

## Questionnaire 2 for Exemption 2 of RoHS Annex IV

### Acronyms and Definitions

CT computer tomography

### 1. Background

Bio Innovation Service, UNITAR and Fraunhofer IZM have been appointed<sup>1</sup> 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.

You submitted information to substantiate your request for the renewal of the above-mentioned exemption. This information was reviewed and as a result, we ask you to kindly answer the below questions for further clarification of your request until 22 January 2021 latest.

### 2. Questions

- 1) In your request, you explain that rotating anodes can use three (!) types of bearings. What is the third type of bearing besides the lead and liquid metal ones?

The three types of bearings are lead coated, liquid metal and silver coated. Silver coated bearings have several disadvantages which include temperature requirements, wear and noise generation.

- 2) We understand that bearings with silver have disadvantages as you describe, but is it excluded that such bearings with silver are used in applications in the scope of the exemption?
  - a. Are there manufacturerers who use such bearings in such equipment?

COCIR is aware of a few medical uses of X-ray tubes that have used silver coated bearings. However, silver coated bearings are inferior to lead coated bearings and they were used only in a few low roatation speed applications (~60Hz), which had the disadvantage of being noisy and having a reduced lifetime due to the high wear experianced. In one discontinued application (no longer in use for new imaging equipment), higher temperatures were used by the manufactuere to soften the silver coating, however the increased noise generation was not able to be overcome. The consumer accepted the higher noise generation for this singular application because at that time, there was no alternative. Since tubes with liquid metal bearings have become available and are much quieter, users of this type of X-ray system will no longer accept the high noise level generated by silver coated bearings so they cannot be used. X-ray tubes with silver coated bearings are now sold only as replacement spare parts for this no longer produced type of X-ray system.

To implement a design change in current systems to silver bearings would constitute a major change due to the higher temperature requirement. Notwithstanding the temperature consideration, the disadvantage of noise cannot be overcome and would

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

result in products not conforming to IEC standards. Consequentially this substitution is therefore not possible for the vast majority of solutions.

It is possible that they might be used in category 9 applications, but COCIR has no knowledge of category 9 X-ray equipment.

We would like to note that the use of lead for this application is about 25 grams per year, an insignificant fraction of the use of lead in medical devices. As stated in the dossier for the renewal of Annex IV, exemption 5 for lead in shielding, a X-ray device contains, on average, 14 kgs of lead, with a total of 26 tonnes of lead per year.

- b. If these bearings are used, how were the disadvantages overcome which you describe?

Please see above

- 3) In the answers to the clarification questionnaire you explain that X-rays with liquid metal bearings use exotic materials such as gallium.
  - a. Are gallium-based liquid metal bearings the only solution, or are types of liquid metal bearings used as well?

Gallium-based alloys are the only type of alloy that can be used. No other metallic alloys are liquid at temperatures that are close to room temperature except mercury (which is restricted by RoHS).

- b. In case, what are the specific properties of these “gallium-free” liquid metal bearings compared to gallium-based ones and compared to lead-based bearings?

There are none

- 4) You state in your exemption request that recently designed X-ray tubes use bearings with balls with a thin lead coating, which typically have a thickness of 150 nm although the thickness is variable.
  - a. How were the lead bearings designed in older X-ray models?

150 nm is the maximum thickness used for X-ray tubes. Due to advancements in coating technologies the coating thickness tends to become thinner in recent bearings, but overall the bearing design hasn't changed considerably over time.

- b. Is this technique used in the new X-ray designs common for all new design x-rays? If not, why not?

Current designs of medical X-ray tube utilise leaded bearings due to the technical performance (as described in the exemption renewal request) they offer. There are some limited applications where other bearing types are used, where higher noise or wear are acceptable due to the function of the equipment.

- c. What is the range of lead coating thicknesses, and on which parameters does the thickness depend?

The maximum coating thickness has a maximum of about 150nm, however the minimum thickness is confidential. Variation in coating thickness is due to a number of factors which include: material and manufacturing process of the sphere, surface quality, bearing geometry, rotation speed of bearing, forces on the bearing, coating supplier, X-ray tube design and heat input in the tube.

- d. Did you take into account this coating technique in the estimates of annual lead use under the exemption?



COCIR estimated the total amount of lead using data from three COCIR members. The lead coating thickness used by manufacturer A is not the same as the thickness used by manufacturer B. COCIR was not provided with a thickness value used by manufacturer C who provided only the total amount of lead that they use.

- 5) You explain in your exemption request that several medical device manufacturers have patented X-ray sources which use liquid metal bearings. These are used in some types of CT scanners, but usually cannot be used in most other medical imaging applications such as fluoroscopy and angiography.
- a. We interpret the above statement that the use of liquid metal bearings is technically practicable also in most other medical applications, even for fluoroscopy and angiography, provided their design is adapted accordingly, and that such devices are actually in the market or underway. Is this correct?

No this is not correct. Fluoroscopy and angiography are used to continuously image patients while medical procedures are carried out. This means that the X-ray equipment must be small and not prevent access by surgeons and nurses to their patients. COCIR's exemption 13 renewal request shows an example where the space available for surgeons who use fluoroscopy is very limited. Please check for reference COCIR renewal request for exemption 13, in Annex IV to see problems with bulkier components.

Liquid metal bearings and their associated equipment are much too large and would obstruct the medical staff so that they would not be able to treat the patient in applications like intra-operative imaging, mobile imaging and standard fluoroscopy. Liquid metal bearings have a high mechanical friction that leads to much higher heat generation than ball bearing tubes. They must be actively cooled, but fluoroscopy systems used in operating theatres must be compact and inclusion of bulky cooling systems would be impractical as space will be limited.

Furthermore the physical parameters of liquid metal bearings require adaptations to drive frequency and stator which result in different anode speeds. The difference in anode speed then effects image performance (exposure start with bearing ramp up and/or exposure stop with slow down/breaking phase) and x-ray generation. Not all clinical application can be driven with these changes by rotation frequency and imaging performance changes.

- b. If yes, could you please explain why liquid metal and not lead bearings are used in these devices?

Not applicable

**Please note that answers to these questions may 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.**

**It would be helpful if you could kindly provide the information in formats that allow copying text, figures and tables to include them into the review report.**