Application for granting new Exemption: Lead to enable thermal compression process to make a vacuum tight connection between aluminium and steel for X-ray image intensifiers

1. Name and address of applicant

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2. Summary of the application

Image intensifiers are assembled from steel and aluminium parts that need to be physically connected and maintain an internal high vacuum. As aluminium and steel have different coefficients of thermal expansion, the vacuum seal material must be able to withstand repeated distortion due to temperature fluctuation. This repeated distortion has been found to cause all soft metals other than lead to be damaged giving rise to leaking seals. The high vacuum is achieved by vacuum baking at ~200°C to remove contamination but there are very few soft ductile materials which are able to withstand this temperature and maintain a permanent vacuum and only lead has been found to be suitable.
The only potential design alternative is to replace image intensifiers with digital detectors. These have different characteristics to image intensifiers and so are not drop-in replacements. Both have advantages and disadvantages, there are medical treatments carried out where image intensifier systems require lower radiation doses than digital detector systems offer, so replacement by digital detectors would have a negative impact on health. Unlike most electrical products, the price of medical equipment can also have a negative impact on health, as explained below, as digital systems are typically double the price of image intensifier systems.

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

Image intensifiers are used to amplify the weak images produced by X-ray imaging equipment and are often supplied as integral parts of these products. They must have a permanent high vacuum to function reliably and they are assembled from a variety of materials that need to be attached with vacuum-tight bonds. A high vacuum is essential as any gases will reduce the performance and could impair quality of the image.
Image intensifiers are assembled from many different metals including aluminium parts where transparency to X-radiation is required (aluminium is a metal with low atomic mass so is transparent to X-rays) and steel is used for high strength. Steel is also needed where glass to metal seals are required because vacuum-tight bonds directly between glass and aluminium cannot be made. The aluminium and steel parts are assembled together with the lead seal so that the

interior space can be evacuated. After assembly, the interior of the image intensifier is evacuated by pumping with a vacuum pump.
There will be a variety of contaminants inside the assembled image intensifier such as cutting oil residues and extrusion greases. These contaminants will slowly emit gases in a high vacuum environment which will degrade the vacuum, increasing the pressures inside the image intensifier and as a result degrade its performance. It is therefore necessary to remove all of the organic contaminants which is achieved by heating the assembly to 200 - 220°C during evacuation with the vacuum pump. Heating and evacuation are carried out until all of the impurities that could degas have been removed. Because the assembly needs to be heated to over 200°C, the seals need to withstand the temperature of this process as well as the design life of the image intensifier which should ideally be the same as the X-ray imaging equipment, typically 25 years. Pure lead is a fairly soft metal which will retain structural integrity at 200°C and will not emit gases in a high vacuum. Lead is the only material that has been found to be suitable for making permanent vacuum tight seals between aluminium and steel and has been found to be very reliable giving long service lives for image intensifiers. The diagram below illustrates the construction of an image intensifier showing the location of the lead seal between the X-ray transparent aluminium dome and the steel body.

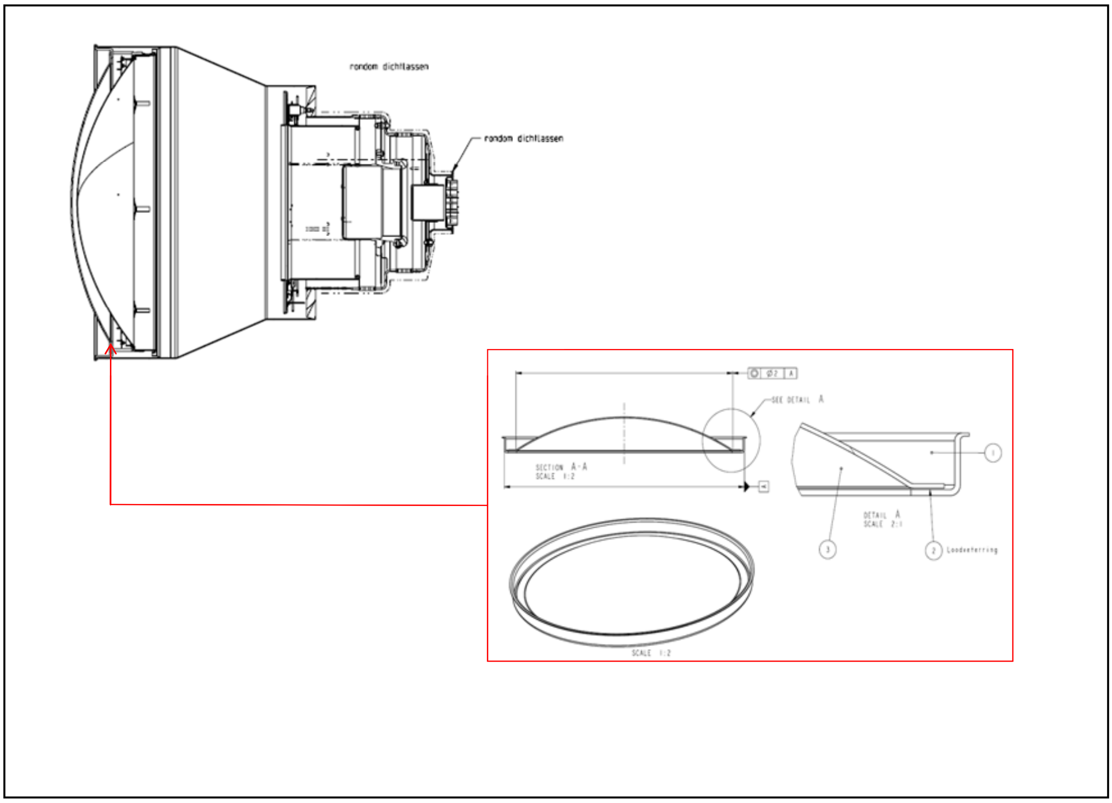

Figure 1. Construction of image intensifier showing location of lead seal

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 in the EU only as spare parts as replacements for faulty units in older X-ray systems.

4. Justification for exemption

The reason for this exemption request is that manufacturers have not been able to identify alternative seal materials or designs of image intensifier that give equal or better performance and reliability. Alternative designs potentially have a greater negative impact on human health as explained below.

4.1. Alternative seals

Image intensifiers are widely used to amplify X-ray images to minimise the dose given to patients because X-radiation is harmful. It is essential that the interior of the image intensifier retains a high vacuum throughout its life. It is constructed from different materials that need to be bonded using seals that retain the high vacuum. The design of image intensifiers varies considerably but most need to use lead to maintain a vacuum tight seal. The entrance shields of X-ray image intensifiers are made of a low density and low atomic mass metal, such as aluminium, which are fairly X-ray transparent to be able to minimise the X-ray dose for the patient. Next to this is the steel body needed for strength to retain the high vacuum. Through the walls of the steel there is the need for glass-metal (steel) joints to make electrical connections to internal parts. Glass is used for electrical insulation reasons and because it retains the high vacuum. The steel body and aluminium entrance shield must be joined in a way that does not damage the glass-to-metal seals and so high temperature thermal processes such as brazing are not suitable. Glass to metal seals can be made with several metals but not aluminium because glass will not easily form a vacuum tight bond to aluminium and the thermal coefficient of expansion (TCE) of glasses and aluminium are not the same. The TCE of aluminium and steel are also not identical and so the seal material must be flexible enough to allow for movements due to temperature changes but not distort permanently and leak.

Polymer seals and adhesives are unsuitable as these are all porous to gases so that the vacuum is lost. They also tend to degas in a high vacuum and most polymers cannot withstand 200°C that is used for the assembly process.

Soldering, brazing and welding of ceramics or glass to a metal such as steel or aluminium is extremely difficult or impossible with a high risk that the bond will leak. Therefore the only way of producing vacuum tight bonds in image intensifiers and also in other types of vacuum equipment is with gaskets made of soft metals. Gold is used in some types of high vacuum chemical analysis equipment but this is always used to produce a seal between two pieces made from the same material so that temperature changes do not cause distortion of the seal due to thermal expansion differences. The only metal found that creates a permanent high vacuum seal between dissimilar materials is lead.

4.2. B. Alternative designs – 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 are 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.

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.

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 metal seals.

The characteristics that are required are:

- Fairly soft at ambient temperature so that it can accommodate small movements caused by the differing thermal expansion coefficients of aluminium (23 x 10^{-6}/°C) and steel (~12 x 10^{-6}/°C although this depends on type of steel).
- Must be able to slide across the metal surface without degrading the vacuum. The metal seal must not bond to the aluminium or steel (i.e. cold weld) as this would cause damage to the seal when movement between aluminium and steel occurs due to ambient temperature changes causing differential expansion of these two metals. If the seal were to adhere to the aluminium and steel, when movement occurs, there is a risk that the seal metal will tear causing a leak.
- A melting point of at least 300°C so that it does not melt or become too soft during vacuum pumping at ~220°C.
- Does not significantly work harden (i.e. remains soft during life of equipment)

There are several soft metals which have been investigated as possible substitutes:

5.2. Possible alternative seal metals

Metal	Characteristics
Lead	Pure lead is ductile but not too soft so that sufficient contact force is maintained. It does not cold weld to steel or aluminium so does not adhere to either surface. Retains strength at the temperature of ~200°C used for cleaning interior during image intensifier assembly process. M. pt. 327.5°C
Tin	Slightly harder than lead and tends to form micro-cracks which can cause leaks. M. pt. 232° is only ~15°C above the vacuum pumping temperature so tin will be too soft at this temperature.

Metal	Characteristics
Gold	The main reason why gold is unsuitable is that most soft noble metals such as gold readily cold weld and this would cause it to stick to the steel and aluminium causing damage to the seal when the ambient temperature changes. Gold work hardens in the same way as copper but it is initially softer so this may be less of an issue. A similar technical situation (vacuum tight seals between a low TCE glass-ceramic and higher TCE steel) existed with supercomputer for thermal conduction modules (exemption 12 of Annex III). In this case, a hermetic seal (to retain a high vacuum for 30 years) between glass-ceramic and steel was required and only lead was found to be suitable. Gold and silver were evaluated and both resulted in leaks and so were not suitable[1] (see additional comments below*).
Indium	Very soft and cold welds to all materials so that movements caused by temperature changes would destroy the seal. M.pt. is 156° so seal would melt during vacuum pumping and destroy the vacuum.
Copper	Used to create vacuum seals between pairs of stainless steel parts but it is not suitable where differential movement occurs due to the differences in TCE of steel and aluminium. Copper work-hardens (due to repeated distortion) and then will not distort to accommodate differential movements and so will leak.

TCE = Thermal coefficient of expansion

* Gold has a much higher price than lead and although this does not in itself justify this exemption request, it is the reason whey less research with this metal has been carried out previously although the results described above obtained by a supercomputer manufacturer indicate that it would not be reliable. For a 31 cm image intensifier, the price for one lead seal is €0.35 whereas one gold seal of the same size is close to €10,000[2] which would be much more than double the price of the image intensifier. This would affect hospitals with limited new equipment budgets so that they could not afford as much new equipment and this will affect patient's health and this would justify this exemption as explained elsewhere in this request dossier. However the main reason why gold is not used is that the limited research that is available shows that it will leak when used to bond dissimilar metals and this will greatly shorten the life of the equipment.

Of the alternative metal options that are fairly soft, there are no obvious substitutes to lead. Copper and gold are used as vacuum seals but only to bond identical metals. Where two different metals are required, there will be sideways distortion due to the difference in thermal expansion coefficient (TCE). This will cause sideways movement which in the case of copper will cause work hardening until it is too hard. In the case of gold, as gold is noble (does not oxidise in air unlike lead) it cold welds to clean metal surfaces that could cause it to be damaged and leak.

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[1] P. Goodman, P. Strudwick and R. Skipper "Technical adaptation under Directive 2002/95/EC (RoHS) - Investigation of exemptions", ERA report 2004-0603.

[2] Based on 340 mm diameter gold ring of 2.2 mm diameter, gold density of 19.3g/cm^3 and a gold price of €22/g.

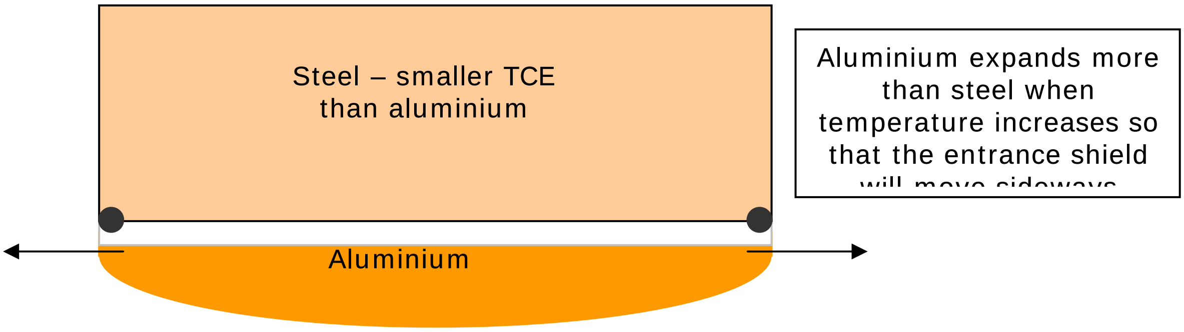

Figure 2. Effect of temperature increase on movement between aluminium and steel. The lead seal (●) has to remain intact between these two surfaces.

5.3. Alternative bonding methods

Brazing and soldering: There are two difficulties associated with soldering and brazing aluminium and steel. Brazing requires a temperature of 500 – 600°C which is likely to damage the glass to metal seals and so is unsuitable. Soldering to aluminium and steel are possible but very difficult because both metals have stable inert air-formed oxides. Before solder can wet the surface, a very corrosive flux is needed to remove this oxide and some would remain inside the image intensifier and could cause corrosion and eventual failure. Also, because the units have to be vacuum pumped at ~200°C, only high melting point solders can be used (standard lead-free alloys have too low melting point). All flexible and ductile high melting point solders are lead-based (with >90% lead) so if they could be used they would provide no health or environmental benefit over lead seals. However soldering large area bonds with lead-free solders is very difficult and soldering these alloys to aluminium and steel is never carried out due to its extreme difficulty. Lead-free high melting point solders exist but suitable fluxes for bonding to aluminium and steel are not available. If these could be developed, they would need to be very corrosive and so unsuitable. An example of a high melting point lead-free solder is 80%Gold20%tin solder with a m.pt. of 280°C. This and other gold based solders are very difficult to use and so avoiding leaks may be impossible. Furthermore, if a leak-free bond could be made which is very unlikely, these alloys are hard and very brittle so are likely to fracture, causing leaks when differential thermal expansion occurs due to temperature changes. A major drawback of soldering, if this were possible, is that it would be much more difficult and probably impossible to dismantle and then reassemble the image intensifier should repairs be required.

5.4. Life cycle assessment – seal materials

Research has shown that the potential alternatives to lead are not technically viable. However a comparison of the life cycles of several alternative metals is illustrated below:

Metal	Mining and extraction	Use phase	End of life
Lead	Occurs at fairly high concentrations in ores so less energy consumed and less waste rock than from mining rare metals such as gold	No impact	Easily recycled
Gold	Occurs at low concentrations in rocks so mining creates vast amounts of waste. Potentially creates emissions of hazardous substances (much more than lead). Cyanide used for refining and sometimes also for extraction from rock.	No environmental impact but risk of theft due to high value	Easily recycled
Copper	Readily available as sulphide ores and easily extracted using a process similar to that used to extract lead from ores	No impact	Easily recycled

Mining, extraction and refining of gold consumes far more energy than lead as shown by published figures:

- Gold 143,000 MJ/tonne[3]
- Lead 168 MJ/tonne[4]

Lead refining in the EU is well controlled due to strict legislation so that harmful effects are rare. Cyanide used for gold extraction and refining is very toxic and has caused several serious accidents in the EU[5].

6. Alternative designs – digital detectors

6.1. Materials use

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

[3] From http://www.eoearth.org/article/Gold_mining_and_sustainability:_A_critical_reflection
[4] Calculated from data in http://www.epa.gov/dfe/pubs/solder/lca/lfs-lca-final.pdf
[5] For example http://archive.rec.org/REC/Publications/CyanideSpill/ENGCyanide.pdf

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.

6.2. 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.

6.3. 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 at low concentrations in ores. Thallium is very toxic, similar to cadmium	Usually recovered as a by-product 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

7. Re-use and recycling of materials from end of life equipment (WEEE).

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 with very high yields. The lead seal is high purity lead and so can be melted and re-used with no need for purification processes. Large amounts of lead are safely recycled in the EU where strict and effective safety legislation is applied.
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. The detector panels are silicon which has a low value and so recycling is not carried out commercially.

8. Other information

It is estimated that EU consumption of lead for this application is ~50kg per year.

9. Proposed plan to develop substitutes and timetable

It is very unlikely that an alternative material will be found to replace lead for the reasons explained in this dossier. There is however 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 and also 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 hospitals are able to afford without affecting healthcare. Manufacturers estimate that this work may be complete by ~2018 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, 2018 may be optimistic and 2020 may be a more realistic date.

10. Proposed wording for exemption

Lead to enable thermal compression process to make a vacuum tight connection between aluminium and steel for 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.