Application for granting a new RoHS exemption: Hexavalent chromium in alkali dispensers for in-situ production of photocathodes

1. Name and address of applicant

COCIR : European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry
Blvd A. Reyers 80
1020 Brussels
Contact: Mr. Riccardo Corridori
Tel: 027068966
corridori@cocir.org

2. Summary of the application

Image intensifiers, photomultipliers and other similar devices use a component known as a photocathode which converts visible light (from an input phosphor) into electrons. Photocathodes used in these devices must be fabricated in-situ in vacuum inside the device due to the chemical reactivity of the alkali metals. The fabrication process is by a chemical reaction between a layer of antimony and an alkali metal vapour that is generated from alkali dispensers. The alkali dispenser contains a mixture of an alkali metal chromate and a reactive metal which when heated emits the alkali metal as a gas. Research into substitutes for chromate salts has so far been unsuccessful with alternatives giving inferior quality photocathodes. Alternative designs have also been considered but have technical disadvantages or a negative impact on health. This exemption is required because some hexavalent chromium remains inside the product that is placed on the market.

3. Description of materials and equipment for which the exemption is required

Several types of vacuum devices including image intensifiers (II, used with X-ray imaging equipment) and photomultiplier tubes (PMT, used for measurement of electromagnetic radiation) are fabricated by a process that uses alkali dispensers. The alkali dispenser is a sealed tube containing a mixture of an alkali metal dichromate with a reducing agent, usually zirconium/aluminium (Zr/Al) alloy powder. This mixture is heated electrically (via the electrical connections) and reacts to generate the alkali metal vapour and in some designs the gas pressure created also opens the dispenser.

$$Cs_2CrO_7 + Zr/Al = ZrO_2 + Al_2O_3 + Cr_2O_3 + Cs \text{ (vapour)}$$

The alkali metal vapour reacts with a thin antimony coating on a support structure to produce the alkali antimonide photocathode. This exemption is requested because the chemical reaction with the dichromate salt is usually incomplete and some hexavalent chromium remains in the dispenser device that remains inside the finished image intensifier or photomultiplier tube. The dispenser device is only used in the manufacturing process, and plays no part in the operation of the device.

Image intensifiers, photomultipliers and other similar devices use a component known as a photocathode which converts visible light into electrons. Image intensifiers use the following steps to amplify X-radiation to generate bright visible light images.

- X-radiation that has passed through the patient strikes an input phosphor with a photoemissive layer. This converts the weak input X-radiation into a weak visible light image that is projected and focussed onto a photocathode.
- The photocathode is a layer consisting of compounds of alkali metals such as caesium with antimony and arsenic and typically caesium antimonide is used although more complex mixtures are also used. The photocathode is charged to a high voltage so that where light from the input phosphor strikes it on one side, this is converted and amplified into electrons that are emitted from the other side that travel to the output phosphor screen which converts the electron image into a bright visible light image.

The best performing photocathodes are complex mixtures of compounds of alkali metals such as potassium and caesium with Group V elements such as antimony and arsenic. Alkali metals are very reactive and will react extremely rapidly with minute traces of oxygen and moisture vapour and so the alkali antimonide photocathode coating layer must be fabricated in-situ in the absence of air and moisture and kept permanently within a high vacuum. The fabrication procedure used is to first assemble the II or PMT with a thin coating of antimony metal on the photocathode support. The alkali dispenser is inserted inside the assembled II or PMT with electrical connections to the alkali dispenser's heaters and then the II or PMT is evacuated to remove all traces of air and then sealed. It is normal to bake the equipment while pumping under vacuum to desorb moisture and other contamination from internal surfaces that would react with alkali metals or degrade the performance. Internal parts including the alkali dispenser must therefore be stable at baking temperature which is typically ~200°C. Once evacuated and sealed, the alkali dispenser is electrically heated causing the mixture of substances inside the dispenser to chemically react and release the alkali metal as a vapour. This vapour then reacts with the layer of antimony on the photocathode support to create the photocathode, e.g. caesium antimonide.

$$Cs + Sb = CsSb$$

It is important to generate sufficient alkali metal at a controlled rate without particulate or other contamination. Some alkali dispensers emit traces of hydrogen when heated because zirconium adsorbs this gas and then releases it when heated. Hydrogen has to be removed by "hydrogen getters".

The image below shows an example of alkali dispensers.

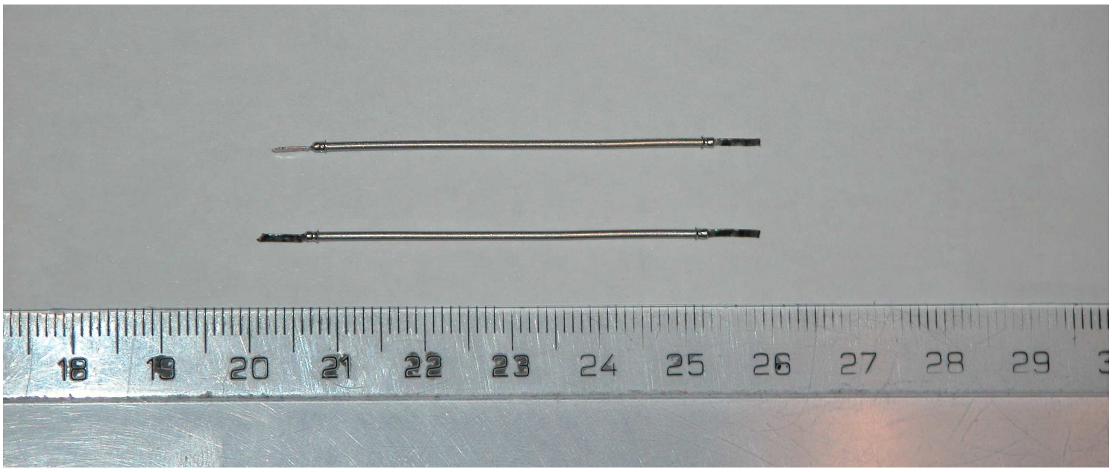


Figure 1. Alkali dispensers used in image intensifiers
The tubes contain the mixture of chemicals and a heater element with electrical connections at each end. The images shows below how these are connected inside an image intensifier and a fully assembled image intensifier.

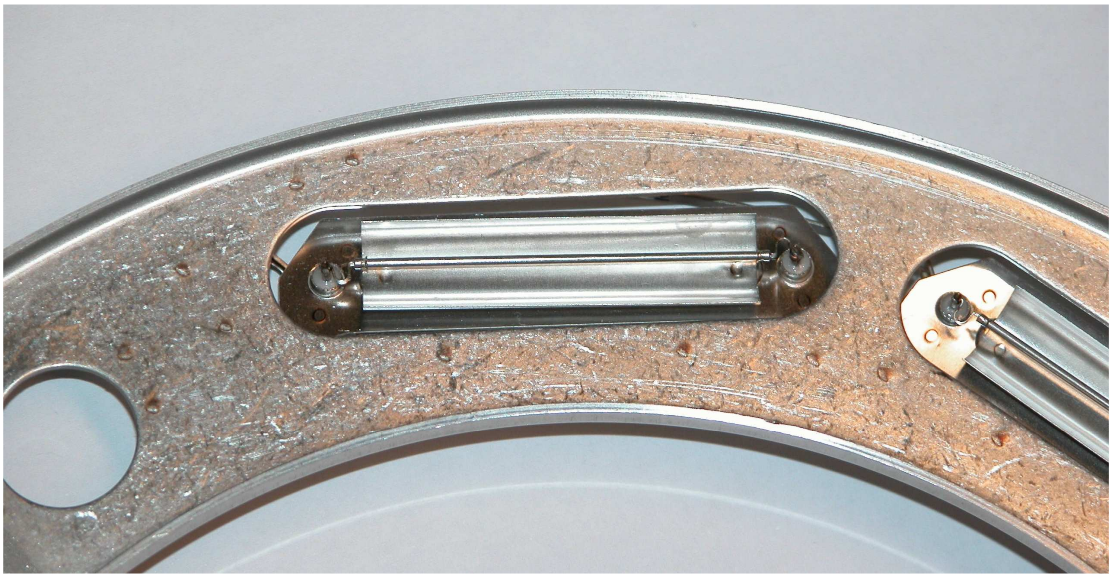


Figure 2. Alkali dispensers in mounting frame that will be installed into the image intensifier

Figure 3. Fully assembled image intensifier which will be installed in the X-ray system

X-ray image intensifiers were first used for X-ray imaging in 1948. They are gradually being replaced by digital semiconductor detectors which have several technical advantages although they also have some disadvantages and so image intensifier systems are the preferred choice for certain applications. Currently, digital detectors are considerably more expensive and are used only in "high-end" systems. High-end systems have much higher prices than image intensifier systems (about double) and this is a serious limitation for many hospitals in the EU because the treatment times for both systems are similar.

Image intensifiers are used in two main types of X-ray imaging equipment:

- **Mobile X-ray C-arc** – these are smaller systems that are moved around hospitals to examine patients that cannot be moved, for example if they are receiving emergency treatment or during surgery. These are relatively simple low priced systems but are robust and are not damaged by being moved. Flat digital detectors are used in some high-end mobile C-arc systems but these detectors are relatively fragile and so there is a risk of damage with mobile systems. Within the EU as a whole, it is predicted that by 2014, about 75% of mobile C-arc systems are expected to use image intensifiers.
- **Nearby controlled C-arc** - are stationary systems where the patient is brought to the equipment. As these are stationary, they can be larger and more complex and much more frequently have digital detectors with only 15% of systems in the EU being image intensifier types by 2014.

The continued availability of low-end image intensifier systems will be needed until digital detectors do not require higher radiation doses for all applications and also until the prices of digital detectors can be reduced to an extent that all health care providers in the EU are able to afford them. Image intensifier technology will still be needed for new equipment after medical devices are included in scope of the RoHS directive on 21 July 2014 but should not be needed in new systems after 2020 when it is expected that research into silicon digital detectors has resolved the technical issues that exist (such as reducing the radiation dose needed) and enabled digital systems to be sold at lower prices. After this date, image intensifiers will be needed as spare parts as replacements for faulty units in older X-ray systems.

4. Justification for exemption – Article 5 criteria

This exemption is required because of the issues with potential substitute designs and materials. Potential alternative designs for use with II and PMT are:

1. Alternatives substances to hexavalent chromium salts
2. External alkali dispensers and
3. The use of digital semiconductor detectors instead of image intensifiers for X-ray imaging.

The reasons why each of these cannot be universally used to replace hexavalent chromium are as follows:

4.1. Alternatives to chromates

Research into alternative substances that emit alkali metals in a controlled way is one potential alternative but no suitable alternatives have yet been developed as explained below. None of the potential alternatives give photocathodes with suitable performance.

4.2. 2. Location of alkali dispenser

Most current II designs use internal alkali dispensers although it is possible to connect an external alkali dispenser to the II or PMT and then to remove the dispenser after fabrication of the photocathode and creation of the vacuum seal. This however requires a significant design change and current designs cannot be adapted to use this approach. There are also technical disadvantages with external alkali dispensers as explained below. The cost of design change to move to an external dispenser would be very high because new designs of IIs would have to be built with new production lines. Existing production lines could not be used as these would still be needed to build replacement IIs that will continue to be used as spare replacement parts for existing pre-2014 X-ray imaging equipment (and so would not need to comply with RoHS). As the market for II is declining, manufacturers would not invest in redesigning their IIs or build new production lines and so the availability of IIs would very significantly decline. This would leave only a few models from one supplier who would dominate the market, removing competion. This would severely restrict the availability of IIs in the EU and insufficient to supply EU hospitals with the number of lower-end imaging systems that they currently purchase. With very little competition, prices of II would inevitably rise and this will also impact on healthcare providers in the EU.
Digital detectors are used only in high-end X-ray imaging products but image intensifiers are used in lower priced low-end systems. Lowe priced low-end performance systems are often the only option for hospitals that have limited new equipment budgets.

4.3. Digital detectors

Image intensifiers can be replaced by digital array detectors but these are used only in high-end imaging systems. The best performing digital semiconductor detectors contain Cd, Pb or Hg and so should not be considered as suitable substitutes. Silicon digital array detectors is the most common type used in high-end systems.

Digital detectors are considerably more expensive than image intensifiers and are used only in "high-end" systems although they are gaining an increasing market share in the EU. In Nordic countries, most new systems have digital detectors whereas some new image intensifier systems are sold in France, Germany and the UK. Hospitals in southern and eastern European countries currently buy more image intensifier systems than digital systems so that at present in the EU, about 45% of new X-ray systems sold have image intensifiers.
Digital detectors give good images compared to image intensifiers but have disadvantages as well as advantages. For some treatments, II systems and digital systems use similar X-ray doses but there are some treatments where digital detectors require slightly higher doses which will have a negative health impact on patients as is explained below.
If image intensifier systems were not available from 2014, this would have a negative impact on healthcare in the EU due to the larger radiation dose required for certain treatments as well as from the higher prices of digital systems. These are explained below.

Digital detectors are currently used mainly for "high-end" X-ray imaging systems that will be too expensive for smaller hospitals and private hospitals where more basic designs of X-ray imaging equipment are used, especially for mobile C-arc systems where high-end digital versions have a price that is double that of the image intensifier versions. As a result, there would be a much larger investment cost to install new digital systems which would prevent some hospitals in the EU from being able to buy new X-ray imaging equipment if image intensifiers were no longer available. This would have a negative effect on healthcare as patients would be forced to travel larger distances for treatment and this treatment could be delayed as there would be fewer facilities available.

Systems are designed as "high-end" or "low-end" to meet hospitals needs and minimise treatment costs. The cost of treating a patient is a combination of the cost of the equipment and the time needed for treatment. For example, if more advanced and more expensive technology shortens treatment time, the overall treatment cost could be lower than with a low-end system that requires a longer treatment time. Hospitals make these calculations to determine whether low or high end systems are appropriate for each type of X-ray system they buy. Treatment times for most x-ray imaging is however the same for image intensifier and digital systems. Currently, most mobile C-arc imaging systems use image intensifiers and these are moved around the hospital to take single X-ray images quickly. Mobility is a potential risk to the more fragile digital detectors which are difficult to repair but a few mobile digital C-arc systems were sold in the EU in recent years.

4.4. Impact of equipment price on health

If only more expensive "high-end" systems were available to healthcare providers in all EU States, this could prevent some hospitals from investing in as much new equipment as they would if low-end systems were available. Increases in healthcare equipment costs (due to RoHS) are unlikely to be matched by increases in funding available to healthcare providers such as the NHS in the UK and its counterparts in other EU Member States. Without increased funding, even

a small overall equipment price increase will restrict the quantity of new equipment that each healthcare provider can purchase as medical staff always asks for more new equipment than budgets allow. Typically, image intensifier imaging systems cost from less than €100,000 to up to ~€200,000 whereas a digital detector system range from €200,000 - 300,000 or more. Note that the price of image intensifiers is much less at about €7000 but image intensifiers and digital detectors are not interchangeable in x-ray system designs.
Large hospitals in the EU have equipment budgets of several million Euros but smaller hospitals budgets can be less than €1 million and so a price difference of ~€100,000 is very significant. If only the more expensive digital systems were available, purchase of new, state-of-the-art equipment could be delayed for a year or more to compensate for this funding shortfall.
All hospitals consider the cost of treatment of their patients and so if treatment time can be reduced, then it is cost effective to buy more expensive equipment. However, treatment times for II and digital systems are the same and so treatment costs per patient with digital systems are higher. For the price of one digital system, the hospital could buy two II systems and treat double the number of patients giving shorter waiting times and more comprehensive treatments, both of which would improve healthcare.

4.5. Effect of equipment age on healthcare

It is difficult to determine quantitatively the impact of a one year delay in purchase of new equipment to replace old equipment. For example, the National Radiotherapy Advisory Group which advises the UK Government Ministers said in 2007 that radiotherapy equipment should be replaced every 10 years. Their reasoning was that old equipment suffers from breakdowns due to wear causing longer recovery times, is less accurate and so causes more side-effects, whereas modern equipment gives superior performance so that full recovery is more likely and shorter treatments are needed. This is true of all types of medical equipment including X-ray imaging with image intensifiers. Overall, the healthcare costs from using older equipment are higher than with new equipment for these reasons but there is also an impact on patient’s health. The extent of this impact on health is however impossible to quantify. Over a ten year period there will have been improvements in diagnosis expertise, drug treatments, etc. as well as advances in medical technology so that the success rates of equipment built 10 years ago cannot be directly compared with success rates with new equipment but clearly there will be a difference. Where there are significant equipment price increases incurred by healthcare providers, the resulting restriction on new equipment must be detrimental to the health of patients.

5. Analysis of possible alternatives

5.1. Alternative alkali dispensers

Research has been carried into alternative types of alkali dispensers for many years, partly to avoid using hazardous hexavalent compounds but also because the alkali dispenser mixture can release detrimental impurities as well as the alkali metal. These include hydrogen gas released from the Zr/Al alloy which must be removed from the vacuum by a separate “getter”. There are several patents describing possible alternatives including one belonging to SAES Getters which is an Italian manufacturer of alkali dispensers although the only type of alkali dispensers currently sold by SAES Getters are the type that contain

dichromate salts. However an Austrian manufacturer, Alvatec, produces and supplies alkali dispensers that do not contain hexavalent chromium . These contain intermetallic compounds of bismuth with the alkali metal such as Bi_3Cs. A review of patents identified gold, aluminium and silicon as possible alloying elements with alkali metals that release the alkali metals on heating. However, none of these are available commercially.
Research by manufacturers since the 2006 ERA study has not however resolved all technical issues to enable any of the CrVI-free substitutes to be used. Investigations by one manufacturer have shown that many of the possible alternatives that they have evaluated are unstable and so either cannot be used or they give unreliable results so that the performance of the photocathode was poor. Reduced photocathode performance is unacceptable as this reduces the quality of the X-ray image. Lower II sensitivity results in higher X-ray doses to achieve the same image quality and so poses a health risk to patients.

One manufacturer of photomultiplier tubes (PMT) has evaluated Alvatec's alkali dispensers and found two problems. Most PMT designs are fairly small and are made of glass that is sealed by melting the glass after the parts including the alkali dispenser are assembled. The dispenser is hermetically sealed with a low melting point metal and indium is chosen as it melts at a low temperature, forms a good gas-tight seal and is non-toxic. No other metals would have all of these properties. However the glass melting temperature is much higher than the melting point of indium so that the indium melts when the PMT is sealed and some of the alkali metal escapes before it can be used. This leaves insufficient alkali remaining to form the photocathode. The second problem is that a high current is needed to activate the alkali dispenser mixture. This current is passed from outside of the device into the PMT via wires that bond to the glass. The high current however causes the wire temperature to rise and this causes the wire to expand and can crack the glass which would then leak destroying the vacuum. This problem would also occur with larger image intensifiers that are made of metal, usually steel and glass to metal (steel) seals. The heater wires must be insulated from the metal with a glass hermetic seal to maintain the vacuum. Resistance heating of the alkali dispenser wires could cause the glass seal to crack compromising the vacuum. This has not been an issue with traditional alkali dispensers containing hexavalent chromium.

One image intensifier manufacturer has also evaluated the Alvatec dispensers. Because of the design of the Alvatec dispensers, they found that the alkali metal is produced at a very different rate to CrVI-type dispensers so that the image quality was very poor. Also, many loose particles are formed which remain in the image intensifier and are unacceptable as they appear randomly in images and could give misleading or incorrect diagnoses. Another issue is the indium seal. Image intensifiers are baked at about 200°C to remove contamination while they are evacuated. Indium melts at well below 200°C so that the mixture could react prematurely releasing the alkali metal vapour during vacuum baking so that it is lost. No other alternative alkali dispensers are available in the EU although research is being carried out and prototypes may be available in 2012.

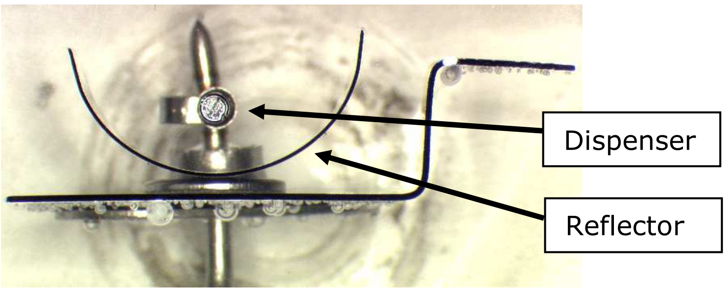
Research has shown therefore that only the chromate-based alkali dispensers give acceptable performance in terms of photocathode quality and least defects from cracks in the glass seals. The early research with possible substitutes described by ERA in its review of the possible inclusion of categories 8 and 9 in the scope of RoHS in 2006 has not yet resulted in a reliable alternative and clearly further research is needed. Some of the possible alternatives that were being considered in 2006 have since been evaluated but found to be unsuitable. Some manufacturers have found that they are able to complete the chemical reaction between chromate and Zr-Al so that no CrVI remains but this is not always possible and cannot be guaranteed and so some hexavalent chromium will usually remain in some products.

5.2. Alternative image intensifier and photomultiplier design

One option is to locate the alkali dispenser in a separate "side-arm" attached to the photomultiplier or image intensifier. In order to do this it must be possible to disconnect the separate alkali dispenser after dispensing the alkali vapour to create the photocathode and maintain the high vacuum inside the device. This is not possible with most current designs of image intensifier or photomultiplier.

Image intensifier bodies are made of steel and aluminium and disconnecting the dispenser while maintaining a high vacuum is extremely difficult. The only option is to include a valve which can be closed before removal of the dispenser. Valves are not totally reliable and can cause leaks which will shorten the life of the product. If the body of the device included a glass tube, this could be sealed by fusion but there is a risk that the high temperature will damage other parts of the device causing cracks which will leak. Also, this will leave a protrusion that could interfere with other equipment and so would be technically impractical.

The main technical disadvantage of using an external alkali dispenser is the distance that the alkali metal needs to travel before reaching the photocathode and it also coats other parts of the image intensifier where condensed metal can degrade the performance. Also, with the tortuous path from an external dispenser, a larger amount of hexavalent chromium need to be used to ensure that sufficient reaches the photocathode. The approach used with internal dispensers is to mount the dispenser inside a reflector plate as shown below in a cross-section view.



By using this concept of dispenser and reflector, the alkali metal vapour is directed mainly onto the input screen were the photocathode is formed. In this way the quantity of alkali metals that reach the output section (such as the output phosphor screen) is reduced drastically. This increases the stability of the image intensifier under working conditions (High voltages). It also improves the image quality and lifetime of the image intensifier.

Use of an external alkali dispenser does not avoid the use of hexavalent chromium and a larger quantity would be used in the life cycle of the device. As the external dispenser is removed and so is not present in the final product, the image intensifier etc. complies with RoHS without the need for an exemption but the used alkali dispenser contains some hexavalent chromium and this becomes waste for disposal and so this approach does not prevent the use of hexavalent chromium and may increase the amount used.

5.3. Alternatives to image intensifiers

Materials used in digital systems: Digital array detectors are used in high-end systems to digitally record X-ray images as an alternative to image intensifiers. Various types of semiconductor are used depending on the type of imaging technique and the performance that is required but types based on silicon were the first to be introduced and are the most common. Amorphous silicon photodiode or CMOS detectors are used but as silicon is a light element it adsorbs X-radiation inefficiently. Silicon detectors therefore usually have a coating of an X-radiation sensitive phosphor based on heavy metals that efficiently adsorb radiation and convert this into visible light that is detected by the silicon. Thallium doped caesium iodide is the most common type of phosphor used to convert X-radiation into visible light that the silicon detects. Thallium is very toxic and this type of phosphor is used only in digital silicon detectors. The input phosphor of image intensifiers usually uses sodium doped caesium iodide because this converts incident X-radiation into light with a maximum wavelength which is the most sensitive for the photocathode.

Recently, more efficient types of digital detector such as cadmium zinc telluride (CZT) have been developed. These are more sensitive than silicon detectors so that lower radiation doses can be used but they contain cadmium which is a RoHS restricted substances. However, cadmium in digital X-ray detectors are covered by an existing RoHS exemption (item 1 of Annex IV of the recast).
CZT detectors are new and are difficult to assemble and so only a few manufacturers are able to use these and then only in the more expensive systems. They will however give health advantages as they will require lower radiation doses.
Other types of digital detector based on silicon but without thallium do not efficiently adsorb radiation because silicon is a low atomic mass element. Gallium arsenide detectors are used for non-medical applications only but arsenic is toxic and a carcinogen and it also has a lower sensitivity than heavy metal semiconductor detectors such as CZT detectors. Some types of silicon detectors require cooling and so consume more energy. Overall silicon detectors have lower sensitivity than CZT and so require higher radiation doses than CZT.

Radiation dose and imaging speed: Radiation doses for silicon detectors and image intensifiers depend on the medical treatment.

- For single exposure imaging, high spatial resolution is important and so to minimise the noise level, higher doses are used although these are comparable for image intensifier and digital systems.
- For diagnostic fluoroscopy where real-time imaging of the patient is required such as during surgical operations, it is essential to use very low doses to minimise the risk of potentially lethal side-effects such as

cancers. For these treatments, it is acceptable to have a certain image noise level and this is possible with image intensifier systems. Flat digital detectors however have a higher spatial resolution than II systems and so need to have higher radiation doses to overcome their higher noise level. Therefore for these treatments, II systems allow lower radiation doses and as the dose levels for dynamic fluoroscopy, such as is used for angiography are relatively high, this would affect the number of patients contracting cancer (see discussion above on relationship between dose and cancer)

Some dynamic fluoroscopy examinations require relatively high speed imaging which is possible with analogue image intensifiers but is inferior with large area digital systems. For example, speech pathology studies require imaging at a rate of 30 frames per second which is straightforward with image intensifiers. Current digital detectors can achieve this frame rate only in small areas (up to 15 x 15cm) which is too small for the area of the patient that needs to be examined which is ~ 25 – 30 cm square.

5.4. Life cycle assessment – digital detectors

Digital detectors are made from either silicon or CZT semiconductor wafers. Single crystals of semiconductor are fabricated from melts of high purity materials and so is a very energy intensive process. Silicon detectors are coated with thallium doped caesium iodide. The table below compares these materials with those used in image intensifiers:

Design and materials	Abundance and toxicity	Extraction, refining and production	Other comments
Image intensifiers			
Steel, aluminium	Very abundant, low toxicity		Metals are always recovered at end of life
Lead seal	Very abundant, less toxic than thallium and cadmium	Straightforward, no risk at well regulated modern facilities	Pure lead is easy to recycle with very high yield
Input phosphor – caesium iodide	Iodine is widely available but caesium occurs at useful concentrations at only a few locations. Both have low toxicity	Caesium is produced on a relatively small scale and iodine on a larger scale using sequences of chemical process steps	
Silicon detectors			
Silicon	Common and non-toxic	High purity silicon semiconductors production is very energy intensive	Silicon is not recovered at end of life
Thallium doped caesium iodide	Thallium is moderately abundant but occurs	Usually recovered as a by-product	

	at low concentrations in ores. Thallium is very toxic, similar to cadmium	from lead, zinc and copper production. See above for caesium and iodine	
CZT detectors			
CZT	Cadmium is toxic and a carcinogen but widely available	High purity CZT semiconductors production is very energy intensive	Modern efficient recycling processes are able to recover cadmium, zinc and tellurium

6. Life cycle comparison of alternative options

6.1. Alternative alkali dispensers

The only currently available and viable alternative design that avoids having hexavalent chromium in the finished product is an external alkali dispenser. This will use at least the same quantity of hexavalent chromium as an internal dispenser and the life cycle impact of all life cycle phases would be overall the same. The only difference is that the residual hexavalent chromium, left after dispensing with an external dispenser is disposed of by the image intensifier or PMT manufacturer whereas with an internal dispenser it is disposed of by the equipment at end of life. The risk however is insignificant as a total of **only 5 - 10 grams of hexavalent chromium** is used in image intensifiers sold in the EU in new imaging systems per year.

6.2. Digital detectors

Most digital detectors are made from silicon and a small number from CZT semiconductor wafers. Single crystals of semiconductor are fabricated from melts of high purity materials and so is a very energy intensive process. Silicon is not recovered at end of life but modern efficient recycling processes are able to recover cadmium, zinc and tellurium.

7. Re-use and recycling of materials from waste EEE.

When image intensifiers reach end of life, the parts are separated and are recycled or may be re-used in refurbished units. The separated parts are mostly steel and aluminium which are recycled as metals with very high yields. The mass of output hexavalent chromium in image intensifiers is extremely small and is safely treated as hazardous waste to be converted into trivalent chromium which is an essential mineral in the human diet.

Digital detectors have a disadvantage over image intensifiers in that they are very difficult to repair and so if a fault develops, they become waste. Silicon detector panels have a low materials value and so recycling is not carried out commercially.

8. Other information

It is estimated that only 5 to 10 grams of hexavalent chromium is placed on the EU market annually by this application.

9. Proposed plan to develop substitutes and timetable

There are two options;
1. Possible substitute hexavalent chromium-free alkali dispenser may be available for trials by 2013.

- R & D is needed to evaluate alternative dispenser to determine optimum process conditions and whether photocathode performance is acceptable. This is expected to take two years (after 2013) so would be complete by 2015 if successful
- Carry out reliability testing to obtain data to support submission for approval under the Medical Devices Directive – expected to be two years so complete by 2017
- Submit data to Notified Body and request approval under Medical Devices Directive - one further year to 2018.

By 2018, most new X-ray systems sold in the EU will use digital detectors if the current technical issues can be resolved and so these new types of alkali dispenser would be used only in image intensifiers used as spare parts for existing X-ray systems.
2. There is a trend to change new systems to use digital detectors. Further research into digital detectors is still needed to enable these to use radiation doses that are the same or less than with image intensifiers for all medical treatments, in particular for fluoroscopy and also so that they can achieve the same speed. More research into fabrication processes is also needed to reduce the price so that digital detectors can be used in low-end systems that smaller EU hospitals are able to afford without affecting the healthcare they provide. Manufacturers estimate that this work may be complete by ~2017 or possibly a few years later so after this date image intensifiers will no longer be used in new x-ray imaging systems although image intensifiers will continue to be used for up to 20 years more as replacement spare parts in systems placed on the EU market before this date. As research cannot guarantee results, 2017 may be optimistic and 2020 may be a more realistic date.

10. Proposed wording for exemption

Hexavalent chromium in alkali dispensers used to create photocathodes in X-ray image intensifiers until 31 December 2019 and in spare parts for X-ray systems placed on the EU market before 1 Jan 2020.