Exemption Renewal Form - Exemption 2 Annex IV

Date of submission: **15 January 2020**

Attached documentation:

- **COCIR - Exemption 2 request confidential data.docx**

1. Name and contact details

1) Name and contact details of applicant

Company:	COCIR	Tel.:	00327068966
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Function:	EHS Policy Senior Manager	Address:	Blvd A. Reyers 80, 1030 Bruxelles

2) Name and contact details of responsible person for this application (if different from above):

Company:	_____	Tel.:	_____
Name:	_____	E-Mail:	_____
Function:	_____	Address:	_____

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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: 2 of Annex IV

Proposed or existing wording: Lead bearings in X-ray tubes

Duration where applicable: Maximum validity period of seven years

☐ Other: _____

3. Summary of the exemption request / revocation request

This exemption is required for thin lead coatings on steel bearings used in rotating anode X-ray tubes. To avoid overheating of the focal track (portion of the anode where the electrons bombard) the target needs to rotate. The rotating anode is supported by a bearing, which has to be lubricated with vacuum compatible materials. Lead coated ball bearings are used due to their reliability and low noise. Low power X-ray tubes can use stationary targets (anodes) and some very high power designs used in CT equipment with high power X-ray tubes use liquid metal bearings, but neither are technically suitable in the types of X-ray equipment that currently use lead coated bearings.

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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: Medical X-ray imaging equipment including computed tomography, fluoroscopy, mammography, angiography, etc.

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: Also used for category 9 applications, such as X-ray inspection

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: Bearing material to enable free rotation of the anode within X-ray tubes

4. Content of substance in homogeneous material (%weight): 99.9%

5. Amount of substance entering the EU market annually through application for which the exemption is requested: Estimated at ca. 25 grams per year
   Please supply information and calculations to support stated figure.
   This is confidential so has been provided as a separate document

6. Name of material/component: Lead in bearings of X-ray tube. The X-ray tube bearings are lead coated steel spheres

7. Environmental Assessment: Not used to justify exemption but some data is provided in support of analysis of alternatives
   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?

X-ray tubes for medical imaging generate radiation that passes through patients in order to form an image on the detector. The X-rays are generated by accelerating an intense beam of electrons from a cathode to an anode. In the anode the electrons are deaccelerated and X-rays (by the Bremsstrahlung process) are generated. Typically about 1% of the energy is converted into X-rays by the Bremsstrahlung process, the majority (99%) is converted to heat. The focal track on the anode becomes very hot reaching temperatures which can lead to the destruction of the X-ray unit if the heat is not distributed over a larger surface area and the heat is subsequently removed from the unit. The X-rays are generated in sealed vessel which is under ultra-high vacuum (to prevent arcing, or more general interaction of the electron beam with residual gas) with the electron emitting cathode and anode (target) rotating so that the heat generated by the electron beam does not melt or deform the anode material.

In addition to this the anode rotation prevents the electron beam from impinging at one location for too long and distributes the power equally in the circumference of the focal track. The rotating anode is supported by bearing units. The bearing unit cannot be lubricated by greases or polymers because these substances have too high vapour pressure so that gases are generated which would be ionised by the electrons causing arcing to occur which would disturb the electron beam and therefore the generation of x-rays subsequently the effects (arcing) can destroy the X-ray tube and the High voltage generator. Due to the need to withstand a combination of high temperature and the required vacuum, the lubricant must have very low vapour pressure and must not outgas. All organic materials outgas and have too high vapour pressure and so bearings with suitable lubricity have to be used.

In recently designed X-ray tubes the balls are coated with solid lubrication in the form of a thin lead coating. Typically coatings have a thickness of 150 nm although the thickness is variable.

Medical X-ray tubes are used for imaging patients. A wide variety of X-ray equipment is used, depending on the diagnosis or treatment procedure being used. Dental X-ray use the lowest X-ray power whereas Computed Tomography (CT) scanners use high power. Some procedures require a brief burst of X-rays, such as to view a bone fracture, whereas some procedures require continuous imaging, such as during surgery.

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

Lead is used as the bearing material because it is inert in the X-ray tube vacuum and it is not affected physically or chemically by the X-radiation. Lead is fairly soft and does not cold weld to other surfaces so that it slides against them and the wear rate is very low giving a long lifetime. Lead has a sufficiently high melting point and low vapour pressure for use in all but the highest power X-ray tubes. Lead also does not cause corrosion or cause wear to the surfaces that it contacts and does not cause corrosion of the steel balls over which it is coated.

The bearing material should not become radioactive when exposed to X-radiation. Many metals can generate long lived radio-isotopes when exposed to high energy X-radiation (although this is not likely to be an issue with X-ray tube voltages), but any daughter products from lead all have relatively short half-lives which enables used X-ray tubes to be safely refurbished for reuse or disposed of at end of life.

The bearings must also be very quiet as loud noises disturb patients, especially children. Sudden noise can cause involuntary movement by the patient that blurs

X-ray images. Noise is also annoying to medical staff and can pose a hazard when X-ray imaging is used during surgical operations.

The X-ray tube must be usable in any position for most applications as the tube and detector need to be positioned at opposite sides of the part of the patient's body that is being examined.

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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.)

Most used X-ray tubes are returned to the manufacturer or their approved agents. Typically the reusable parts of X-ray tube assemblies will be reused on average about three times before disposal by recycling of materials. However ball bearings are not reusable and so are recycled for materials recovery.

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: Tube housings including shielding, electronics and anodes.

☒ The following parts are subsequently recycled: All damaged parts that cannot be reused are refurbished as well as all bearings which are recycled

☐ Article cannot be recycled and is therefore:

☐ Sent for energy return

☐ Landfilled

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

☐ In articles which are refurbished ______

☒ In articles which are recycled 100% of lead from bearings is recycled, estimated at less than 25 grams per year.

☐ 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

Several potential alternatives could be considered to be substitutes, but as will be explained, none meet all of the essential requirements of medical imaging X-ray tube lead coated bearings in the types of medical device where these are currently used.

Alternative bearing materials

The choice of alternative bearing materials is limited because organic lubricants and polymers are unsuitable because they will emit volatiles which when exposed to electron beam will cause arcing that destroys the X-ray tube.

Most metals are too hard and so will cause excessive wear without oil-based lubricants resulting in short lifetimes and the bearings could seize due to over-heating. Relatively soft metals may be more suitable but many cold weld to other oxide-free metal surfaces. The tubes are evacuated so as the wear surface on which the balls move are abraded, this creates an oxide-free surface because there is no oxygen inside the tubes. Many metals such as indium and gold cold weld to clean oxide-free metal surfaces causing excessive wear to the bearing or seizure. Some metals could react with the substrate such as tin which reacts with copper or steel at the temperatures at which X-ray tubes operate and so are unsuitable. Lead does not readily form intermetallic phases with other metals or cold weld to other metal surfaces such as steel and so is an ideal choice.

Silver coated bearings

Some publications suggest that silver can be used as the bearing material without lubricants and it does have the advantage of a higher melting temperature than lead and so the X-ray tube can operate at a higher temperature. Silver coated steel ball bearings are available as X-ray tube bearings but are they usually too noisy for medical imaging applications. Several publications state that silver bearings are much noisier, because it is harder than lead[1]. Excessive noise is an indication of wear and would indicate a shorter lifetime. However the main problem with noisy bearings is that the sudden noise created when the tube is switched on will disturb patients who are required to keep very still while being imaged. Carrying out repeated exposures to obtain a clear image can be harmful to patients as repeated exposure to X-rays is known to increase the risk of getting cancer. As noisy bearings can cause alarm to patients, this can prevent the system from being approved for use by an EU Notified Body under the Medical Devices Directive and so silver is not being used in new designs of X-ray

[1] http://www.ams-medical.net/understanding-noise-in-x-ray-and-ct-tubes/

systems. Noise also disturbs medical staff, which can be a hazard to patients during operations or other treatments.

Silver could also react with the steel base metal when it becomes hot causing grain boundary cracking leading to premature bearing failure[2]. This will create additional waste due to inferior reliability, but also could harm patients when the X-ray imaging equipment is unexpectedly no longer usable. X-ray tube manufacturers have not seen cracking of steel due to lead.

Alternative designs of X-ray tube

The following potential substitutes are alternative designs of X-ray tube that are used commercially, for specific and limited medical applications that are different to the applications where lead-bearings must be used. The choice of medical X-ray tube design depends on a combination of X-ray output power and the time period for which the X-ray beam may need to be generated:

- Low power or medium power for a very short period of time are unlikely to cause heat damage to the anode and so a fixed anode can be used.
- At medium power or low power with the X-ray beam on for longer periods of time will cause heat damage to the anode, so a rotating anode must be used. Rotating anodes can use three types of bearing and of these, the simplest design that uses least materials and energy consumption as well as having technical and other advantages (described below) is with lead coated steel bearings.
- Some of the highest power applications, such as for some CT scanners, lead may be unsuitable because the bearings become sufficiently hot for the lead metal to vaporise inside the vacuum (this depends on other variable such as the length of time that the X-rays are generated). Silver has a higher boiling temperature than lead and so is less likely to vaporise, but, silver coated bearings can be unacceptably noisy and also can be unreliable (as explained above). Also, the highest power tubes may be too hot for silver to be suitable without significant cooling.
- Some of the highest power applications have to use liquid metal bearings. These use gallium alloys as the liquid metal bearing. These types of X-ray tube are much larger and heavier than tubes with fixed anode or with rotating anodes with lead bearing. They also consume much more energy to manufacture and in use. CT X-ray tubes rotate around the patient and so are used in one orientation and rotate about one axis. This ensures that the liquid metal remains in the correct position (although there are some designs of liquid bearing X-ray tubes that can be used in multiple orientations).

[2] US Patent 6891928 B2, May 10, 2005, T. S. Martin et.al "Liquid metal gaskets in X-ray tubes" and https://app.aws.org/wj/supplement/WJ_1984_12_s355.pdf.

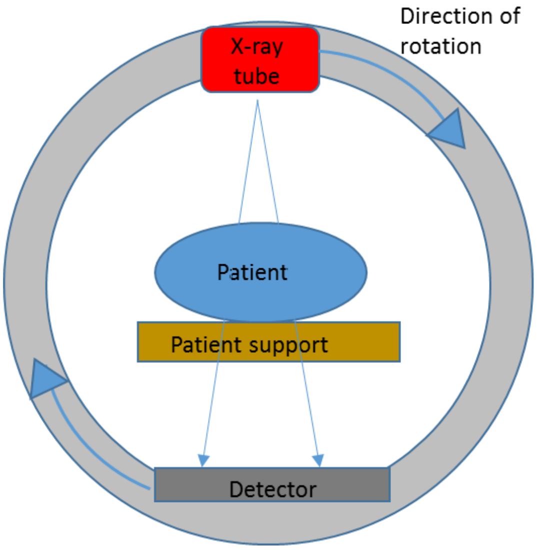

Figure 1. Diagram showing orientation of X-ray tube in CT scanner. Tube rotates around patient

Below is the layout used with C-arm imaging where the X-ray tube and detector are positioned either side of the part of the patient being examined.

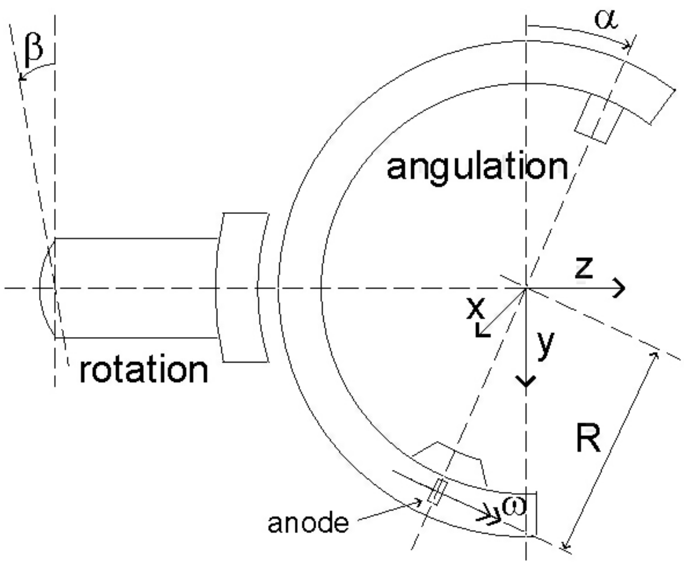

Figure 2. Diagram showing orientation of X-ray tube in C-arc system. C arc for angiography is either located in a fixed position or the C arc scans a trajectory around the patient

The choice of X-ray tube type depends on several variables; required power output, time of output, choice of anode metal (which can affect the output wavelength), required orientations, etc. and so it is not straightforward to specify the circumstances when a fixed anode can be used or when a rotating anode with liquid metal bearings must be used. X-ray imaging equipment manufacturers will use fixed anode if this is technically possible because these are a simpler design and lower cost, but they cannot use these if the use conditions will result in rapid damage to the anode. The main uses of X-ray tubes are summarised below:

- Skeletal X-ray imaging – this can be one of the lower power applications which can sometimes use fixed anode tubes although for the equipment to be useful for a wider range of diagnostic techniques, rotating anodes are often installed to give greater flexibility to hospital staff. Various designs are produced including lightweight mobile c-arm or systems on stands which are heavier and are not portable. If a stand based system is used, the x-ray tube has to be able to be positioned in all directions and angles for good access to the patient, so cannot be too large or heavy (see figure 3 below).

Figure 3 Example X-ray system, courtesy of Philips

- Dental X-ray – probably one of the lowest energy techniques so fixed anodes can be used.
- Fluoroscopy – this is used for real time imaging of parts of the body. As imaging may be required for extended periods, rotating anode tubes with quiet lead bearings are used unless very high power is needed in which case liquid metal bearings have to be used.
- Angiography – used to image arteries, veins and internal organs, often using contrast agents. Imaging is often required for extended periods, so rotating anodes with quiet lead bearings must be used.
- Computed Tomography (CT) – Most X-ray imaging techniques generate two-dimensional images, but with CT the X-ray tube and detector rotate around the patient (as shown above in Figure 1) to generate a computer generated three dimensional image. This technique requires higher power and for X-rays to be generated for longer periods than with some other techniques. CT scanners on the EU market use X-ray tubes with rotating anodes either with lead coated steel bearings or with liquid metal bearings. The type of bearing used depends on how often the CT scanner will be used and other variables. Frequent start stop operation is less suitable for liquid metal bearings as the gallium alloy may need to be heated to melt it before the CT scanner can be used (alloys that are liquid at room temperature are used by at least some

manufacturers, but in cold climates, without heating this can freeze). However the main cause of higher energy consumption is that the liquid metal creates much higher friction than ball bearings, so that the drive unit must deliver permanent power to spin the bearing. The mode of use of a CT however depends on the types of CT scan that are being carried out. Whole body scans require longer periods of use than scanning a limb or the head and this affects the frequency of start / stop and the periods of inactivity as well as energy consumption.

- In high power X-ray tubes (such as for some types of CT) the rotating anode is supported by a sliding bearing with a liquid metal as lubricant. The liquid lubricant has more restrictive temperature limits (due to the corrosive nature of gallium) than lead or silver coatings, which leads to a requirement for active cooling of the sliding bearing including cooling fluid, pumps and heat exchangers. This adds an enormous amount of apparatus to the system which results in a much more bulky and heavier x-ray system compared to solid lubricated ball bearing units.

Use of liquid metal bearings

Several medical device manufacturers have patented X-ray sources which use liquid metal bearings. These are used in some types of CT scanner because other designs of tube cannot achieve the required performance. However, these usually cannot be used in most other medical imaging applications such as fluoroscopy and angiography. Each manufacturer has their own proprietary designs of X-ray tubes including those with liquid metal bearings. Some designs cannot be tilted (see Figure 1). In some designs of liquid metal bearings, the liquid metal stays in the bearing by using small bearing gaps providing sufficient capillary forces so may be used in more than one orientation.

However all liquid metal bearing tubes have significant disadvantages that mean they are used only if solid metal bearings cannot be used:

1) Much higher friction (typically, a drive power of about 1kW is needed due to the use of liquid metal bearings, whereas ball bearings have nearly no friction). This means that power is consumed to accelerate the bearing and to maintain an operation frequency. This means higher effort in the power chain of such high power X-ray tubes (drive unit). One manufacturer has measured the heat required to drive the liquid metal bearing at 700 W (and another has quoted 1 kW). If the CT scanner is used for eight hours per day 365 days per year, this is an additional electricity consumption of 2 MWh per year per liquid metal X-ray tube. Hospitals have very limited budgets and will not want this additional cost unless this type of tube is essential for the medical procedures being used. In practice, X-ray tubes with liquid metal bearings need to be operating continuously which is why these tubes consume significantly more energy than tubes with lead bearings.

2) The friction generates heat which is in addition to the heat from X-ray generation. Therefore, the heat has to be removed. Active cooling of the bearing shaft leads to an enormous increase in apparatus required for operation due to additional cooling fluid, heat exchanger, pumps, etc.[3] with the additional size and weight additions having a negative consequence on the operation of the equipment. Hospitals often have limited space so need the X-ray equipment to be a small as possible.

Liquid metal X-ray tubes are on average larger and heavier than other types and can be at least an additional 20 kg (plus the weight of the additional cooling equipment), although the size and weight varies considerably and depends on application. Also, some manufacturers have proprietary designs that affect the overall mass of the tube.

Most X-ray imaging equipment, apart from CT, needs to be fairly small and compact because it has to be moved by hospital staff, either around the patient to focus on the required part of the body or moved around the hospital to different locations. Very large and heavy X-ray tubes would make the equipment difficult or impossible to move as required. An example of the difference in weight is[4]:

Rotating anode tube example with lead bearings	25.6 kg
Rotating anode tube with liquid metal bearings	58 kg

Heavier X-ray tubes (with both liquid metal and with lead coated steel bearings) are used for some applications, some are over 90 kg, but the two examples above are shown only as illustrative examples.

X-ray tubes require internal shielding to protect hospital staff, patients and electrical equipment from radiation. Lead is usually used (RoHS exemption 5 of Annex IV) and there can be a much larger quantity of lead used in a liquid metal bearing X-ray tube than the types of tubes with lead bearings, although the amount of lead shielding used depends on tube design and application. Using the same two examples as above (note that <1 gram of lead is in the lead coated bearings of each tube):

Rotating anode tube example with lead bearings	5.4 kg of lead shielding
Rotating anode tube with liquid metal bearings	8.3 kg of lead shielding

3) The liquid metal contains gallium, which is highly corrosive at high temperatures. Therefore, the bearing has to be actively cooled to maintain temperatures below the temperature at which gallium attacks the metal (Tcrit). This critical temperature is much lower than the melting temperature of lead ~ 300°C.

[3] Some of the largest types of X-ray tube with lead coated steel bearings also need to be cooled but as there is no need for energy to overcome friction, these cooling units are typically smaller as less heat needs to be removed, although this depends on the application.

[4] https://www.philips.co.uk/healthcare/resources/recycling-passports/x-ray_tubes

4) Gallium is aggressive to many metals including steel and so molybdenum has to be used to house the gallium alloy. The quantity and equivalent global warming potential of the molybdenum that is used is overall much larger than the steel that can be used in tubes with lead bearings[5].

Table 1 Global warming impact comparision

Type of bearing	**Quantity of bearing housing metal**	**Global warming potential from production (kg CO_2-eq/kg)**	**Calculated global warming impact kg CO_2 eq per tube**
Rotating anode tube example with lead bearings	600g Steel	1.5	0.9
Rotating anode tube with liquid metal bearings	1800g Molybdenum	5.7	10.26

The molybdenum in this example X-ray tube has an environmental impact from equivalent CO_2 emissions that is over 11 times larger than the steel in lead-bearing tubes. In addition, gallium has a much larger global warming potential (GWP) from its production than lead (also much more gallium is used than lead for bearings):

Gallium production GWP 205 kg CO_2-eq/kg

Lead production GWP 1.3 kg CO_2-eq/kg

Therefore, in conclusion, liquid metal bearing X-ray tubes cannot be used with most X-ray equipment because:

- They are relatively heavy and bulky (including the cooling system) and so not suitable for mobile systems or systems that need to be used in confined spaces (very common in EU hospitals);
- They consume more energy to operate and require significant extra cooling equipment;
- Although lead bearings contain a very small amount of lead (< a few mg), the quantity of lead shielding needed for each tube is much more (many kg). The quantity of lead shielding required around the larger liquid metal tubes can be more than the total lead in the types of tubes with lead bearings due to the lead shielding plus lead in bearings); and

[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

- The equivalent CO_2 emissions for manufacture of the materials used in liquid metal X-ray tubes is far larger than those with lead bearings.

Non-rotating anodes:

This option removes the need for bearings, but has limitations, as explained above and here. The original X-ray tube was invented by Crookes using a stationary anode. At low energy, the structure of the tube is able to conduct sufficient heat away from the anode to prevent it from melting. Also, if X-rays are generated for relatively short periods, the anode does not get hot enough to distort or melt and so rotation would not be needed. Modern medical X-ray sources need to be compact so that they fit into the structure of the medical device, so heat needs to be conducted away very efficiently from the location on the anode where the electron beam strikes to avoid melting. Usually this can be achieved only by evenly distributing the power from the beam in a circumferential direction by the rotation of the target/anode and this can be impossible with stationary anodes.

When the electron beam strikes the anode, X-radiation is emitted in a range of directions, but most are emitted in a direction that is guided by the angle of the anode with respect to the cathode (the anode is made of a high density metal so is an effective barrier to X-rays). Stationary anode X-ray tubes use fixed angled anodes to direct the X-ray beam into the required direction, however, if the X-ray generation needs to continue for more than a short period, the anode metal will become too hot and will distort and this can cause the anode's angle to change so that the X-rays do not travel in the correct direction. As a result, medical X-ray tubes often have to use rotating anodes to prevent deformation and melting of the anode. Deformation of the anode leads first to high unbalances and consequently to higher noise and vibrations. Vibration can alter the image quality and if the target is massively deformed it will lead to the destruction of the anode target, bearing unit and maybe also the vacuum containment.

Ceramic bearings

Bearings could be made of ceramics, but these materials are hard and are likely to cause excessive wear and excessive noise so would be unsuitable.

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

Silver bearings are reported to be less reliable due to grain boundary cracking of steel[6].

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7. Proposed actions to develop possible substitutes

[6] https://app.aws.org/wj/supplement/WJ_1984_12_s355.pdf

(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.**

Most recent research has been to develop liquid metal bearings that are lead-free, although the reason why these have been developed was to achieve higher power output that is needed for CT scanners which is not possible with X-ray tubes using lead bearings. However these cannot be used in other types of equipment as explained above.

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

There are no alternative metals in the periodic table that have all of the essential properties that lead provides so it is difficult to envisage that an alternative material will be discovered. Silver is the only potential alternative but because of the technical issues described here, usually cannot be used. However at least one manufacturer is planning to carry out further research with silver as a potential alternative although this will require the complete redesign of the X-ray systems in which they are used to ensure that the noise levels are at an acceptable level. This will be essential to obtain Notified Body approval although success is uncertain. Due to a lack of alternative bearing materials, this exemption will be needed for many years in the future; at least another 20 years seems likely based on current knowledge.

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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 Lead was added to the Candidate List in June 2018

☒ Candidate list

☐ Proposal inclusion Annex XIV

☐ Annex XIV

☐ Restriction

☐ Annex XVII – lead is restricted only in jewellery so this is not applicable

☐ Registry of intentions

☒ Registration – lead has been registered – see https://ila-reach.org/our-substances/lead-metal/ and 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: See section 6 above
2. Can the substance named under 4.(A)1 be substituted?
   ☐ Yes.
   ☐ Design changes:
   ☐ Other materials:
   ☐ Other substance:
   ☒ No.
   Justification: Substitute designs and substances are scientifically and technically impractical or will be less reliable (see section 6)
3. Give details on the reliability of substitutes (technical data + information): Silver coatings cannot be used due to the noise they create as explained in section 6. There is some evidence that it may also negatively affect reliability[2].
4. Describe environmental assessment of substance from 4.(A)1 and possible substitutes with regard to
   1) Environmental impacts: Liquid metal bearing tubes have a considerably larger environmental impact than lead bearing X-ray tubes as explained in section 6. However, liquid metal tubes cannot always be used for technical reasons as explained in section 6
   2) Health impacts: There would be a negative impact if medical equipment were not available, when needed, due to premature failure due to overheating of anodes or bearing failure
   3) Consumer safety impacts: There could be a negative impact on patients if medical equipment were not available due to premature failure due to overheating of anodes or bearing failure

⇨ Do impacts of substitution outweigh benefits thereof? Substitutes cannot be used for the technical reasons explained in section 6 and so although liquid metal tubes have a much larger environmental impact than tubes with lead bearings, this is not the main justification for this exemption renewal request
Please provide third-party verified assessment on this:

(C) Availability of substitutes:

a) Describe supply sources for substitutes: Silver coated bearings and liquid metal bearing materials are readily available, but are not suitable in equipment that require lead coated steel bearings as explained above

b) Have you encountered problems with the availability? Describe: No

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? Availability of substitutes has no impact

(D) Socio-economic impact of substitution:

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

☐ Increase in direct production costs – not applicable as no alternatives exist

☐ Increase in fixed costs – not applicable as no alternatives exist

☐ Increase in overhead – not applicable as no alternatives exist

☒ Possible social impacts within the EU – Without this exemption, EU hospitals would not be able to buy or replace the current range of imaging equipment or replacement X-ray tubes that they need to treat patients. If they are forced to use existing X-ray equipment for much longer than is normal, this older equipment will become increasingly unreliable as it ages so that it will more often be unusable. Therefore there would be a gradual deterioration in overall health of EU citizens without this exemption as they more often cannot be treated. The EU estimates that there are about 600 million X-ray images taken each year in the EU although this includes dental X-rays which do not require rotating anodes[7]. If we assume that about half of X-ray images require rotating anode X-ray tubes with ball bearings (dental X-ray and mammography usually used fixed anodes and these are estimated to account for up to half of all images), then eventually, if rotating anode X-ray tubes cannot be sold in the EU up to 300 million EU citizens could not be examined by X-ray each year and their health would suffer, very significantly in most cases, as a result.

☐ Possible social impacts external to the EU – Unlike in the EU X-ray tubes with lead bearings could continue to be supplied so non-EU citizens would not be harmed if this exemption is not renewed, unlike EU citizens.

☐ Other: ______

⇨ Provide sufficient evidence (third-party verified) to support your statement: Non-RoHS compliant medical devices cannot be sold in the EU and so it will be impossible for hospitals to buy the current range of X-ray imaging equipment which uses tubes having lead bearings unless this exemption is renewed.

[7] https://ec.europa.eu/energy/sites/ener/files/documents/RP180web.pdf

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:

Calculation method for the quantity of lead used in this application in the EU annually is provided separately as it is calculated using proprietary data from several manufacturers.
