# Questionnaire for Further Clarification

**Exemption Request "Reuse of parts from medical devices including X-ray tube components in new X-ray tube assemblies"**

## Background

The Öko-Institut together with Fraunhofer IZM has been appointed within a framework contract for the evaluation of applications for granting, renewing or revoking an exemption to be included in or deleted from Annexes III and IV of the new RoHS Directive 2011/65/EU (RoHS 2) by the European Commission.

You have submitted the above mentioned request for exemption which has been subject to a first completeness and understandability check. As a result we have identified that there is some information missing and a few questions to clarify before we can proceed with the online stakeholder consultation on your request. Therefore we kindly ask you to provide answers for the following questions and to reformulate your request if necessary.

You proposed three new exemptions for reuse of the following parts from medical equipment:

a. Lead, cadmium and hexavalent chromium in refurbished parts from professional medical devices that are reused within a closed loop business to business return system used for the repair of medical equipment placed on the EU market after 21 July 2014 until 22 July 2026
b. Hexavalent chromium in housings from X-ray tube assemblies that are reused within a closed-loop business to business return system until 22 July 2026
c. Lead in component parts from X-ray tube assemblies that are reused within a closed-loop business to business return system until 22 July 2026

## Questions

1. In your proposal different applications are mentioned on the one hand
   - Refurbished parts from all professional medical devices and on the other hand
   - Only X-ray tube components
     a. In your proposed wording you limit your request to X-ray MRI coils, printed circuit boards and detectors (e.g. radiation detectors). For which of these applications a further exemption from the requirements of the RoHS-Directive will be needed?

2. Please clarify the scope of the exemption request.

The scope is not limited. Widest scope is the reuse of all repairable parts which are already existing in running systems. These repaired parts will only be used as spare-parts, never in "new" systems. Most common and prominent examples are x-ray tubes, MRI coils, special PCBs (not standard PCBs, were repairing and reuse does not makes sense) and detectors; we listed them as examples. We emphasized the example X-ray tubes, because it can be well calculated. No further exemption from requirements of RoHS directive is needed than reuse of these valuable repairable parts as spare parts and prevent to scrap them all immediately after July 2014.

3. You mentioned that your exemption is only required for RoHS-Substances as lead, cadmium and hexavalent chromium. You further stated in section 3 (page 2) that the parts of X-Ray tube assemblies do not contain additional RoHS restricted substances. What about the RoHS-substances in all other in medical devices?

Currently there is no Mercury in our parts except for the backlighting of Displays (which is exempt). The flame retardants are not used in medical products for years. So lead, cadmium and hexavalent chromium are the only substances we need an exemption for.

4. Even if WEEE (Waste Electrical and Electronic Equipment Directive 2002/96/EC) were collected separately and submitted to recycling processes, its content of mercury, cadmium, lead, chromium VI, would be likely to pose risks to health or the environment especially when treated in less than optimal conditions.
    - Could you please elaborate more detailed the (existing) efforts which have been made for a closed-loop business-to business return system? Please provide evidence in more detail.
    - Refurbished system business: taking back systems all over the world.
    - Closed loop for X-ray tubes; 95% of tubes come back
    - EMAS Award 2010 for refurbished systems and reusable products

- http://www.medical.siemens.com/webapp/wcs/stores/servlet/CategoryDisplay~q_catalogId~e_-11~a_categoryId~e_1010354~a_catTree~e_100010,1007660,1010354~a_langId~e_-11~a_storeId~e_10001.htm
- http://www.emas.de/aktuelles/emas-award/emas-award-2010/
    - Please describe more in detail which parts of X-ray components contain RoHS substances. (housing and PCB of beam controller)

5. In section 9 of your request, you mentioned that research on substitutes is completed and all medical equipment manufactures developed alternative processes. Against this background you require this exemption solely for the reuse of the parts, taking an average life of the components of 5 years with a re-use of three times into consideration. Could you please provide evidence for these conditions? and why you proposed the exemptions until 2026 ?

We switched most of our parts to RoHS conform in 2011 and calculate a reuse time uf 15 years (3 x 5 years) = 2026

6. You are proposing an exemption valid until 2026. Will new technical features, as well as innovation recycling for medical devices allow a complete substitution after 2026?

Complete substitution is possible already in 2014. The goal of this exemption is to save resources. The affected parts are already in the market in 2014. If we don't get this exemption, we are forced to scrap the parts because it is impossible or economically not feasable to remove the RoHS substances from the parts (e.g. soldering on PCBs). In 2026, most of these repairable parts are at end of life; the rest will be scrapped.

7. You mentioned that two manufactures estimated the environmental benefits from re-use. Please could you provide these studies?

8. Regarding cadmium you stated that it will be very uncommon and represents a very small amount in the medical devices components. In which parts of medical advices is the use of cadmium necessary for defining technical features?

As stated in 6. there is no need to use cadmium in parts produced after 2014 exept in already exempt applications. However the affected parts are produced before 2014, so they might contain cadmium.