Questionnaire No. 6

“Lead to enable thermal compression process to make a vacuum tight connection between aluminium and steel for X-ray image intensifiers”

Background

The Öko-Institut together with Fraunhofer IZM has been appointed for the technical assistance in reviewing the requests for exemptions from the requirements of the RoHS Directive 2011/85/EU (RoHS II) by the European Commission. You have submitted the above mentioned request for exemption which has been subject to a first completeness and understandability check.

As a result we have identified that there is some information missing and a few questions to clarify before we can proceed with the online consultation on your request. Therefore we kindly ask you to reformulate your request taking the following points into consideration.

Questions

1. How much lead is used in image intensifiers (II) per X-ray equipment? Please provide figures for a typical or average single device for Europe and worldwide. 33 – 42 grams lead per image intensifier. This is the same for units sold in the EU and countries outside the EU. Each imaging system has one image intensifier.
2. How much cadmium or other toxic substances like thallium are used in an average or typical digital detector (DD)? Please provide figures for a typical or average single device for Europe and worldwide. We estimate that there is 6.5 grams of cadmium in a digital cadmium telluride detector of average size (20 x 20 x 6mm). Thallium is used as thallium doped caesium iodide with silicon digital detectors at a concentration typically of ~1% of the thin phosphor layer. These coatings are typically 6 – 8 microns thick so would contain ~6 µg thallium in a 20 x 20 detector. The same types of detectors are sold in the EU and the rest of the world so the cadmium and thallium content are the same worldwide.
3. You state a trend to change new systems to use digital detectors. Why? Please explain the advantages and disadvantages of both technologies.

Advantages of digital detectors	Disadvantages of digital detectors
Lower radiation dose required for single images	When used for techniques where continuous imaging (diagnostic fluoroscopy) is required, patients are exposed to a larger radiation dose
Better spatial resolution	Currently much more expensive (explained in request dossier) so smaller hospitals may not be able to afford these
Fast frame rate imaging possible so fast changes and movement can be viewed.	30 frames/second can be achieved only with small area detectors which may give too little visual information. Maximum frame rates for larger detectors is much less.

There is a trend to use digital detectors for producing single X-ray images but where continuous exposure is required such as for diagnostic imaging, angiography and radioscopically guided interventional procedures.

4. You say that digital detector equipment is more expensive, and a ban of II thus would prevent important replacements of older equipment. If so, how can you take the responsibility and replace these systems by more expensive digital ones thus endangering human health? A risk to human health would be created where hospitals with limited budgets are forced to retain their older systems for longer than they would otherwise do so if cheaper image intensifier systems were available (available after 2014 only with this exemption). The affect on health from using older equipment is complex and is discussed in the dossier. X-ray systems suppliers cannot sell digital systems at a loss and the price differences given in the dossier are due to the higher costs involved with manufacture of digital systems.
5. You put forward that several technical issues are still to be resolved with digital detectors, such as reducing the radiation dose. Which other technical issues need to be resolved?

Speed; large area digital detectors have much lower frame rates for dynamic imaging than II systems. One prevalent fluoroscopy study is the so-called “swallow study”. Speech pathologists require that these studies are taken with 30 frames / second. Currently only small size digital detectors can reach this speed, with areas up to 15x15 cm which is too small to adequately represent the human anatomy (area of interest is 25-30 cm). In other words, this important exam cannot be done with digital detectors in line with the current medical requirements – only II’s provide the necessary coverage at the required speed.

6. Which are the applications/examinations where the radiation dose would be higher using digital detectors instead of II? How much higher would the dose be? In which other applications/examinations is the II equipment still indispensable? Higher radiation

does occur where continuous real-time images are required during surgery (fluoroscopy). This occurs during angiography (heart surgery), inserting implants, gastrointestinal tract investigations, orthopaedic surgery, angiography (blood vessels), inserting catheters, urology, implanting pacemakers, etc. discopgraphy and other procedures. In general, single images require similar doses with digital detectors and with image intensifiers. The reason is that with dynamic continuous imaging, the radiation does should be minimised to prevent harm to the patient. This is possible for II systems as the loss of definition is acceptable for these procedures. However the radiation level cannot be significantly reduced with digital detectors because the background electronic noise level dominates the digital signal so that imaging would be impossible.

7. You explain that organic contaminants are removed from the inside of II by heating the assembly to 200 - 220°C during evacuation, which is one reason why the lead is required. Did you try alternative cleaning methods, such as vacuum storage of the parts prior to assembly or others? Heating the assembled and evacuated image intensifier to this temperature in combination with getter techniques is needed to get rid of the organic contamination that remains in the image intensifier during evacuation These contaminants form gases when they are heated to this temperature. If these gasses are not removed sufficiently these will seriously harm the functionality of the photo cathode and therewith the functionality of the image intensifier. Image intensifier manufacturers also perform extensive cleaning (washing, etching, etc) before assembling and parts are stored in a very clean nitrogen environment but research has shown that this type of cleaning and storage does not remove the organic contaminants that form gasses in the image intensifier tube. Vacuum heating of parts before assembly is not sufficiently effective because the parts usually become contaminated after this treatment due to handling and storage due to trace organic contaminants in the air that are adsorbed onto the clean surfaces. Vacuum baking is a common process for all types of vacuum equipment and it is necessary to do this whenever high vacuum equipment is assembled or reassembled after repair.
8. Figure 1 in your submission: Please provide a better quality figure. The current one is unreadable. This will be sent separately
9. You put forward the digital detector equipment causes higher investment cost. Please provide cost of ownership data comprising cost such as energy consumption, maintenance, treatment time, upgradeability, overall life time, etc., for the two systems.

The market for lower priced II systems sold to hospitals in countries with smaller budgets such as those in some South and Southeast EU Member States is rapidly growing. These countries require state of the art systems that are economically attractive enough to invest in. Those systems can only be realised when the IITV system is offered. We see an increase in the Value Systems market for the IITV system. This strengthens the need for the IITV based systems to be available for the coming years or decade.

10. You claim that mobile C-arc imaging systems use image intensifiers as mobility is a potential risk to the more fragile digital detectors, and they are difficult to repair. Nevertheless, "a few mobile digital C-arc systems were sold in the EU in recent years." Why? How did these manufacturers solve the above problems related to mobility?

Detectors are bonded using large area array solder ball bonds. Lead-free solder bonds can fail when exposed to severe vibration as numerous studies have shown that these alloys are more susceptible to vibration than tin/lead. Various methods are being pursued to increase reliability such as using solder alloys that are more resistant to vibration and by using new types of underfill material such as those with BGAs.

11. You explain that other metals than lead and alloys cannot be used in the II. Please provide the tests you conducted with such alternative materials. It has not been possible to carry out tests with alternative seal metals because none have been identified that have all of the essential characteristics that are required. Tin and Indium have a too low melting point taking into account the required temperature to remove gasses by vacuum baking. Copper is only suitable as a seal for (stainless) steel/steel joints (same thermal expansion coefficient no thermal mismatch). Image intensifiers require a combination of stainless steel / aluminum so movement due to temperature changes is significant. Originally gold was not considered because of its price but is not expected to be suitable because of its like cold welding characteristics. This is explained in the request dossier.
12. You state that gold and other soft metals cold weld and therefore are inappropriate. Cold welding, however, forms a connect, which is needed. Please explain why the cold welding is a problem in this context. The steel and aluminium have different thermal expansion coefficients and so it is necessary for one of these to slide over the seal to prevent losing the vacuum (see figure 2). If a cold weld forms, the differential expansion and contraction of the aluminium and steel would distort and tear the seal so that it leaks. Metals that cold weld such as gold are used as vacuum gaskets in mass spectrometers but this is to seal the same metals (stainless steel) and so no sideways movement due to thermal expansion mismatch occurs.
13. What happens to the thallium in the DD at end of life of the equipment? As the amount is very small (~6µg), this is no recovered. If the electrical waste is treated thermally, this will be emitted as thallium oxide vapour and this should be collected by scrubbers and the scrubber waste would be disposed to landfill (as hazardous waste). Due to the extremely small amount, thallium is not monitored specifically. Used detectors may alternatively be discarded to landfill as silicon has no value. However, digital detectors are relatively new and so none as yet have reached end of life.
14. You state that doses for II and DD equipment are comparable in single exposure imaging, in the diagnostic fluoroscopy they are not. Why are doses comparable in the

single exposure imaging, despite of the higher spatial resolution, while in diagnostic fluoroscopy, the digital detectors require higher doses?

For a diagnostic fluoroscopy examination (dynamic imaging) a very low X-ray dose is used because it is diagnostically acceptable to have a certain "noise" level – however, digital detectors have a higher spatial resolution which tends to increase the noise level at dose levels comparable to II so that it is necessary to use higher doses to obtain a useful image. Therefore, the flat detector's advantage (higher spatial resolution) is of no use in dynamic imaging fluoroscopy.

For single exposure imaging, a high spatial resolution is an advantage and will probably be used with II systems. Such an image would probably "shot" with 3-4 times the dose of a dynamic fluoroscopy II image but would have a lower resolution and so may miss fine details such as hairline fractures. For single exposure radiographic exams at full resolution the dose applied for II and digital are comparable.

15. You state that mining and refining of lead is no risk at well regulated modern facilities. Most lead, however, is mined in developing or emerging market countries at low environmental and safety standards causing pollution and health impacts as well as losses of lives. Please explain. Please also explain whether and how far lead mining happens in countries with such well organized and high standard plants. We are referring to countries in the EU where industry must comply with the Industrial Emissions Directive. This legislation imposes limits on emissions of hazardous substances from lead extraction, refining and recycling installations. We agree that these strict controls are not imposed in some developing countries so that harmful emissions do occur. However this is a problem with mining of many metals so that harmful emissions may also occur when mining and extracting the potential substitutes materials.
16. You propose the following wording for the exemption: "Cadmium in phosphor coatings in image intensifiers for X-ray images until 31 December 2019 and in spare parts for X-ray systems placed on the EU market before 1 Jan 2020." This proposal is probably a oversight. Please provide a correct wording proposal. "Cadmium in phosphor coatings in image intensifiers for X-ray images until 31 December 2019. Cadmium may be used in phosphor coatings of image intensifiers for X-ray systems placed on the EU market before 1 Jan 2020."