Questionnaire 1 (Clarification) Exemption 1 of RoHS Annex IV

Cadmium and lead in detectors for ionising radiation:

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 has 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 September 1st 2020 latest.

2. Questions

About detectors:

1. If I understood well, there are alternatives to CdTe and CZT that are currently used for ionizing radiation detectors, but you would like to enlarge the scope of applications of CdTe and CZT and replace other materials by Cd-based detectors. The main reasons are the higher image quality and the shorter time exposure for patients. Is it correct?

   Yes, this is correct although dose-reduction for the patient is also important. It should be noted that the applications that are transitioning to cadmium alternatives are still within the current scope of the exemption, so the exemption scope is not being enlarged.

2. You mention that zinc telluride and cadmium telluride do not need a cooling system to achieve an acceptable signal to noise ratio.

   a. Would it be possible for some applications to use another material combined with a cooling system to achieve the same performances as Cd-based materials?

      For the applications described in our exemption extension request the use of a cooling system is not technically practical. Additionally, those materials which use Ge and which required cooling, have a higher diffusion radius which leads to a reduced spatial resolution (pixel size) compared to Cd-based materials, so could not be described as achieving the same performance. CdTe and CZT are wide band gap room temperature semiconductor radiation detectors that do not need cooling.

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

3. You mention research on GaAs, HgI2, InSb, TlBr, PbI… There are currently not commercially available for medical imaging equipment. Are they close to be commercially available? What is the status on their development?

   Not as far as we know. At present they are available only in small sizes and small numbers for research. Current development of GaAs can be compared to the stage of development of CZT in the 1990's due to its performance and yield. Development of CZT required since the 1990s an additional 10 years of development for niche applications and 25 years for mainstream medical applications such as CT.

   For CT detector application (energy range 20keV to 140keV) one would need a sensor of 5mm in thickness (for comparable absorption to 1.6mm CdTe). Such a thickness in a quality being sufficient for CT X-ray detectors is not yet available – even at research level. For manufacturing GaAs in X-ray detector grade quality, one has in principle two possibilities, either slicing a big ingot in wafers and performing Post-growth doping with chromium or by using epitaxial growth techniques. Both, the Post-growth doping and the epitaxial growth are limited to low thickness as of about 500µm[2]. This is still less than the required 5mm. All other disadvantages of GaAs demonstrating that GaAs is inferior to CdTe and CdZnTe as outlined in the data of table 3 of COCIR's exemption renewal request would also remain.

   The other materials stated are even further away from being commercially available, in addition to the fact that HgI2 or PbI could not used without an exemption.

4. Flat panel detector with scintillator are currently used in many medical applications. They are gradually replaced by CdTe and CZT to improve image quality and reduce the exposure time. Can you give a qualitative comparison on these two aspects between the two types of materials? What is exactly the exposure time and x-ray dose reduction with CdTe and CZT?

   The data in table 1 of COCIR's exemption renewal request shows that the efficiency of CdTe and CdZnTe detectors is 60% whereas flat panel detectors with scintillators are only 40%. This allows the radiation dose to be reduced by about 30%. In fact the difference is even larger because, as shown in table 2, CdTe and CZT semiconductor detectors can detect single photons, so are able to count number of photons per pixel, in comparison a flat panel with scintillator has a detection limit of 10^4 photons/mm so is much less sensitive at low levels of X-ray energy. To be able to achieve a reading with a flat panel with scintillator patients would have to be exposed for longer due to the lower sensitivity.

   A recent verification test during clinical lung imaging using CZT confirmed that exposure can be reduced to 1/5 (20%) of the radiation dose, compared to state of the art non-CZT technology[3]. Other sources from preclinical prototype CT based on CdTe sensors show for certain applications a reduction in dose of about up to 30% at the same image quality[4]. This very large decrease in exposure to radiation will significantly reduce the risk of cancer from the X-radiation.

5. It seems that not all medical application require the same spatial resolution (from 1 to 20 mm^{-1} according to the characteristics given in page 9). For the applications requiring a high pixel size, can an alternative material be sufficient?

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[2] Veale et al.; Chromium compensated gallium arsenide detectors for X-ray and γ-ray spectroscopic imaging; Nucl. Instrum. Meth. A

[3] S. SiMohamed, L. Bussel, P. Douek, fig 6.1 in Spectral, Photon Counting Computed Tomography Editors: K Taguchi, I Blevis, K Iniewski CRC Press 2020

[4] Kappler et al.; A Hybrid Research Prototype CT Scanner with Photon Counting Detector; IEEE Transactions on medical imaging

As flat panel silicon detectors with scintillator coatings are widely used, they could be deemed as sufficient due to their current use. However, this overlooks the increased diagnostic capability that will still be useful in all applications, such as ‘afterglow effects’ causing blurring or temperature or moisture sensitivity as mentioned for scintillators in the exemption request. Furthermore, the reduction in the level of exposure to X-ray dose, due to increased sensitivity of CdTe and CdZnTe is important for all applications.

6. What is COCIR’s interest to have the CdTe and CdZT detectors in non-industrial monitoring and control instruments included into the scope of the exemption? How would this be of relevance for medical devices, hospitals and other medical institutions?

   COCIR’s concern is medical devices only . However some medical device manufacturers also produce veterinary products which might use these types of detector. If these are produced solely for animal use, they are not medical devices and would probably be regarded as industrial monitoring and control instruments. These veterinary products use the same designs as medical devices and the reasons for using CdTe and CdZnTe are the same.

About the ionization chamber:

1. The operation of the ionization chamber is not clear. What is the link between the current generated (between the anode and cathode) and the capacitor that shuts down the X-ray tube? What is the role of lead?

   Lead is used as the negative electrode of the ionization chamber. X-rays cause secondary electrons to be emitted from the negative lead coated electrode. Which generates a current through the chamber and the associated circuit, which includes a capacitor. The capacitor is charged at a rate which is determined by the quantity of ionisation in the chamber from the X-radiation exposure. When the capacitor is charged to a certain voltage, it automatically shuts down the X-ray tube and stops X-ray exposure.

2. The position of the ionization chamber is not clear. On the scheme page 7, the ionization chamber is between the patient and the detector. In table 4, you write that the ionization chamber is between the X-ray source and the patient.

   We apologize, there is an error in table 4. Table 4 should state “after X-rays emerge from patient”.

3. You mention that it is not possible to replace Lead by another metal since the complete equipment is calibrated and designed for a lead-based ionization chamber. It is now already scientifically and technically practicable that all new developed systems are free from lead. Is it correct? Is tin the only substitute?

   So far tin is the only alternative to lead which one manufacturer has been able to develop for newly designed and calibrated imaging systems. However, this does not mean that it is possible for all systems.

4. If the exemption was renewed, we propose the below wording with a more precise scope definition:

   a. Cadmium in cadmium telluride and cadmium zinc telluride X-ray detectors for digital imaging

   b. Lead in coatings of ionization chambers of medical X-ray devices

As stated in the exemption renewal request, although beyond the scope of the COCIR application, there are many other applications which would not fit into the above proposed wording.

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.