Test &
Measurement
Coalition

Exemption Renewal Form – Exemption 5, Annex IV

Date of submission: _____

This dossier is submitted by COCIR for category 8 medical imaging devices. As the same exemption is also needed by Category 9 Industrial equipment, the contact details for such categories are reported here below. The technical justification information in the dossier applies to all 2 categories. Where additional information for Cat 9 equipment is required, it has been included at the end of this dossier.

Attached documents:

- REG0364001 COCIR RoHS exemption 5 Pb shielding LCA assessment v2.1 repf.pdf
- COCIR - LCA Lead and tungsten in shielding - Project presentation_18072019 final.pdf

1) Name and contact details of applicant: Medical Imaging Devices

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2) Name and contact details of applicant: Category 9 equipment.

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3) Name and contact details of applicant: Category 9 equipment.

Company: **TMC: Test and Measurement Coalition**
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Address:

2. Reason for application:

Please indicate where relevant:

☐ Request for new exemption in:

☐ Request for amendment of existing exemption in

☒ Request for extension of existing exemption in Annex IV

☐ Request for deletion of existing exemption in:

☐ Provision of information referring to an existing specific exemption in:

☐ Annex III ☐ Annex IV

No. of exemption in Annex III or IV where applicable: _____

Proposed or existing wording: **Lead in shielding and in collimators used for ionising radiation**

Duration where applicable: **Maximum validity period of seven years**

☐ Other: _____

3. Summary of the exemption request / revocation request

Several types of medical imaging equipment utilise ionising radiation. It is essential that the safety of workers and patients is protected from stray radiation as well as to protect sensitive electrical circuits and so shielding is required as part of this equipment. Lead is usually the best material for radiation shielding and also for collimation of radiation. Lead has both significant technical advantages over other materials as well as having a significantly less negative overall health safety and environmental impact compared with alternative materials that might be considered. In some applications such as for anti-scatter grids, no suitable substitutes for lead exist. In applications where complex or intricate shapes are needed, this is currently possible only with lead. Many of the potential substitute metals (e.g. tantalum) are too brittle or are so expensive (e.g. gold) that hospitals could not afford to buy the medical device and there would be a significant risk that the expensive metal would be stolen.

This exemption renewal requests explains the many technical reasons for using lead and why substitution is usually not possible as well as providing an independent life cycle assessment that compares lead with tungsten metal and tungsten composites.

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4. Technical description of the exemption request / revocation request

(A) Description of the concerned application:

1. To which EEE is the exemption request/information relevant?

Name of applications or products: <u>As a barrier to X-radiation, α, β and γ radiation and other energetic particles used for X-ray imaging, radiotherapy, SPECT (Single-photon emission computed tomography), PET (positron emission tomography), and other types of medical device.</u>

a. List of relevant categories: (mark more than one where applicable)

☐ 1	☐ 7
☐ 2	☒ 8
☐ 3	☒ 9
☐ 4	☐ 10
☐ 5	☐ 11
☐ 6	

b. Please specify if application is in use in other categories to which the exemption request does not refer:

c. Please specify for equipment of category 8 and 9:

The requested exemption will be applied in

☒ monitoring and control instruments in industry

☐ in-vitro diagnostics

☒ other medical devices or other monitoring and control instruments than those in industry

2. Which of the six substances is in use in the application/product?

(Indicate more than one where applicable)

☒ Pb ☐ Cd ☐ Hg ☐ Cr-VI ☐ PBB ☐ PBDE

3. Function of the substance: <u>Lead is used to block and absorb ionising radiation to prevent medical staff, patients and the electrical equipment from exposure to radiation that would otherwise cause damage. Ionising radiation can damage human cells resulting in harm to patients and hospital staff and it can also damage electrical circuits of the medical equipment that would malfunction and fail if not protected. Lead is also used to collimate or focus ionising radiation to improve image quality as well as to ensure that only the required areas of patients are exposed, not surrounding tissue.</u>

4. Content of substance in homogeneous material (%weight):

- Commercial purity lead metal of 99.9% and harder alloys such as 95%Pb5%Sb are used
- Transparent glass is used to view patients in types of equipment where the position of the patient must be closely observed. It is also used for some types of X-ray tube. The glass contains ca. 60 - 70% of lead

5. Amount of substance entering the EU market annually through application for which the exemption is requested: COCIR estimated that 759 tones was used by the medical sector in the EU in 2006. Medical device manufacturers aim to minimise the amount of lead used to reduce weight and so the total quantity may have decreased since 2006. COCIR now estimates that about **400 tonnes** is used per year
   Please supply information and calculations to support stated figure.

   The quantity of lead shielding used in medical devices varies considerably, depending on the design and application. X-ray imaging systems typically contain 10 – 16kg of lead with 14kg being estimated as a typical amount.
   COCIR estimate that sales in 2016 in the EU28 countries was:

X-ray radiology digital non-mobile	ca. 560
X-ray radiology digital mobile	ca. 400
X-ray radiology analogue non-mobile	ca. 86
X-ray radiology analogue mobile	ca. 64
X-ray Mammography	ca. 769
TOTAL number X-ray units	1,879
Total amount of lead at an average of 14kg/unit	26.3 tonnes
CT (25kg lead per unit)	ca. 1140 = 28.5 tonnes
PET (100kg lead per unit)	ca.50 = 5 tonnes
SPECT (ca. 300kg lead per unit)	ca.100 = 30 tonnes
In addition, there is lead shielding in:	
Replacement X-ray tubes	estimated for all manufacturers at ca. 200 tonnes p.a.
Estimated other uses	ca. 100 tonnes
Total	ca. 400 tonnes per year

6. Name of material/component: Lead metal and alloys or lead-based glass

7. Environmental Assessment: _____
   LCA: ☒ Yes
   ☐ No

(B) In which material and/or component is the RoHS-regulated substance used, for which you request the exemption or its revocation? What is the function of this material or component?

Lead is used in various forms and shapes as follows:

- Sheet, thicker sections and complex shapes are used as a barrier to X-rays;
- Machined and moulded parts of intricate shapes;
- Lead-bearing transparent glass

Lead as ionising radiation shielding has the following uses:

- **Shielding** - this is constructed from sheets of various thickness as well as complex shapes.
- **Collimators** – various types are used to either focus X-rays or to remove radiation that is not travelling in the correct direction to achieve a clear image. Fixed collimator are used at the windows of X-ray tubes for beam trimming and blade-types (made with stacks of thin sheets) are used as movable collimators are also used for beam trimming. Radiation can be scattered (e.g. by the patient and parts of the equipment) and this causes radiation to travel on many unintended directions which can lower quality images if not removed by a collimator (or an anti-scatter grid). The preferred design of lead collimators that are used with flat panel detectors have a hexagonal cell structure that resembles a bee's honeycomb. These are also known as anti-scatter grids.
- **X-ray tubes** – X-ray tubes are either made of high lead content glass or metals. Metal inserts are lined internally with lead sheet. All X-ray tubes contain a high vacuum and so must be perfectly sealed and this is fairly straightforward with glass. Glass is however relatively fragile and so larger heavier inserts are usually metal to prevent damage.
- **Viewing windows** – These are essentially glass sheet that is used either as an integral part of a medical device or is used in a separate shielding screen between the radiation source and hospital staff. Patients who are being scanned or examined may be very ill and so must be continuously observed and this is easier and more reliable through a window than by viewing than via CCTV. Lead-based glass shielding used to protect hospital staff when they are observing the patient when being imaged and this is necessary where the position of the patient is critical, such as for mammography;

The main types of medical device that utilise lead in radiation shielding are described below.

X-ray imaging equipment.

Lead is used in various devices to improve X-ray images where lead is used for its radiation shielding properties, including:

- Anti-scatter grids used to eliminate scattered radiation that would otherwise blur the image;
- As a layer of lead behind or in X-ray detectors to absorb X-rays;
- In glass of capillary plates used for X-ray collimation;
- Viewing windows, often used for mammography to ensure that the patient is in the correct position.

Examples of X-ray imaging equipment that uses of radiation shielding include:

- Computed Tomography (CT) which generates 3D images
- Radiography, used, for example for skeletal X-ray. Machines can be fixed or portable,
- Angiography, used for real-time viewing of the heart, blood flow, etc.
- Fluoroscopy, real time viewing of internal organs, usually using contrast agents
- Mammography.

The shielding is needed to prevent radiation from emerging from the radiation source (the X-ray tube) in directions other than towards the part of the patient that is being imaged. Also, some X-radiation is scattered when it strikes solid surfaces and so shielding is also needed to protect patients, hospital staff and electronic circuits. The image below shows the lead shielding used inside an X-ray tube.

Figure 1. Lead sheet shielding used inside an X-ray tube

Lead is also used in CT scanner collimators which are used to focus the X-ray beam and in anti-scatter grids that are adjacent to detector panels to block scattered radiation that would otherwise cause a blurred image. When X-radiation hits objects, not only does it pass through or be absorbed by these objects, it can also be scattered in all directions. The inside of collimators use lead to focus X-radiation to prevent radiation from escaping in directions that are unwanted and would blur images and also could cause harm to a patient, or hospital staff.

Lead shielding is also needed in X-ray detector modules to obtain clearer images. A lead layer is used to prevent back-scattered X-rays being reflected back into the X-ray photographic plate or digital array detector which would cause blurring of the image. Figure 2 shows an example of lead shielding used in a portable X-ray detector.

X-ray Detector TFT + Lead sheet + Plate

Figure 2. Lead sheet used in a portable X-ray Detector

The X-ray detector module shown above in Figure 2 includes a lead metal sheet incorporated in the X-ray detectors between the Thin Film Transistor (TFT) array detector and the metal plate at the rear. This lead sheet prevents back-scattered X-rays being reflected back into the TFT sensor which would blur the image.

PET and SPECT

Lead shielding is also used in Positron Emission Tomography (PET) and single-photon emission computerized tomography (SPECT), which are 3-dimensional imaging techniques that detects β and γ radiation emitted from a variety of radio-isotopes that are given to patients to view specific parts of the body.

Both techniques use shielding to protect sensitive electronics and for collimators. Lead is used in the container that houses the PET and SPECT detector crystal and photomultiplier tubes to shield them from high energy photons. Another use of lead shielding in some products is around the edges of the PET detector module to prevent off-axis photons from the patient significantly from hitting the detector crystals which could cause misdiagnosis.

PET uses of lead to shield "out of field of view events" or “singles”. Failure to shield these events will lead to increased noise in clinical scans as well as longer scans. There is also a risk of misdiagnosis if the image statistics are low.

The image below shows the design of SPECT imaging equipment that uses two detectors, located at opposite sides of the patient and which rotate around the patient.

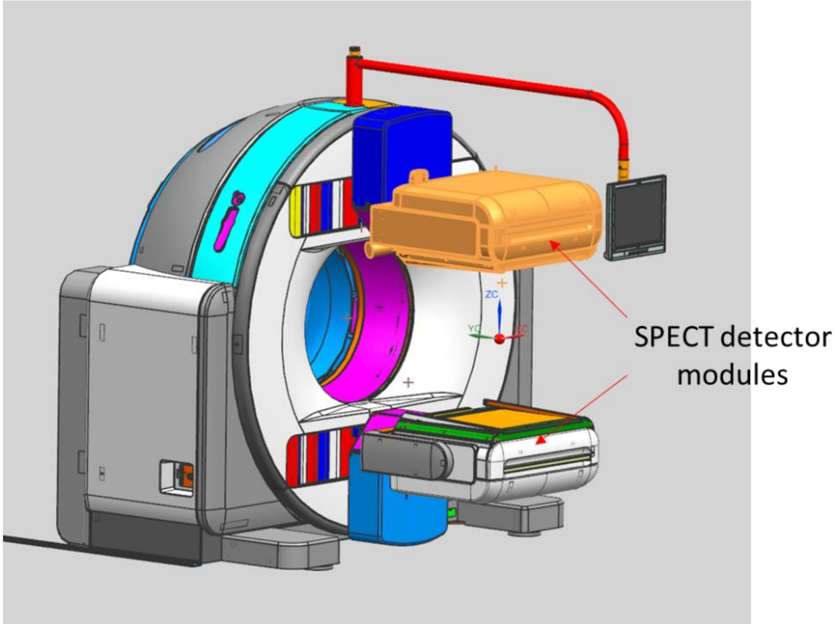

Figure 3. SPECT scanner with two detectors

In SPECT equipment, lead is used in collimators to significantly reduce the off-axis photons from reaching the scintillator crystal or digital detector (used to detect energetic photons from radioisotope sources in patients), which reduces scattered radiation and improves image quality (primarily contrast resolution). The optimal design of collimators is a hexagonal grid structure, as shown below:

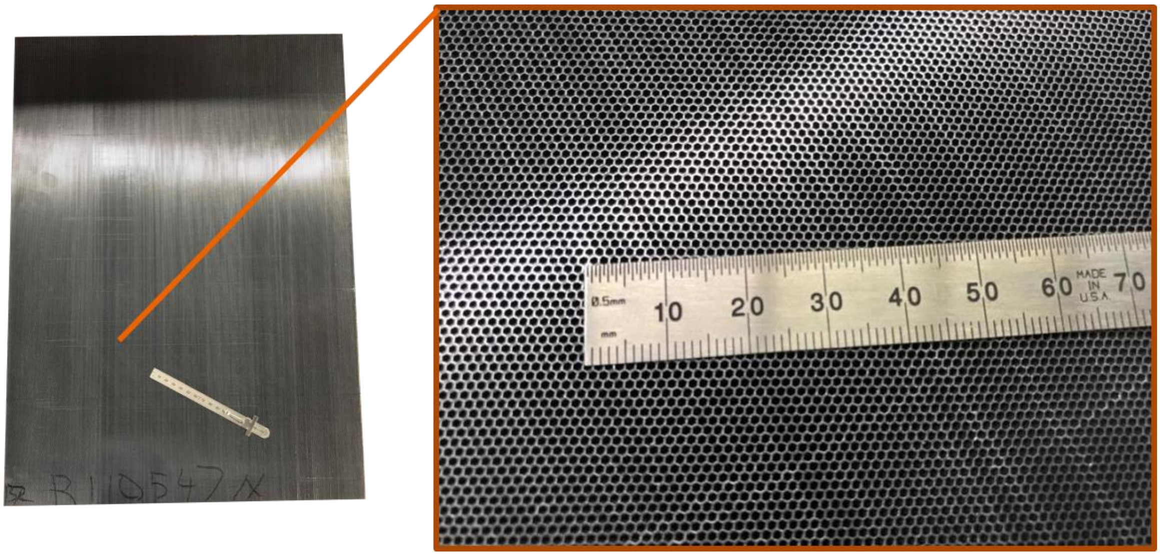

Figure 4. Image of a SPECT anti-scatter grid.

Due to the small hexagonal hole size, grids as shown in Figure 4 cannot be made with materials other than lead.

Radiotherapy

Higher energy radiation is used to destroy cancerous and benign tumors using a technique called radiotherapy. Various designs of equipment are used, but relatively thick layers of shielding are needed to protect hospital staff, the patient and electrical equipment. Collimators which also contain lead shaped to focus the radiation onto the tumor with as little radiation as possible reaching healthy tissue.

(C) What are the particular characteristics and functions of the RoHS-regulated substance that require its use in this material or component?

The material is required to have a high atomic number and high density to be effective. The thickness of shielding required depends on the energy of the radiation, the shielding material's atomic number, material density and the k-edge values of the shielding element or elements. The k-edge energy is that of the k-electrons of the element and x-ray adsorption is more efficient when the energy of the ionising radiation is at and above the k-edge energy. At the energies used for medical imaging and for radiotherapy, the thickness of lead required as a barrier to ionising radiation will be less than that of metals which are less dense and have lower atomic number, such as steel.

Materials with lower atomic number or lower density would need to be thicker to achieve equivalent barrier performance to be effective as a barrier to ionising radiation and with many materials they would need to be considerably thicker. There is frequently very little space available for radiation shielding so that it is not technically feasible to use lower atomic number materials. Some forms of treatment require health workers (nurses, etc.) to have access to patients so shielding must not prevent this by reducing the space available. Thicker shielding would be severely restrictive if it had to be used and may also make it impossible to construct equipment with enough space for patients and access to them. The size of imaging equipment such as CT machines is dependent on the size of all the component parts that are required and these include radiation shielding to ensure that X-rays are focussed only where required and to shield hospital staff and the very sensitive X-ray detector and electrical circuitry.

Other requirements are:

- The material used should have a low overall environmental and health impact. Very expensive materials would prevent hospitals from being able to buy new medical devices and this would have a negative impact on the health of EU citizens.
- Manufacturability is essential. Lead is easy to make into complex shapes by extrusion, deep drawing, rolling, brazing, etc., whereas materials such as tungsten and tungsten

composites are much more difficult or impossible to fabricate into the required complex shapes.

- Some of the shielding used inside X-ray tubes is exposed to cooling oil. Metals are suitable, but polymer composites may absorb oil, swell and disintegrate so are unsuitable.
- It is essential that the shielding material is stable and does not degrade or disintegrate when exposed to ionising radiation.
- In some applications, high thermal conductivity is important to conduct heat away from warm electrical components

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5. Information on Possible preparation for reuse or recycling of waste from EEE and on provisions for appropriate treatment of waste

1) Please indicate if a closed loop system exist for EEE waste of application exists and provide information of its characteristics (method of collection to ensure closed loop, method of treatment, etc.)

It is very common for X-ray imaging equipment, PET and SPECT to be returned to manufacturers by users. These are refurbished for reuse if possible otherwise parts are removed for reuse. Damaged and unusable parts are recycled. Therefore most equipment is collected within a closed loop system.

2) Please indicate where relevant:

☐ Article is collected and sent without dismantling for recycling

☒ Article is collected and completely refurbished for reuse

☒ Article is collected and dismantled:

☒ The following parts are refurbished for use as spare parts: Many parts are refurbished including X-ray tubes, detectors, circuitry, etc.

☒ The following parts are subsequently recycled: All radiation shielding that is not part of refurbished parts

☐ Article cannot be recycled and is therefore:

☐ Sent for energy return

☐ Landfilled

3) Please provide information concerning the amount (weight) of RoHS sub-stance present in EEE waste accumulates per annum:

☒ In articles which are refurbished	Estimated at about 200 tonnes
☒ In articles which are recycled	Estimated at about 300 tonnes
☐ In articles which are sent for energy return	_____
☐ In articles which are landfilled	_____

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6. Analysis of possible alternative substances

(A) Please provide information if possible alternative applications or alternatives for use of RoHS substances in application exist. Please elaborate analysis on a life-cycle basis, including where available information about independent research, peer-review studies development activities undertaken

Substitutes for metal shielding and for glass will be considered separately as each has different potential substitutes. Collimators has particular technical issues which are also described below separately.

Metal shielding

The relative thickness required for some substitute materials has been demonstrated from experimental tests. The test results show that the ratio of lead and other materials, such as steel, depends not only on the type of shielding material, but also on the energy of the radiation. One publication[1] showed the following:

Energy of radiation	Ratio of steel to lead	Ratio of concrete to lead
200 kV	Steel needs to be 13.6 times thicker than lead for equal effectiveness	Concrete needs to be 55 times thicker than lead for equal effectiveness
600 kV	Steel needs to be 2.9 times thicker than lead for equal effectiveness	Concrete needs to be 9.3 times thicker than lead for equal effectiveness
1400 kV	Steel needs to be 1.7 times thicker than lead for equal effectiveness	Concrete needs to be 5.2 times thicker than lead for equal effectiveness

Note that medical X-ray imaging typically uses 60 to 200kV energy. PET and SPECT uses radio-isotopes which emit radiation in broad range of energy from about 0.7 to over 7MeV, depending on the isotope used which is determined by the part of the body being examined. Radiotherapy uses higher energies of at least 300kV and frequently over 1MV.

To avoid having to use much thicker layers of shielding which would be technically impractical, high atomic number and high-density materials must be used. The following table shows that relatively few metals have both high density and high atomic number and are not radioactive or toxic.

[1] Relative Thickness of Lead, Concrete, and Steel Required for Protection Against Narrow Beams of X-Rays. George Singer, * Harold O. Wyckoff, and Frank H. Day, U. S. Department of Commerce National Bureau of Standards, paper RP1806, vol 38, June 1947. Downloaded from: http://nvlpubs.nist.gov/nistpubs/jres/38/jresv38n6p665_a1b.pdf

Table 1. Atomic number, density and limitations of the heavier elements

Element	Atomic number	Density	Limitations
Uranium	92	19.05	Radioactive
Bismuth	83	9.8	Less dense so thicker material needed
Lead	82	11.3	Currently used
Thallium	81	11.8	Very toxic (as also is mercury atomic number 80)
Gold	79	19.3	Very expensive, likely to be stolen if used, making medical device un-usable and so harming patients
Platinum	78	21.1	Very expensive, likely to be stolen if used, making medical device un-usable and so harming patients, same with other platinum group metals.
Tungsten	74	19.3	Limited suitability as shielding, but see discussion below.
Tantalum	73	16.7	Has been evaluated but is difficult to fabricate and brittle so thin sheets are easily broken.
Hafnium	72	13.3	May be suitable, but less so than tungsten, difficult to fabricate and difficult to extract from minerals
Barium	56	3.51	Too reactive as a metal and gives inferior shielding glass due to lower atomic number and density
Molybdenum	42	10.3	Similar density as lead but much lower atomic number so needs to be much thicker

<u>Note that all elements with atomic number larger than bismuth are radioactive so cannot be used.</u>

The table above shows that several metals potentially could be used instead of lead, however in practice the only other metal that is sometimes used as radiation shielding is tungsten, which is discussed separately below.

Rare and very expensive metals are unsuitable as alternatives because:

- Firstly, the global supply of most of the platinum group metals would be insufficient to replace lead. For example, global production of platinum was 164 tonnes in 2015[2], compared to 759 tonnes used for shielding in medical devices in 2006[3]. The quantities of the other PGMs are smaller than platinum.
- A significant concern is that the cost of using very expensive materials such as gold would make the price of the medical devices much more expensive and as national budgets for publicly funded healthcare in EU Member States is always limited and will not increase due to RoHS, hospitals will not be able to afford new equipment. Patients will therefore not benefit from new technology used in new equipment and they will also suffer as old equipment tends to be less reliable and would not be available when a fault occurs. The end result will be a negative impact on health of EU citizens. Another potential negative impact on health is from the high likelihood that very expensive metals such as gold are easily resold and so are at risk of being stolen. Hospitals cannot be made very secure as they have to be open to the public. If the shielding were stolen, the medical equipment cannot be used, having a negative impact on the health of EU citizens.

Hafnium is not used for radiation shielding and tantalum has been assessed for use in collimators but is too brittle. However, these metals and all other potential substitutes for lead have considerably larger impacts on the environment from their mining, refining and production than lead. Research[4] to compare metals production environmental impacts shows the following:

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[2] Mining Weekly estimate production of platinum in 2015 was 6.4 million troy ounces which is 164 tonnes http://www.miningweekly.com/article/global-platinum-production-to-rise-marginally-to-2020-2016-12-22 .

[3] Review of Directive 2002/95/EC (RoHS) Categories 8 and 9 - Final Report, Dr. Paul Goodman, ERA Report 2006-0383, contract ENV.G.4/ETU/2005/0014

[4] Life Cycle Assessment of Metals: A Scientific Synthesis, Philip Nuss, Matthew J. Eckelman http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0101298

Table 2. Global warming potential from mining, refining and production of heavier metals

Metal	Global warming potential from production (kg CO_2-eq/kg)
Lead	1.3
Bismuth	58.9
Thallium	376
Mercury	12.1
Gold	12,500
Platinum	12,500
Iridium	8,860
Osmium	4,560
Rhenium	450
Tungsten	12.6
Tantalum	260
Hafnium	131
Molybdenum	5.7

Production of all of the “heavy” and high-density metals that could potentially be used as shielding creates emissions with much higher global warming potential than lead production with many metals having considerably larger impacts. The metals with the smallest impact, apart from lead, are mercury, which is also banned by RoHS and so could not be regarded as a possible substitute, and tungsten, which will be discussed in more detail below. Molybdenum is unsuitable due to its much lower atomic number (it is also too brittle and difficult to fabricate) As the GWP of all other non-toxic metals listed above in Table 2 are larger than tungsten, the overall impacts of these materials would be more negative than the overall impact tungsten and so a comparison of tungsten with lead can be used to demonstrate the relative overall health and environmental impacts of all potential substitutes using a comparative life cycle assessment. However, there are also technical reasons why tungsten and other hard brittle metals cannot be used as substitutes for lead.

Tungsten as a substitute

Tungsten is used commercially as shielding for ionising radiation, as solid tungsten metal, as solid tungsten alloys and as composites of polymers with tungsten powder. The technical performance as a barrier to ionising radiation is similar to lead. As pure metal, the thickness required is usually less than lead, but as a drop-in replacement in existing designs, the same thickness may have to be used. The actual thickness required depends on the energy of the radiation with thicker layers being needed for high energy γ-radiation that X-rays used for imaging. If thinner layers of shielding can be used, this can be an advantage where space is very limited, especially with some types of collimators. Tungsten metal is however extremely hard and difficult to fabricate into the required shapes. It is also very brittle and easily damaged, which increases the quantity of production waste.

The density of tungsten metal (19.2 g/cc) is much higher than lead (11.3 g/cc) and so the use of an equal volume of metal would make the shielding considerably heavier if equal thickness of metal is used. This is a technical disadvantage in equipment which is moved by hospital staff. For example, X-ray tubes need to be moved around patients to image the required part of their body. The heavier weight needs to be counterbalanced so that movement is possible, but this then makes the equipment much heavier due to the increased weight of shielding and its counterbalance weights. Some types of X-ray imaging equipment often have to be moved by hospital staff and this increased mass makes this much more difficult and potentially could cause injury

Metal-polymer composites will need to be thicker than lead (by about 1.5 times) to give the same performance, which limits its suitability where space is limited. Composite materials are less difficult to fabricate than tungsten metal and are less brittle, but extrusion of large parts, deep drawing and bonding are all very difficult or impossible with these materials and so they can be used only for a few limited applications where it is possible to use simple shapes. Composites also have the disadvantage that they cannot currently be recycled at end of life as no commercial processes exist. Tungsten-polymer composites have been developed for use as radiation shielding with density of about the same as lead and these can be used although with larger thickness (about 1.5 times thicker). This does not have the disadvantage of handling heavy material with a higher density, but more space is required for the ticker material.

Typically lead sheet of 1 – 4mm thickness is used, for example inside X-ray tubes or in collimators. Manufacturers design these parts to be as small as possible as well minimising the amount of lead to reduce weight as far as possible. If they were forced to switch to composites, because these have to be 1.5 times thicker for the same shielding performance, the sheet would not fit into current designs of equipment. Redesign is often not possible as making the parts larger reduces space available for the patient and hospital staff.

Tungsten-based shielding has the apparent advantage of not containing lead, which has an EU harmonised classification as a category 1A reproductive toxin whereas tungsten is claimed to be not hazardous (except as a fine powder). Tungsten has the significant disadvantage over lead, because its overall environmental and health impacts are more negative than for lead, as shown by independent life cycle assessments[5]. Lead and tungsten life cycles are compared

[5] Life Cycle Assessment of Metals: A Scientific Synthesis, Philip Nuss, Matthew J. Eckelman. http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0101298

below:

Table 3. Comparison of lead and tungsten life cycles

Life cycle phase	Lead	Tungsten
Mining	Lead ores are common and found in many countries globally. Estimated at 14ppm of the earth's crust with over 4.8 million tonnes mined in 2016[6], mostly as galena, its sulphide.	Tungsten is classified by the EU as a Critical Raw Material. Most is mined in China but the Chinese government issues quotas to limit supply. Tungsten is not a rare element, with an abundance of 1.25ppm (according to the British Geological Survey), but economically extractable ores are not as widespread as lead. USGS reports that global tungsten mining in 2016 was 86,400 tonnes[7]. It is mined mainly as tungstates of calcium, lead and other metals[8].
Extraction and refining process	Conversion of galena to lead metal is a relatively simple one-stage process where it is heated with a limited air supply to yield impure metal and sulphur dioxide. Impure lead metal is then refined to remove impurities. Sulphur dioxide is a useful by-product that is used to manufacture sulphuric acid which has many commercial uses.	Tungsten minerals, after pre-concentration and beneficiation are converted to metal by a series of five chemical steps[8]: 1. Tungsten minerals are simultaneously heated and ground in an autoclave ball mill to dissolve the tungsten in sodium hydroxide to give soluble sodium tungstate. 2. Impurity removal from the sodium tungstate solution. 3. Conversion into ammonium isopolytungstate (APT) by ion exchange or solvent extraction. 4. APT is heated to convert it into tungsten trioxide 5. Tungsten oxide is then reduced to tungsten metal powder by heating in a furnace under reducing conditions. Each of the above steps creates wastes that must be disposed of. Some wastes contain hazardous by-products including lead.

[6] https://minerals.usgs.gov/minerals/pubs/commodity/lead/mcs-2017-lead.pdf
[7] https://minerals.usgs.gov/minerals/pubs/commodity/tungsten/mcs-2017-tungs.pdf
[8] British Geological Survey, tungsten profile, http://www.bgs.ac.uk/mineralsUK/statistics/mineralProfiles.html

Fabrication of shielding	Lead has a low melting point of 327.5°C. At this temperature, melting emits no lead emissions to air. Lead metal is relatively soft so that it can easily be formed into shapes or sheet with minimal input of energy and no waste. Lead shielding suppliers have confirmed that recycled lead metal is usually used.	Tungsten melts at 3422°C and so melting into shapes is extremely difficult and energy intensive. The most commonly used fabrication method is from powder that is produced by the refining process. This powder can be hot-pressed into a limited range of solid metal shapes or combined with polymers as composites. Solid tungsten blocks made from powder are extremely hard and are very difficult to shape, requiring a large energy input.
Use phase	High energy radiation can generate radioisotopes but with lead these have very short half-lives so that the metal is not radioactive after a few days.	High energy radiation generates radioisotopes from tungsten shielding with half-lives of many years. Used tungsten shielding from radiotherapy equipment is radioactive and so must be safely stored for many years until the radioisotopes have decayed to safe levels. Ionising radiation causes degradation of the polymer used in composites
End of life	Lead radiation shielding as block or sheet is high purity lead and only needs to be melted and recast for reuse. This is a low temperature process that does not emit lead to air and would create minimal waste. Globally, about 55% of lead is from recycled sources (data from the International Lead Association). When slightly harder lead is needed, metal with 4 – 6% of antimony can be used. This composition is used in lead-acid batteries, the predominant use of lead globally by far and so these alloys are readily available as recycled metal and can be used to make more lead-acid batteries as well as new shielding.	Solid tungsten metal scrap from used medical devices is not reused in new machines but can be recycled, usually to make alloys. Some tungsten alloys are recycled and used to manufacture hard steel alloys, but it is not known whether scrap shielding is used for this purpose. Globally the International Tungsten Industry Association (ITIA) report that 35 – 40% of used tungsten metal is recycled globally. Recycling of polymer composites is much more difficult than solid metal because the metal powder would first need to be separated from the polymer of the composite and this is possible only by pyrolysis. This would leave impure tungsten that would probably need to be processed by similar methods to the complex refining process used for production of metal from ores[9]. However it is believed that this material is not recycled commercially, as no facilities currently exist, and so it is currently disposed of via landfill.

[9] This is described by USGS https://pubs.usgs.gov/of/2005/1028/2005-1028.pdf

	Leaded glass can also be re-melted for reuse.	

Tungsten's toxicity

The toxicity of tungsten and its compounds has been the subject of debate and research. Tungsten metal is not classified as hazardous in the EU but the compounds that are produced when converting ores to metal and also potentially during chemical recycling are classified as hazardous. Tungsten trioxide is classified as an acute toxin category 4 and STOT SE 3. Ammonium tungstate is also STOT SE3 whereas sodium tungstate has an EU harmonised classification as acute toxin category 4 and aquatic chronic toxin category 3. There have also been claims that there is an increased incidence of leukaemia associated with tungsten mining. Initially research at Fallon, Nevada, USA indicated that tungsten may have caused an increased incidence of leukaemia, but subsequent research showed that there is no statistically meaningful link and the increased incidence could have other causes[10]. However more recent research has indicated that tungsten is not benign and may have a harmful effect on human health[11]. The toxicity of lead is well known after many decades of research, but research into tungsten is at a much earlier stage with far less published research available, so possible hazards may not yet have been identified.

The main negative health and environmental impact from tungsten is from emissions released when energy (e.g. electricity) used for refining, manufacture, etc. is generated. Coal and oil combustion in particular emit lead, cadmium, mercury, arsenic, nickel and other toxic substances and these can have a larger negative overall impact than the very small emissions from lead from production and from recycling of lead shielding.

End of life of medical devices

Lead shielding can be easily and safely recycled by melting and casting and this does not emit lead fumes or vapour. The process is very simple with yields of over 99.9% with minimal solid waste. Recycling is the only route used in the EU and is also likely to be used in countries outside of the EU due to the value of lead metal. Therefore, if medical devices that were originally placed on the EU market are resold to second users outside of the EU, when these reach end of life, the lead shielding will be easily and safely recycled[12]. Tungsten metal may be recycled in countries outside of the EU, but tungsten composites could pose a health risk if they were attempted to be recycled without suitable safe processes. Options for disposal of composites include landfill or burning to recover the tungsten metal powder (in an impure form). Burning of the polymers without suitable safety precautions can emit a wide variety of toxic substances, depending on the temperature and type of polymer used. Polycyclic aromatic hydrocarbons are emitted from all types of polymers when these are burned on open fires and

[10] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1314934/

[11] https://www.nature.com/articles/leu2011160

[12] Note that this is different to printed circuit boards and lead-acid batteries where unsafe recycling generates dust that can be inhaled or consumed. Recycling of lead sheet from shielding will not generate dust or lead fumes.

these substances are carcinogens and toxic. This should be less of an issue in the EU as legislation controls the use of incinerators to minimise the release of toxic by-products.

Technical reasons why tungsten is not a suitable substitute

The RoHS Directive has encouraged medical equipment manufacturers to search for substitutes for lead, but there is no drop-in replacement available. Shielding made with tungsten metal, its alloys and as composites is sometimes used in some limited applications where its hardness and rigidity give technical advantages over lead. However, tungsten based shielding has many disadvantages that usually make it unsuitable, as follows:

- Tungsten composites need to be thicker than lead for equivalent shielding performance (see below) and the extra space is often not available
- Tungsten metal, alloys and composites cannot be made into complex shapes, unlike lead.
  - Tungsten metal and its alloys are very hard and so are very difficult to form into shapes.
  - Only simple shapes can be made using powder metallurgy
  - Lead can be cast and extruded into very complex shapes. This is technically possible only for very small tungsten-polymer composites
  - Lead sheet is flexible so can be formed inside of X-ray tubes and other parts to perfectly conform to the inner surface including cable feed throughs. It can also be overlapped and formed to avoid seams and gaps. None of these are not possible with tungsten metal, alloys and tungsten composites
- Often thin sheet is needed such as to protect sensitive electronics and to block back-scattered X-rays from reaching flat panel detectors. Thin sheets of tungsten metal and its alloys are too brittle and fragile as are most other heavy metals including molybdenum, bismuth and tantalum. Tungsten-polymer composites can be formed into thin sheets that are less easily damaged, but each sheet needs to be thicker to have the same shielding properties as lead and this can limit the accuracy of collimation
- Some applications require accurate shapes and dimensions. This is straightforward with lead as it is ductile and easily formed into the required shape. This is much more difficult with tungsten metal, alloys and tungsten composites and as a result, the quality of parts will not be satisfactory and be disposed of as waste. The rigidity of tungsten is an advantage for few applications, such as pin-hole collimators, as it is less likely to be damaged and distorted in use, but these are more difficult to make with tungsten and they have an inferior field of view.
- Lead is easily formed into the optimum hexagonal honeycomb structure that is optimum for anti-scatter grids (see Figure 4). It is not possible to make this shape with tungsten metal or its alloys. It is also very difficult to extrude this shape with tungsten-polymer

composites and in any event, as it needs to be thicker, it would block more of the desired radiation than lead do that the image is inferior (see "collimators" below).

- Tungsten-polymer composites cannot be recycled.
- Tungsten-polymer composites are known to degrade when exposed to ionising radiation (all polymers are affected) and this could shorten the lifetime of the medical device.
- The thermal conductivity of tungsten composites that have the same density as lead metal have a thermal conductivity which is much lower than lead:
    - Tungsten composite 3.5W/m-K
    - Lead metal 33W/m-K

  PET is often combined with MRI in a single medical device. MRI detectors are very sensitive to temperature and so heat generated by the detector circuits must be conducted away. Lead metal shielding is a good thermal conductor, but there is a risk of heat build-up if metal-composites are used which would negatively affect image quality and detector lifetime.

Tungsten metal is much heavier than lead due to its higher density so is more difficult to handle. It is also extremely hard and so is very difficult to cut into the required shapes. Tungsten-polymer composites overcome handling and some, but not all, of the fabrication issues as composites are more easily cut and they can be made with a density that is the same as lead. However, tungsten-polymer composites must be thicker than lead (by about 1.5X) to achieve the same radiation barrier properties. This causes several problems:

- It cannot be used as a drop-in replacement for lead in existing designs as there will not be sufficient space.

  PolyOne manufacture tungsten/polymer composites which they state on their website have a density of 11.2g/cc (same as lead) and use Nylon 6 as the polymer[13]. Tungsten has a density of 19.25 and Nylon 6 has a density of 1.08 g/cc and so a blend with density of 11.2 will contain 95.7 weight % of tungsten metal or 55.6 volume %. A medical equipment manufacturer has calculated that the equivalent thickness of tungsten metal to 10mm of lead would be 8mm of tungsten metal to achieve the same barrier properties to typical X-ray imaging radiation. As the polymer composite is 55.6

[13] http://www.polyone.com/files/resources//GraviTech_PSG.pdf

volume % of tungsten metal, the calculated thickness of polymer composite is 14.4mm, which is significantly thicker than 10mm of lead metal.

- It is essential that medical staff have access to patients. Often the available space is quite limited and so the use of thicker shielding may not be possible.
- In most applications, tungsten and tungsten composites cannot be fabricated into the shapes that are required, so are technically impractical and cannot be used

Overall health and environmental disadvantage of tungsten

Medical equipment manufacturers are endeavouring to replace RoHS substances that are still permitted by exemptions. The RoHS Directive does not require manufacturers to consider the overall environmental, safety and health impacts of substitutes, which is unfortunate in circumstances where the substitute is substantially more negative overall than lead overall. However, such a comparison can and should be used as justification for an exemption to allow the use of lead shielding due to the overall much more negative overall impact of tungsten. The independent life cycle analysis described below shows that tungsten has overall a more negative impact on health, safety and the environment than lead and so justifies this exemption for lead in shielding for ionising radiation, even if tungsten continues to be used for certain applications for technical reasons.

Life Cycle Assessment comparison of lead with tungsten

A comparative life cycle assessment has been carried out by independent experts "Thinkstep AG" using data for a representative medical device provided by COCIR. The representative device is a skeletal X-ray imaging system which is constructed using 11.3kg of lead metal in the form of metal sheet. Another manufacturer of skeletal X-ray systems uses from 10 to 16kg of lead sheet The equivalent quantities of tungsten metal and tungsten composite are calculated values because neither are used in skeletal X-ray systems. The calculation method is as follows:

Tungsten composite material with a density that is similar to lead metal is commercially available and contains about 96% by weight of tungsten powder in Nylon 6[14].

X-ray equipment manufacturers have calculated that the following quantities of shielding materials are required as a barrier to X-radiation of energies used for X-ray imaging (at 70keV)

- Lead = 1.13 g/sq. cm
- Tungsten = 1.54g/sq. cm

Therefore, the calculated conversion rate is 1.363 times more tungsten by weight than lead.

[14] http://www.polyone.com/files/resources//GraviTech_PSG.pdf

An area of $1m^2$ of the type of lead sheet shielding[15] used for skeletal X-ray system would contain 11.3 kg of lead and so this would be equivalent to:

- 15.5 kg tungsten, or
- 16.0 kg of tungsten/polymer composite

These differences are consistent with published data[16].

The only difference between an X-ray system constructed with lead shielding and a hypothetical system constructed using either tungsten metal or tungsten composite shielding will be the shielding material. All other parts of the system will be identical irrespective of the type of shielding material used. Also, there is no difference in the use phase as it is assumed that all three types of shielding are equally effective at blocking radiation (if sufficiently thick) and no maintenance is required.

Thinkstep has calculated 11 human health and environmental impacts using GaBi software[17] for the three shielding materials and with three scenarios:

- Basic – uses the most likely end of life routes for the three materials which is lead is recycled and tungsten is landfilled
- Best - Tungsten is recycled, not landfilled
- Worst case – assumes lead is landfilled, not recycled

Assumptions

Each imaging technique uses a different radiation energy. Some, such as mammography use lower energy that skeletal X-ray and others such as PET and SPECT use higher energy. The radiation wavelength has a small impact on the relative quantities of lead and tungsten.

The basic scenario assumes that no tungsten is recycled, and the best scenario assumes that 100% is recycled. While it is currently impossible to recycle or reuse tungsten-polymer composites (reuse is not possible due to polymer degradation due to radiation damage), some tungsten metal is recycled and the International Tungsten Industry Association estimate that 35 to 40% of tungsten metal scrap is recycled. The true impacts are therefore somewhere between those of basic and best scenarios for tungsten metal, but the basic scenario for tungsten composites is more realistic.

The International Lead Association estimate that 55% of lead is recycled globally, however, close to 100% of lead shielding from medical devices will be recycled due to its positive value.

Thinkstep have used published data for grinding and sintering tungsten to obtain solid from powder. Published values vary to some extent and it has been assumed that the value for

[15] An area of $1m^2$ is used as this can be scaled to give comparative LCA data for any medical device.

[16] Published data on the relative thickness of lead and tungsten alloys is available at: https://www.wolfmet.com/wp-content/uploads/2017/01/Wolfmet_Radiation_Shielding.pdf The mass required is calculated from the thickness using the density of these materials.

[17] https://www.thinkstep.com/software/gabi-lca

production of tungsten metal shielding will be the same as typical published values[18].

Results of LCA

The results of the life cycle assessment are provided as a separate Annex in the form of a presentation prepared by Thinkstep. For all three scenarios, for all but one of the impacts, those from the use of tungsten or tungsten composite were significantly more negative than for lead. Three example impacts from lead and tungsten composite are listed below. The corresponding impacts for tungsten metal are larger than for the composite:

Impact	Lead	Tungsten composite
Global warming potential GWP (kg CO2 eq.)	13	490
Human toxicity potential (kg DCB eq)	1.6	116
Freshwater aquatic toxicity (kg DCB eq)	0.05	13.4

The impacts from lead are clearly much small than for tungsten shielding. The Thinkstep LCA shows that the largest impacts are at the "raw material" life cycle phase for all three materials. If the alternative scenarios calculated by Thinkstep are considered for two of the impacts, the following results are obtained:

[18] For example http://aip.scitation.org/doi/abs/10.1063/1.1713072?journalCode=jap and https://www.sciencedirect.com/science/article/pii/0022508863900079

Scenario	GWP (kg CO2 eq.)	Human toxicity potential (kg DCB eq)	Comments
Lead recycled at end of life	13	1.6	Most lead shielding will be recycled at end of life
Lead to landfill at end of life	21	2.5	Unlikely to occur
Tungsten composite landfill	490	116	Most likely route at end of life of composite currently
Tungsten composite - metal remelting	62	-	Not currently possible. Only possible for tungsten metal scrap
Recycling of metal powder without melting	23	-	Currently impossible commercially
Sintered tungsten metal remelted	252	-	This is carried out commercially, but only 35 to 40% of tungsten metal scrap is recycled globally

The difference in the size of the impacts between lead and tungsten appears smaller with these alternative scenarios, however, recycling of tungsten composites for metal recovery is currently not possible and the GWP impact for tungsten metal, even with 100% recycling at end of life (in practice only 35 to 40% is recycled) is still much larger than the impacts from lead, irrespective of whether it is recycled or landfilled.

The only impact which is larger for lead than for tungsten is ozone layer depletion potential. This is because the standard data used by Thinkstep assumes that lead is produced and recycled in the EU including using electricity generated in the relatively older designs of nuclear power stations than the newer types which are used in China where most tungsten metal originates. Thinkstep also point out that the raw data used for the LCA is old and out of date so will not be accurate. The difference between these impacts will decrease in the future as the oldest EU nuclear power stations that use R22 refrigerant are closed and replaced. This is already underway and many first generation nuclear plants in the EU have already reached end of life and have been closed down.

This LCA clearly shows that the overall health and environmental impacts of lead and smaller than the overall impacts of both tungsten metal and tungsten composites. As the only difference to the medical devices is the composition of shielding materials, there are no differences in safety, to workers who assemble medical devices (as the size and mass of lead shielding parts will be similar to tungsten versions), to workers who recycle medical devices, to hospital workers or patients. The LCA therefore clearly justifies this exemption request. If alternative high atomic number and high density metals are considered, such as those listed in Table 2, all (apart from mercury) require even more energy to manufacture than tungsten and as most impacts are due to energy generation, the results of LCAs for these metals would also show that they are overall more negative than lead.

Collimators

The above comparative life cycle assessment for lead and tungsten is also applicable to collimators, but there are also technical disadvantages with tungsten and other potential substitutes which means that lead is the only technically viable material for these applications.

There are many designs of collimator used. These include shutters of various designs, iris collimators and anti-scatter grids (see Figure 4).

Flat panel detectors are now widely used to detect radiation and create a digital image. However, some of the X-radiation emerging from patients has been scattered and would impair image quality if not removed. Also with PET and SPECT, radiation emerges in all directions as radio-isotopes may be present in various parts of the body as well as the target area and so a clear images can be obtained only if radiation is collimated, so that only radiation travelling in directions incident to the detector are detected, as shown below.

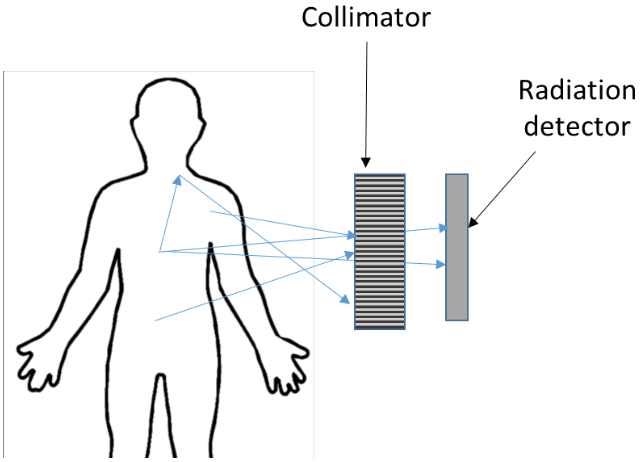

Figure 5. Collimation of γ-radiation from a patient when creating a PET image of an internal organ

The optimum design of a collimator for flat panel detectors is a hexagonal array of high atomic number metal. Hexagonal holes are found to be more effective at blocking stray radiation than square holes. Lead has a low melting point so is easily cast into a hexagonal array, but this is impossible with tungsten because of its very high melting point. Although small amounts can be melted there is no material known that can be used as a mould as all other materials (metals and ceramics) have lower melting points. Ceramic materials that might be used for moulds would be damaged or decompose at this very high temperature. The most efficient way to make a tungsten collimator is to use sheet stock, cut into strips. The strips are then notched and stacked in ninety-degree intersections. This technique can be compared to the cardboard inserts found in wine boxes. Construction with this method yields square or rectangular holes but square-hole collimators are less efficient than the hexagonal holes used in typical lead collimator. This occurs because the walls of each compartment take up a greater amount of the collimator area, reducing its sensitivity. In addition, this construction technique is prone to inter-septal leakage, basically allowing radiation to pass from one septal opening into the next. To counter the loss of sensitivity clinicians must increase radiation dose, or increase scan time, or reduce image quality potentially impacting efficacy.

Manufacturer's simulations confirmed that hexagon septal bores outperform collimators with both round or square holes. It has not been possible to create complex shapes such as a hexagonal grid using powder metallurgy from tungsten powder. As shown above, tungsten-polymer composites need to be about 1.4 times thicker than lead to be equally effective. If this material were used for a collimator, it would require thicker walls and so smaller holes which would reduce the amount of radiation reaching the detector and give an inferior image. Increasing radiation dose to compensate, however, is potentially harmful to patients.

Several designs of collimators are used for SPECT depending on a variety of variables. Pinhole collimators are sometimes selected which can be made from tungsten. Tungsten has an advantage over lead in being hard and so not easily distorted or damaged. However the field of view of this type of collimator is inferior to other types that are made with lead, which limits its applications and so lead often has to be used.

Transparent glass shielding

Lead-based glass is used as shielding and is used for constructing equipment such as some types of X-ray tubes and as windows to allow hospital staff to watch patients while they are being treated.

There are very few stable, tough and transparent glass materials that are efficient barriers to ionising radiation. Glass with a high lead content is easy to make and shape, it is not affected by water or humidity, so is stable and it has very good transparency. Most other high atomic mass elements cannot be added to glass at high concentrations because they either will not form a stable, colourless, transparent material or they cause crystallisation which creates an opaque material. There are a few glass formulations that have been developed based on barium, which is sometimes used with lead[19]. Barium has a lower atomic number than lead and is less dense so the glass is less effective at shielding of radiation and so thicker window would be needed and these would impair visibility.

(B) Please provide information and data to establish reliability of possible substitutes of application and of RoHS materials in application

Reliability of substitutes is mainly no different to lead so this is not used here as justification for this exemption. The only reliability concern is over the long-term stability of composites which are degraded by ionising radiation. However, no data is available for this effect.

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[19] https://www.corning.com/emea/en/products/advanced-optics/product-materials/specialty-glass-and-glass-ceramics/radiation-shielding-glass/corning-med-x-glass.html

7. Proposed actions to develop possible substitutes

(A) Please provide information if actions have been taken to develop further possible alternatives for the application or alternatives for RoHS substances in the application.

Medical device manufacturers have evaluated a variety of materials as possible substitutes for lead radiation shielding. These include the following materials and the results:

- Tungsten – this can and is used for certain limited applications, however, it has technical disadvantages as described above in section 6 which prevents its use in most medical devices. A significant reason for not using tungsten, however, is its substantially more negative overall environmental impact, as shown by the LCA.
- Tantalum – used a metal sheet, but these are very difficult to fabricate into shapes and are too easily broken so its use is impractical.
- Bismuth and barium compounds in polymer composites – these materials need to be considerably thicker to achieve equivalent shielding performance to lead and this makes their use impractical in applications where space for the patient and access by medical staff to the patient is limited (the situation with most medical devices). Testing has also found that these materials are too brittle and were easily damaged, such as from vibration or impact, making the equipment unusable
- Molybdenum has been assessed as a possible substitute, but us too hard and brittle to form into shapes with accurate dimensions and also needs to be much thicker than lead and a greater mass of material is needed, due to its much lower atomic number.
- There is some recent research with glass that contains both barium and bismuth, but as the atomic number and density of barium is much lower than lead and also the proportions of these heavy metals that can be added to the glass are much lower than can be achieved with lead in glass, this material has inferior shielding performance and so is usually unsuitable.

(B) Please elaborate what stages are necessary for establishment of possible substitute and respective timeframe needed for completion of such stages.

All high atomic number and high-density metals that give similar barrier properties to lead with the same or thinner sections have a very much larger overall negative health and environmental impact than lead. This situation is likely to change slowly in the future as energy generation switches from fossil fuels to renewable sources, but it is likely to be very many years before this makes a significant difference to the relative impacts of lead and other heavy metals.

There are also technical disadvantages with other metals such as tungsten and also tungsten-polymer composites which are due to the physical properties (e.g. hardness and brittleness) of the materials, which cannot be changed.

Very expensive substitutes are also impractical because the very large price increases would make it very difficult for EU hospitals to be able to buy new equipment. Also there is a risk of theft of very expensive metals such as gold.

As most of the above issues cannot be changed or will take a very long to change, it will be very many years, probably several decades, before it is likely to be possible to replace lead.

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8. Justification according to Article 5(1)(a):

(A) Links to REACH: (substance + substitute)

1) Do any of the following provisions apply to the application described under (A) and (C)?

☐ Authorisation

☒ SVHC
☒ Candidate list – added June 2018
☐ Proposal inclusion Annex XIV
☐ Annex XIV

☐ Restriction

☐ Annex XVII
☐ Registry of intentions

☒ Registration – lead has been registered – see https://echa.europa.eu/registration-dossier/-/registered-dossier/16063

2) Provide REACH-relevant information received through the supply chain.
Name of document: _____

(B) Elimination/substitution:

1. Can the substance named under 4.(A)1 be eliminated?

☐ Yes. Consequences? _____

☒ No. Justification: More negative overall health and environmental impact. Technical disadvantages in most applications and substitutes have greater difficulty in recycling

2. Can the substance named under 4.(A)1 be substituted?

   ☒ Yes.

   ☐ Design changes:

   ☒ Other materials: But only in some limited circumstances, see Q6 above

   ☐ Other substance:

   ☒ No.

   Justification: Usually there are technical reasons why substitute's designs and materials are impractical as explained above, see Q6.

3. Give details on the reliability of substitutes (technical data + information): No difference in reliability for tungsten, although composites are reported to degrade when exposed to radiation. Some other materials that have been tested were found to be less reliable (see Q7A)

4. Describe environmental assessment of substance from 4.(A)1 and possible substitutes with regard to
   1) Environmental impacts: Yes – see LCA
   2) Health impacts: Yes – see LCA
   3) Consumer safety impacts: Yes, for example, if a high priced substitute were used; a) theft of the metal shielding would result in the equipment not being usable which would negatively affect patients (as they cannot be treated) and b) the higher cost (of tungsten, gold, etc.) would prevent hospitals from buying as much new equipment as at present, resulting in the average age of their equipment increasing. Older equipment can be less reliable and may have inferior diagnostic capability.

⇨ Do impacts of substitution outweigh benefits thereof? Yes
Please provide third-party verified assessment on this: Attached as separate annex

(C) Availability of substitutes:

a) Describe supply sources for substitutes: There are several suppliers of tungsten metal and tungsten composite materials

b) Have you encountered problems with the availability? Describe: Not currently, however, the main global producer (China) imposes export quotas, so difficulties may arise if demand were to significantly increase.

c) Do you consider the price of the substitute to be a problem for the availability?

   ☐ Yes ☒ No

d) What conditions need to be fulfilled to ensure the availability? Not an issue at present, but new supplies from outside of China would help to guarantee supply

(D) Socio-economic impact of substitution:

⇨ What kind of economic effects do you consider related to substitution?

☒ Increase in direct production costs – All substitute materials have higher prices than lead. Metal price of tungsten is considerably higher than lead[20] and the price difference of collimators is even larger due to the higher cost of fabrication with tungsten than lead. There is also a possible increased cost due to increase in amount of waste if hard, brittle materials have to be used. Increased production costs would affect all medical equipment manufacturers equally and so the higher costs will be passed on to hospitals.

The biggest impact is likely to be with collimators. Hospitals usually buy different types to optimise imaging for different isotopes used for PET and SPECT and for different medical procedures. A lead collimator typically costs $1500 where a similar tungsten collimator has been estimated to be $30,000. All EU hospitals have very limited budgets and this higher cost would mean that hospitals buy fewer types of collimator which could result in sub-optimal treatment.

☒ Increase in fixed costs – Hospitals would be impacted by higher equipment prices, see above.

☐ Increase in overhead – None unless tungsten composite degradation increases maintenance costs

☒ Possible social impacts within the EU – This is difficult to predict.

- If equipment is heavier due to replacement of lead metal by tungsten metal, this may cause an increase in injuries to hospital workers who need to move equipment.
- Any increase in the buying price of medical equipment due to the higher cost of tungsten (or other substitutes) when used as shielding would reduce the remaining money available for new equipment that EU hospitals can buy each year as all have limited budgets. The additional cost for tungsten, for example in a new PET, if it could be used, which is not currently possible, see section 6, would add many tens of thousands of euros to the price. If hospitals are forced to buy less new equipment, the average age of medical devices in hospitals would increase as replacements are delayed. Older equipment tends to be less reliable and so more often is not available for treating patients. Some types of older equipment may have inferior diagnostic or treatment capabilities which could delay diagnosis or make treatment take longer, both of which could harm patients and also indirectly increases their treatment costs.
- Another impact on EU citizens' health as described above, is due to the higher costs of tungsten collimators (if these could be made).
- As tungsten metal is often technically impractical and tungsten polymer composites need to be thicker (and have technical limitations), these cannot be used as drop-in replacements for lead. Therefore, if this exemption were not renewed, most types of imaging medical device could not be sold in the EU. New designs would be needed,

[20] Quoted metal prices of tungsten (2018) $30,000 per tonne, lead $2,477 per tonne from https://www.metalary.com/tungsten-price/

although this may not be technically feasible without lead. If this exemption is not renewed, there would be no new medical devices suitable for X-ray imaging, PET, SPECT and diagnosis with these techniques available in the EU for many years, which would be very harmful to EU patients. If research can identify substitutes, this would take many years for redesign, prototype construction, testing, clinical trials and Notified Body approval, which typically takes at least 8 years.

☒ Possible social impacts external to the EU – less than in the EU as lead could continue to be used if this exemption is not renewed. However, in the longer term, if medical equipment manufacturers were forced to substitute, this would negatively affect healthcare globally due to the higher prices caused by substitute shielding materials.

☒ Other: - The LCA shows that the overall more negative health and environmental impact of tungsten and other heavy metals would increase global warming and cause the emission of more toxic substances into the environment.

⇨ Provide sufficient evidence (third-party verified) to support your statement:

9. Other relevant information

Please provide additional relevant information to further establish the necessity of your request:

_____

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10. Information that should be regarded as proprietary

Please state clearly whether any of the above information should be regarded to as proprietary information. If so, please provide verifiable justification:

_____

CATEGORY 9 INDUSTRIAL EQUIPMENT
ADDITIONAL INFORMATION

4.A).1 Description of the concerned application:

Category 9 applications including non-destructive inspection, material identification for recycle, food inspection, baggage inspection and X-ray fluorescence analysis, and general scientific laboratory equipment Please note that the EEEs used for the above applications may also be used by students at universities for study.

4.A).3 Function of the substance:

<u>Lead is used to block and absorb ionising radiation to prevent operations personnel and maintenance personnel from exposure to radiation.</u>

4.A).4 Content of substance in homogeneous material (%weight):

- <u>Commercial purity lead metal of 99.9% and harder alloys such as 95%Pb:5%Sb are used</u>
- <u>Transparent glass is also used for some type of category 9 equipment. The glass contains ca. 60 - 70% of lead. The lead-based glass is also important to protect workers when specimen must be visually confirmed. In case risk of mechanical impact to the window is expected, lead-base acrylic is used to avoid breaking and dropping.</u>

4.B) In which material and/or component is the RoHS-regulated substance used, for which you request the exemption or its revocation? What is the function of this material or component?

The main types of category 9 equipment that utilise lead in radiation shielding are described below.

X-ray imaging equipment.

The content of shielding by lead is the same as for medical devices.

X-ray analytical Instruments.

Lead is used in various devices to improve analytical performance where lead is used for its radiation shielding properties, including:

- Collimators for limiting X-ray irradiating area to improve spatial resolution of analysis;
- Collimators for shielding X-ray detector from stray X-ray incidence;
- In glass of capillary plates used for X-ray collimation;
- Viewing windows, to confirm object being analyzed or to confirm analyzed position on the specimen;
- X-ray tube shielding to achieve space effective and radiation safe housing;

Examples of X-ray analytical instruments that uses of radiation shielding include:

- X-ray fluorescence (XRF) coating thickness gauge;
- X-ray fluorescence (XRF) analyzer;
- X-ray Photo-electron Spectrometers (XPS)
- X-ray Diffraction (XRD) Spectrometers

As defined in IEC62321-3-1, one important application of X-ray analysis is screening of RoHS restricted material.

Electron Microscopes

Electron microscopes are typically using the accelerated particles (e.g. electrons) with energy of several 100 eV to several 100 keV, so also require shielding against caused stray ionizing radiation.

The content of shielding by lead is the same as for medical devices.