11. Given the high price of W and the fact that it is or would be used in compact form rather than in tiny portions distributed over the product like e.g. lead in solders, how realistic is it to assume that in practice only 35 to 40 % of W are recycled? Wouldn't it be plausible to assume that such metal parts – W as well as Pb – are separated possibly even manually before further treatment, also taking into account that medical devices contain steel and other metals in larger parts which may be dismantled rather than shredded and thus be partially diluted over the shredding fractions. It is difficult to imagine that recyclers in the EU and other developed countries would forego this business. The price of W is around 13 times higher than that of Pb, and around six times higher[3] than that of copper, and recyclers already separate larger copper parts. In developing countries, even informal recyclers are normally informed about the prices of materials, since smart phones allow access to market information. It might therefore be reasonable to assume that close to 100 % of W undergo a final treatment in a smelter, taking into account also that almost all medical devices are collected and not ending up on landfills untreated.

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[2] C.f. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2992867/, https://academic.oup.com/mutage/article/20/3/187/1060128 as examples

[3] Price of copper: ~ 5,400 Euro pro tonne (https://www.gold.de/kurse/kupferpreis/); Tungsten: ~ 30,000 Euro per tonne

This information does not come from COCIR. The reasons why today the recycling is not 100% are unknown to us. The 35 – 40% published figure is for all forms of tungsten globally. There are at least two possible reasons.

- Tungsten composites are marketed by manufacturers as radiation shielding for some applications but this material cannot be recycled.

- Recycling occurs only if sufficient clean metal is collected from organisations that disassemble equipment. If the amount of tungsten metal removed from EOL equipment is too small, it will be uneconomic to transport it to a tungsten metal recycler and so will be lost from the waste stream

Note however that the LCA includes an option where 100% of tungsten is recycled (see page 23).

12. You state that "An application of the net scrap approach to W might have a positive impact on the results". You indicate that 35 – 40 % of W are recycled globally, compared to around 55 % of lead. Why didn't you apply the net scrap approach to W as well?

This is because tungsten is not widely used as shielding in medical devices and so no data is available for the hypothetical recycling of tungsten from medical scrap, whereas lead shielding is collected and recycled. In fact 100% recycling of tungsten was considered as two additional LCA scenarios, considering recycling of sintered tungsten metal, which is technically possible and is carried out, and the hypothetical recycling of composites (tungsten powder) which is not currently possible commercially, see slides 36 & 37. The comparison of these scenarios are given in the table in page 25 of the exemption renewal request.

13. How would the result change if the above aspects concerning the functional unit (15.4 kg of W, if applicable), the net scrap approach, impacts from other burdens than energy consumption (if applicable), higher recycling at EoL for W (close to 100 % like for lead) were taken into account?

100% recycling of tungsten was considered, (see slide 37), reference should be made to the results in the table in page 25 of the exemption renewal request.

Please note that answers to these questions will be published as part of the evaluation of this request. If your answers contain confidential information, please provide a version that can be made public along with a confidential version, in which proprietary information is clearly marked.