Questionnaire 1 (Clarification) Exemption 13 of RoHS Annex IV

Wording of the Requested Exemption:

Lead in counterweights of surgical C-arm X-ray and C-arm fluoroscopy designed to have radiologist present with patient

Requested validity period: *7 years*

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1. Acronyms and Definitions

Pb	lead
W	tungsten

2. Background

Bio Innovation Service, UNITAR and Fraunhofer IZM have been appointed[1] by the European Commission through for the evaluation of applications for the review of requests for new exemptions and the renewal of exemptions currently listed in Annexes III and IV of the RoHS Directive 2011/65/EU.

COCIR has submitted a request for the renewal of the above-mentioned exemption, which has been subject to a first review. As a result we have identified that there is some information missing. Against this background the questions below are intended to clarify some aspects concerning the request at hand.

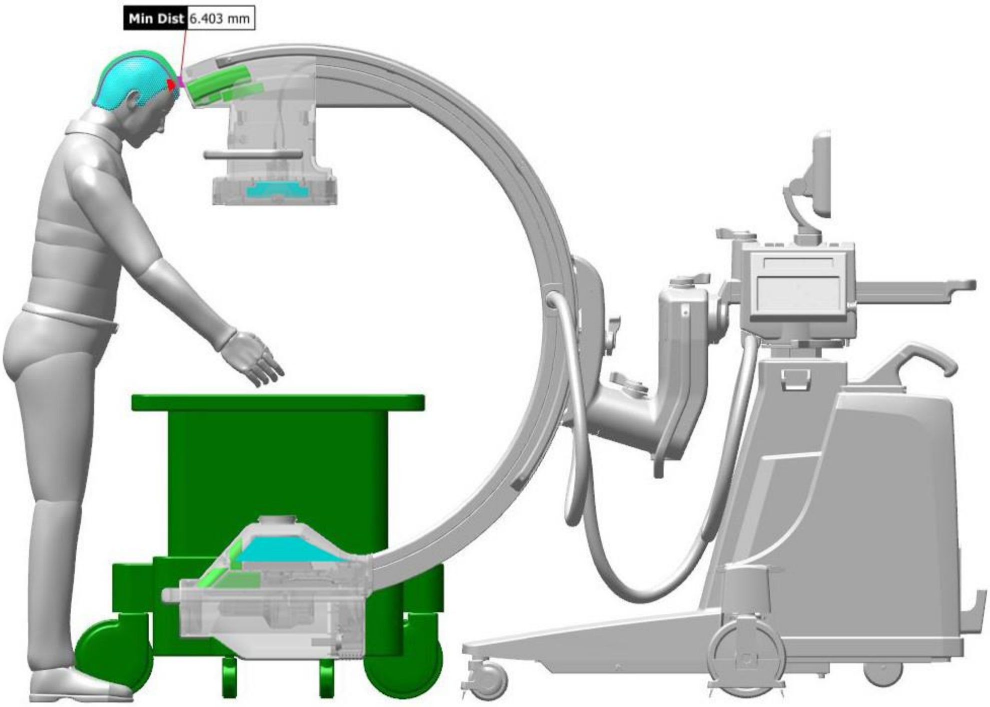
We ask you to kindly answer the below questions until 29 August 2020 latest.

3. Questions

1. Could you please illustrate the location and the difference of the shielding and the counterweights in devices?

   In the diagrams below, counterweights are shown as light green and shielding is blue.

[1] It is implemented through the specific contract 070201/2020/832829/ENV.B.3 under the Framework contract ENV.B.3/FRA/2019/0017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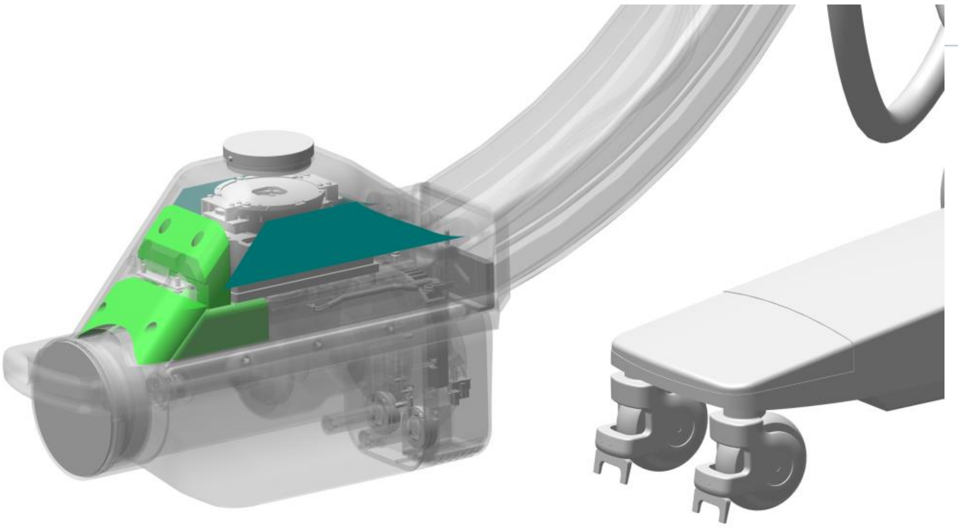
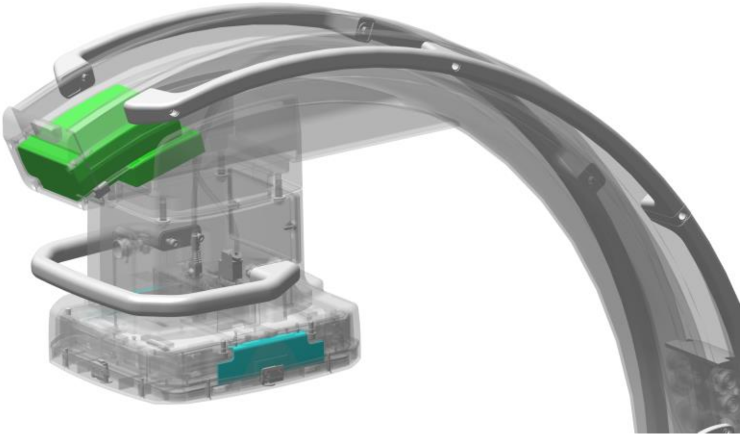
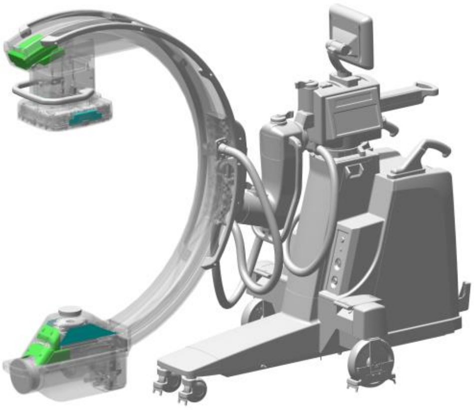
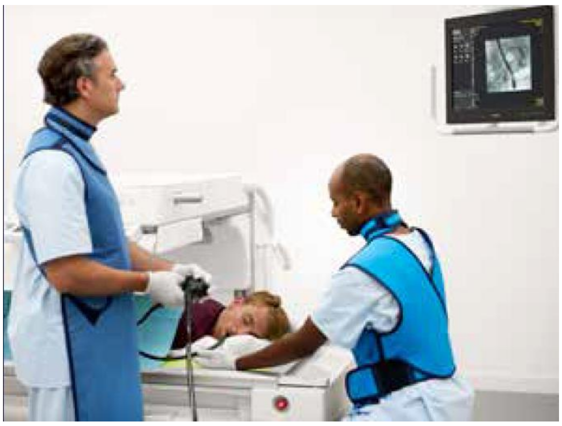






The lead counterweights need to be sizable to counter balance the weight of the C-arm and cables inside the C-arm. Due to limited space near the x-ray tube and detector the shapes have been made to fit unique shapes to make use of all available space.

In fluoroscopy applications the tabletop can be moved by motor in longitudinal and lateral directions. The dynamic flat detector tilts with the table, and can be moved in three directions, relative to the table and to the patient. The table geometry moves from -85^{0} to 90^{0}, which would be restricted if alternatives to lead were to be used which have a larger volume. The shielding has to ensure that all radiation is blocked so is in multiple places, both in the table and above, the counterweights are in the full length of table base, as well as at the end of the table.



2. Why is recycling of tungsten composites not feasible commercially (and or technically)? Any additions of polymers in W should incinerate and evaporize in the final treatment of tungsten scrap given its high melting points.

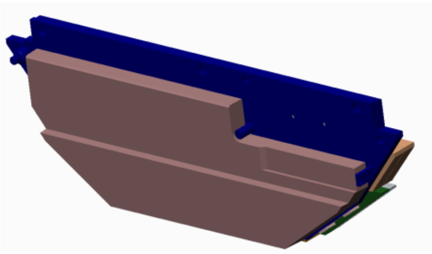
   It is conceivable that a recycling process could be developed, but at present there are no commercial processes available for recycling tungsten composites and so all used tungsten composite has to be landfilled.

3. We are not quite sure about the technical feasibility of manufacturing counterweights from W.

   a. You state that this is much more difficult than from lead. Does this mean it is possible, or so difficult that it is technically impracticable?

      This is technically impracticable as tungsten cannot be cast due to its extremely high melting temperature nor can it be extruded. Grinding is able to form more complex shapes but is energy intensive due to its hardness and it is not possible to make a complex shape from a single piece.

      Below is an additional example of a complex shape which would be required to be manufactured for the counterweights, further highlighting the geometrical challenges. Injection molding of such a shape is not possible and machining of W block to this geometry is also impossible in a manufacturing environment.



   b. Could the shapes of counterweights not be simplified, or which unchangeable necessities guide the geometries of such counterweights?

      The proximity requirements of the surgeon and weight distribution of the counterweight necessitates the complex geometry of the counterweight. The counterweight is designed to utilize all available space while maintaining the functionality of the C-arm, as shown in the diagrams as outlined in the answer to question 1.

4. You plausibly explain that space is crucial in the devices in the scope of exemption 13. For the LCA, you assume that 11.3 kg of lead shielding are balanced with 11.3 kg of W. Due to the higher density of W, the W counterweight would require around 40 % less volume of W compared to lead. Seeing the illustrations of the surgeon operating, would this lower volume not open opportunities for more convenience and easier access to the patient in all situations including emergencies, which could even save lives?

As it is technically impractical to make tungsten counterweights of suitable shapes, this has not been considered as an option. If tungsten metal could be used, it would occupy a smaller volume. There is sufficient space for the surgeon now with lead counterweights so this would not be an advantage.

5. You reference the International Tungsten Industry Association (ITIA) that only 35 – 40 % of used tungsten metal is recycled globally. Would this really apply to pure and rather bulky metals as well? We assume the indicated recycling rate goes back to the fact that W is used in more dispersive uses in alloys and other applications. The high price of W also is a strong incentive.

   The information was sourced from the ITIA website[2] where it makes reference to 'almost every kind of tungsten-containing scrap and waste'. Most scrap and waste that contains tungsten will be in the form of alloys, cutting tools (with tungsten carbide) and relatively little is pure tungsten metal.

6. You report about research into making complex shapes with tungsten composite has been carried out, but has not been successful for the counterweights needed for these applications. Could you please describe this research and its result in more details?

   The research into complex tungsten composite shapes has been limited to the search of potential solutions by medical equipment manufacturers and their supply chain. Due to the reasons mentioned in the exemption request no solution has yet been found. One option that is being considered is powder metallurgy using tungsten metal powder. This typically gives material of about 85% density which may be sufficient. However, if this were to prove to be suitable, its use would have a significant negative socio-economic impact on hospitals. The price difference between a potentially suitable tungsten alternative compared with lead would result in a significant increase in price, which in most cases would be large enough in magnitude to result in hospitals being unable to procure such equipment. This of course would have sever negative health impacts if this equipment were not available in EU hospitals. There would be no point in using tungsten if hospitals are unable to afford the equipment.

   Moreover, as detailed in exemption 5, the use of tungsten has a significantly higher environmental impact that would not qualify tungsten as a suitable alternative according to the Directive.

Please note that answers to these questions will be published as part of the evaluation of this request. If your answers contain confidential information, please provide a version that can be made public along with a confidential version, in which proprietary information is clearly marked.

[2] https://www.itia.info/supply-and-demand.html