Exemption Renewal Form - Exemption 13 Annex IV

Date of submission: **15 January 2020**

Attached documentation:

- **CONFIDENTIAL quantity calculation Renewal exemption 13**
- **COCIR - LCA assessment exemption 5 - Project presentation**

1. Name and contact details

1) Name and contact details of applicant

Company:	**COCIR**	Tel.:	**00327068966**
Name:	**Riccardo Corridori**	E-Mail:	**corridori@cocir.org**
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 Annex IV

☒ 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:**13**

Proposed or existing wording: **Lead in counterweights of surgical C-arm X-ray and C-arm fluoroscopy designed to have radiologist present with patient**

Duration where applicable: **Maximum validity period**

☐ Other: _____

3. Summary of the exemption request / revocation request

Lead has been used as a counterweight material in medical imaging equipment for many years but since medical devices were included in scope of the RoHS Directive, manufacturers have replaced lead in counterweights wherever this is technically possible. However, in the two types of equipment described in this exemption renewal request, surgeons or radiologists need close contact with patients, but without being exposed to radiation and the larger volume required of metals with lower density than lead prevents this access. The use of metals with higher density than lead would allow access as the volumes required would be similar or less that with lead, but a full life cycle assessment shows that the overall health, safety and environmental impact of these substitutes is considerably more negative than the overall health, safety and environmental impact of lead.

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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: Surgical C-arm X-ray imaging equipment and C-arm fluoroscopic X-ray imaging where the radiologist is present with the patient

   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: Counterweight

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

5. Amount of substance entering the EU market annually through application for which the exemption is requested: Submitted separately

   Please supply information and calculations to support stated figure.

   Submitted separately as this includes confidential market data

6. Name of material/component: Lead metal

7. Environmental Assessment: _____

   LCA: ☒ Yes – see Q6A

   ☐ 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?

Since exemption 13 of Annex IV was granted and included in the RoHS recast Directive in 2011, medical equipment manufacturers have been able to redesign most types of medical equipment to replace lead counterweights, usually with steel. However, this has not been possible for two specific types of medical devices. The designs and uses of these two types are described here separately.

Surgical C-arm X-ray imaging

C-arm X-ray imaging equipment is a widely used design where the X-ray source and detector are located at either end of a moveable "C". The patient is located at the centre of the "C" and the source and detector are moved around them to the required imaging location. Both the X-ray source and detector are relatively heavy due to the need for radiation shielding, which is usually lead metal. So that hospital staff can easily move the C-arm to the required position by hand with minimal effort, the C-arm has to be carefully counterbalanced using weights at appropriate locations. The mass and location of weights depends on the C-arm's dimensions, the mass of the X-ray source, the size and mass of the detector, etc.

The size of counterbalance weights should not interfere with the ability of the medical staff to treat patients but in most standard non-surgical C-arm X-ray systems the radiologist and other medical staff move away from the patient during X-ray imaging to avoid exposure to harmful X-rays. In most designs, it has been possible to replace lead with less dense and therefore larger volume steel counterweights. However, as the density of lead is 11.2 g/cc whereas the density of steel is about 7.9 g/cc (depending on the alloy), the use of steel creates a significant volume increase (about 40%), which would interfere with the ability of the surgeon to operate on a patient and use the surgical X-ray equipment simultaneously.

When the surgeon wishes to operate on the patient while the patient is being imaged, the surgeon needs to stand over the patient to look down onto them but not be exposed to X-radiation. The size of the X-ray tube shielding and counterweights is such that if lead is used for both, the surgeon is just able to stand over the patient as shown below.

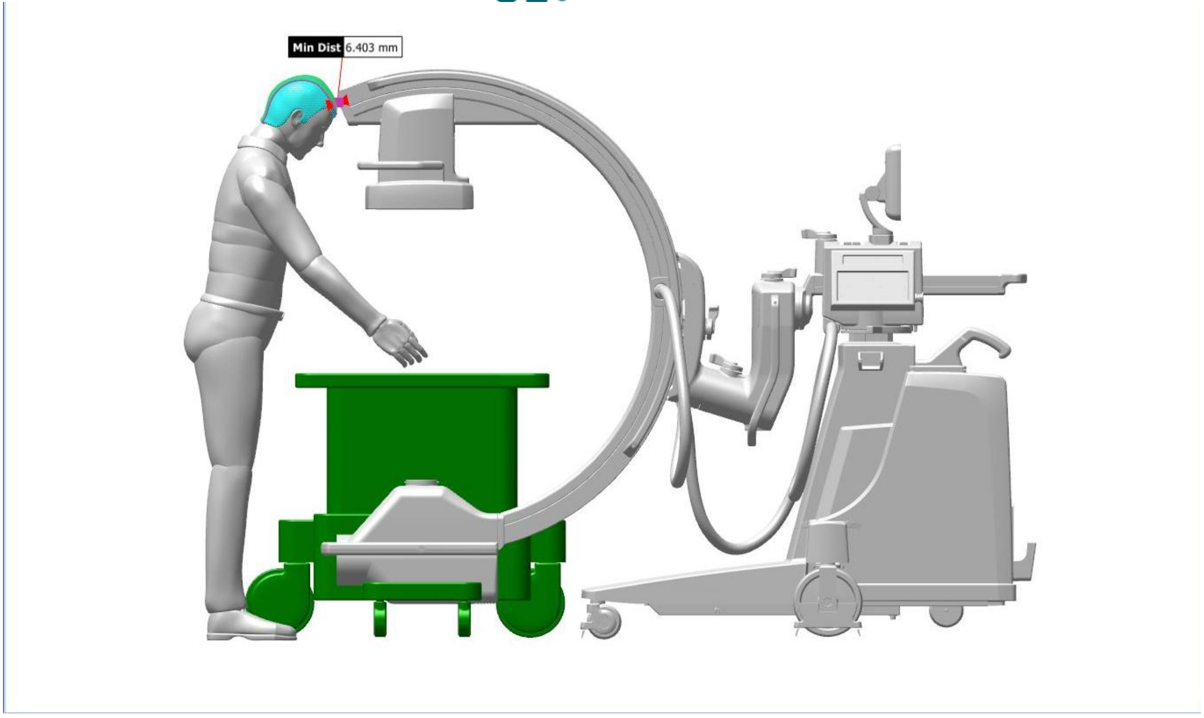

Figure 1. Position of surgeon when operating on a patient. There is a 6.4mm gap between their head and the edge of the c-arm when lead counterweights are used

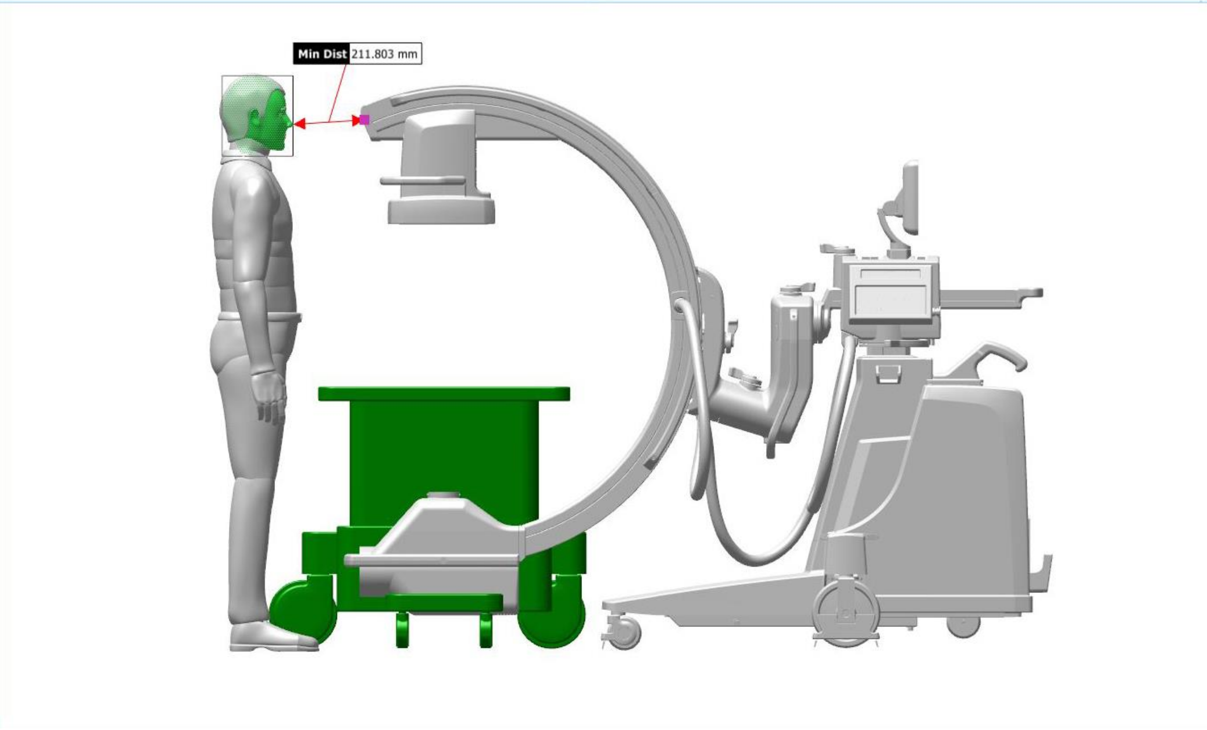

Figure 2. Surgeon standing next to patient. In this position, the gap between their head and the edge of the C-arm is 211.8mm

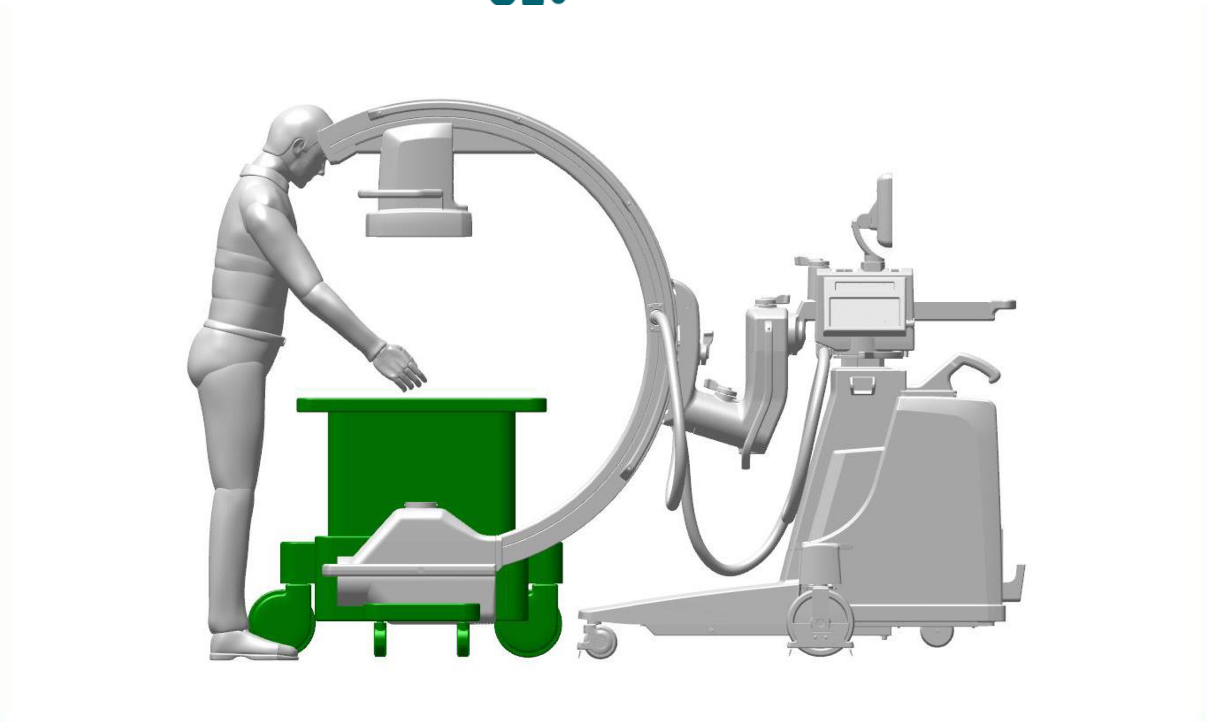

Figure 3. Theoretical position of surgeon while operating on a patient if steel counterweights are used. This is impossible as the edge of the C-arm prevents the surgeon from standing over the patient and so they would not be able to view them properly

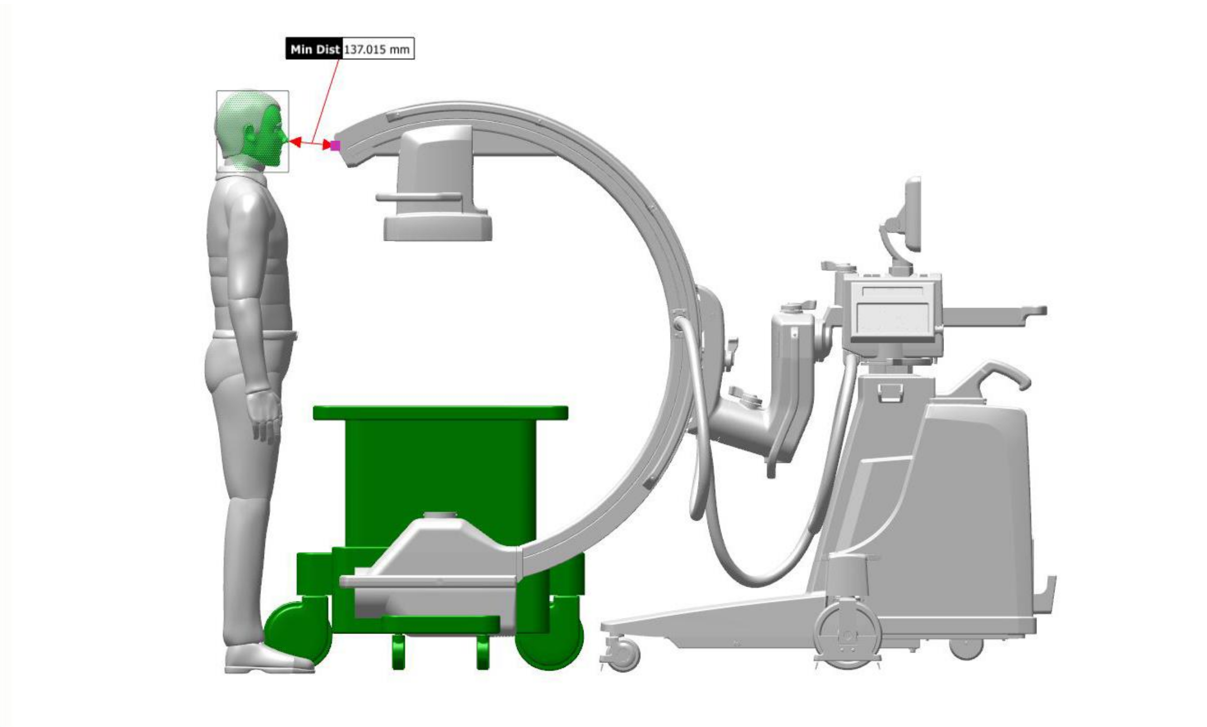

Figure 4. Surgeon standing next to patient. In this position, the gap between their head and the edge of the C-arm is 137mm.

Surgical C-arm equipment is used differently to most types of X-ray imaging equipment as the surgeon uses X-ray imaging as a real-time tool to visualise the inside of the patient while they are operating. As a result, space is extremely limited as shown above.

Although steel as a counterweight occupies a volume of only about 42% more than lead, the space available for the surgeon to be able to look down onto the patient is small with lead and the surgeon's view would be obscured if bulkier steel were to be used. It can be seen from the above diagrams that the only way that the surgeon can have a clear view of the patient while being X-ray imaged, is by placing themselves within the X-ray beam, which is not acceptable as repeated exposure will cause cancer.

Three versions of surgical C-arm system are used:

- Orthopaedic – bone surgery
- Vascular –imaging of arteries and veins during surgical procedures
- Cadiac – heart surgery while the heart is viewed in real-time

Fluoroscopy C-arm X-ray imaging where the radiologist is present with the patient

This is a different fluoroscopic imaging technique that is used for real-time imaging of internal organs of patients, usually by use of contrast agents that enable these to be visualised using the X-ray equipment. This specific type of medical device is used, for example, to image the internal digestive system. The patient drinks a "barium meal", which shows the digestive system as it passes through the stomach, intestines and bowel. Barium sulphate is used as barium has a fairly high atomic number and so is opaque to X-rays but this substances is not harmful. This examination normally is carried out with the patient in a vertical position and usually the radiologist is in a separate room to the patient to avoid exposure to potentially harmful X-rays. However, there are some circumstances when it is necessary for the radiologist to be present with the patient, especially if the patient is very ill, is elderly or a child. The patient and radiologist are supported on a movable table that is counterbalanced to enable it to be moved easily. In these designs of equipment, it is not possible to replace the lead counterweights with lower density material as the larger volume alternative materials prevent the radiologist from being able to have the access they need to the patient. With steel counterweights, for example, he radiologist would be further away from the patient so that they cannot provide the same level of care.

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

All of the following are required:

- High density (of at least that of lead),
- Inert, stable and unaffected by X-radiation
- Easily fabricated into the required shapes,
- Materials with overall environmental and health impacts that are no worse than lead should be used.

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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.)

X-ray imaging equipment is usually returned to manufacturers at end of life. Many units are refurbished for reuse and any parts that cannot be reused are recycled. By keeping the equipment under the control of the manufacturer during its life cycle, this is a closed loop method of treatment.

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: _____
- ☒ The following parts are subsequently recycled: Lead metal from counterweights is always 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 See confidential data

☐ 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

It has been possible to use steel as an alternative counterweight material for most other types of X-ray imaging equipment because fabrication is straightforward and steel is easily recycled at end of life. Steel also has a slightly smaller overall environmental, health and safety impact compared with lead (on a life cycle basis). In the two specific applications in scope of this exemption renewal request, however, steel is unsuitable because larger volumes are needed that would interfere with the ability of the surgeon or radiologist to treat patients as shown above in section 4 (B).

Metals with density values that are the same or higher than lead may appear to be dimensionally suitable candidates as substitutes, but medical device manufacturers are also obliged by the Medical Devices Regulation to take account of the overall environmental and health impact of their products[1]. All alternative high density metals have a more negative overall environmental and health impact than lead (as is shown below). An initial screening of materials shows that in terms of global warming potential for mining, refining and production of materials shows the apparent superiority of lead:

[1] Required by Medical Devices standard EN 60601-1-9:2007 "Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral Standard: Requirements for environmentally conscious design"

Table 1. Density and Global Warming Potential (GWP) values of metals with density similar to or larger than lead[2].

Metal	**Density**	**Global warming potential (GWP) from production (kg CO_2-eq/kg)**
Lead	11.3	1.3
Bismuth	9.8	58.9
Thallium	11.8	376
Mercury	13.5	12.1
Gold	19.3	12,500
Platinum	21.1	12,500
Iridium	22.5	8,860
Osmium	22.6	4,560
Rhenium	21.0	450
Tungsten	19.3	12.6
Tantalum	16.7	260
Hafnium	13.3	131

Notes:

- All metals with atomic number greater than bismuth are radioactive and so are unsuitable.
- Thallium and mercury are very toxic and so are unsuitable
- Bismuth has a lower density than lead and so is less suitable (as well as having a much larger GWP)

Of the metals listed above that have a density higher than lead, all have significantly larger GWP than lead, most are very significantly larger, which indicates that they will have significantly larger negative overall health and environmental impacts. This is indicated by the LCAs discussed below for tungsten and lead which show that most impacts arise from the use of energy for mining and refining of the metals. Tungsten was chosen for this comparison because it has the smallest GWP of the metals in Table 1 (excluding mercury, which is RoHS restricted). Larger overall impacts occur with high GWP metals because generation of energy used to produce the metals causes global warming emissions and also emits hazardous

2 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

substances from burning coal and oil in power stations, refinery furnaces, etc., in particular lead, cadmium, arsenic and mercury are emitted. These are emitted to air and some of these emissions cannot be trapped at power stations or from metal refinery processes and so are emitted[3] to air where they eventually pass into water supplies and onto farmland (via deposited dust or by rain) so potentially causing more harm than the use of lead as a counterweight. Power generation also generates solid waste (from fume emission scrubbers) that contains lead, cadmium, arsenic and mercury which is hazardous and contains large amounts of toxic metals. Coal used for power generation typically contains up to 110µg lead / kg coal[4] as well as cadmium, arsenic and mercury. Crude oil that is refined then used for power generation also contains these heavy metals, most of which is present in solid wastes, but some is emitted to air.

It has been demonstrated by comparative life cycle assessments that the overall health and environmental impact of lead counterweights is significantly less negative than the overall health and environmental impacts of tungsten counterweights. Tungsten is the material in the above table, which apart from lead, has the lowest GWP (ignoring mercury which is RoHS-restricted). All other high density metals have even larger GWPs and so would be even more negative than tungsten. The use of tungsten metal is however impractical, as is explained below, and so tungsten-polymer composites with density that is the same as lead would be a more realistic comparison.

As most of the negative environmental and health impacts from tungsten are due to energy generation, including emissions of hazardous substances and hazardous substances in waste, the overall impacts of the other metals listed above in Table 1 will be even more negative, as they all have larger GWP values than tungsten.

Comparative Life Cycle Assessment.

The life cycles of lead and tungsten are very different and are summarised below:

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[5], 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

[3] European Union emission inventory report 1990–2015 https://www.eea.europa.eu/publications/annual-eu-emissions-inventory-report

[4] https://link.springer.com/article/10.1007/BF00282962

[5] https://minerals.usgs.gov/minerals/pubs/commodity/lead/mcs-2017-lead.pdf

		reports that global tungsten mining in 2016 was 86,400 tonnes[6]. It is mined mainly as tungstates of calcium, lead and other metals[7].
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[7]: 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.
Fabrication of counterweights	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.	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 simple 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 radio-isotopes but with lead these have very short half-	High energy radiation can generate radio-isotopes from tungsten with half-lives of many years. This could be an issue in high energy X-

[6] https://minerals.usgs.gov/minerals/pubs/commodity/tungsten/mcs-2017-tungs.pdf

[7] British Geological Survey, tungsten profile, http://www.bgs.ac.uk/mineralsUK/statistics/mineralProfiles.html

	lives so that the metal is not radioactive after a few days.	ray systems. A more serious concern though is that radiation degrades the polymer phase of tungsten-composites making them disintegrate.
End of life	Lead counterweights are high purity lead that 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).	Solid tungsten metal scrap from used medical devices that is not reused in new machines 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 only 35 – 40% of used tungsten metal is recycled globally. Recycling of polymer composites is however 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[8]. 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.

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

Tungsten has been compared with lead as a potential substitute because in Table 1, it has the lowest GWP (apart from mercury, which is toxic and RoHS-restricted) and lead. Global warming is however not the only environmental and health impact of mining, refining, production, use and disposal of materials and so tungsten metal, tungsten-polymer composites and lead metal have been compared by a full life cycle assessment. This has been carried out by Thinkstep for COCIR using published data sources and GaBi software. This was originally prepared to support COCIR's request to renew exemption 5 of Annex IV, but as this LCA compared a specific amount of lead metal with an equivalent amounts of tungsten and tungsten composites, this LCA has also been used here for exemption 13 where a specific mass of lead might be compared with a similar mass of tungsten metal or composite. The comparison is in practice slightly different because the mass of tungsten metal needed for radiation shielding is not the same as the mass of lead and so the following figures were used from the exemption 5 LCA whereas this exemption renewal request should compare equal masses of materials.

Table 2. Mass of materials used for the exemption 5 LCA and the corresponding amounts used for this exemption request.

Material	Exemption 5 (kg)	Exemption 13 (kg)
Lead	11.3	11.3
Tungsten metal	15.4	11.3
Tungsten composite	16.1	11.3

Thinkstep's LCA results are provided as a separate Annex to this request. This shows that for all but one environmental and health impact, tungsten and tungsten-polymer composites are much more negative than the corresponding impacts of lead metal. If the differences in mass used for exemptions 5 and 13 are taken into account (

Table 2), these results are changed as follows:

Table 3. Equivalent impacts of lead, tungsten metal and tungsten composite for exemption 13 calculated from the values determined for exemption 5.

Impact	Exemption 5 results			Calculated values for exemption 13		
	Lead	Tungsten composite	Tungsten	Lead	Tungsten composite	Tungsten
Quantity (kg)	11.3	16.1	15.4	11.3	11.3	11.3
Global warming potential (kg CO2eq	13	490	714	13	344	524
Abiotic depletion – ADP elements (kg Sb eq)	1.4×10^{-3}.	0.46	0.47	1.4×10^{-3}.	0.32	0.34
Abiotic depletion - fossil (MJ)	133	8,960	12,100	133	6,289	8,881
Acidification potential (kg SO2 eq)	0.05	3.48	3.73	0.05	2.44	2.74
Eutrophication potential (kg phosphate eq)	0.01	0.65	0.69	0.01	0.46	0.51
Photochemical ozone creation potential (kg ethene eq)	-1.52×10^{-4}.	0.10	0.23	-1.52×10^{-4}.	0.07	0.17
Primary energy demand from renewable and non-renewable resources (MJ)	167	9,360	13,100	167	6,569	9,612
Human toxicity potential (kg DCB eq)	1.56	116	138	1.56	81.4	101.3
Terrestrial ecotoxicity potential (kg DCM eq)	0.52	1.22	3.21	0.52	0.86	2.4
Freshwater aquatic ecotoxicity (kg DCM eq)	0.04	13.4	13.9	0.04	9.83	10.1
Marine aquatic ecotoxicity (kg DCM eq)	780	53,000	63,000	780	37,200	46,200

Thinkstep also considered the following three different scenarios:

- Lead is not recycled, but is sent to landfill
- 100% of tungsten metal is recycled
- Tungsten powder is separated from composites and then recycled.

Commercially however, the following are applicable:

- Lead metal has a significant value and so most used lead metal will be recycled.
- The International Tungsten Industry Association (ITIA) claims that 35 to 40% of tungsten metal scrap is recycled globally.
- Recycling of tungsten composites is not currently possible and is not carried out commercially.

Therefore if the actual end of life impacts of lead, tungsten metal and tungsten composites are compared, the overall impacts of lead in Table 3 for counterweights are significantly less than those for tungsten metal or its composites.

The only impact calculated by Thinkstep that is larger for lead metal than for tungsten metal and composites is ozone layer depletion potential. However, Thinkstep report that the published data available to be used for this LCA is no longer representative as ozone depleting substances are now banned and so the data used is out of date.

Other disadvantages of tungsten

There are also technical disadvantages with tungsten. The surgical C-arm X-ray equipment has very little available space for the counterweight and so the counterweights have to be made in relatively intricate shapes to fit into the space available (e.g. see Figure 1). This is straightforward with lead because this metal can easily be cast into moulds with complex shapes and at fairly low temperature. However, this is impossible with tungsten metal due to its extremely high melting point of 3,410°C. Example weights are shown below in Figure 5. Tungsten metal is also extremely hard and so cannot be extruded and grinding into complex shapes is impractical.

Counterweight shape is less of an issue with fluoroscopy X-ray imaging where the radiologist is present with the patient, although the production of tungsten counterweights is far more difficult and energy intensive than with lead as tungsten metal is very hard and so difficult to fabricate even into fairly simple shapes.

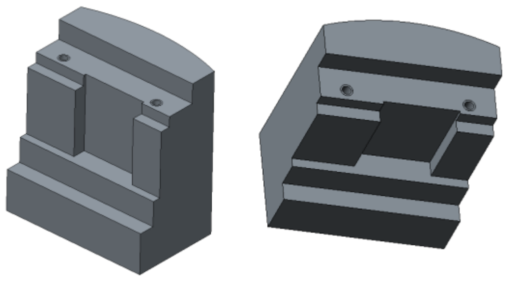

Figure 5. Couterweights used with fluoroscopy C-arm X-ray. Simple to make from lead, but much more difficult with tungsten.

A potential alternative to tungsten metal is tungsten-polymer composites. This material is available commercially with the same density as lead (11.2g/cc). This material could be used in the fluoroscopy equipment but would be difficult to use with the surgical C-arm equipment. This is because tungsten-polymer composites are available in the form of sheet which may be suitable for fluoroscopy but is unsuitable in surgical C-arm systems which require counterweights of complex shapes, such as shown in Figure 5. Extrusion of tungsten-polymer into complex shapes is possible only for small pieces and medical equipment manufacturers and their suppliers have not been able to fabricate complex pieces of the size needed for counterweights.

Another disadvantage of tungsten-polymer composites is that the X-radiation degrades the polymer causing the composite to disintegrate[9]. If this results in dimensional changes, which is likely, this would negatively affect the counterbalance effect of the weights and would shorten the lifetime of the equipment.

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

The abstract of the reference in footnote 9 states that tungsten filled polymers suffer from aging and degradation under X-ray radiation. This is likely to negatively affect equipment lifetime and reliability.

7. Proposed actions to develop possible substitutes

[9] Tungsten Heavy Alloys for Collimators and Shieldings in the X-Ray Diagnostics, D. Handtrack, B. Tabernig, H. Kestler, P. Pohl, W. Glatz, L.S. Sigl, 18th Plansee Seminar 2013.

(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.**

The approach used for most X-ray imaging equipment has not been possible with the two types of equipment described in this exemption request. Furthermore, there are technical and environmental / health disadvantages of tungsten and tungsten polymer composites, which are described above in section 6. Research into making complex shapes with tungsten composite has been carried out, but has not been successful for the counterweights needed for these applications.

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

The eventual method of replacing lead counterweights in the two types of equipment described here may be to develop alternative medical devices that can be used to assist with the treatment of patients that give similar end results. To date this has not been possible and further research is needed. This is likely to take at least 8 years before designs with lead-fee counterweights are available, but the timescale is very uncertain.

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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 – lead was added June 2018

☐ Proposal inclusion Annex XIV

☐ Annex XIV

☐ Restriction

☐ Annex XVII – lead is restricted in jewellery articles (item 63) only, which is not applicable to counterweights

☐ 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: Most materials require larger volumes which will interfere with medical procedures. More dense materials have a more negative overall impact. Fabrication of large and complex shapes is not possible with tungsten metal or composites. For more details, see Q6.

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

☐ Yes.

☐ Design changes:

☐ Other materials:

☐ Other substance:

☒ No.

Justification: Most materials require larger volumes which will interfere with medical procedures. More dense materials have a more negative overall impact. Fabrication of large and complex shapes is not possible with tungsten metal or composites. For more details, see Q6.

3. Give details on the reliability of substitutes (technical data + information): Use of tungsten-polymer composites exposed to ionising radiation could shorten product lifetime and negatively affect reliability as described in Q6 (B).
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 if a high priced substitute were used; a) theft of expensive metals (e.g. gold) would result in the equipment not being usable which would negatively affect patients and b) the higher cost of tungsten, or gold, may prevent hospitals from buying as much new equipment as at present, resulting in the average age of their equipment increasing. The increased cost for metal only (excluding counterweight fabrication costs, which would be larger for tungsten than for lead) using an example of 10kg counterweight per X-ray system is that tungsten will add to the equipment's price at least an additional $275,230 or €235,500[10] (this does not include any increased fabrication costs). This is a significant amount for most hospitals in the EU and will prevent or delay purchase of

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

new equipment so that less reliable old equipment (and sometimes with inferior performance) has to be used for longer.

⇨ Do impacts of substitution outweigh benefits thereof? Yes, see Thinkstep LCA in separate annex.

Please provide third-party verified assessment on this: See assessment of Thinkstep LCA for COCIR exemption 5 renewal request.

(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 in the future if quotas are reduced.

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

☐ Yes ☒ No. Availability may be limited by Chinese quotas, not price

d) What conditions need to be fulfilled to ensure the availability? Not applicable

(D) Socio-economic impact of substitution:

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

☒ Increase in direct production costs - conceivably as all substitute materials have higher prices than lead and are more difficult (or impossible) to fabricate into complex shapes. Metal price of tungsten is typically about 40 times higher than lead. There is however a possible increased cost due to the increase in the amount of waste if brittle materials have to be used. These increased costs would be passed on to hospitals when they buy new equipment.

☒ Increase in fixed costs – Hospitals would be impacted by higher prices

☒ Increase in overhead – Potentially if tungsten composite degradation increases maintenance costs

☒ Possible social impacts within the EU – As tungsten is much more expensive than lead, there would be an increase in the price of this equipment. All EU hospitals have limitations on available funds for new equipment and so any prices increase would have a negative impact in that the hospitals will not be able to buy as much new equipment resulting in the average age of their equipment increasing. Older equipment tends to be less reliable and can give inferior results compared with new equipment. These issues could result in overall a negative impact on the health of EU citizens. Without this exemption, the types of equipment described in this renewal request could not be sold in the EU and this would negatively impact on the treatment of EU citizens, although this is difficult to quantify in terms of patients affected or increased hospital costs.

☐ Possible social impacts external to the EU – should be none as lead can continue to be used.

☒ 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:

The quantity of lead used and the calculation method are confidential, so are provided separately.
