COCIR
Brussels, Belgium

RoHS exemption 31a

Assessment of life cycle assessment on the reuse of recovered parts containing RoHS substances.

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1 BACKGROUND

The EU RoHS Directive (2011/65/EU) restricts six substances, but allows the continued use of substances through exemptions where there is justification according to the criteria outlined in Article 5(1) of the Directive. Exemption 31a in Annex IV allows parts that contain lead, cadmium, hexavalent chromium, and deca-brominated diphenyl ethers to be recovered and reused for repairs and refurbishment.

The medical sector frequently recovers parts from used medical equipment for reuse to repair other equipment and for refurbishment of used medical equipment. In support of this COCIR, the European Trade Association representing the medical imaging, radiotherapy, health ICT and electromedical industries, is requesting that RoHS exemption 31a be renewed for another 7 years. This exemption request is justified by COCIR on the basis that the overall health, safety and environmental impact with the exemption are less negative than the overall impact without this exemption.

COCIR has prepared an exemption renewal request for 31a including life cycle assessments (LCA) to justify this exemption request. COCIR has asked RINA to provide a third party assessment of these LCAs.

2 ASSESSMENT OF COCIR LCA

The LCA methodology is generally based on ISO 14040, consisting of four distinct analytical steps: defining the goal and scope, creating the life-cycle inventory, assessing the impact and finally interpreting the results. This report independently assesses if the LCAs used in support of exemption 31a have been employed to their full extent to ensure that each assessment has appropriately examined environmental inputs and outputs related to a product or service life-cycle from cradle to grave in accordance with ISO 14040, i.e. from raw material extraction, through manufacture, usage phase, reprocessing where needed, to final disposal.

The LCAs used in support of the exemption request were not undertaken to ISO 14040 protocols but follow the overall themes and analytical steps of the standard. The only exception to this is the LCA which considered the impact of printed circuit board parts reuse versus new parts manufacture.

2.1 OVERVIEW

COCIR has used the following LCAs to justify its exemption request covering two scenarios:

- **Scenario 1**: With the requested exemption granted in full; or
- **Scenario 2**: Without this exemption.

Table 1 Overview of LCA used in support of 13a exemption request

Description	Analysis Basis	LCA Review (this document)	LCA Evidence in Section 6 (Exemption application document)
Equipment refurbishment LCA	Qualitative	Section 2.2	Page 13
LCA for MRI and X-ray system refurbishment versus new parts manufacture by Gabriel I Zlamparet[1]	Quantitate	Section 2.3	Page 18
LCA for printed circuit board parts reuse versus new parts manufacture by VHK[2] using EC Ecodesign methodology	Qualitative	Section 2.4	Page 18

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[1] Energy savings and environmental impacts of refurbishing medical devices approaching end-of-life: A case study of MRI and X-Ray scanners, Gabriel I Zlamparet et.al. Unpublished work that can be provided to the European Commission

[2] Methodology for Ecodesign of Energy-related Products, MEErP 2011, Prepared for the European Commission, DG Enterprise and Industry, Unit B1 Sustainable Industrial Policy, contract SI2.581529, R. Kemna.

Description	Analysis Basis	LCA Review (this document)	LCA Evidence in Section 6 (Exemption application document)
Reuse of X-ray tube housings	Quantitative	Section 2.5	Annex I

Comparative LCAs are usually carried out using proprietary software for specific materials or a type of equipment for which all of the materials and quantities are known. Due to the very large variety of recovered parts and the fact that the quantities of each type of part reuse each year will not be known, it is reasonable that the usual approach cannot be used, therefore COCIR has carried out two qualitative LCA and two quantitative LCAs for specific types of equipment and parts as illustrative examples.

2.2 EQUIPMENT REFURBISHMENT LCA

The LCA undertaken by COCIR for the 31a RoHS exemption request in 2019 details, in qualitative terms, the overall health, safety and environmental impact of exemption renewal and expiry for all recovered reused parts for medical devices.

2.2.1 Scope

Due to the diverse technological and geographical coverage of the LCA, the system boundary is not well defined and data is not able to substantiate claims within the LCA. To this end, COCIR has described in qualitative terms the potential impacts which it is reasonable to infer given that the data is not available due to the complexity of gathering. Availability of information is an acknowledged potential limitation of LCAs; to manage this the report clearly stated its embedded assumptions to allow the linkage between medical systems and potential impacts.

Attempts have been made in the past by government bodies and international consortia to place a value on human life or the costs of ill health (e.g. from exposure to pollutants), but these figures are very variable and no consensus has been reached. Therefore it has been deemed reasonable that it is not possible to determine how many people would die, or to calculate the additional cost of treatment that might be caused by delays in obtaining spare parts or from the non-availability of refurbished equipment. It is recognised that the health of EU citizens and their medical treatment is affected by multiple parameters (as discussed by COCIR), as well as the diverse technological and geographical coverage of the LCA. Therefore, although the LCA is unable to provide quantitative data, the simplifications and the potential related distortions do not influence the results overly and result in a robust qualitative analysis.

2.2.2 Impact and Interpetation

In terms of completeness, the LCA has captured all relevant qualitative information required for the interpretation. The lack of data does not significantly impact the degree of confidence in the validity of the results of this study and so it is reasonable to conclude that additional resource do not need to be expended on the quantification of inputs and outputs, as this would not significantly change the overall conclusion of the study.

In terms of sensitivity of the LCA, the lack of data will not be impacted by aspects such as allocation methods or calculation of category indicator results. The LCA, given the fact that it relies upon qualitative arguments, consistently applies the elements of the impact assessment across all products and regions within the system boundary.

In conclusion, COCIR's arguments are transparent and consistently demonstrate that the health of EU patients would be negatively impacted if this exemption were not granted. The interpretations reflect the limitations of the availability of data to substantiate claims, but substantiate the claims adequately with qualitative arguments.

2.3 LCA FOR MRI AND X-RAY SYSTEM REFURBISHMENT

This LCA undertaken by Gabriel I Zlamparet compares the refurbishment of MRI, PET and CT scanners with the construction of new, but otherwise identical, devices using all new parts. The LCA demonstrates the potential for energy savings and environmental impacts/benefits through refurbishment processes.

2.3.1 Scope

MRI and X-ray systems were selected, according to the LCA's author, because MRI has a very high refurbishment potential, i.e. most parts can be reused whereas X-ray systems had the lowest potential of the types of equipment that were considered (although 65% of parts can be reused). As the LCAs of these two systems give large differences between these scenarios, it is therefore a reasonable assumption that the impact of all other types of medical devices that are refurbished (such as CT) will lie somewhere between these extremes.

2.3.2 Life-cycle inventory

Commercially available software was used to calculate 17 health and environmental impacts for the whole system boundary. However, as the software source was not stated within the LCA, the reliability and accuracy of the information in the underlying databases shall have to be assumed. The raw data used for the calculations contained within the report was measured quantities of materials, energy, wastes, etc. which was obtained from medical device manufacturers who refurbish large numbers of MRI and X-ray systems. All calculations were explicitly documented and applied consistently throughout the LCA.

The LCA included all environmental inputs and outputs associated with a product's refurbishment including packaging, transportation, disassembly, decontamination, cleaning, parts testing, replacement or refurbishment, painting, software upgrades, reassembly and system testing followed by repackaging and delivery to users.

2.3.3 Impact and Interpetation

It is clear that all relevant phases of the refurbishment and new build processes have been considered and, although the LCA software used was not specified, the comparative LCA does appear to accurately reflect the differences in overall impacts. The life cycle impact assessment is sufficiently robust to support the conclusion that all health and environmental impacts from refurbishment are much smaller than those for new systems (all are <40% of new system impacts). Owing to significant differences in impacts demonstrated, the sensitivity of the data underpinning the determination is small. Therefore any changes in data due to allocation methods or uncertainties in the data will not significantly affect the overall conclusion.

The LCA has captured all relevant information and data needed for the interpretation with a focus on environmental impacts, but also importantly includes human toxicity. The assessment has also identified climate change impacts that can have both environmental and human impacts (including particulate matter). The choice of impacts is determined to be reasonable so that the overall human and environmental impacts can be compared for the two scenarios.

As all impacts from refurbishment were determined to be much smaller than for new systems, it is clear that the overall health and environmental impacts from refurbishment are less negative than from new systems built with new parts, based on this LCA.

2.4 LCA FOR PRINTED CIRCUIT BOARD PARTS

In 2011, VHK prepared an LCA methodology and this has been used by COCIR for the reuse of recovered printed circuit boards (PCB) including surface mount components and integrated circuits to building new parts. The LCA calculated the total human health and environmental impacts from reuse of making new PCBs and assumes that reuse has negligible impacts.

2.4.1 Scope

COCIR's members reuse many thousands of different parts each having a different materials composition and energy "footprint". COCIR reports that 2,000 tonnes of parts per year are recovered for reuse, with a large proportion of these likely to be PCBs. Although this metric is unable to be verified independently, it is reasonable to argue that manufacturers are best placed to determine this value.

COCIR has considered the comparative impacts of PCBs, which are commonly reused, refurbished, or used as spare parts for repair of medical devices. The choice of PCBs for this LCA is reasonable as large quantities of PCBs are reused and the mining, refining and production phases of these parts are significant, as shown by the VHK methodology. Medical device PCBs vary in size and complexity enormously. To manage this, several different types of PCB impacts have been calculated, which should give a good indication of PCBs used in a typical medical device used by COCIR members and therefore is deemed as appropriate and reasonable in relation to the goal of the study.

2.4.2 Life-cycle inventory

The VHK eco-design methodology is used for preparatory studies which enables the health and environmental impacts of different types of energy-using products, principally electrical equipment, to be compared. COCIR has therefore used this approach appropriately to compare reuse of recovered parts with building new parts using the VHK data for PCBs.

The underlying assumptions embedded in the LCA are that recovered used PCB parts already exist and therefore there would be no impact from mining and refining raw materials, or from the production of parts. Another assumption is that the impact of disposal of these parts at end of life will be the same, independent of use/reuse, the only difference is the date when this occurs. COCIR therefore concludes that part reuse has a very small human health or environmental impact.

These assumptions do not take into consideration factors such as the recovery of items, which would require a certain level of manual effort, as well as the requirement to test before reuse. For the latter point this may be negated by new built PCBs are often also tested. In addition to this, recovered parts that are intended for reuse may need to be cleaned and repackaged. This would not occur if they were disposed of and so the assumption has to some degree oversimplified the scenario. Environmental and health impacts from cleaning used parts will be extremely small in comparison with the manufacture of replacement new parts and so ignoring this very minor impact will not significantly change the very clear result that reuse is preferable to new replacement. Overall, the assumptions build into the LCA masks minor points that have not been accounted for in the LCA; however, the inclusion of all factors should not alter the relative contribution of health and environmental impacts.

2.4.3 Impact and Interpetation

This scenario has adequately demonstrated in a transparent and robust way that the impacts of reuse of recovered PCB are smaller than those from building new parts. The environmental problems of relevance have been captured by the study and the data used is adequately defined. The outcomes of the study are sufficiently robust to demonstrate that the data utilised should not be able to influence the conclusions due to variations in data and therefore is determined not to be sensitive.

The LCA has adequately demonstrate that reuse of recovered PCB has a lower impact in comparison to building new parts.

2.5 LCA FOR REUSE OF X-RAY TUBE HOUSINGS

The LCA prepared by COCIR as part of the exemption request in 2019 , details in quantitative terms the health and environmental effects of the reuse of X-ray tube assemblies versus manufacturing new parts.

2.5.1 Scope

COCIR estimates that 16,000 X-ray tubes are refurbished annually, of which 85% of housings are reusable. These metrics were unable to be verified independently and is only an estimate as some X-ray tubes are made and refurbished by companies that are not members of COCIR, however, the estimate is likely to be fairly accurate as COCIR members have a large proportion of this market. It is also reasonable to argue that the manufacturers are best placed to determine these values.

X-ray tubes are a good example to compare new build with reuse because X-ray tubes used in medical devices are relatively large (some weighing over 60kg) and contain aluminium housings, lead sheet as radiation shielding, electronic circuitry and scarce materials such as tungsten used for the anode. Refurbishment is also commonly carried out to recover parts for reuse, usually multiple times. The data supporting the LCA is limited to two of COCIR's members undertaking their own calculations. The data supplied is not directly comparable as it pertains to aluminium alloy housings for manufacturer A and the whole X-ray tube assemblies for manufacturer B. Even so it does allow quantitative assessment of health and environmental effects.

2.5.2 Life-cycle inventory

Two manufacturers have calculated the energy consumption for manufacture of A) new housings made of aluminium alloy and B) new X-ray tube assemblies that include the same size of aluminium housing. Energy consumption arises mainly from mining, refining and production of parts; this data is published for commonly used materials such as aluminium and is used for commercial LCA software. An appropriate exclusion used in the report is energy consumption in the use phase, as it will be the same for a new tube or a refurbished tube and only depends on how the X-ray equipment is used at hospitals.

COCIR relies here on energy consumption only for this LCA. Other LCAs, including that from VHK, show that most other (non-energy) impacts are due, to a significant extent, on energy generation; especially from coal and oil combustion. This emits hazardous substances, particulates and creates hazardous and non-hazardous wastes. Energy consumption is therefore a useful guide to comparison of two scenarios and is realistic if the differences between the scenarios are very large. In this case, refurbishment avoids mining and refining of raw materials and also avoids parts construction and their associated impacts. Refurbishment also consumes significantly less energy than new part construction but the detail concerning this in the LCA is limited.

2.5.3 Impact and Interpetation

The reliance on energy consumption for the LCA results in incomplete data, however the absence of data for all health and environmental parameters will not significantly influence the results. Reliance on energy consumption only for the comparison of refurbishment with new builds probably underestimates the benefits of refurbishment as other emissions and impacts from mining and refining of raw materials for new parts are not taken into account and will probably be significant. Overall the significant environmental issues relating to energy generation are found to represent the most important results of the study in accordance with the goal and scope definition.

This LCA has adequately demonstrated in a transparent and quantitative way that the reuse of X-ray tube assemblies in comparison to building new parts has a positive health and environmental impact.

3 CONCLUSIONS

COCIR has used multiple LCAs to justify the application for renewal of exemption 31a. Each shows that the overall health and environmental impacts of reuse of recovered parts is significantly less than the overall impacts from disposal of usable parts and manufacture of new replacement parts. Safety is unaffected and is determined to be the same for both new and refurbished parts – as both are thoroughly checked and tested before use. The wide variety of types of parts and their uncertain composition has prevented the use of formal LCA calculations (e.g. by using commercial LCA software) except for the MRI and X-ray system refurbishment LCA, but the difference in impacts arising from the two scenarios is so large that the this conclusion would be the same irrespective of data accuracy.

One LCA covering all refurbishment cannot be carried out because a huge variety of parts are reused but their composition cannot be determined. Even so, the quantitative LCAs include a large proportion of the parts that are refurbished – X-ray tubes and PCBs being two of the more commonly refurbished types of part. The results of each quantitative LCA would be the same for any type of part because refurbishment always avoids the impacts from mining and refining of raw materials as well as production of parts. Use phase energy consumption is the same for both scenarios and refurbishment delays end of life so can only have an overall smaller impact. COCIR also show that there are other potentially significant impacts to healthcare in the EU that would arise without this exemption.

4 ABOUT RINA CONSULTING

RINA is a global corporation that provides engineering and consultancy services, as well as testing, inspection and certification. RINA provide a wide range of traditional and innovative services to critical industry sectors, including Oil & Gas, Power, Renewables, Space & Defence, Transport & Infrastructure sectors.

RINA is the result of the integration of a number of internationally respected companies including RINA Services, D'Appolonia, Centro Sviluppo Materiali, G.E.T., Logmarin Advisors, OST Energy, Polaris, SC Sembenelli Consulting, Seatech, and ERA Technology Ltd ("Edif ERA").

Through the acquisition of ERA Technology Ltd, RINA has accumulated over 15 years of consultancy experience on the RoHS Directive including:

- ERA carried out the first exemption review study for the European Commission in 2004;
- ERA carried out a study for the Commission into whether it was possible to include categories 8 and 9 in the scope of RoHS in 2006;
- ERA and BIO Intelligence Service carried out a scope review of the RoHS directive in 2012 for the European Commission.

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