Questionnaire Exemption Request No. 2

"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.

The European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR) applies based on mentioned above request wordings for three exemptions

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

The applicant puts forward the following main arguments.

- Most used X-ray assemblies are returned to manufacturers who reuse as many parts as possible but some of these, including the housing, contain RoHS-restricted substances and so without an exemption, these cannot be reused in new equipment after 21st July 2014.
- All medical equipment manufacturers will stop using hexavalent chromium before 21st July 2014 for new housings and so allowing reuse of existing housings after this date will not pose a risk to health or the environment because the only significant risk from this substance is during the production life-cycle phase.
- The applicant further claims that the reuse of parts from used assemblies will have a smaller negative impact on the environment than without re-use.

- Many other medical equipment parts are refurbished and are used to repair medical equipment. These would become waste early if they cannot be used to repair medical devices placed on the EU market after 22 July 2014

For details, please check the applicant's exemption request at http://rohs.exemptions.oeko.info/index.php?id=132. This exemption request has been subject to a first completeness and plausibility check. The applicant has been requested to answer additional questions and to provide additional information (c.f. link above).

The objective of this consultation and the review process is to collect and to evaluate information and evidence according to the criteria listed in Art. 5 (1) (a) of Directive 2011/65/EU (RoHS II), which you can download from here:
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011L0065:EN:NOT.

If you would like to contribute to the stakeholder consultation, please answer the following questions:

Questions

1. Do you agree with the scope of the mentioned exemptions (a, b and c) as proposed by the applicant? Please suggest an alternative wording and explain your proposal, if you do not agree with the proposed exemption wordings (a, b and c).
   Do you consider any other aspects or details to be of importance, which have not yet been taken into account?
2. The applicant mentions that research on substitutes is completed and all medical equipment manufacturers have developed alternative processes. Furthermore, the applicant claims that the repaired parts will only be used as spare-parts, never in "new" systems. Against this background the consultants assume that the applicant requires this exemption solely for the reuse of the spare parts.
   a. Please state whether you either support the applicant's argumentation or whether you would like to provide argumentation against the applicant's request.
   b. Please provide clear detail for which kind of already existing medical equipment assemblies / applications will reused spare parts be used within a closed- loop business to business returns system for the repair.
3. Please provide an overview (for instance a flowchart etc) that these reused parts take part in auditable closed loop business to business return systems, and that reuse of parts is notified to the customer.

4. The applicant claims that all three proposed wordings take in to consideration an average lifetime of components of 5 years with refurbishment and re-use carried out three times per part. Thus the applicant proposes an exemption until 2026.
   Please state whether you either support the applicant's validity date or whether you would like to provide argumentation against the exemptions until 2026. In both cases please provide detailed evidence in line with your proposal. Please consider that if the exemption should to be adopted, it would be included into Annex IV of RoHS II and expire on 22 July 2021[1].

Finally, please do not forget to provide your **contact details** (name, organisation, e-mail and phone number) so that Öko-Institut/Fraunhofer IZM can contact you in case there are questions concerning your contribution.

[1] Due to the maximum validity period, which may be renewed, shall for categories 9, seven years from placing on the market after 22 July 2014 as stated in Article 5 (2) of Directive 2011/65/EU