Application for granting new Exemption: Cadmium in phosphor coatings in image intensifiers for X-ray images

1. Name and address of applicant

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2. Summary of the application

Cadmium is a constituent of output phosphors of image intensifiers. Image intensifiers are used to amplify very weak X-ray signals that pass through patients to create bright images that can be recorded with digital cameras. Cadmium-based phosphors are used because they are the brightest so that the lowest x-ray dose can be used which minimises the risk of health problems due to radiation. Several cadmium-free phosphors with similar light output colour have been developed but all require higher x-ray doses to obtain suitable images. The only other potential design substitute is to replace the image intensifier by a digital detector. These have different characteristics to image intensifiers and so are not drop-in replacements and digital detector systems are quite different to image intensifier systems. Both have advantages and disadvantages but there are some medical treatments carried out where the image intensifier system uses lower radiation doses than digital detector systems and 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 is explained here) and digital systems are typically double the price of image intensifier systems.

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

As X-radiation can cause serious harm to patients, the radiation dose must be minimised as far as possible. To avoid harming patients, the intensity of the X-radiation used to pass through the human body is very weak and is too weak to detect using X-ray film or cameras. Image intensifiers are used to amplify the X-ray images by up to 5000 times so that clear visible images can be viewed and recorded from relatively low radiation doses. Modern image intensifier images are usually viewed with digital still or video cameras. 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 which is usually sodium doped caesium iodide which is a very sensitive phosphor material. This converts the weak input X-radiation into a 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 and these travel to the output phosphor screen.
- When electrons are projected onto the output phosphor, they are converted into a bright visible light image that can be viewed or recorded.

The most common output phosphor material is silver doped cadmium zinc sulphide (type P20). This is used because it efficiently converts the electron image into a bright green image and this colour is ideal for viewing with cameras. Cameras are less sensitive to other colours so that higher radiation doses would be required. There are several yellow-green light output phosphors available but P20 was originally selected because it had the highest light output.

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 the potential alternatives create unacceptable difficulties. The two potential alternatives that could be used to avoid using P20 phosphor are:

- Use different types of phosphor coating in the image intensifier or
- Replace the image intensifier by digital detectors.

4.1. Phosphors

There are many types of phosphor available but relatively few produce yellow-green light. Of these, P20 is used for this application because it emits the most light of all of the yellow-green phosphors available and so allows the use of the lowest possible radiation dose. Alternative phosphors such as P43 potentially would have greater negative impact on health (of patients) because a larger X-ray dose is required (by ~10%) to obtain an acceptable image of the same brightness. The larger radiation dose increases the risk of side effects such as cancer from the radiation. Image intensifiers based on output phosphors are a mature but declining technology. Although cadmium-free phosphors exist, these phosphors are not drop-in replacements and have different characteristics as well as lower light output and so few current designs of image intensifiers can use these alternative types of phosphor.

4.2. 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.

4.3. 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.

4.4. 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

Originally all manufacturers used silver doped cadmium zinc sulphide as the output phosphor but a few manufacturers have developed alternative designs that avoid using this material. Image intensifiers are usually specifically designed as components of X-ray imaging equipment.

The technical differences between cadmium-based phosphors and the two potential alternatives are as follows:

5.1. Alternative phosphors

Many types of phosphor have been developed with a wide variety of characteristics. These are used for many different applications where they are activated by different energy sources and emit light of different wavelengths, decay times and conversion efficiency. It is important for this application that the output phosphor has a high conversion efficiency for photocathode electron excitation and ideally emit green light output as this is ideal for recording the image with X-ray film or digital cameras.

Research into cadmium-free phosphors has been carried out during the past few decades and several types which emit visible light of similar wavelengths have been developed but each has its unique combination of characteristics. Cadmium-based phosphors were used in CRT televisions until cadmium-free substitutes were developed. In this application, there is no risk to users from increasing the electron beam energy to maintain a bright image.
P20 phosphor emits yellow-green visible light (560 nm peak) and at least five cadmium-free types have also been developed which emit similar wavelengths of light.

Phosphor designation	Peak wavelength	Composition	Comments
P20	560 nm	ZnCdS:Ag	Selected as the II output phosphor
P22G	565 nm	ZnS:Cu,Al	Used in colour televisions as the green phosphor
P31	520 nm	ZnS:Cu	Used in oscilloscopes
P43	545 nm	$Gd_2O_2S:Tb^{3+}$	Used in non-medical image intensifiers
P46	530 nm	$Y_3Al_5O_{12}:Ce^{3+}$	Used in flying spot test instruments because it has a much shorter decay time than

			P20
P53	544 nm	$Y_3Al_5O_{12}:Tb^{3+}$	With a longer decay time (at least 1000µs). This is used for aircraft "head-up displays"

Each image intensifier output phosphor screen contains a very small quantity of phosphor material and so material cost is irrelevant but it is very important that the phosphor has a combination of characteristics that result in the patient receiving the smallest possible radiation dose. This is achieved by the output phosphor having specific performance characteristics:

- Emits yellow-green visible light. Digital cameras are most sensitive to these wavelengths.
- High quantum efficiency to convert the incident electrons from the photocathode into visible light.
- Light output decay should not be too short or too long

P20 is based on zinc sulphide with cadmium sulphide added to shift the output light wavelength to yellow-green. The silver dopant is an activator that distorts the crystal lattice to give the material luminescent properties. Zinc sulphide with different additives can also give yellow – green light as shown in the list above but these all emit less light from the incident photoelectrons. This would be harmful to patients because higher radiation doses would be needed to achieve the same image quality.

P20 is particularly efficient because its light emission spectrum is a fairy narrow peak in the visible spectrum whereas some ZnS based phosphors have broader or double peaks (e.g. P31) so that a proportion of the light is not in the optimum yellow-green region.

Rare-earth phosphors have also been developed that emit yellow-green light and are used for many different applications. Their characteristics vary depending on composition so that output light colour and light output decay rate can be varied to suit each application. P53 for example is used primarily for head-up displays used in military aircraft and P22G is the yellow – green colour used in colour CRT televisions. All of these however emit less light than P20 when used in x-ray image intensifiers

One of the cadmium-free phosphors with similar characteristics that is used in non-medical image intensifier is type P43 which is terbium doped gadolinium oxysulphide (Gd2O2S:Tb). This has a peak light output wavelength of 545nm, which is similar to P20 at 560nm. The light spectrum of P20 and P43 are however very different as shown below:

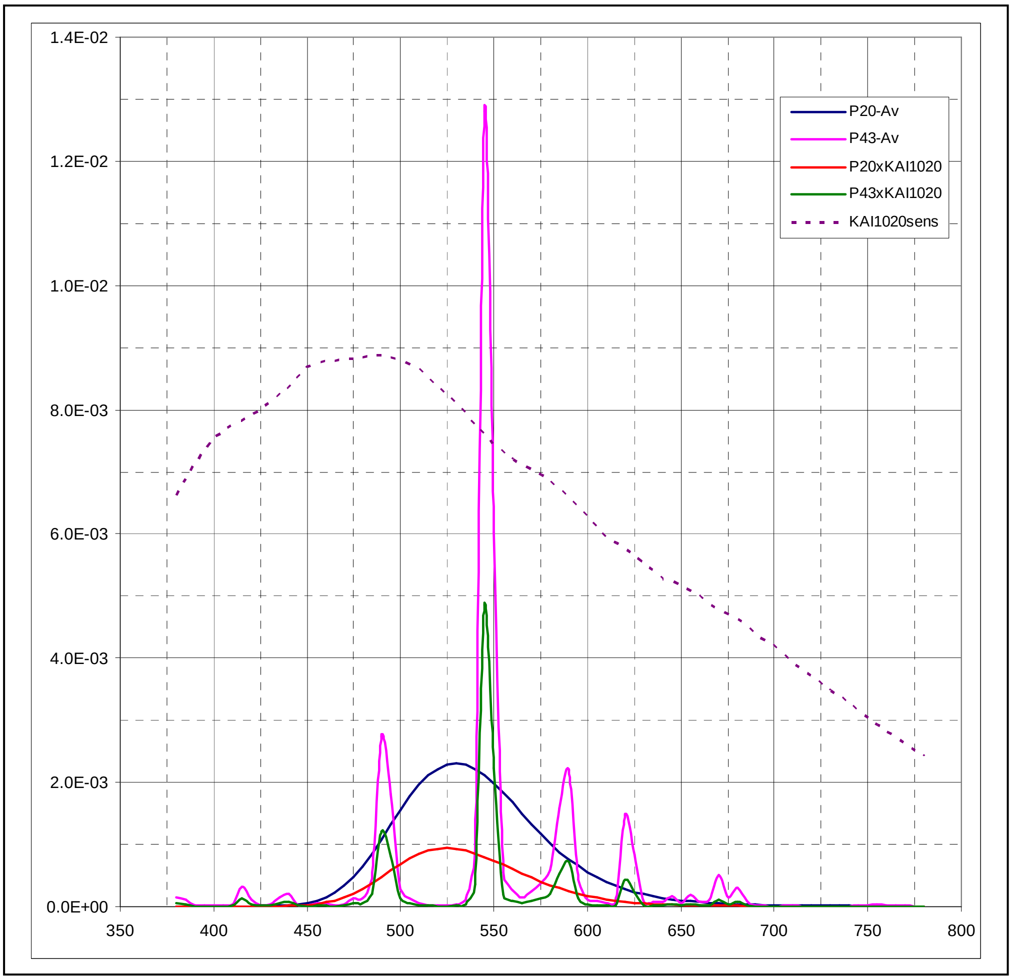

Figure 1. Visible light output spectrum of P20 (red and blue) compared to P43 (green and pink)

Measurements have shown that if a P43 phosphor is used in an X-ray image intensifier, the output light intensity is about 10% less than when P20 is used. This means that a 10% higher X-ray dose is needed to achieve the same image quality and the patient will have an increased health risk from the ionising radiation (e.g. cancer). One image intensifier manufacturer has measured the visible light output from P20 and P43 phosphors in image intensifiers by using identical X-radiation doses. They found that the P43 visible light intensity was on average 10% less than from P20 although under certain conditions, the difference was greater. In general, yellow-green rare earth phosphors are less efficient than zinc sulphide types when excited by UV light[1] but quantum efficiency values for light emission from photoelectrons generated in X-ray image intensifier photocathodes are not published.

The light decay behaviour of P43 and other yellow-green phosphors are different to P20 and so P43 and other phosphors cannot be used as a drop-in replacement in existing image intensifier designs although this difference can be compensated

[1] Qualitative UV emission data available in "Inorganic Phosphors", W. M. Yen and M. J. Weber, CRC Press, 2004

for. When the electrons from the photocathode strike the phosphor screen, green light emission occurs instantly and then the light emission rapidly decays. The rate of decay of emitted light from P20 depends on the incident energy intensity with faster decay from high intensity electrons. P43 light decay is independent of energy intensity as shown below:

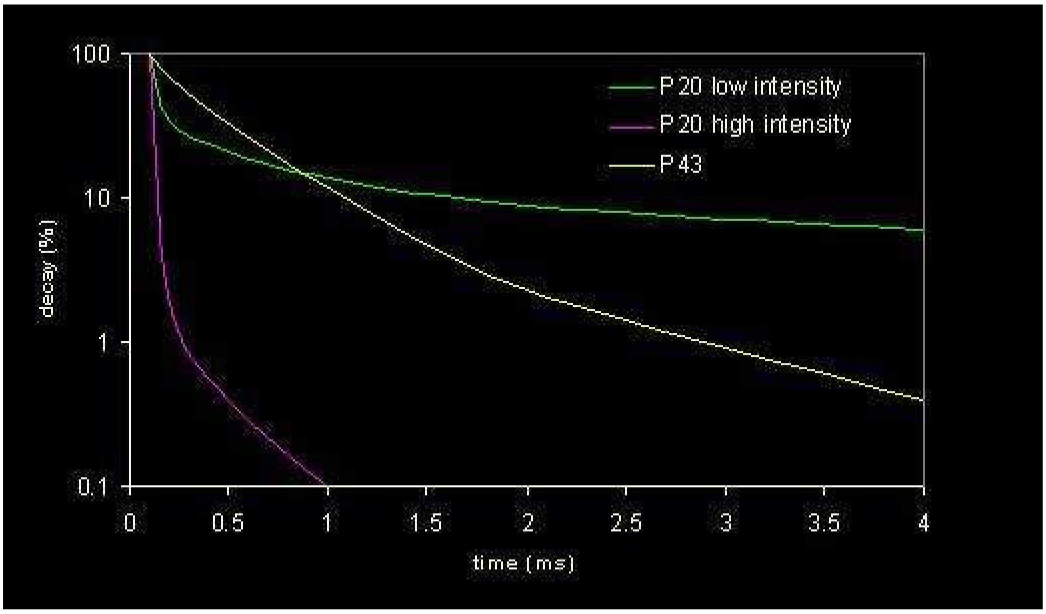

Figure 2. Decay curves comparing P20 and P43 phosphors

The difference in decay rate for P43 can however be accommodated by the equipment design but very fast decays are unsuitable for video cameras and too slow decays are unsuitable where real time imaging us used such as for angioscopy.

Effect of increased radiation dose on human health

It is understood that there is a linear relationship between radiation dose and risk of cancer. Therefore a 10% increase in X-radiation dose leads to 10% more people having cancer from the radiation. The International Commission on Radiological Protection (ICRP)[2] has determined that the risk coefficient is 5% at 1 Sievert although this is a very high dose and low mS doses are more typical of medical imaging. One of the highest X-ray doses used for imaging is used for cardiology where continuous irradiation is needed to view blood vessels during surgical procedures. Huda[3] has established that typical CT doses which are similar to cardiology doses cause about 1 person in 1,000 (0.12%) to have cancer. In this case, a 10% increase in radiation dose will cause statistically one additional person in 10,000 to have cancer. Clearly, it is important to minimise radiation doses and the "Directive 97/43/Euratom – Medical Exposures Directive" requires that all patient exposures are optimised and so if implementation of RoHS were to result in higher doses, this would conflict with existing EU legislation.

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[2] ICRP publication 103 "The 2007 Recommendations of the International Commission on Radiological Protection.

[3] W. Huda, W. T. Rowlett and U. J. Schoef "Radiation dose at cardiac computed tomography: facts and fiction" J. Thorac. Imaging, 2010 Aug; 25(3) p 2014

5.2. Digital detectors

Materials used: 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 and so 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 caesium iodide is the most common type of phosphor used to convert X-radiation into visible light that the silicon detects. Thallium doped caesium iodide is very toxic (due to thallium) and 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 that 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 RoHS substances. Cadmium in digital X-ray detectors are covered by an existing RoHS exemption (item 1 of Annex IV of the recast). Each CZT detector contains a much larger quantity of cadmium than is used in one phosphor screen from one image intensifier and so this substitute potentially has a larger negative impact than the amount of cadmium in one image intensifier.

Toxic substance	Mass of cadmium per imaging system
Cadmium in image intensifier	~ 0.006 mg (25 mm diameter x 6µm thick)
Cadmium in CZT detector	~ 6500 mg (20 x 20 x 6 mm wafer)

CZT detectors are new and are difficult to assemble and so only a few manufacturers are able to use these as digital detectors and they are used only in the most 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 prevent side-effects such as cancer. For these treatments, it is acceptable to have a certain 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 30 frames per second 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. Life cycle assessment

6.1. Comparison of P20 with different phosphors

Availability – P43 contains Gadolinium and terbium which are rare earth elements available in fairly limited supply although only small amounts would be needed. Overall abundance of rare earths is not especially low, being more abundant than gold but useful ores in which the elements are sufficiently concentrated to be extractable are very rare. Most rare earth metals arise in China which severely restricts exports[4] and shortages are a real possibility. Terbium is one of the least abundant rare earths at 1 ppm of the earths crust (gadolinium is ~5 – 6 ppm) whereas cerium (used in P46) is the most abundant rare earth at 66ppm.

- **Mining, extraction and refining** – rare earth minerals contain all 13 rare earth metals usually with several transition metals. Separation of the rare earths is not straightforward because the chemical properties of the rare earth elements are exceptionally similar and so they are extremely difficult to separate to obtain pure single elements. Either solvent extraction or ion chromatography are used and both of these are complex processes. Terbium is one of the less common rare earth elements and so large quantities of chemicals and energy are consumed to produce pure terbium. **Other phosphors** – most of the yellow-green light output phosphors contain relatively common elements that are widely available except for terbium. Cerium is one of the most abundant rare earth elements but is easier to extract from the other rare earths as it has a stable tetravalent oxidation state unlike most other rare earths. Yttrium is more abundant in the earths crust than silver and gold but usually occurs with other rare earths and has very similar chemical properties and so is difficult to extract and purify.
- **Use phase** – no emissions or losses occur during the use phase

4 http://www.atlanticlightingandsupply.com/Images/document/Phosphor%20Shortage%20May%2011%202011.pdf

- **End of life** – phosphors from image intensifiers are treated as medical equipment waste and so is recycled but rare earth metals are not recovered being present in the waste at too low a concentration and in too small a quantity.

6.2. Comparison with P20 – silver doped cadmium zinc sulphide

Although silver and cadmium are less abundant in the earths crust than terbium, their ores are relatively common and the elements easily extractable unlike the rare earth metals. No cadmium emissions occur in the use phase and it is recovered for reuse or safe disposal during electrical waste recycling by modern efficient processes that are used in the EU and are available in many other countries.

6.3. 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	Usually recovered as a by-product from lead, zinc and copper production. See above for caesium and	

	to cadmium	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 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 with very high yields. The mass of output phosphor in image intensifiers is extremely small and so is treated as hazardous waste although its constituents can be recovered by modern recycling processes.
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

~ 0.01 kg (10 grams) of cadmium will be used in the EU annually for this application.

9. Proposed plan to develop substitutes and timetable

Research with alternative phosphors has so far failed to find a cadmium-free substitute that gives the same or better light output intensity as P20. As increasing radiation doses to patients is not permitted, using alternative phosphors is not an option. Therefore the only currently known alternative is to replace image intensifiers by 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 so that they can achieve the same speed where this is important. More research into fabrication processes is also needed to reduce the price so that digital detectors can be used in low-end systems that all EU hospitals are able to afford without affecting healthcare. 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

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.