Questionnaire 1 (Clarification) Exemption 2 of RoHS Annex IV

Wording of the Requested Exemption:

Lead bearings in X-ray tubes

Requested validity: *7 years*

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.

COCIR 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 24 August 2020 latest.

2. Questions

1. On page 7 of your exemption request you alternative x-ray tube designs. Low and medium power tubes are operated with fixed anodes (first paragraph), highest power applications with liquid metal bearings (third paragraph). In the second paragraph, it seems that lead may no longer be viable, but gallium not (yet) required. Is there a third design of X-ray tubes besides the lead and liquid bearing types?

   There are three designs of X-ray tubes described on page 7.

   - Fixed anode – these do not require bearings as the anode does not rotate. This is possible only when the power is very low or on for a short time so that the anode does not melt from the electron beam
   - Rotating anodes with lead bearings. These are used when the electron beam power is sufficient to melt a stationary anode, but not so high that the lead metal of the bearings vaporizes inside the X-ray tube
   - Rotating anode with liquid metal bearings. These are large, complex and use exotic materials such as gallium and consume more power than the other two types. They are used when the electron beam power is too high for lead coated bearings to be used.

   Note that the electron beam power and "on-time" which are required for imaging depends on many variables including the types of medical diagnosis or treatment which the X-ray equipment is intended to be used.

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

2. You describe that metal bearings are likely to cause excessive wear and noise.
Ceramic bearings are used in many high quality and challenging applications, ranging from ceramic highest quality hubs for bicycles (lowest friction!) to industrial hubs with high frequencies (high durability and stability). If noise is a sign of friction and energy losses, it could be assumed that ceramic bearings might be a viable option given their above uses.

    a. Do you have any clear evidence that such bearings are inappropriate? Did you ever test this?

Medical X-ray tube manufacturers have considered many materials for bearings including ceramics. In X-ray tubes, **heat dissipation** is key as the Bremsstrahlung process converts the majority (99%) of energy to heat which must be conducted away and a significant proportion of this is via the metal bearings. If heat is not conducted away, the focal track on the anode becomes very hot reaching temperatures which can lead to the destruction of the X-ray unit if the heat is not distributed over a larger surface area and the heat is subsequently removed from the unit. Some of the heat generated is conducted away via the bearings, but ceramics in general show a low thermal conduction.

The bearings also need to be **electrical conductors** for the X-ray tube to function correctly, with some manufacturers requiring up to 1A current at 150kV to be transferred with low resistance via the bearing. All commercially available ceramics bearing are electrically and thermally insulating, so due to the intrinsic properties of ceramics, they cannot be used. Even if an additional contact was to be used it cannot be ensured that the tube current only passes over the contact point. If the tube current was to pass over the ceramic (rather than the contact point), high temperatures and pitting may occur in the bearings, leading to current interruptions, problems with the electronic signals of the system and interrupt the X-ray exposure.

COCIR understand that there are two types of ceramic bearings used commercially. Pure ceramic bearings without lubricants are suitable only in low rotation speed applications whereas rotation speeds in X-ray tubes are very high (up to 9000rpm[2] / 9700rpm[3]). At higher speeds "hybrid bearings" bearings are sometimes used but require the use of lubricants, which cannot be used in X-ray tubes, which must maintain a **high vacuum** for many years.

Another limitation of ceramic bearings is their **poor resistance to shock loads** as ceramics are relatively brittle materials in comparison with the coated steel bearings that are used. Because ceramics bearings can fail when impacted, they cannot be used as X-ray tube bearings. The consequence would be a so called "hard down situation", in which no further x-ray exposure and imaging as planned by the medical staff is possible in the clinical application (e.g. this could be with a catheter still inside the patient during a procedure).

    b. If not, what are the reasons why this was not tested?

Please see answer to 2a.

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.

[2] https://www.dunlee.com/c-dam/dunlee/downloads/5117253_Dunlee_Datasheet_DU33100-E.pdf