Questionnaire 5 for Exemption 2 of RoHS Annex IV

Acronyms and Definitions

1. 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.

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 August.

2. Questions

1) We understand from your renewal request and from the previous questionnaire that the more voluminous liquid metal bearings are used in higher performance X-rays. You state in the previous questionnaire that "Larger size bearings will always require more lead shielding than smaller-size bearings." We are not sure whether the higher amount of shielding is going back to the fact that the higher performance X-ray tubes, which require liquid metal bearings, need more shielding, or whether the surplus shielding is required for additionally shielding the bearings.

   To clarify the situation, let's assume a medical X-ray device manuafacturer buys two identical X-ray tubes (same wattage, voltage, same geometries, etc.). The manufacturer produces two X-ray devices with them, one with lead bearings, another one with liquid bearings, but for the same application and use environment. We understand that the liquid metal bearings would need to be larger than the lead bearings. We wonder why this would require more lead shielding. We are not clear about which parts of the device actually need to be shielded, i.e. whether the bearings are shielded as well, or whether it is just the tube. To clarify and narrow down the background of the question, we prepared a prepared the below figures modified from the figure in your exemption renewal request.

   Firstly, the hypothetical situation described above is not possible and would never occur. No manufacturer would make two identical X-ray tubes, one with liquid metal bearings and the other with lead bearings. This is because, the choice of bearing depends on the amount of heat that has to be conducted through the bearing and out of the X-ray tube. If there is sufficient heat generated to vapourise the lead coating on the ball bearing then the manufacturer is forced to use the larger-size liquid bearings. X-ray generation is inefficient and results in heat being generated. It is X-ray energy output power that determines the quantity of heat generated and so which type of bearing can be used, although output frequency, X-ray on-off time and other variables also determine which type of bearings can be used. X-ray Tube housing assemblies with liquid metal bearing require also an active cooling system which makes the device much more complex and bulky.

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

Only the tube is shielded. All manufacturers aim to make the X-ray tube as small as possible and to use the smallest amount of lead shielding needed for safe use, not only to protect health and the environment but also to ensure that the X-ray tube is as light-weight as possible, especially with portable X-ray equipment. Lead radiation shielding is located in the X-ray tube housing. Bearings are located inside the X-ray tube assembly. Therefore the larger the size of tube, the more lead shielding will be required.

We hope this helps to explain the reason why each type of bearing is used. Liquid metal bearings are relatively large, complex and occupy much more space than lead coated ball bearings, which are much simpler and so occupy a lot less space. We have answered the questions below even though the comparison would never occur in reality.

a. Based on the above fictive example of the X-ray device manufacturer: Would the X-ray device produced with liquid metal bearings contain more lead in shieldings than the other one produced with lead bearings?

In general yes, because liquid metal bearings are much larger-size than small lead-coated ball bearings

b. Does the shielding cover the X-ray tube only (option A), or are the bearings (and the supporting structures) shielded as well (option B)? In case of option B: Why are the bearings shielded as well?

The shielding covers the x-ray tube only-option A. The shielding is located in the X-ray tube housing.

c. In case neither of these two options are correct, please explain the real situation.

The diagrams below show the arrangement of a CT scanner where the X-ray tube and detector rotate around the patient (option A is more accurate but there is also shielding in the detector). The bearings that allow this rotation of a CT scanner are not X-ray tube bearings that are in scope of exemption 2 and these bearings do not contain lead. X-ray tube bearings are located inside the X-ray tube. There are also many other types of X-ray equipment in which the X-ray tube and detector are located at fixed positions and so do not rotate around the patient.

It may help to see diagrams of an X-ray tube. The diagram below shows a simple design with rotating anode held inside a vacuum case. There is a vacuum inside the vacuum case and the vacuum case is coated with lead shielding except for an opening that allows the X-rays to emerge. Note that modern commercial medical X-ray tubes use aluminium alloy as the vacuum case instead of glass as this is less likely to be damaged in use.

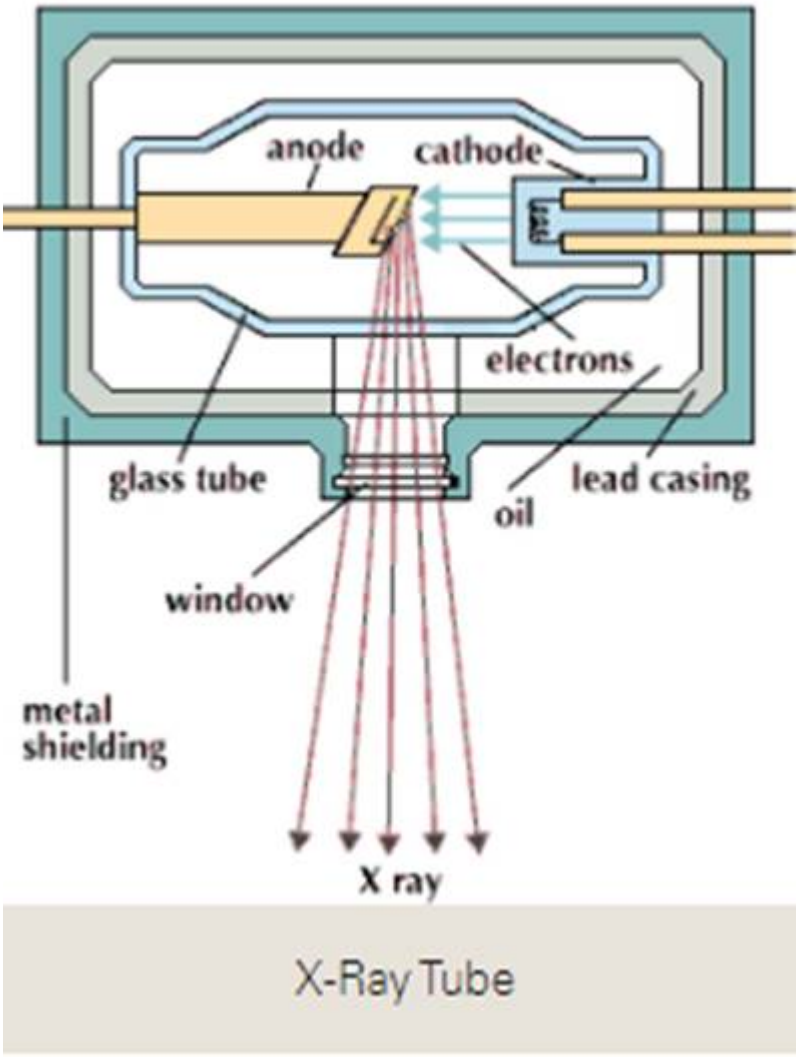

Figure 1 Conventional X-Ray Tube Housing

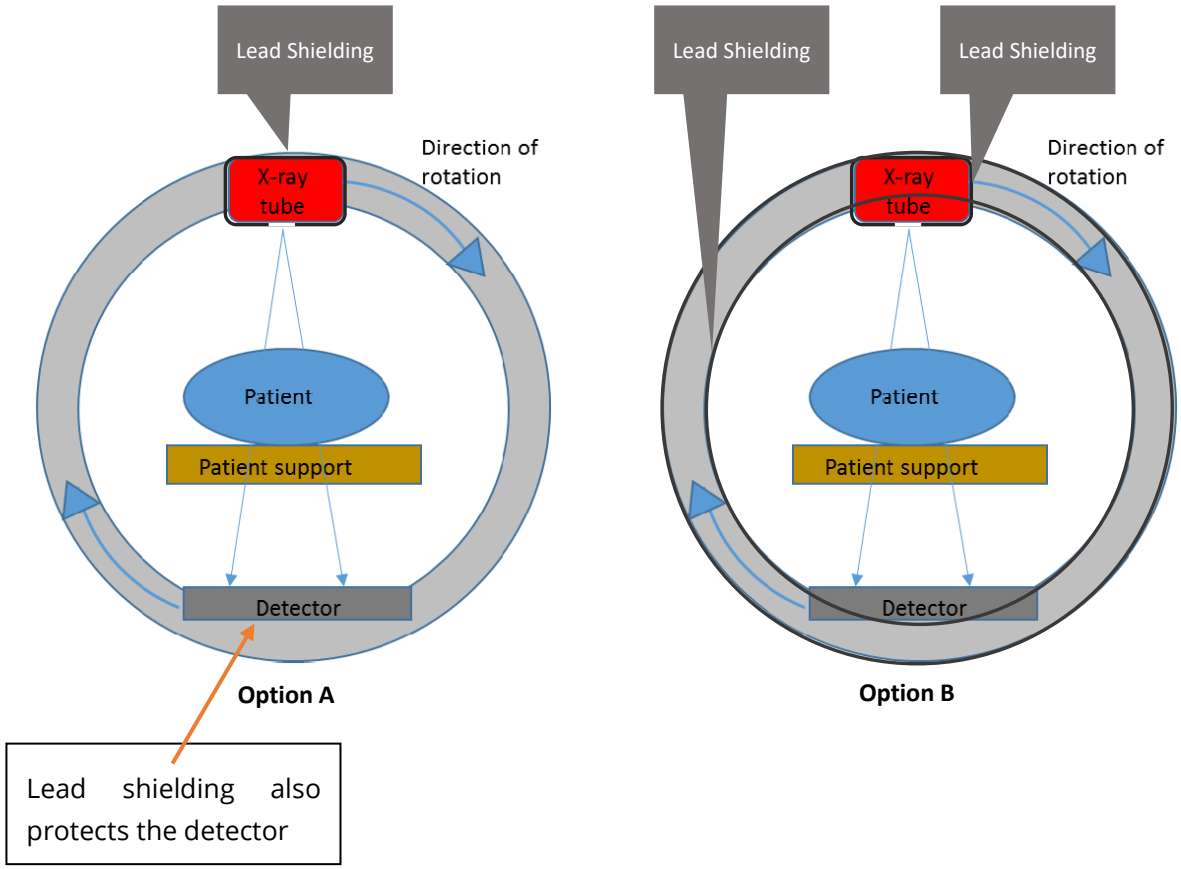

Figure 2 Diagram of Option A and Option B Shielding

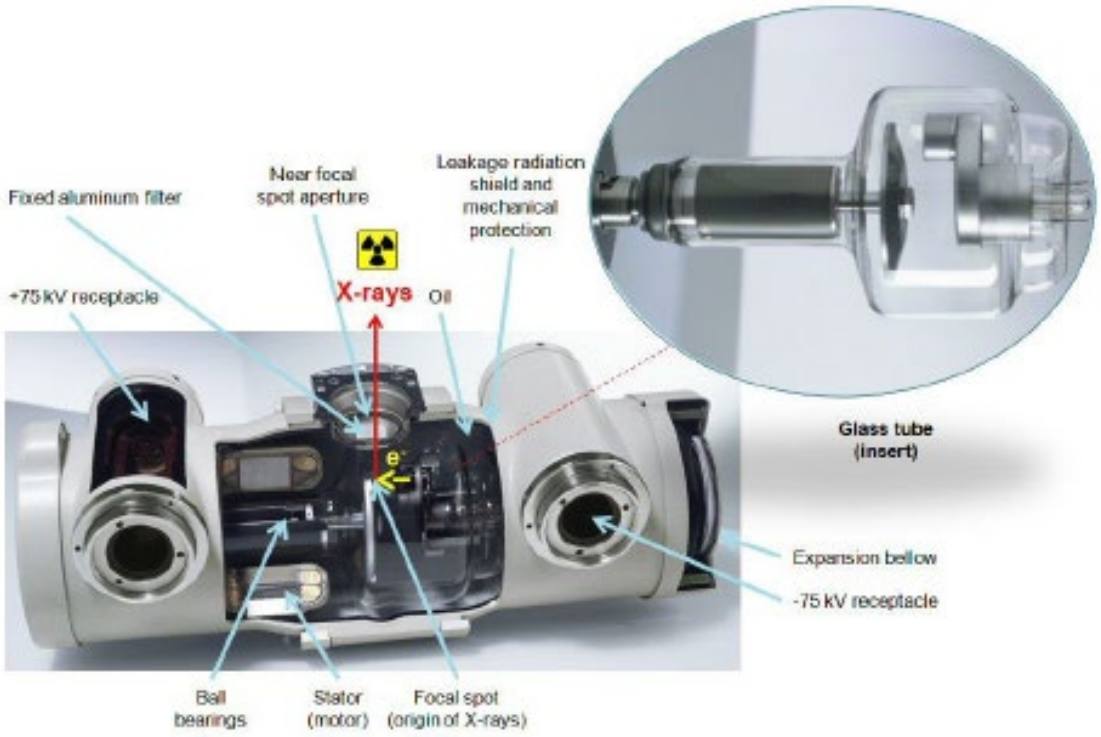

Figure 3 Conventional X-Ray Tube Housing Assembly with ball bearing

Item	Designation
1	Pressure relief valve
2	High-voltage receptacle, cathode side
3	Radiation protection housing
4	Heat exchanger

Table 1: Overview of the X-ray tube assembly

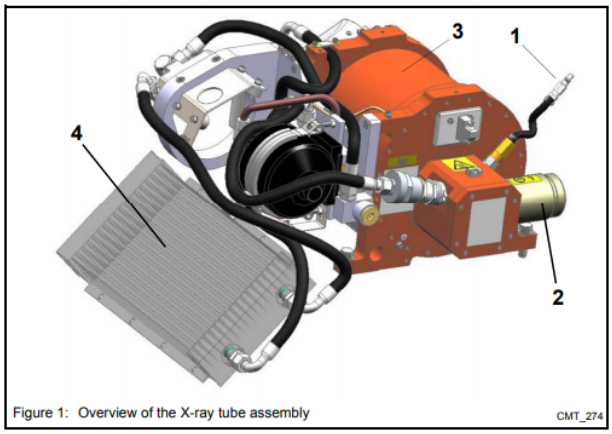

Figure 1: Overview of the X-ray tube assembly CMT_274

Figure 4 X-Ray Tube Housing Assembly for CT application with liquid metal bearing

Please be informed 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.

3. References

Goodman (2006): Review of Directive 2002/95/EC (RoHS) Categories 8 and 9. Final Report. ERA Report 2006-0383. Unter Mitarbeit von Paul Goodman, ERA Technology Ltd. ERA Technology Ltd. Online verfügbar unter https://ec.europa.eu/environment/pdf/waste/weee/era_study_final_report.pdf, zuletzt geprüft am 06.12.2013.