Questionnaire 3 COCIR Exemption 1 of RoHS Annex IV

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 26 September 2021.

2. Questions

1) You mentioned in Questionnaire 1, that one manufacturer has been able to produce an ionization chamber with tin instead of lead.

   a. Who is that manufacturer and since when has this ionization chamber been on the market already?

      Manufacturer: Siemens Healthcare GmbH

      The first x-ray model using this new technology was placed on the market in 2013 by Siemens.

      We received some information that Varex Imaging Corp have also made lead free ionisation chambers available since 2014 but we have not been able to confirm. The website and technical sheets do not report any information about lead free solutions, so it may not be accurate.

   b. Has this lead-free ionization chamber already been used in any X-ray devices?

      Today a few entirely new developed radiology systems by Siemens Healthcare GmbH use the lead-free chamber.

   c. Do you have any information about the experiences of the few X-ray devices already operating with this lead-free ionization chamber?

      The devices by Siemens are working within their specifications.

   d. Why has the lead-free ionization chamber not yet been used in other X-ray models so far?

      As we said previously the design cycle for x-rays devices varies between 5 and 7 years. A new device uses most of the technology used by previous generations.

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

The innovative part is always a small one. The ionization chamber is part of the image chain (tube, generator, chamber, collimator, detector). This technology has a design cycle that is far longer than the device itself and is used unchanged in successive generations. The chamber in particular plays a critical safety role and, for instance, unlike tubes and detectors, cannot be changed without redesigning the whole image chain. To use lead-free ionization chambers the whole calibration process of the image chain for every system variation would have to be to be significantly changed. It is a huge development effort. First have to find out a way to design and manufacture such chambers, or work with manufacturers of lead-free chambers, in a way to ensure absolute reliability.

Secondly, the redesign of the image chain is not even possible at the level of single product redesign as it would require more time than what is required to redesign the product (it can be assimilated to design a new car engine, versus redesigning a car model. Cars are designed to adapt to the new the engine, it is not the engine that is redesign to adapt to cars).

Therefore, the introduction of such lead-free technology could only happen at a very slow pace, at the moment when companies launch a redesign of the image chain. It can be additionally considered that the lead-free technology does not offer any clinical advantage compared to the lead based one.

2) You state that this lead-free ionization chamber can be used with very few newly designed X-ray devices. We interpret this in the sense that after a redesign taking into account the specific properties of the ionization chamber, each X-ray can be operated with this lead-free ionization chamber. Is this correct? If not, please specify technical parameters of X-rays which would exclude the use of lead-free ionization chambers even in those cases where these X-rays would have been redesigned specifically to allow the use of these chambers.

To date there are no technical parameters which preclude the use of lead-free ionization, beyond the requirement that the system is specifically designed for lead-free chambers (to allow for different calibration algorithms etc.). This will mean that even though new systems are currently under development, the consideration for lead-free must have been implemented from the outset as the entire image chain needs to use either the lead or lead-free version, as mixing is not possible. Please also note, as explained in the previous answer that lead-free chambers are not available on the market to be purchased. It is a new technology that has been developed by one single manufacturer to our knowledge. Most manufacturers of x-ray devices simply purchase lead-based ionization chambers. The time to develop a similar technology and to ensure it is reliable, should also be taken into account.

3) In the renewal request you stated that the replacement of lead containing chambers takes time and a lot of development steps. Could you please specify the necessary development steps and how long every step will take?

Development of the chamber itself, the generator and the radiology systems, would need to be undertaken. The resulting changes in the image chain (X-Ray-Tube, Generator, Ionizing Chamber, Software and Calibration) effectively results in a new device as changing in one part affects the others.

Every combination of the available flat panel detector energy dependent behaviour of the chain radiation-ionization chamber-generator-detector would have to be measured/found. After having found the right combination values the calibration algorithm has to be developed in the generator/system-software.

The development on system level firstly requires adaptation of the adjustment, calibration procedures and eventually reflecting those in the system software (system service software). The entire component chain (chamber, generator and system service software) then would need to be integrated, tested and undergo regulatory approval tests such as EMC, electrical safety typically by authorized test houses.

For Siemens Healthcare GmbH which has models utilising lead-free chambers the following timeframes could be expected for the redesign of a device:

Development: Integration of chamber and definition of interface electronic (value): 3-4 years

Development of the generator respectively modification of the generator electronics: 2-3 years

However, manufacturers which do not have this experience or an already working lead-free chamber , could take significantly longer as the function lead provides to such devices is so integral to the function of the device.

For global approvals, after successful testing of the component changes, results need to be shared with specific authorities for renewal of the respective country licenses, which can require confirmation test by local authorities e.g. China.

Please be informed that answers to these questions may be published as part of the review process of this request and thereafter. 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 help the review process if you could kindly provide the information in formats that allow copying text, figures and tables to be included into the review report.